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EVALUATION

of Regulation (EC) No 1831/2003 on additives for use in animal nutrition

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Glossary

TERM OR ACRONYM	MEANING OR DEFINITION
AFIA	American Feed Industry Association
AH Europe	Animal Health Europe (ex IFAH-Europe; ex FEDESA)
AMR	Antimicrobial resistance
ANAC	Animal Nutrition Association of Canada
ANTIBIOTIC	Means antimicrobials produced by or derived from a micro-organism, which destroys or inhibits the growth of other micro-organisms.
ANTIMICROBIALS	Means substances produced either synthetically or naturally used to kill or inhibit the growth of micro-organisms, including bacteria, viruses or fungi, or of parasites, in particular protozoa.
AUTHORISATION HOLDER	The authorisation of additives can be linked to the specific legal person applying for the authorisation, who is the 'holder' of the authorisation (holder-specific authorisations), or not (non-holder specific, or generic, authorisations). In the case of additives belonging to categories d) (zootechnical) and e) (coccidiostats and histomonostats) referred to in Article 6(1) of Regulation (EC) No 1831/2003, and of additives consisting of/containing/produced from genetically modified organisms (GMOs), no person may place the product on the market other than the authorisation holder named in the authorisation Regulation, his legal successor(s) or a person acting under his written authority. The authorisation holder has obligations for the supervision of conditions of marketing of the additive, including post-market monitoring in the case of some additives (e.g. coccidiostats).
BEUC	European Consumers Organisation
BR	Better Regulation
C&Hs	Coccidiostats and histomonostats
CAGR	Compound Annual Growth Rate
CATEGORIES OF FEED ADDITIVES	According to Article 6 of Regulation (EC) No 1831/2003, additives may belong to one or more of five categories, depending on their functions and properties: ➢ Technological additives: any substance added to feed for a technological purpose, e.g., preservatives, antioxidants, emulsifiers, stabilising agents, acidity regulators, silage additives. ➢ Sensory additives: any substance, the addition of which to feed improves or changes the organoleptic properties of the feed, or the visual characteristics of the food derived from animals, e.g., flavourings, colourants. ➢ Nutritional additives: any substance added to feed to improve nutritional values, e.g., vitamins, minerals, amino acids, trace elements. ➢ Zootechnical additives: any additive used to affect favourably the performance of animals in good health or used to affect favourably the environment, e.g., digestibility enhancers, gut flora stabilisers. ➢ Coccidiostats and histomonostats: substances intended to kill or inhibit protozoa
CLP Regulation	Regulation on the classification, labelling and packaging of substances and mixtures (Regulation (EC) No 1272/2008).
COCCIDIOSTATS AND HISTOMONOSTATS	Means substances intended to kill or inhibit protozoa.
COCERAL	Comité du Commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures.
COMPLEMENTARY FEED	Means a compound feed which has a high content of certain substances but which, because of its composition, is sufficient for a daily ration only if used in combination with other feed.
COMPLETE FEED	Means a compound feed that, due to its composition, is sufficient for a daily ration.
COMPOUND FEED	Means a mixture of at least two feed materials, whether or not containing FA, for oral animal feeding in the form of complete or complementary feed.
COPA-COGECA	European farmers and European Agri-Cooperatives

DFID	UK Department for International Development
DG SANTE	Directorate-General for Health and Food Safety
EAAP	European Federation for Animal Science
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EFARO	European Fisheries and Aquaculture Research Organisations
EFISC-GTP	European Feed and Food Ingredient Safety Certification
EFSA	European Food Safety Authority
ENDPOINTS	Is what you have to measure to demonstrate an effect. For example, if you want to demonstrate performance in laying hens you measure the number of eggs during the period of the trial.
EMFEMA	European Manufacturers of Feed Minerals Association
ENSSER	European Network of Scientists for Social and Environmental Responsibility
ESVAC	European Surveillance of Veterinary Antimicrobial Consumption
EURL	European Union Reference Laboratory for FA
EUVEPRO	European Vegetable Protein Association
FCEC	Food Chain Evaluation Consortium
FEAP	Federation of European Aquaculture Producers
FEDESA	European Federation of Animal Health (now, Animal Health Europe)
FEDIAF	European Pet Food Industry Federation
FEED	Any substance or product, including additives whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals.
FEED ADDITIVES	Substances, micro-organisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform one or more of the functions to improve the quality of feed and the quality of food of animal origin, or to improve animal performance, animal health and animal welfare.
FA	Feed Additives
FEED ADDITIVES / PREMIXTURES ONLY INTENDED FOR EXPORT	These additives are produced only for export in accordance with Article 12 of the General Food Law. They must be safe and must comply with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country. They can be exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the Community.
FEED BUSINESS OPERATORS (FeBOs)	The natural or legal persons responsible for ensuring that the requirements of food law are met within the feed business under their control (Article 3.6 of Regulation (EC) No 178/2002). This encompasses all FeBOs along the feed supply chain: feed additives producers and business FeBOs that are users of additives (manufacturers of compound feed and pre-mixes; and pet food manufacturers).
FEED MATERIALS	Means products of vegetable or animal origin, whose principal purpose is to meet animal's nutritional needs, in their natural state, fresh or preserved, and products derived from the industrial processing thereof, and organic or inorganic substances, whether or not containing FA, which are intended for use in oral animal-feeding either directly as such, or after processing, or in the preparation of compound feed, or as carrier of premixtures.
FEEDAP	Panel on Additives and Products or Substances used in Animal Feed
FEFAC	European Feed Manufacturers' Federation
FEFANA	EU Association of Specialty Feed Ingredients and their Mixtures
FESASS	European Federation of Farmers' Animal Health Services
FIC	Regulation (EU) No 1169/2011 on Food Information to Consumers

FUNCTIONAL GROUPS	Within a category of FA, the additives are classified into functional groups in accordance with the function they perform – e.g., within the category "sensory additives", there are two functional groups: colourants and flavourings.
FVE	Federation of Veterinarians of Europe
GENERIC ADDITIVES	This term "generic" is used in the additives' sector to name additives not linked to an authorisation holder, belonging to the technological, sensory and nutritional categories, except if those additives consist of, contain or are produced from GMOs. In that case, they should be linked to an authorisation holder and are not "*generic*".
GFL	Regulation on the General Food Law (Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety).
GMI	Global Market Intelligence
GMOs	Genetically modified organisms
HACCP	Hazard Analysis and Critical Control Points
IFIF	International Feed Industry Federation
IFOAM EU	International Federation of Organic Agriculture Movements (European umbrella organisation for organic food and farming)
LABELLING TOLERANCES IN PREMIXTURES	Premixtures may contain different additives. The level of incorporation of each additive is to be declared on the label. For different reasons, those levels are not stable (interaction with other additives, degradation by light), therefore, during the commercial life of the premixture the levels may change over the time. This is why tolerances might be necessary. For example, if for ascorbic acid the tolerance was (1%), in case of analysis, a variation of 1% on the quantity declared on the label would then be acceptable.
MCA	Multi-criteria analysis
MINOR SPECIES	Means food-producing animals other than bovines (dairy and meat animals, including calves), sheep (meat animals), pigs, chickens (including laying hens), turkeys and fish belonging to the *Salmonidae*.
MS	Member States
NCA	National Competent Authority(ies)
OIE	World Organisation for Animal Health
POST–MARKET MONITORING (PMM)	After the assessment, EFSA may propose to the applicant to carry out a PMM plan to trace and identify any direct, indirect, immediate, delayed, or unforeseen effect – resulting from the use of feed additives – on human or animal health or the environment, by using a product tracing framework similar to the one already existing in other sectors and in line with the traceability requirements laid down in the General Food Law. A proposal for PMM is requested for nutritional, zootechnical additives, coccidiostats and histomonostats and for additives consisting of, containing or produced from GMOs.
PREMIXTURES	Means mixtures of feed additives, or mixtures of one or more feed additive(s) with feed materials or water used as carriers, not intended for direct feeding to animals.
PREPARATIONS	Are feed additives composed of one or several active substances and other components (technological additives, feed materials or carriers) that are incorporated to facilitate the stability or the administration of the active substance – e.g., vitamin A as the active substance and one antioxidant to stabilise the vitamin and prevent its oxidation.
R&D	Research and development
RASFF	Rapid Alert System for Food and Feed
REACH	Regulation on Registration, Evaluation, Authorisation, and Restriction of Chemicals (Regulation (EC) No 1907/2006)
REFIT	The European Commission's regulatory fitness and performance programme
SDGs	United Nations' Sustainable Development Goals (SDGs)
SCM	Standard Cost Model
SCoPAFF	Standing Committee on Plants, Animals, Food and Feed
STDF	Standards and Trade Development Facility
TARGET ANIMALS	Animals for which the additive is intended – e.g., if an additive is intended for dairy cows, the target animal will be dairy cows.

MICROTRACERS	Substances used to trace other substances with a reliable and accurate method and to ensure that ingredients are present (or not) at the formulated and desired levels within the feed. This can contribute to preventing cross-contamination – e.g., to ensure that in a feed intended for pigs there are no traces of coccidiostats, used in the previous manufacturing batches for poultry.
ToR	Terms of Reference
WTO	World Trade Organisation

Abbreviations to legal references:

Regulation (EC) No 1831/2003:	FA Regulation
Commission Regulation (EC) No 429/2008:	Commission Rules for Applications
Directive 70/524/EEC:	1970 FA Directive
Regulation (EC) No 178/2002:	General Food Law ('GFL')
Regulation (EC) No 767/2009:	Feed Marketing Regulation
Regulation (EC) No 183/2005:	Feed Hygiene Regulation
Directive 2002/32/EC:	Directive on Undesirable Substances in Animal Feed
Regulation (EC) No 1829/2003:	Regulation on Genetically Modified (GM) Food and Feed
Council Directive 90/167/EEC:	Directive on Medicated Feed[1]
Directive 2001/82/EC:	VMP Directive (veterinary medicinal products)[1]
Regulation (EU) No 528/2012:	Biocidal Products Regulation
Regulation (EC) No 1907/2006:	REACH Regulation (Registration, Evaluation, Authorisation and Restriction of Chemicals)
Regulation (EC) No 1272/2008:	CLP Regulation (classification, labelling and packaging of substances and mixtures)
Regulation (EU) 2017/625:	Official Controls Regulation

Other abbreviations

EM	Evaluation Matrix

[1] It is noted that the current legal framework for veterinary medicinal products and medicated feed (Directive 2001/82/EC and Directive 90/167/EEC) has been replaced by Regulation (EU) 2019/6 on veterinary medicinal products and Regulation (EU) 2019/4 on medicated feed; the new regulations apply from 28 January 2022.

1. INTRODUCTION

The purpose of this evaluation is to assess how well the 2003 FA Regulation[2] has performed based on the five evaluation criteria of the Better Regulation Guidelines: effectiveness, efficiency, coherence, relevance and added value. The FA Regulation is based on Article 43[3] and Article 168(4) (b) of the TFEU with its primary aims of protecting human health as well as animal health and the environment and contributing to the well-functioning of the Single Market.

The FA Regulation has not been evaluated since its adoption in 2003. More than 776[4] FA have been authorised since then. An evaluation is thus justified.

This evaluation is part of the combined evaluation/impact assessment that will inform decisions on the revision of the FA Regulation, as announced under the Farm to Fork Strategy. The Farm to Fork Strategy for a fair, healthy and environmentally friendly food system was adopted on 20 May 2020[5] as one of the key actions of the European Green Deal[6], an ambitious EU initiative to move towards a clean circular economy, restore biodiversity and cut pollution.

The evaluation addresses the legal obligations laid down in the 2003 FA Regulation, including the conditions and procedures for the authorisation, the conditions for placing on the market and use of FA, including labelling and packaging, the enforcement of those rules and the phasing out of antibiotics (see more details in Annex III). It also covers implementing rules, including detailed rules for the preparation and presentation of applications (Commission Regulation No 429/2008[7]) and EFSA guidance for the assessment of FA.

The evaluation covers the period 2004 to 2021. It draws on data collected through an external study which focused on the period 2004-2017, a period that is largely representative of the questions raised by the new authorisation and assessment regime that had been introduced. The findings of the study are complemented by additional more recent information (see details in Annex II) wherever needed, especially on the question of authorisation renewals, as the first renewals only occurred in 2017. References to the evaluation matrix (EM) presented in Annex III

[2] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

[3] All EU legislation concerning animal feed is based on both Article 43(2) and Article 168(4) (b) of the TFEU. Article 43(2) TFEU refers to provisions necessary for the pursuit of the objectives of the Common Agricultural Policy. To aim for harmonised and adequate production conditions for the EU livestock farmers can be also derived from this Article. Livestock production occupies a very important place in the agriculture of the EU and satisfactory results depend to a large extent on the use of safe and good quality feedingstuffs.

[4] SANTE database.

[5] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and The Committee of the Regions- A Farm to Fork Strategy for a fair, healthy and environmentally friendly food system. COM (2020) 381 final.

[6] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions. The European Green Deal. COM (2019) 640 final.

[7] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of FA. OJ L 133, 22.5.2008, p. 1.

which was used to collect evidence to support the analysis are included where appropriate in the text. The evaluation covers all the 27 MS plus the UK [8] and EEA countries.

As regards the COVID 19 pandemic, a COPA-COGECA report[9] refers to the increasing prices in some feed materials (by 25% to 35% on average) but FA are not specifically mentioned as affected. The FA industry has not reported any specific problem with FA and the authorisation procedure was not too much affected as meetings of the SCoPAFF were organised online and EFSA replaced physical meetings by online meetings.

2. WHAT WAS THE EXPECTED OUTCOME OF THE INTERVENTION?

2.1. Description of the intervention and its objectives

The EU first legislated in this area in 1970 with the adoption of Council Directive 70/524/EEC on FA[10], in recognition of the potential risks to animal or human health. Following the 2000 White Paper on Food Safety[11] which advanced a strategy to ensure the highest possible food safety standards in Europe, the legislative framework was reconsidered, and in 2003 the legislation was revised, replacing the Directive with a Regulation. The general objectives of the new Regulation were to enhance protection of human health, animal health and welfare, and the environment; to improve the functioning of the EU's internal market; to facilitate innovation in the sector; and to protect the interests of consumers (GOs 1-4).

This section outlines how the Regulation sought to contribute to these general objectives by pursuing more narrowly focused objectives specific to the FA sector. In the absence of any prior impact assessment, the 2003 intervention logic has been reconstructed based on available information (primarily, the text of the Regulation itself and the accompanying explanatory memorandum). The intervention logic set out in the narrative below is summarised visually in a diagram at the end of the section (Figure 1). References to the diagram elements (problems, drivers, actions, objectives) are provided in parentheses were appropriate (P1, P2… D1, D2… etc), to facilitate cross-referencing.

Specific Objective 1 (SO1). Reduction of antimicrobial resistance threats to citizens, animals and the environment (AMR)

Antimicrobials are substances that act directly to reduce or eliminate unwanted microorganisms or parasites within animals (and humans) and that are primarily used to treat or prevent infectious diseases. Over the years, however, their efficacity has been undermined, as rising and sometimes indiscriminate use of antibiotics in both humans and animals has led to the proliferation of strains of bacteria that are resistant to such treatments. Existing antibiotics have thus been rendered ineffective, while alternative or replacement treatments are not always available. This trend has constituted an obstacle to the EU's high-level commitment to continuously improve the protection of public health (GO2).

[8] The evaluation includes the UK as the study performed by the contractor was made before the BREXIT took place.
[9] Impact Of Covid-19 on the Agricultural, Forestry and Fisheries Sectors COPA AND COGECA Assessment November 2021 – February 2022 (COV (22)313:1.
[10] Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs (OJ L 270, 14.12.1970, p. 1).
[11] https://op.europa.eu/en/publication-detail/-/publication/6d4b523b-dad8-4449-b2b4-9fa9b0d6e2be.

Antibiotics have in the past been used as FA because, in addition to their medicinal effects, they can also function as growth promoters. By the 1990s, such FA accounted for 15% of the volume of antibiotics consumed in the EU (by active substance). This use of antibiotics is now considered to have been a serious error for its deleterious effect on public health. Following a scientific opinion[12], at the end of the 1990s the EU withdrew the majority of these substances from the list of authorised FA but did not go so far as to introduce a general ban. As a result, the use of antibiotics as growth promoters in FA continued, albeit on a much smaller scale (D1.1). While some MS, citing the precautionary principle, had already banned all such uses of antibiotics by the late 1990s, policy at EU level lagged behind in this regard[13].

This situation was exacerbated by the fact that the authorisation process for FA under the 1970 FA Directive did not include a comprehensive risk assessment that would have examined whether such continued use in animals might not fuel the continued spread of AMR, for example by looking carefully at the consequences of aggregate dosing levels (feed + medical) (D1.2). These gaps in the legislative framework, combined with competitive pressure on livestock farmers to continually seek greater productivity, created a situation in which certain FA authorised under the 1970 FA Directive may have continued to contribute to the spread of AMR (P1).

To address this problem, the FA Regulation introduced a general ban on the use of antibiotics as FA (A1.1)**.** A special regime was granted to coccidiostats and histomonostats[14] which allowed their continued use on the basis that they were important to prevent coccidiosis in poultry and histomoniasis in turkeys (not for growing effect purposes), and the fact that their AMR effect was relatively weak[15]. The authorisation process was also adapted to include a preventive assessment to ensure that coccidiostats and histomonostats that remained authorised under the special regime did not in fact pose any risk of increasing the spread of AMR (A1.2). To this end, FeBOs requesting authorisation for such substances now need to demonstrate their potential antibiotic action and to provide scientific evidence on the risk of AMR that they represent[16].

By eliminating the continuing use of antibiotics as growth promoters[17] in FA (O1), it was expected that these actions would substantially reduce any remaining risk of AMR due to the use of FA (R1) and would thus have a positive impact on the protection of public health (I1).

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12 Opinion of the Scientific Steering Committee on Antimicrobial Resistance 28 May 1999 https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_ssc_out50_en.pdf

13 Sweden banned all antibiotics used as growth promoters in 1986 and Denmark banned avoparcin and virginiamycin in 1995 and 1998, respectively. See: The European ban on growth-promoting antibiotics and emerging consequences for human and animal health. Mark Casewell1, Christian Friis, Enric Marco, Paul McMullin and Ian Phillips. Journal of Antimicrobial Chemotherapy (2003) 52, 159–161.

14 Although histomonostats were covered by the special regime, no histomonostats have been approved, therefore, for the time being only coccidiostats are concerned.

15 Ionophore coccidiostats (derived from micro-organisms) have demonstrated a low antibiotic effect as opposed to non-ionophore coccidiostats (synthetically produced).

16 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0429&from=EN

17 The sole use of antibiotics in animal feed was as growth promoters. Coccidiostats and histomonostats are substances used to kill or inhibit protozoa, thereby preventing the diseases produced by those parasites.

Specific Objective 2 (SO2). Simplification and harmonisation of the FA authorisation process

As specific objectives 2 and 3 address a common problem set, and the drivers they address to some extent overlap, this sub-section and the next should be read together.

Under the 1970 FA Directive, the rules governing the authorisation system for FA were very complex and tended to make the outcome sometimes difficult for applicants to predict (P2). This can be an obstacle to the proper functioning of the EU internal market and can undermine the possibility of a level playing field for the operators concerned (GO1).

This situation was due to a number of reasons. The process was not standardised, and central guidance was lacking (D2.1, D2.3). The low level of harmonisation was aggravated by the fact that, if MS feared a FA might pose a safety risk, they could act in a wide range of ways to reduce this risk, including by suspending the authorisation of the FA in question, whether for a limited or an unlimited period of time, and/or restricting the conditions of its use by imposing additional requirements (D2.3). It was the case for a vitamin D from the Netherlands that was not permitted in Denmark based on the argument that the presence of impurities in such vitamin might pose serious risks to public health. When seeking authorisation, applications needed to be addressed to a MS rapporteur following the instructions provided by that MS (D2.1, D2.3). No deadlines were set for some steps of the procedure, which could result in undue delays (D2.2). Nor was there an open and readily accessible list of FA that had been authorised which stakeholders could consult before launching their own application (D2.1, D2.4).

The rules established by the 1970 FA Directive were also burdensome for the Commission and MS (D2.5). The Directive allowed for the provisional authorisation of products whose efficacy was simply declared by the applicant without the need to fully demonstrate it: the Commission and MS would then need to re-examine these authorisations, creating additional workload and delays.

To address these drivers and resolve the problem, the 2003 FA Regulation aimed at simplifying the authorisation process by establishing:

- a single harmonised authorisation procedure at EU level (A2.1);
- a centralised risk assessment by EFSA (A2.1);
- timelines to be respected at the different steps of the procedure (A2.1);
- more detailed and comprehensive rules to help applicants prepare their dossiers, including strict data requirements (A2.2);
- a single application form (A2.2); and,
- a public register of FA (A3.2).

These actions were expected to create a more transparent, simpler, faster and more predictable authorisation process (O2), which would therefore place far less burden on all the parties involved, including public authorities (R2.1). In this way, these actions would have a positive impact on the functioning of the internal market and so help ensure a level playing field between FeBOs (I2).

Specific Objective 3 (SO3). Set up clear/comprehensive rules for FA authorisation and labelling.

While part of the complexity of the authorisation process was due to a low level of harmonisation, it was also the case that the rules laid down in the 1970 FA Directive were inherently complicated. This was also true concerning the labelling rules (P2).

Authorisation

The authorisation system was organised around the classification of FA into different types. This classification was complicated both by the intrinsic opacity of some of the rules, and the insufficient clarity as to which safety criteria should be applied to which categories of FA, and how. Thus, FA could for example be authorised under generic entries without it being clear how many FA were covered by those entries (D2.1). There were also cases, as mentioned above, in which MS imposed restrictions on the circulation of FA authorised through another MS because they argued that the appropriate safety criteria had not been adequately taken into account (D2.4).

In response to these drivers, the 2003 FA Regulation sought to solve this concern by introducing a new classification system based on clearly defined functional groups which would allow the risk assessment process to be rigorously performed according to the type and function of the substance (A3.1). New functional groups could always be added to those initially identified, as science evolved, and new technological developments emerged (see table 1 in Annex VII).

The FA Regulation introduced a comprehensive set of safety criteria. These are defined according to the categories of FA and the functional groups to which they are assigned and correspond to different dimensions of risk to be assessed for humans, animals and the environment. For each category, the safety criteria are risk-based (A3.1).

The FA Regulation also introduced an obligation for each substance to be authorised on an individual basis so as to ensure that the proper safety/efficacy assessment is applied. It removed the generic group authorisation process that had previously applied for certain FA under the former 1970 FA Directive (e.g., flavourings, some vitamins) (A3.1). Transparency was also enhanced through the creation of the Register of FA (A3.2), as discussed above under SO2.

Defining clear and comprehensive rules for the FA authorisation process was expected to lead to a more transparent, simpler, clearer and more predictable process (O2, R2.1, 2.2; cf SO2 above), which in turn would have a positive impact on the functioning of the EU single market (I2).

Labelling

It is necessary to know very precisely how a given feedstuff should be used, given the FA that it contains, in order to ensure the safety of animals, consumers, workers and all other persons who may come into contact with it along the feed chain, as well as to avoid any potential negative impacts on the environment. Accurate and precise labelling of premixtures and FA is therefore vital. However, the labelling rules laid down by the 1970 FA Directive were not appropriate for some of the FA and premixtures that were authorised. For example, the batch

numbers were not required for all FA (D2.1). The 2003 FA Regulation therefore specifically sought to avoid potentially harmful confusion on the part of users by establishing detailed labelling rules that would mirror those already applicable to food (A3.1).

The establishment of clear and comprehensive labelling rules was designed to improve information on FA for those who handled them and thus facilitate their safer use along the feed chain (O2, R2.3). In this way, these measures were expected to have a positive impact on the functioning of the internal market (I2) and to promote a better level of protection of human health, animal health, animal welfare and the environment (I1, I3, I4).

Specific Objective 4 (SO4). Ensure rigorous and independent risk assessment.

As specific objectives 4 and 5 address a common problem set, and the drivers they address to some extent overlap, this sub-section and the next one should be read together.

FA safety is a multi-dimensional challenge. Animals are exposed to FA directly through the feed they eat, and FA residues may persist in the food that is made from them, thus possibly posing a risk to human health. When manipulating FA or the products in which they are contained, workers and farmers[18] may also be negatively impacted through direct exposure to these substances. Finally, FA may pose environmental risks depending on how the active substance(s) they contain are metabolised by the animal, and whether they are administered over long periods of time and/or to large groups of animals (P3). All of these can stand in the way of ensuring that human and animal health, and the state of the environment, are properly protected (GO2).

In the 1990s, a sequence of major food crises[19] highlighted a number of weaknesses in the EU food and feed systems that compromised safety on several levels. Among the high-level legislative drivers that were singled out were: a lack of transparency in the central decision-making procedure; the sometimes unclear and unbalanced relationship between scientific opinions and political decisions; and the lack of a global and high-quality scientific overview of the food chain as a whole[20].

The 1970 FA Directive had its own shortcomings, which exemplified or aggravated the high-level drivers outlined here. The risk assessment process was clearly incomplete (D3.1): some key FA, such as amino acids, enzymes and microorganisms, were not subject to a full evaluation, and there was no requirement for a comprehensive assessment of the environmental risks posed. Nor was there any provision for a comprehensive evaluation of worker safety. The process as it was defined was weakened by the widely varying levels of scientific expertise that participants brought to the table (whether at MS level, or in the composition of the Scientific Committee on Animal Nutrition (SCAN) (D3.2) and there was no formal separation between risk management and risk assessment, with both the Commission and MS performing both tasks (D3.3).

[18] In principle, pet owners do not use/directly manipulate FA/premixtures, only feed materials and compound feed containing them. Farmers may only manipulate/use FA if they are registered as FeBOs.

[19] Notably the BSE crisis in 1995 and the dioxin crisis in 1999.

[20] Commission Staff Working Document on the Refit Evaluation of the General Food Law (Regulation (EC) No 178/2002) - SWD (2018) 38 final.

To address these drivers, and in compliance with the requirements introduced by the General Food Law of 2002[21], the 2003 FA Regulation established a clear separation between risk management and risk assessment (A4.1). Risk assessment was henceforth to be carried out by an independent agency (EFSA), of which the members of the scientific panel to perform the FA risk assessment (FEEDAP Panel) would be specifically nominated for their high level of scientific expertise and independence, while risk management would be the responsibility of the Commission, which would take the final decision on whether or not to authorise a FA on the basis of the EFSA's opinion.

A complete set of requirements for the authorisation of FA was introduced, including a comprehensive environmental risk assessment and specific measures to address safe handling of FA, with the goal of covering all the gaps in the existing risk assessment process (A4.2). A 10-year time limit was also introduced for all authorisations, to ensure that products are regularly reassessed in light of evolving scientific knowledge on their effects and impacts, and to encourage the development of safer and more efficient FA (A4.3).

Taken together, it was expected that those measures would result in a far more rigorous assessment of the risks posed by FA (O3, R3), and tangible improvements in worker safety (O4, R4). These measures were thus expected to have a positive impact on the protection of human health, animal health, animal welfare and the environment (I1, I3, I4).

Specific Objective 5 (SO5). Improve FA control, traceability and enforcement rules.

Safety of FA depends not only on rigorous and precise rules, but also on procedures for effectively monitoring and enforcing their implementation. When carrying out controls, public authorities must be able to identify and quantify the presence of FA, including when used as ingredients in compound feed. This requires methods of analysis that are robust, reliable and easy to implement.

Under the 1970 FA Directive, applicants had to propose a method of analysis when they requested authorisation of a FA, but this method did not have to be independently validated. In addition, the methods of analysis approved were not harmonised at EU level, so national control authorities did not have easy access to them as they were not placed in a centralised database or register (D3.4). This undermined the reliability and comparability of the results of controls across MS.

The 2003 FA Regulation addressed this issue by setting up a European Union Reference Laboratory for FA (EURL), supported by a network of National Reference Laboratories (NRLs) (A5.1). The main roles of the EURL are to validate the methods of analysis proposed by applicants for FA, and to store and maintain reference samples of those FA. It also provides scientific and technical support to the Commission and is an important forum for discussion with MS to address challenges related to these methods. All the methods of analysis are available to the public in the database kept by the EURL.

[21] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

Under the 1970 FA Directive, there were some limited provisions to ensure traceability. Yet without seamless traceability, a rapid, targeted and effective reaction in case a safety issue arises may be difficult (D3.5). Restricting authorisation to a specific holder is one way to facilitate more traceability in case of necessity to implement a Post-Market Monitoring (PMM) Plan for possible unforeseen effects resulting from the use of FA (A5.2). Under the Directive, holder-specific authorisations were limited to antibiotics, coccidiostats and growth promoters. The FA Regulation extended these authorisations to zootechnical FA and FA containing, consisting of or produced from genetically modified organisms (GMOs). In this way, the FA Regulation aimed to increase traceability while also promoting innovation by ensuring market exclusivity for those FA which are potentially the most innovative (see further, SO 7 below).

Under the FA Directive, MS could request the person responsible for placing the FA on the market to monitor undesirable interactions with other FA, so as to record and report them to the NCA, but this possibility was restricted to FA having an antimicrobial effect. The FA Regulation enlarged the scope of such PMM to additional categories of FA[22] (A5.3). These PMM plans are intended to trace any direct, indirect, immediate, delayed, or unforeseen effects.

In these ways, the 2003 FA Regulation sought to ensure early detection of potentially harmful effects and timely implementation of corrective measures, including removing unsafe FA from the market, through improved control, traceability and enforcement mechanisms (O5, R5). It was thus expected that the FA Regulation would further enhance the protection of human, animal health and the environment. (I1, I2, I4).

Specific Objective 6 (SO6). Address specific interests of pet owners and their animals.

Under the 1970 FA Directive, the needs of pets and their owners were not taken sufficiently into account, neither with respect to safety nor to efficacy (D4). The 2003 FA Regulation considered that since pet food is not part of the human food chain and has no environmental impact on arable land, specific provisions should be developed in this regard. In order to ensure that the health of domestic animals was properly protected (GO2), the FA Regulation addressed this by setting detailed rules for FA destined for use in pet food (A6). New obligations to perform specific toxicity studies (using either laboratory animals or *in vitro* tests)[23] were introduced. The obligation to demonstrate the efficacy of substances was also established, together with specific provisions[24] on data requirements related to applications. For animal welfare reasons, the requirements reduced the need for testing on pets themselves, for example by implementing alternative testing strategies. These provisions were complemented with strict labelling obligations.

It was expected that the new rules would result in greater availability of safe and efficacious FA on the market specifically for use in pet food (O6, R6), which should have a positive impact on animal health and consequently meet pet owners' expectation to be able to provide a safe and nutritious diet for their companion animals (I3).

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22 Including: nutritional FA, zootechnical FA, coccidiostats, histomonostats and FA consisting of/containing/produced from genetically modified organisms (GMOs).

23 In particular: on chronic toxicity, reproductive toxicity, mutagenicity and carcinogenicity of substances.

24 Regulation (EC) No 429/2008 ('Commission Rules for Applications').

Specific Objective 7 (SO7). Encourage the placing on the market of innovative and efficacious FA.

FA can significantly contribute to achieving a positive balance between animal nutrition and well-being, environmental protection, increased productivity and improved quality of animal-based food products. In doing so, they can make a tangible contribution to innovation in the sector (GO3).

However, under the 1970 FA Directive, this potential remained under-realised in the EU: many opportunities for FA that could support productivity, animal welfare and environmental protection were missed, and the market as a whole did not reflect the actual state of technological progress (P4). The reluctance of FA producers to invest in innovation depends not only on market conditions and opportunities (D5), but also on the regulatory environment within which they have to operate (D6).

The regulatory drivers (D6) behind this problem were linked to the fact that once functional groups and categories were defined in legislation, they were not easily revised, and so tended not to evolve and adapt to scientific and technical progress. The 2003 FA Regulation set out to address this issue by creating new functional groups and categories specifically to address this concern (A7.1). More recently (in 2015)[25], the FA Regulation was further adapted so that categories may be more easily modified wherever necessary, in line with technological progress and scientific developments, in order to ensure that the existing classification does not become an obstacle to innovation (e.g., the case of hygiene condition enhancers[26]).

The concerns created by the classification of FA were exacerbated when the marketing authorisation associated with a category did not provide for any period of market exclusivity during which investments made in innovation could be reliably recovered by the original firm that carried out the R&D. Prior to the FA 2003 Regulation, significant segments of the FA market were failing to attract investment in innovation, in part because new FA did not receive holder-specific authorisations. This was the case for enzymes and microorganisms (currently classified mostly as zootechnical FA). In order to promote innovation, the 2003 FA Regulation introduced market exclusivity (i.e., holder-specific authorisation) for the full duration of the authorisation (10 years) *a newly created category of zootechnical additives, which introduce new mechanisms of action or new functions*" (A7.2). These "zootechnical additives" included essentially the categories of enzymes and microorganisms as defined in the 1970 FA Directive, but also embraced other types of FA which can have positive effects on animal welfare and the environment.

Under the 1970 FA Directive, there was also no requirement to demonstrate efficacy in certain cases – not only for provisional authorisations, but also for some entire categories of FA (e.g., certain vitamins and flavourings). The 2003 FA Regulation introduced an obligation to

[25] Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union. OJ L 198, 25.7.2019, p. 241.

[26] A new functional group was created for hygiene condition enhancers that are substances or, when applicable, microorganisms which favourably affect the hygienic characteristics of feed by reducing a specific microbiological contamination.

demonstrate efficacy for all FA (A7.1). This helps protect FA against unfair competition from FA whose claimed benefits may not in fact be scientifically demonstrated.

The establishment of clear criteria and accurate definitions of categories and functional groups in the 2003 FA Regulation, together with the data requirements specifically required to demonstrate efficacy as set out in the Commission Rules for Applications, were key elements intended to encourage firms to develop new and efficacious FA for placing on the EU market.

It was also expected that the obligation to renew an authorisation after 10 years would promote innovation, as it would provide an additional incentive for producers to ensure their FA incorporate the benefits of the latest science and are clearly differentiated from their competitors.

One particular area in which innovation had been blocked under the 1970 FA Directive was the use of FA in water for drinking, which was simply not permitted. By 2003, this prohibition was no longer aligned with the best technical and scientific evidence, and the FA Regulation therefore included provisions to allow the authorisation of new and innovative FA that were most efficient when administered in drinking water (A7.3).

Taken together, these measures were designed to make it easier to authorise and market innovative and efficacious FA in the EU, while maintaining high standards of safety (O7). They were thus expected to have a beneficial impact on European innovation, and thus on the economics of the EU livestock sector more generally (R7, I7), in addition to the positive contributions individual FA might make to other objectives, especially environmental protection, and animal health and well-being (I1, I3, I4).

Specific Objective 8 (SO8). Ensure FA cannot mislead consumers on the quality of food.

The interests of consumers (GO4) were already taken into account in the 1970 FA Directive to some extent, as the need to prevent FA from impairing the characteristics of animal products was already an element to be considered during the authorisation process. However, this still left the door open to using FA to disguise or conceal the nature or origin of animal food products that are offered for sale (P5), due to a lack of precision in the rules concerned (D7). The 2003 FA Regulation therefore took steps to further extend the protection offered to consumers by explicitly prohibiting the use of FA to mislead people as to the distinctive features of the animal products they eat (A8). In other words, FA may not be authorised if they serve to falsify the quality of the food product, for example by changing the characteristic flavouring of a food in such a way as to disguise its animal origin. In addition, appropriate labelling rules were laid down to ensure that relevant information on the use of FA is available throughout the whole chain, so that livestock farmers and feed producers know how the FA they use may alter the character of the food that is produced, and so ensure that they do nothing which may lead consumers to purchase and consume food on the basis of false assumptions as to what they are actually eating.

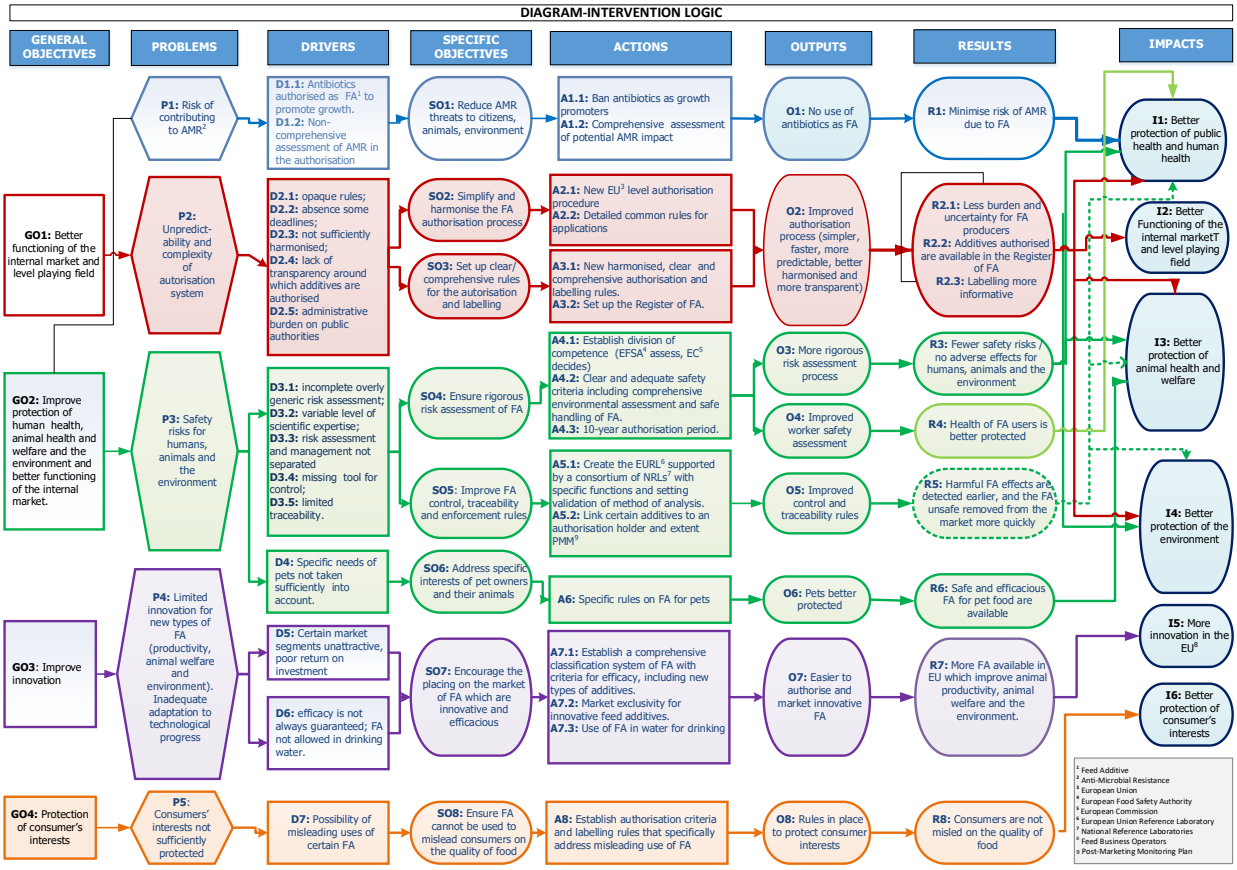
Through the establishment of these rules (O8), it was expected that it would become more difficult for FA to be used in ways that would mislead the consumers of animal products (R8).

United Nations' Sustainable Development Goals (SDGs)

The concept of sustainability did not have the central place in EU policy in 2003 that it has today, and the UN Sustainable Development Goals were not themselves declared until 2015. Nevertheless, many of the measures introduced by the 2003 revision of the FA legislation can be understood as seeking to ensure that the European livestock industry would operate on a more sustainable basis.

More specifically, the FA Regulation contains measures that implicitly address certain of the sustainable development goals (SDG), in particular by creating a more sustainable system for livestock farming (SDG 12), one that will be more economically prosperous and more environmentally secure. The opportunities for businesses to invest in innovative FA that improve animal welfare conditions and reduce the impact of livestock farming on the environment are clearly related to SDGs 2, 3, 9, 13, 14 and 15. The comprehensive environmental risk assessment for all FA intended for farmed animals should reduce pollution of waters and soils, in line with SDGs 13, 14 and 15. The measures intended to reduce antimicrobial resistance and ensure a rigorous risk assessment of FA with regard to human and animal health directly promote the health and well-being of animals, consumers and workers/users along the food chain (SDG 3). Driving sustainability objectives throughout the supply chain can thus be seen as an overarching (though largely implicit) objective of the 2003 FA Regulation, which sought to enable a more responsible animal production system, and which in this way was already to some extent already pre-aligned with the UN SDGs even before they had been formally articulated and accepted by the EU.

Figure 1 - Diagram of the intervention logic



2.2. Point(s) of comparison

The point of comparison for the evaluation is the situation before the FA Regulation became applicable (October 2004) when the rules governing FA were essentially those laid down in the 1970 FA Directive. These rules covered the authorisation, placing on the market and control (inspection) of FA, as well as labelling provisions for FA incorporated into feed materials and compound feed, and safeguard measures, control measures and provisions applicable to establishments and intermediaries.

Several types of FA (including silage additives, amino acids and urea) were either subject to other legislative frameworks, or simply not regulated. A centralised, though not fully harmonised, authorisation system at the Community level existed with authorisation decisions adopted by Commission acts, involving MS in the assessment procedure. Antibiotics, coccidiostats and growth promoters were authorised on a holder-basis for a 10-year period, after which they would need to be renewed (each renewal also being valid for ten years). The majority of FA (technological additives, colourants, vitamins, enzymes and microorganisms) had an unlimited authorisation period and were not linked to an authorisation holder. More details on the situation preceding the introduction of the FA Regulation are described under the intervention logic (Section 2.1).

In the context of the transition to the new regime established by the 2003 FA Regulation, FeBOs notified 2,567 FA which had been either authorised individually or by group under the 1970 FA Directive or which were outside the scope of the Directive (amino acids and silage additives). Upon the adoption of the 2003 FA Regulation, FeBOs presented applications for the re-evaluation of 830 FA. The FA that were notified but for which no application was introduced were withdrawn from the market.

From 1997 to 2002[27], 18 antibiotics[28] used as growth promoters were banned. Before the adoption of the FA Regulation, four remaining antibiotics were still used as growth promoters[29] (EM 1.4.18).

In terms of innovation, from 1979 to 2003 there were 104 patent applications for FA (EM 2.2.5).

Information from Argentina, Canada, Chile, China, Japan and the USA was used to compare their respective authorisation procedures with the EU system and to assess to what extent EU authorisations are recognised in those countries.

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[27] Commission Directive 97/6/EC, Commission Directive 98/19/EC, Council Regulation (EC) 2821/98, Commission Regulation (EC) 2788/98, Commission Regulation (EC) 45/1999, Commission Regulation (EC) 2205/2001, Council Regulation (EC) 1756/2002.

[28] Amprolium, ethopabate, arprinocide, avoparcin, bacitracin zinc, carbadox, dinitolmide, dimetridazole, ipronidazole, meticlorpindol, methylbenzoquate, nicarbazin, nifursol, olaquindox, ronidazole, spiramycin, tylosin phosphate and virginiamycin.

[29] Flavophospholipol, avilamycin, monensin sodium and salinomycin sodium (no substance used in human medicine).

3. HOW HAS THE SITUATION EVOLVED OVER THE EVALUATION PERIOD?

3.1. Current state of play

3.1.1 Reduction of antimicrobial resistance threats to citizens, animals and the environment

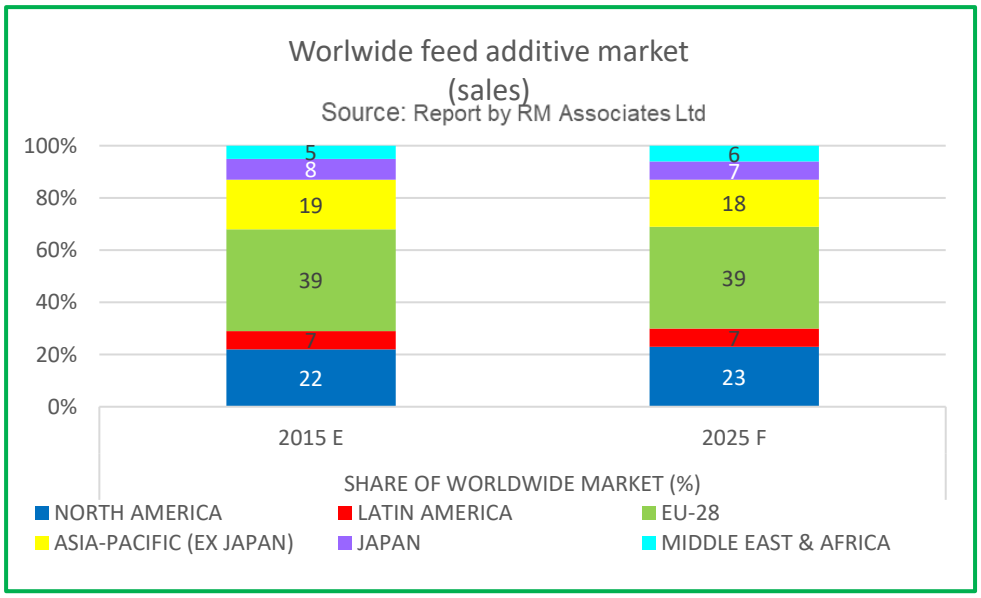
With the entry into force of the FA Regulation, the four remaining antibiotics still in use as growth promoters were taken off the EU market in January 2006. Furthermore, the authorisation of FA that directly enhance performance (zootechnical additives) indirectly contributed to reducing the need for the therapeutic use of antibiotics. During the 2004-2021 period[30], 99 new FA were authorised for this purpose - 84 "gut flora stabilisers" and 15 "other zootechnical additives" (EM1.4.19).

3.1.2 Placing innovative and efficacious FA on the market.

Global and EU markets[31]

The **global FA market** was valued at approximately $21.77 billion in 2015 and is expected to reach $28.22 billion by 2022. The EU represents some 40% of the global market with Argentina, Canada, Chile, China, Japan and the USA also accounting for an estimated 40%.

Figure 2 - Worldwide FA market



The **EU-28 market** is estimated at around €15.7[32] billion in 2020, which represent around 35% of the total (see table 1 below). Market data do not include coccidiostats and histomonostats, but these have been estimated based on industry information which points to them representing around 35% of the total market by value.

30 Each time that this period is mentioned it refers to May 2021.

31 2018 Report by RM Associates Ltd carried out for the organisation representing the EU FA industry (FEFANA) based mainly on industry insights/interviews, cross-checked with data from various market research providers.

32 Based on data of Mordor Intelligence but adding an estimation of coccidiostats value.

Structure of the EU market

Table 1 - Estimations of economic value 2021-2026. EUR millions in EU market.

	2020	2021E	2026E	CAGR* % (2021-2026)
Vitamins	803	836	988	3.0
Antioxidants	1,150	1,189	1,379	2.6
Amino Acids	1,572	1,639	2,145	4.8
Enzymes	460	481	585	3.5
Mycotoxin Detoxifiers	390	408	471	2.5
Prebiotics**	1,289	1,344	1,776	5.0
Probiotics (microorganisms)	930	969	1,268	4.8
Flavours and Sweeteners	272	283	330	2.7
Pigments	1,029	1,073	1,299	3.4
Binders	1,150	1,193	1,396	2.8
Minerals	865	894	1,132	4.2
Acidifiers	1,005	1,050	1,314	4.0
Others	599	609	728	3.2
Total without prebiotics	**10,227**	**10,621**	**13,001**	**3.8**
Estimation of coccidiostats * **	**5,507**	**5,719**	**7,000**	
TOTAL (with coccidiostats but excluding prebiotics) * **	**15,734**	**16,340**	**20,001**	

Source Mordor Intelligence, 2022.

* Compound annual growth rate (CAGR) including prebiotics.

** They are regarded as speciality feed ingredients although from the legal point of view they are feed materials.

*** Commission estimation considering that 35% of the value are coccidiostats.

Note: Data provided by Mordor Intelligence have been converted from USD to Euro at the exchange rate of 1 USD = 0.87 Euro. Projection of 2021-2026 calculated based on the base year 2020.

The pet food sector has an annual sales volume of 8.8 mt. and the turnover is estimated at €21 billion (2018), providing an estimated 80 million EU households[33]. The sector is growing at an annual rate of 2.5%[34].

The FA sector as a whole is relatively concentrated with 94 companies accounting for an estimated 80% of EU production value[35]. 60% of them are SMEs, which tend to focus on specific (niche) segments of the market and to mainly produce FA which are not linked to an authorisation holder.

[33] Latest data available from the association representing the pet food industry (FEDIAF): at least 25% of EU households own one dog and at least 23% own one cat.

[34] FEDIAF: European Pet Food Industry.

[35] Source: FEFANA Data 2018.

Trade and competitiveness

According to a FEFANA survey of their members carried out in 2018, innovation is the most significant part of overall investment. EU companies are also very important exporters: exports account for 60% of annual turnover for SMEs and 42% for large businesses.

Imports from non-EU countries play an important role across all FA categories. For some specific FA, such as vitamin B_{12} or amino acids, imports may account for more than 75% of EU supply[36]. Although the main countries of origin differ per functional group, six countries play a major role across all categories (USA, China, India, Brazil, Japan and Canada), in particular the United States and China (EM 2.2.1).

More precisely, the Asia-Pacific is expected to continue to dominate the FA market in terms of volume and value and is projected to exhibit the highest annual growth rate until 2025[37]. In this region, China is the major producer and exporter of FA.

Innovation

Some trends at global level show a growing interest in FA that can prevent the use of antibiotics. Those additives may improve digestion and conversion e.g., microorganisms. In addition, there is interest in FA intended for the organic sector that are more natural in origin (e.g., plant extracts)[38].

In the EU, during the period 2004-17, the largest number of innovations were in the zootechnical additives category and, specifically, in the functional group 'other zootechnical additives'; 61 out of 79 applications and 28 out of 35 authorisations were in this category. The other two innovative groups are 'reduction of contamination by mycotoxins' (12 applications and 6 authorisations) and 'hygiene conditions enhancers' (6 applications and 1 authorisation) (EM 2.1.1). In the period between 2004 and 2019, the number of patent applications increased to 207 (compared to 104 during the preceding 24 years) (EM 2.2.5).

According to industry data, large and medium size companies seem to be less specialised in FA than smaller companies: FA account for less than half of the turnover for 70% of large companies and 60% of medium size companies as compared to some 30% of small companies. The same survey results also indicate a total investment in R&D ranging from 26% to 14% of the turnover for small and large companies, respectively, compared to 8% for medium-size businesses (EM 2.1.7).

3.1.3 Simplifying and harmonising authorisation and labelling rules and processes and ensuring a rigorous risk assessment.

Authorisation process

The authorisation process is a centralised system and unfolded in figure 1, ANNEX VIII, which involves the Commission, the MS, EFSA and the EURL.

[36] vi Case studies, page 23.
[37] Allied Market Research.
[38] Future market insights. Animal FA Market Forecast. March 2020

The Commission is responsible for receiving applications for authorisation and, under the control of MS via the 'comitology' procedure, taking the risk management decision together with MS through decisions that are adopted in the form of Implementing Regulations. Risk assessment is performed independently by EFSA. The EURL has a role in assessing and validating the detection methods for FA during the risk assessment step, to ensure traceability and effective controls by MS. Details of the authorisation process are described in Annex VIII. There are several steps in the authorisation process:

- **Submission of applications**: During the period 2004-2017, 791 applications for authorisation were presented to the Commission (SANTE applications).
- **Risk assessment**: during the same period, EFSA processed 969 applications (EFSA applications) resulting in 613 opinions. 20% of all opinions issued under Article 4(1) applications (new authorisation) and 12% of all opinions issued under Article 10(2) applications (re-evaluation) were issued within the six months deadline. The average period to issue an opinion was 27 months for Article 4(1) applications and 36 months for Article 10(2) applications (EM 1.3.5). During the period 2004-2019, the EURL issued 628 validation reports on detection methods (EM 1.4.8).
- **Risk management**: During the same period, the Commission authorised 775 FA through 482 authorising Regulations. 37% and 31% of authorisations were granted for Article 4(1) and Article 10(2) applications, respectively within six months of receipt of the opinion.

More detailed information on the number of authorisations by type of authorisation (holder-specific or non-holder specific) and by type of purpose is presented in Annex VIII.

Labelling

The 2003 FA Regulation laid down much more detailed labelling rules than the 1970 Directive. For instance, to improve safety and traceability, it became mandatory to include the identification number of the FA and the batch number for all FA. More details on labelling requirements for FA and premixtures are presented in Annex VIII.

3.1.4 Addressing specific interests of pet owners and their animals.

The FA Regulation established some provisions concerning pets, which were detailed by the Commission Rules for Applications. EFSA set out specific guidance for applicants: "Guidance on the assessment of additives intended to be used in pets and other non-food producing animals"[39]. The 2003 FA Regulation also took into account the potential hazards of FA for pet owners and provided a comprehensive set of labelling rules to ensure proper information along the feed chain.

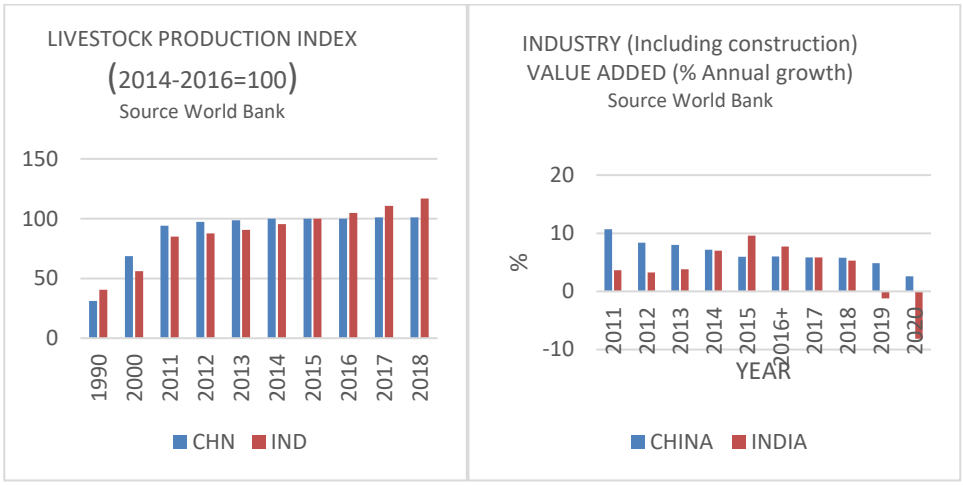
[39] This guidance was applicable for many years but now has been replaced by a more generic guidance that also includes the pet's specifications.

3.2. External factors or market developments affecting the results of the intervention.

3.2.1 Increase of industrial development in third countries

The Asia-Pacific region has shown significant growth patterns not only in relation to growth of economic and industrial activity, but also in population growth and the shift from a plant-based diet to a diet including more food from animal origin. For instance, China and India have implemented modern husbandry practices with a standardisation of livestock production which generates increasing demand for feed, and thus for FA. Lower labour costs and looser environmental restrictions allowed those countries to develop an important FA industry and to increase exports to the EU, though this cannot be quantified as no reliable data exist specifically on the production and trade of FA. India, China and Japan are very present in the medicine and health technologies sector, which uses similar production techniques to FA. Global pharmaceutical companies are also important producers of FA and many of them have research/development centres[40] and production sites in these countries.

Figure 3 - Livestock production index and industry value added in China and India



3.2.2 Frequency of mergers and acquisitions

Another significant external factor influencing the FA sector is mergers and acquisitions activity. This has a direct impact on the functioning of the 2003 FA Regulation, since changes to the holder of an authorisation due to mergers and/or acquisitions required the adoption of 28 (Implementing) Regulations by the Commission during the period 2004-2018.

3.2.3 Scientific and technical developments in safety/efficacy assessment

Finally, another factor influencing the preparation of dossiers for applications was the 2016 decision of the EFSA's FEEDAP panel to update most of the guidance documents it had produced. Six guidance documents for assessment of safety, efficacy and characterisation of FA were updated between 2016 and 2019 (see Table 1 in Annex III). This revision ensured a higher level of safety than before but required applicants to invest in the production of additional data

[40] The Converging Technology Revolution and Human Capital Potential and Implications for South Asia. 2021 International Bank for Reconstruction and Development / The World Bank.

sets, in particular regarding environmental safety and the characterisation of microorganisms used as, or for the production of, FA.

3.2.4 New challenges related to pollution associated with animal production.

Environmental impact is at the top of many legal initiatives, strategies and actions such as the Biodiversity Strategy[41], the Chemicals Strategy for Sustainability[42], the Organic Action Plan[43], or the Zero Pollution Action Plan[44]. This latter plan intends to review the Industrial Emissions Directive to curb ammonia emissions from the intensive rearing of livestock. In addition, further measures to reduce ammonia emissions may be needed, *inter alia* under the Common Agricultural Policy. Governments have prioritised actions in key sectors driving environmental impacts such as agriculture activities. Those changes in the regulatory framework and science are challenging for the livestock sector and consequently for FA. Recent innovations in environmental concepts, processes and tools may also cause changes in the data requirements for the assessment.

4. EVALUATION FINDINGS (ANALYTICAL PART)

4.1. To what extent was the intervention successful and why?

4.1.1 Reduce AMR threats to citizens, animals and the environment.

The FA Regulation has been effective in banning antibiotics as growth promoters (four remaining antibiotics as growth promoters were banned in 2006 (EM 1.4.18). The pre-market assessment of all FA for their potential antimicrobial effects also helped reduce the risks of placing FA on the market which would have AMR effects. In addition, a comprehensive post-market monitoring (PMM) was introduced for certain categories of FA.

Microorganisms used as FA could potentially also induce antimicrobial resistance[45]. Even though a PMM for those FA is not required for all micro-organisms as such, EFSA examined carefully this aspect. In the 15 renewals of authorisation carried out from 2019 to 2021, no safety hazards or issues were discovered by EFSA in relation to AMR. The evaluation of AMR performed by EFSA is also relevant for FA intended for pets. Due to their close contact with humans, medicinal products, FA or other substances used in pets may easily spread AMR in humans[46]. The pre-market approval process led the Commission to withdraw or deny the authorisation of five FA and led applicants to withdraw applications as they could not prove absence of antimicrobial resistance development.

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41 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions EU Biodiversity Strategy for 2030. COM (2020) 380 final.

42 Communication the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of Regions Chemicals Strategy for Sustainability Towards a Toxic-Free Environment. COM (2020) 667 final.

43 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on an Action Plan for The Development of Organic Production COM/2021/141 final/2.

44 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil. COM/2021/400 final.

45 Microorganisms are widely used as FA under different categories. For the authorisation of microorganisms, specific data are required to ensure that they do not contain in their genome genes that codify for antimicrobial resistance so they can spread resistance to animals but also to the environment and finally to human beings. Regulation (EC) No 429/2008 contains specific data requirements to permit a full assessment on AMR for all additives.

46 Reflection paper on the risk of antimicrobial resistance transfer from companion animals. 15 January 2015 - EMA/CVMP/AWP/401740/2013.

The trend visible in the few existing studies[47] indicates a positive correlation between the reduction of antibiotics used as growth promoters and the reduction of cases of specific antibiotic-resistant microorganisms present in livestock farming. In a few examples[48], specific measures to reduce antimicrobial use have been associated with a reduction of AMR in bacteria from food-producing animals or foods derived therefrom. A positive impact on animal health parameters was demonstrated for certain alternatives such as organic acids or probiotics (microorganisms) that are regarded as FA. These FA (microorganisms) have positive effects through different mechanisms on the intestinal flora (e.g., maintenance of the epithelial barrier of the intestine). The physiological status of animals improves, and they become more resistant to infections (EM 1.4.21).

Use of antibiotics decreased and is now lower in food-producing animals than in humans, as reported by EFSA, EMA and ECDC[49]. The fall in antibiotic use in food-producing animals suggests that the measures taken to reduce their use are proving to be effective. These results can however not be clearly associated with the FA Regulation as other measures impacted the reduction of antibiotic use in food-producing animals: the Commission's Action Plan (2011-2016), the EU One Health Action Plan Against AMR adopted in 2017, the EU Guidelines on the Prudent use of Antimicrobials in Animal Health, the different National Action Plans and Strategies, and the surveillance and audits. EMA and EFSA concluded that "*assessing the impact of measures to reduce antimicrobial use on the occurrence of AMR in food-producing animals and food is difficult for several reasons. For example, several measures may have been applied simultaneously, trends can only be observed where there is a sustained period of longitudinal, standardised monitoring data (which is not available from all MS) and it is difficult to establish causality in such complex systems."*[50]

The ban of antibiotics as FA encouraged innovation in FA by developing alternatives (EM 1.4.19). The EU has demonstrated that the ban of antibiotics has not reduced animal production for the most relevant species (figures 2 and 3 of Annex VII). By May 2021, there were 84 authorised FA (microorganisms) and 15 authorised "other zootechnical additives" contributing to reduce the use of antibiotics[51]. They were authorised following a stable growth pattern (figure 3 of Annex VII). The value is around 930 million euros (table 1).

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47 Graveland H, Wagenaar JA, Heesterbeek H, Mevius D, van Duijkeren E and Heederik D, 2010. Methicillin resistant Staphylococcus aureus ST398 in veal calf farming: human MRSA carriage related with animal antimicrobial usage and farm hygiene. PLoS ONE, 5, e10990; Torneke K, Torren-Edo J, Grave K and Mackay DK, 2015. The management of risk arising from the use of antimicrobial agents in veterinary medicine in EU/EEA countries - a review. Journal of Veterinary Pharmacology and Therapeutics, 38, 519–528; DANMAP, 2016. Use of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from food animals, food and humans in Denmark. ISSN 1600-2032; DANMAP, 2018. Use of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from food animals, food and humans in Denmark. ISSN 1600-2032; Swedres-Svarm, 2017. Consumption of antibiotics and occurrence of resistance in Sweden. Solna/Uppsala ISSN1650-6332.

48 EMA and EFSA Joint Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety (RONAFA) https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4666

49 Third joint inter-agency report on integrated analysis of consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/EEA. https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6712

50 EMA and EFSA Joint Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety (RONAFA) https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4666

51 SANTE database does not permit to do statistics as those FA are under the functional group "other zootechnical additives". This group includes FA having many different functions; therefore, it is not possible segregate the data for those that contribute to reduce the use of antibiotics.

Stakeholders, including some MS, the industry, FA users and veterinary professionals, have recognised the effectiveness of the FA Regulation in banning antibiotics used as growth promoters and in reducing the risks for developing antimicrobial resistance stemming from FA placed on the market.

The different measures set up by the FA Regulation for that specific objective provide benefits not only for human health but also for pets and their owners. In terms of benefits for human health, 72% of respondents agree that the ban on the use of antibiotics played an important role in preventing AMR (WPC). FA will not pose risks of AMR for pets and their owners as those FA are subject to pre-market assessment to eliminate any AMR effect.

The ban of antibiotics as FA fostered innovation for sustainable alternatives contributing to a reduction in the use of antibiotics that directly benefits farmers by facilitating the conversion pathway to more sustainable methods of livestock farming.

4.1.2. Simplifying and harmonising the authorisation, risk assessment, risk management processes

4.1.2.1 Credibility of the risk assessment and risk management process

The 2003 FA Regulation lays down a comprehensive set of safety requirements so as to fill the gaps left by the 1970 FA Directive. Some of these gaps were specific to certain groups of FA, others were more general (see 1.3 Annex III).

The clear separation of risk assessment and risk management established in line with the General Food Law, led to a more independent, objective and transparent risk assessment. The underlying basis of the EU authorisation process is the credibility of the safety and efficacy assessment performed by EFSA. The results of the surveys carried out for this evaluation showed that the safety assessment was not contested, and a strong consensus was achieved across all categories of stakeholders.

In addition, EFSA's assessment is also valued at international level. Some elements of the EFSA safety assessment are recognised in the authorisation process carried out by some third countries for fast-track registration of EU products, particularly in the South-East Asian and African regions.

Even though EFSA's risk assessments were challenged in five cases, the administrative review by the Commission[52] each time dismissed the allegations (EM 1.5.1). In relation to the Commission's risk management decisions, only one case was lodged at the Court of Justice of the EU against a Commission decision to suspend a FA authorisation. The Court ruled in favour of the Commission and thus confirmed the original decision[53] (EM 1.5.2). At international level,

[52] Article 19 of the FA Regulation: "*Administrative review - Any decision taken under, or failure to exercise, the powers vested in the Authority by this Regulation may be reviewed by the Commission on its own initiative or in response to a request from a Member State or from any person directly and individually concerned. (…) The Commission shall take a decision within two months (…)*".

[53] Case T-201/13 ("Toyocerin"): judgment of the General Court of 21 May 2015 (Rubinum v. Commission). Application for annulment of Commission Implementing Regulation (EU) No 288/2013 of 25 March 2013 concerning the suspension of the authorisations of the preparation of *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I-1012). The action was dismissed by the Court (*i.e.,* ruling in favour of the Commission).

there were three cases[54] during the period 2004-2021 that led to comments in the context of the mandatory notification of draft acts to the World Trade Organisation (WTO-SPS). Commission arguments responding to relevant comments were not further contested (EM 1.5.3).

4.1.2.2 Effectiveness of the authorisation system

As a result of the revised risk assessment and risk management process introduced by the 2003 FA Regulation, positive effects on human health, animal health, animal welfare and the environment can be observed. 90% of respondents to the Public Consultation, who were mainly business representatives, consider that the safety assessment carried out by EFSA can be relied upon to ensure that FA are safe for **human health**, animal health and the environment (see PC). A majority of NCAs also considers that FA are safe for animals, workers, consumers and for the environment (EM 1.2.6). In addition, 75% of respondents see benefits from the FA Regulation for human health (see SH survey). The FA Regulation is believed to have a positive effect for farmers (83% of respondents noted such benefits), especially in terms of preventing losses from animal diseases (e.g. due to the safe use of vitamins, trace elements, coccidiostats), making animals more resistant to diseases (e.g. due to the safe use of microorganisms as gut flora stabilisers) and reducing the environmental impact of animal production (e.g. due to the safe use of enzymes or amino acids). **Consumers** also benefit from food of animal origin that does not contain residues that may compromise their health (92% of respondents believe that FA are safe for consumers). Benefits for **workers / users** were also identified: 84% of stakeholders consider that FA are safe for workers/users and a majority of users have the same opinion (EM 1.2.5). Users of FA also consider that FA are efficacious (59 out of 63 respondents (EM 1.1.9)). **Pets and their owners** benefit from FA that are evaluated following a complete set of safety requirements that take the specificities of pets into account and, in particular, their longer lifespan. The surveys indicated that 85% of respondents considered that FA have benefits for animal welfare, although according to some FA producers and pet food industry representatives, those benefits have not been fully exploited, as the studies are mainly targeted on performance criteria[55]. Although there are many FA that have indirect effects on animal welfare, no FA have been authorised under the FA Regulation with the specific purpose of having a direct effect on animal welfare. Finally, many FA authorised such as amino acids and enzymes have clear positive effects in terms of mitigating the **impact of livestock farming on the environment** (e.g., greenhouse gas emissions, excess of nitrogen and phosphorous in soils and waters, etc.).

In 2003, the scope of the legislation was extended to cover additional categories of FA not covered by the 1970 FA Directive (amino acids, urea and silage substances). 140 applications were submitted for those FA during the period 2004-2017. This allowed for the safety of these substances to be established. There were still FA however for which safety was not at all or only partially assessed (some sensory FA, the majority of vitamins, amino acids, enzymes, gut flora stabilisers, coccidiostats and histomonostats, corresponding to 458 applications, 352 opinions

[54] G/SPS/N/EU/455, G/SPS/N/EU/190 and G/SPS/N/EU/420.
[55] ii FA Final Report _FCEC, page 84.

and 1136 FA. Those FA are fully evaluated under the 2003 FA Regulation (EM 1.2.1, 1.2.2, 1.2.3 and 1.2.4).

There were FA for which efficacy was not at all or only partially evaluated under the 1970 FA Directive, and that are now fully evaluated under the 2003 FA Regulation. In total, these represent 339 authorised FA corresponding to 432 applications (EM 1.1.1, 1.1.2 and 1.1.3). Eight Regulations were adopted to withdraw FA from the market (EM 1.1.6).

The FA Register allowed for greater transparency of the market, providing FeBOs with open access to information about all FA that have been authorised, and their conditions of authorisation.

In response to the lessons from the food/feed crises of the 1990s (cf. BSE and dioxins), a 10-year authorisation period for FA was established. Even though those crises did not involve the FA sector directly, political leaders acted to reduce mistrust towards the feeding of animals in general, and to improve the public perception of the safety of the food chain, which had been seriously damaged. It was expected that setting a time limit on authorisations would also encourage the development of FA with a better safety and/or efficacy profile.

The 10-year authorisation period was perceived as effective for safety purposes by a slight majority of MS authorities (17 out of 27). Six MS authorities did not respond and four disagreed (NCAs survey). FeBOs were divided on the effectiveness of this 10-year period for safety and innovation purpose (see SH survey). Business associations and FA producers find that this period is too short to make it worthwhile developing innovative FA that require substantial upfront investment. The possibility to extend the authorisation period for FA with a long history of safe use was mentioned in particular by some MS authorities, business associations and companies. Some of the MS authorities that disagreed or did not provide responses noted that the 10-year limit is not sufficient to encourage innovation by SMEs.

4.1.2.3 Drivers and barriers to effectiveness of authorisations

The different steps in the authorisation procedure concerning FA were analysed to identify what elements drive or hinder effectiveness in the authorisation, re-evaluation and renewal of authorisation, and which are the most relevant procedures. It was also analysed whether the provisions introduced to simplify and harmonise the authorisation system had been effective. Elements to further simplify and reduce costs were identified.

In general, FeBOs understand the administrative procedures put in place. Stakeholders (mainly FeBOs) and MS recognised that the measures were simplified and better harmonised compared to the 1970 FA Directive. Stakeholders, including NCAs, the industry (i.e., FA and compound feed producers), FA users and veterinary professionals, recognised that the authorisation procedure set out in the FA Regulation is central to the achievement of a high safety standard. As regards timelines, they were considered as appropriate by the MS authorities, whereas the industry tends to consider that delays were such as to hamper competitiveness and innovation.

Some delays in the authorisation process for new authorisations and for the re-evaluation of existing authorisations could be observed during the risk assessment carried out by EFSA and to a lesser extent during the adoption process of the Commission Implementing Regulations

authorising the FA (see 1.4.2. Annex III). While delays during the re-evaluation process did not affect the sale of those FA, they might have a more pronounced effect on new FA for which the placing on the market was somehow delayed, thus potentially triggering a loss of market opportunities.

Time periods at the risk assessment step

78% of applications for the authorisation of **new FA** and 88% of applications for **re-evaluation** of authorised FA suffered from some delays during the **risk assessment** process, which were caused by missing and/or incomplete information presented in the application dossiers. Incomplete dossiers triggered the request for additional information by EFSA[56].

The reasons behind the possible delays during the assessment period are mainly related to missing information in the application dossiers:

- different interpretation of EFSA guidance documents, in particular for the design of studies. This is particularly complex for studies to demonstrate efficacy of innovative FA (understanding of endpoints or end points not defined);
- the update of EFSA guidance documents (see table 1, Annex III);
- a lack of pre-submission meetings[57] with EFSA until these were set up by the GFL (to provide advice on the rules applicable to, and the content required for, the application dossier, prior to its submission), which could be an important handicap that reduced the applicants' capacity to prevent future shortcomings;
- a lack of experience in the preparation of application dossiers for FA that had never been evaluated before (see 1.4.2.1 Annex III).

While simplification of the risk assessment process in comparison to the previous legislation was recognised, FeBOs perceived the regular revision of the EFSA guidance as burdensome. The achievement of a high food and feed safety level clearly demands the continuous updating of the guidance by EFSA. Although the adoption of revised EFSA guidance documents may reduce the capacity of FeBOs to adapt in time, different mitigation measures were already put in place[58] some years ago by EFSA to minimise the burden on FeBOs. More information in 1.4.2. Annex III.

Time periods at the risk management step

Possible delays during the **risk management** step were mainly caused by the complexity of some of the dossiers, but maybe also by the need to bring more clarity as regards the application of some of the provisions (see below under "internal and external coherence"). These triggered lengthy discussions at several SCoPAFF meetings to come to an agreement or internal discussions within the Commission.

[56] "Stop the clock" mechanism, referred to in Article 8(2) of the FA Regulation.
[57] Those are meetings with EFSA before the application is lodged, as referred to in Article 32a of Regulation (EC) No 178/2002.
[58] https://www.efsa.europa.eu/en/engage/stakeholders; https://www.efsa.europa.eu/en/applications/about/services

Risk management and risk assessment process

The observed time period for the whole authorisation process of FA (risk assessment and risk management) are indicated in the table below:

Table 2 – Time period for the whole authorisation process

PERIOD	ARTICLE 4(1) APPLICATIONS	ARTICLE 10(2) APPLICATIONS
12 months	7%	2%
≥ 12-18 months	19%	8%
≥ 18-24 months	25%	7%
≥ 24 months	50%	84%

The average time period across all applications during 2004-2017 has been 3.3 years (1,218 days) (EM 3.2.5). A majority of MS authorities and only 32% of FeBOs consider that the procedure of authorisation does not need to be modified. In relation to the timelines, a majority of MS authorities and FeBOs find them proportionate (EM 3.2.3 and 3.2.4). A detailed analysis of the time frame at the different steps of the authorisation procedure (risk assessment by EFSA and risk management by Commission and PAFF Committee) is presented in Annex III 1.4.2.

Modification and renewal of authorisations

The rules on modification and renewal of authorisations might be considered as burdensome for both applicants, users and authorities and a lack of transition provisions might lead to unintended shortages.

- In case of holder-specific authorisations, the current system requires an EFSA opinion and the adoption of an Implementing Regulation each time the authorisation holder of a FA changes, such as in case of mergers/acquisitions of companies. These represent 10% of the acts adopted for holder-specific authorisations.
- Article 13(3) of the FA Regulation only addresses the modification process introduced by the holder of an authorisation but does not foresee rules for requests for modifications of non-holder specific authorisations. In such cases, a full evaluation is not required, but instead only a verification whether the modification may give rise to a safety concern or may undermine efficacy. This situation has been largely mitigated by using Article 13(1) and (2) of the FA Regulation, that permits the Commission to modify any authorisation (including non-holder specific authorisations) on its own initiative, after consultation of EFSA. A clarification of the FA Regulation should be considered as it affects around 1214 FA[59] that are not linked to an authorisation holder.
- If the application for renewal is presented in due time, the FA will remain on the market until a decision on the renewal is taken by the Commission (even if the 10-year period has expired), provided that the reasons for the possible delay are beyond the control of the applicant. When an applicant withdraws the application during the renewal process, the FA concerned is no longer authorised. Feed producers thus face a "sudden" expiry of the authorisation, without any transitional period allowing an

[59] FA Register, May 2021.

adaptation of the products concerned on the market. As the renewal process of FA only started in 2017, there have been few cases, but this might become a challenge as more generic FA – that are currently widely used – are starting to come up for renewal. The procedure to renew the authorisation is not considered efficient by 66% of FeBOs (EM 3.2.2).

During the period 2017-2021, considering that the applications for renewal started to be submitted in 2017, 65 applications for renewal were received by the Commission. The average time taken for the risk assessment of those applications was around 10 months. The clock was stopped 91 times to request complementary information (EM 1.3.9). The authorisation procedure (risk management) did not suffer major delays as normally there are no contentious issues to consider in such cases.

4.1.2.4 Simplification – extrapolation of study results for FA

Elements to reduce costs and to incentivise applicants were included in the 2003 FA legislation.

- Elements to incentivise the submission of applications for authorisation of FA for minor animal species, for which the return on investment is limited, were not successful. The legislation allows to extrapolate the results of some data generated for the authorisation of a FA for a major animal species (e.g., chicken) to a minor animal species which is physiologically comparable (e.g., quail), to avoid duplication of tests. Applicants requesting an authorisation for minor species are further incentivised by extending the data protection period by one additional year for each minor species for which a use extension authorisation is granted. Many FA may be authorised for minor species because they are authorised for all animal species (947 in May 2021) or because one or several minor species were included in the authorisation (358 in May 2021). The Commission Rules for Applications set up the principle of extrapolation but did not develop very detailed requirements. The procedure to request extrapolation from major to minor species did not work well[60], according to stakeholders (mainly FeBOs) (SH survey and EM 1.3.11). The reasons given are the following: 1) the target market is limited and there is a lack of involvement of users further down the chain in the process to ensure that minor species of interest are covered by an application; 2) it requires investment in data generation and the users do not contribute to the costs; 3) the return on investment is not clear, in particular for small markets. Some MS authorities (NCA Survey) share some of the stakeholders' views, although 18 of them felt that the extrapolation worked well. Some MS authorities noted that extrapolation is difficult for certain pets as they are physiologically different from other species, and for those species that do not have a 'major species' counterpart (so-called 'orphan species', e.g., insects, snails, rabbits). For some species such as rabbits, there is consequently a limited number of specific FA (e.g., zootechnical additives) available. One NCA indicated that the assessment of efficacy should not be an obstacle to extend an authorisation to minor species, as long as safety is ensured. See 1.4.2.3 Annex III.

[60] ii FA Final Report _FCEC, pages 41 and 42.

- Extrapolation from food to feed: the legislation allows to extrapolate to a certain extent the results of data generated for additives already authorised for food use to FA. A majority of applicants (23 out of 43) considers that this extrapolation does not work well (EM 1.3.10 , SH Survey). In contrast, 16 out of 25 national authorities consider that it works well, eight regard it as neutral and one considers that it does not work (NCA Survey). As the quantities of FA to which animals are exposed are much higher than those to which humans are exposed, the extrapolation from food to feed is not possible for many applications for safety reasons[61]. As for efficacy studies, the extrapolation works well for flavouring compounds but there is room for improvement for other functional groups, such as some technological additives or colourants, provided that the specifications of the FA and the function that the product performs in food and feed are the same. A simplification of that system could consist of the recognition of the efficacy of certain categories of additives already authorised for food use without any longer the necessity to extrapolate or to provide additional information. This could work for the efficacy for new colourants or for certain technological additives but is unlikely to produce major savings as those groups remain quite stable, and therefore not many new FA would probably benefit from that suggested simplification in the provisions of the FA legislation. The costs of efficacy studies for those FA are in any case not very high as the efficacy needs to be demonstrated on the feed (e.g., if the feed is coloured) and is not related to the animal species. A range of € 20,000 - € 100,000 per application is estimated as reasonable, but it is not possible to evaluate how many new FA will be authorised in these groups and indeed whether they will be authorised for food use so as to make the extrapolation possible.

Although some progress in simplifying and harmonising the authorisation process has been achieved, the process might still be considered as burdensome for some applicants and MS authorities. A majority of stakeholders, especially FeBOs, and in particular applicants, observe in some cases insufficiently precise predictability in the authorisation procedure, requesting *i.a.* improved coherence/clarity of some provisions.

4.1.2.5 Attractiveness of the EU authorisation system and comparison with major global players

It is not possible to establish with certainty whether the EU authorisation procedure is attractive to third countries as Commission data do not make it possible to identify all the operators from non-EU countries who requested an authorisation. However, it has been established that operators from at least seven non-EU countries have requested an authorisation to place their products on the EU market. These countries are the USA (13 companies), Japan (8), China (3), India (2), Australia (2), Switzerland (1), Turkey (1) and Korea (1). These figures however do not reflect the level of attractiveness of the EU authorisation system for non-EU operators as many multinational companies have direct access to the EU market through their subsidiaries located in the EU (EM 2.3.2).

A comparison of the EU system with systems in place in third countries, based on the results of a targeted survey addressed to NCAs of six third countries accounting for around 40% of the

[61] ii FA Final Report _FCEC, page 40.

world FA market (Argentina, Canada, Chile, China, Japan, and the USA) (EM 2.3.3), revealed the following:

- FA are not always defined as a distinct category and tend to be classified less precisely than in the EU. In some countries, certain EU FA are regarded as feed materials and as such do not need authorisation.
- All countries have a process in place for FA approval, which includes a scientific risk assessment, though generally with lighter requirements which vary significantly from country to country.
- The time taken to process an application for authorisation can vary considerably from one country to another, from a few months (in the case of three countries) to about a year (in the case of two countries).
- EU authorisations of FA are not fully recognised by these countries due to different approaches taken to authorisation. However, Chinese authorities indicated that technical data on FA authorised in the EU are used as a reference for technical assessments in their country. Two countries (Chile and Canada) appraise substantial parts of the EU authorisation procedure, largely because their approaches are relatively aligned.

More details on the different aspects examined are developed in point 3.5.3 of Annex V.

4.1.3 Coherence

Internal coherence

The following points have been noticed as regards coherence:

Data sharing: the rules and procedures on data sharing in the 2003 FA Regulation have had only a limited effect on reducing animal testing. Even though the applicants needs to take all measures to reach agreement on sharing the use of information in order to prevent repetition of toxicological tests on vertebrates, in case of disagreement between the present applicant and the other party concerned (i.e. the previous applicant), the Commission is neither obliged nor does it have the tools to take a decision based on objective parameters (more information in 1.4.3.2 Annex III). Only three requests on data sharing were made and in those three no agreement could be reached. Respondents expressing a negative view (30%) on this topic in the public consultation indicated that data sharing is not being used to its full potential (see PC).

The absence of certain definitions or the possible need to improve clarity of certain provisions or definitions as observed by MS national authorities but also by FeBOs, may hamper:

- the correct categorisation of FA in relation to “processing aids”.
- the establishment of additional conditions of authorisation of FA regarding “maximum recommended levels” or “recommended levels” (see 1.4.3.4 Annex III).
- the legal status for certain FA: “preparations” are not defined as such and the introduction of such definition could not be done by implementing rules and required a modification of the FA Regulation. To mitigate this absence of formal definition, some provisions on the compositional and labelling requirements were introduced in 2015 by implementing rules (more information in 3.1.1 Annex III).

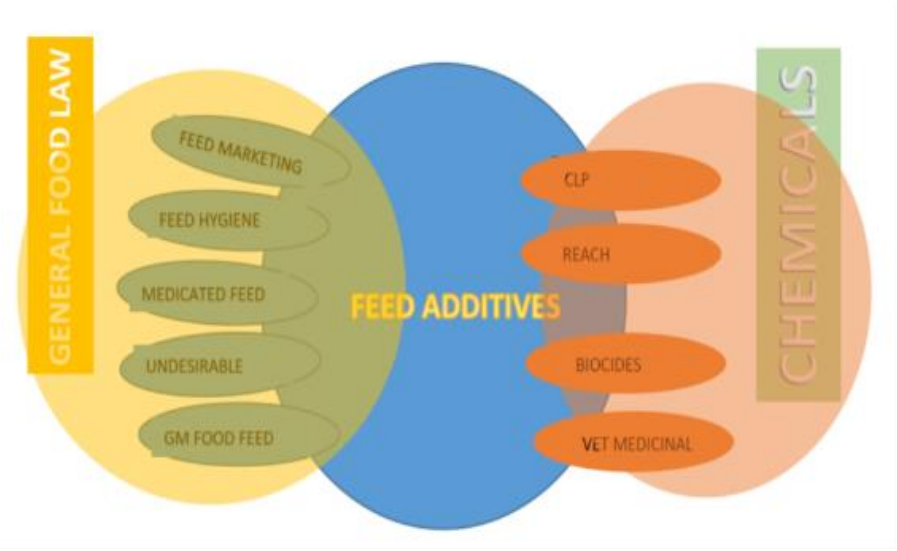
Use of FA in drinking water: clarity on the use of FA in drinking water could be improved. The definition of FA refers to the use of all FA in drinking water, but Article 6 and Annex I of the Regulation restrict the use of FA in drinking water to certain functional groups. Consequently, applicants withdrew their applications for 789 flavouring compounds for use in water for drinking that were only authorised in feed (EM 6.6). This unveiled a need to improve coherence between the general definition and the specific provisions of Article 6 and Annex I of the FA Regulation. In addition, FeBOs have requested more technical clarity on the practical implementation of the use of FA in drinking water (see 1.4.3.1 and 1.8.4 of Annex III).

The comprehensive evaluation of few FA that may be intended for farmed non-food producing animals: it would be appropriate to introduce some clarification regarding the environmental safety requirements applicable to the use of FA for farmed non-food producing animals (e.g., fur animals) in order to accommodate the requirements related to the safety criteria laid down in the FA Regulation and in EFSA Guidance[62]. This situation did not affect the safety for the environment as EFSA already performed this assessment and no application specifically addressing this type of animals was submitted. The authorisations granted for all animal species (including non-food producing animals) have considered the environmental impact of the FA concerned. Nevertheless, for future possible applications specifically targeting those animals, this point needs to be examined.

Finally, the absence of specific and harmonised labelling requirements for FA and premixtures only intended for export is another issue that does not bring lightness to the system (see 1.4.3.7 Annex III).

External coherence

Figure 4 - Coherence with other legislation



The coherence with the following legal texts on feed and chemical substances was analysed:

[62] Guidance on the assessment of the safety of FA for the environment. EFSA Journal 2019;17(4):5648.

Legislation on feed: General Food Law, Feed Hygiene Regulation, Feed Marketing Regulation, Regulation on Genetically Modified (GM) Food and Feed, Regulation on Medicated Feed and Directive on Undesirable Substances in Animal Feed (see abbreviations).

Legislation on chemical substances: CLP Regulation, REACH Regulation, Biocidal Products Regulation, Regulation on Veterinary Medicinal products (see abbreviations).

While no inconsistencies were found with the Regulations on Medicated Feed, GM Food and Feed, with the Directive on Undesirable Substances in Animal Feed (EM 4.7.4.8, 4.9, 4.10, 4.11, 4.12)[63] or with the REACH Regulation (EM 5.7-5.10)[64], different concerns were identified in relation to the following pieces of legislation:

- Feed Marketing Regulation
- Feed Hygiene Regulation
- Biocidal Products Regulation
- General Food Law
- CLP Regulation

All the details may be found in Annex III 3.2.

Conclusions

Several definitions or questions on the relationship between the FA Regulation and other pieces of legislation may be a source of difficulties at various levels in the preparation of applications for authorisation, during the processing of those applications, in the renewal or modification process of authorisations and/or in the circulation of FA within the EU or during import or export. Those points do not seriously impair the effectiveness of the Regulation but nevertheless could usefully be addressed should the legislation be revised (EM 4.16 to 4.19, 5.11 to 5.14 and 6.1 to 6.3).

4.1.4 Overview of costs and benefits (efficiency)

The estimated costs compared to those expected at the time of adoption of the FA Regulation were not calculated as there was no impact assessment performed at that time. Unless specifically indicated, the different figures are calculated over the period 2004-2017. Those figures are collected from the surveys, interviews and case studies. In each case, the source of the information is indicated.

4.1.4.1 Overview of costs

Costs for consumers

No significant costs for consumers have been identified. There is no evidence on whether the FA Regulation has led to an increase in terms of prices.

[63] FA Final Report _FCEC, pages 99-101.
[64] FA Final Report _FCEC, pages 100 and 103-104).

Costs for businesses

The costs for businesses to prepare an application for a new authorisation or re-evaluation depend on the type of FA, on whether the FA represents an important innovation and on the type of animal species covered by the application.

On average, the **direct costs** of an application for authorisation are €1.1 million, of which the major components are **safety and efficacy studies** (37% and 32%, respectively), followed by **internal staff costs** (22%). In particular, the following cases have been identified:

- €50,000 for certain FA with a substantial history of consumption for feed use;
- €373,000 for FA requested by a consortium of companies under Article 10(2) of the FA Regulation;
- €2.6 million for a zootechnical FA (i.e., important innovations);
- €3.4 million per application for coccidiostats.

With regard to **studies**, the direct costs vary between species. *In vitro* study costs range from less than €10,000 to €50,000, studies on laboratory animals from less than €10,000 to €400,000, studies on ruminants can vary between €18,000 and €200,000 and studies on pigs, poultry and fish range from less than €10,000 to €400,000. The use of non-animal tests (e.g., *in vitro* tests using human/animal cells and tissues or computer-modelling techniques) has been identified as a factor that may reduce the cost of applications, especially for the demonstration of efficacy. This was pointed out during the case studies by one NCA and some applicants[65].

No significant **differences in average costs for SMEs and large companies** were identified. Therefore, the costs for the preparation of an application for authorisation have an important impact on SMEs, in particular as SMEs tend to focus on fewer animal species in the case of innovative FA (in view of a holder-specific authorisation). In the case of FA with non-holder specific authorisation, new trials on target animals or laboratory animals may not be required, as scientific literature may provide the necessary evidence.

Operators indicated that there are **indirect costs derived from the time required for the authorisation process,** both during the EFSA evaluation ("stop the clock" mechanism) and the Commission decision for the authorisation. For instance, the period of time devoted to the risk management procedure is now shorter than under the 1970 FA Directive as 37% of applications are processed within a period of 6 months[66] and 41% within 10 months. However, operators were not able to estimate these indirect costs in monetary terms. When it comes to **renewal procedures**, the costs for the preparation of the dossier are on average €216,000.

In terms of **labelling costs,** the direct costs for producers of FA are negligible, however for premixtures they range between €80,000 and €223,000 per plant per year. For pet food manufacturers, costs occur in a few cases where a FA must be withdrawn from the market and the transitional period is shorter than the period before the expiry date of their existing

[65] FCEC Final Report, EQ1.3, "5.1.2 Conclusion".

[66] According to Article 9(1) of the FA Regulation, "*Within three months of receipt of the opinion of the Authority, the Commission shall prepare a draft Regulation to grant authorisation or to deny authorisation.*". This period may be extended in complex cases. There is no legal period established for the final adoption of the act by the Commission. The indicated 6-month period is not a legal period, it has been used as a reference to evaluate the effectiveness of the management process.

inventory. The estimated costs for re-labelling compound feeds are for 2,000 references €1 million (a reference is the form by which the feed is placed on the market, e.g., if the product is presented in three different packages, each presentation is a reference so that the product has three references). For feed intended for food-producing animals, the costs are negligible.

There are also **compliance costs due to regulatory changes** (new conditions introduced when a new authorising Regulation or implementing measures are adopted) which require labels adaptation or disposal or products to be removed from the market. These costs are estimated at around €2,000 for disposal of labels for premixtures when applying the usual transitional period. The compliance costs can be estimated between €24,000 and €40,000 per product and €13,500 for labels for premixtures when the change affects an important widely used FA and the transitional period is shorter than the usual transitional period. However, the occurrence of this possibility is very low[67].

Finally, the **administrative costs** which relate to notifications to the Commission are negligible. More details on costs for businesses can be found in point 2.1 of Annex III.

Costs for MS

Costs for MS authorities involve their participation in the SCoPAFF meetings and, more generally, performance of their duties deriving from the implementation of the FA Regulation, in particular with regard to the authorisation process concerning FA. The staff time dedicated to those activities has been calculated based on data available for 14 MS[68] over the period 2016-2018. **The total costs per MS are less than € 29,000[69] per year on average. The total costs per MS over the 2004-2017 period are therefore estimated at €405,000.** These can be broken down as follows:

- 791 applications processed by the Commission during the period 2004-2017, corresponding to 454 standard Regulations over the same period. Considering that the application is the most relevant step that triggers all the different actions, the costs per MS are estimated at:
  - €500 per application for both new authorisation and re-evaluation.
  - €860 per standard authorising Regulation.
- There were 28 Regulations changing the authorisation holder over the period 2004-2017. The costs are estimated at:
  - €500 per Regulation changing the authorisation holder.

In addition, it is estimated that each MS spent on average €74,000 per year for **enforcement** actions under the Official Controls Regulation[70]. Thus, when the official control activities are considered, the total costs per MS per year can amount to €103,000 on average. More details on costs for MS are in point 2.2.4 of Annex III.

[67] Annex IV Case studies, page 24.
[68] Other Member States cannot estimate the costs of the FA Regulation *versus* other feed legislation.
[69] Figures are rounded.
[70] Although the costs of the Official Controls Regulation are not under the scope of the FA Regulation, it has been considered important to do those calculations in order to provide an overview on how the FA Regulation works.

Costs for the European Commission, EURL and EFSA

European Commission

The costs for the Commission relating to the authorisation process refer to staff costs encompassing all the activities required to process the applications for authorisation (breakdown of costs is available in point 2.2.1 Annex III). On average, the yearly costs are estimated at €756,000.

- Considering that the application is the key step that triggers all the subsequent actions, the costs for the Commission are estimated at:
  - €13,400 per application for both new authorisations and re-evaluation.
  - €22,400 per standard authorisation Regulation.
- In case of change of authorisation holder (28 implementing Regulations), the costs are estimated at €13,400 per Implementing Regulation. This amounted to €375,200 for the period 2004-2017 (corresponding to €26,800 per year).

As the number of new applications increased during the period 2012-2017, increased efficiency in the management of these applications can be observed. The number of meetings of the SCoPAFF has been reduced but their duration has been extended, resulting in a stable number of days of meetings per year. This has permitted savings in travel expenses, interpretation costs and administrative support.

EURL

The costs for the European Union Reference Laboratory for FA (EURL) are calculated on the basis of the duties and tasks assigned to the EURL by the FA Regulation, in particular Article 21 thereof, for its implementation. The main obligation of the EURL is the evaluation of the analytical methods proposed by applicants. Another important task is to maintain a bank of reference samples of all the authorised FA in their facilities. Other tasks considered when estimating their costs are participation in SCoPAFF meetings and in the annual coordination meeting with the consortium of National Reference Laboratories (NRLs) organised by the EURL. The average annual costs for the EURL are estimated at **€684,000.** These mainly stem from evaluation reports on analytical methods. **37 evaluation reports per year were prepared on average during the 2004-2017 period, at an estimated cost of €18,500 in staff costs per validation report.** This cost is considered justified as the validation process entails, on some occasions, the organisation of an inter-laboratory comparison study to verify whether the different laboratories have the same results in the implementation of the method of analysis. More details on EURL's costs are available in point 2.2.2 of Annex III.

EFSA

During the period 2004-2017, EFSA processed 969 **applications,** corresponding to 69.2 applications per year on average. **The cost per application is estimated at €27,450** (new authorisation and re-evaluation), €15,900 of which are internal staff costs. The **average cost for a renewal is estimated to be around €16,470**. More details on EFSA's costs are available in point 2.2.3 of Annex III. EFSA has implemented some measures to increase efficiency, including reduction in the number of physical meetings, increase in the number of assistants instead of

increasing administrators (AD) staff, changes to the operational procedures and increase in digitalisation.

Overview of costs

Table 3 - Overall costs per year for the implementation of the FA Regulation

	TOTAL COSTS (EUROS) PER YEAR
FeBOs[71]	62,700,000
NCAs of MS	2,884,000
COMMISSION	756,000
EURL	684,000
EFSA	1,900,000
TOTAL	68,924,000

The costs of labelling are not included as they cannot be calculated annually.

Costs on health and the environment

The costs for health, animal welfare or the environment could not be quantified (see Annex II).

4.1.4.2 Overview of benefits

Quantification of the benefits of the use of FA for animal health and welfare and for the environment was not possible. Some benefits are evident, as they directly result from the implementation of strict safety and efficacy requirements and from the definition of the functions for which FA may be authorised. However, clear causal links could not be firmly established as there is no data on the actual use of FA by the farming sector which could be used to measure the extent to which such benefits have materialised. In addition, it was not possible to single out the impact of any single FA as opposed to the simultaneous use of several FA together (see Annex II).

Benefits for animal health and animal welfare (EM 3.1.9)

The benefits for animal health and welfare are associated with the placing on the market of FA that are safe and efficacious, and that are used in accordance with the labelling requirements. The absence of adverse effects on animal health is one of the basic conditions for authorisation of all FA under the 2003 FA Regulation. Many FA such as vitamins, trace elements, gut flora stabilisers and coccidiostats have a positive impact on animal health and welfare by directly addressing the physiological status of animals. A new functional group was created in 2019 – 'physiological condition stabilisers' – to provide specific benefits on animal welfare (e.g., resilience to stress). Three applications have been submitted under that functional group but no FA belonging thereto have been authorised yet.

Another important element is the fact that with the application of the FA Regulation, 1743 FA that were potentially unsafe or inefficacious were withdrawn from the market, thus minimising any negative effect on animals.

[71] €1,1000,000 per application (57 applications year).

The benefits for animal health from FA vary according to the functional group under which they are authorised: for instance, vitamins (category of nutritional FA) bring benefits to the health of animals by satisfying their nutritional needs. The benefits for animal welfare as they currently exist and can be estimated are closely linked to benefits for animal health, as the welfare of animals is *de facto* impaired when they are unhealthy. In addition, specific functional groups of FA focus on the improvement of animal welfare: for instance, the functional group "physiological condition stabilisers" (e.g., resilience to stress).

The qualitative benefits for animal health and animal welfare are related to the improvement of the physiological status of the animals and consequently animal health and welfare:

- The needs of animals for vitamins or trace elements can be satisfied via FA preventing diseases or deficiencies in animals. Animal welfare may be compromised for example if animals do not take sufficient levels of vitamin D: lameness, difficulty walking, a tendency to sit on their haunches occuring in growing pigs.[72]
- Preventing occurrence of coccidiosis in poultry, one of the most important parasitic diseases.
- Preventing the occurrence of diseases by promoting a desirable gut ecosystem through administration of animals' beneficial species of microorganisms.
- Preventing the occurrence of antimicrobial resistance via for example administration of microorganisms that improve the beneficial flora in the gut. Also, the safety evaluation to prevent any AMR effect of the FA contribute to this aim. In this regard, by Commission Implementing Regulation (EU) 2015/1399, the authorisation of *Bacillus toyonensis* (NCIMB 14858) was denied as it posed a risk for the spread of genes coding for resistance to tetracycline and chloramphenicol, which are antibiotics of human and veterinary importance.
- Improving animal welfare: some amino acids that reduce nitrogen excretion contribute to reduce ammonia in urine and improve animal welfare of animals, as ammonia may increase the respiratory stress[73].

Benefits for human health (consumers and workers) (EM 3.1.10)

<u>For consumers</u>

FA are assessed to make sure that they do not transfer to food of animal origin microorganisms, toxins, residues or other substances that may pose a risk to consumers. For instance, in the authorisation of some colourants used as FA, maximum residue levels are established. Labelling provisions ensure that FA are properly used, e.g., the indication of the maximum level of use is mandatory for certain FA that may pose a risk if those levels are exceeded. Consumers are also protected from the risk of FA spreading AMR by the general ban introduced concerning

[72] The pathology of vitamin D deficiency in domesticated animals: An evolutionary and comparative overview. Elizabeth W Uhl. Int J Paleopathol. 2018 Dec; 23:100-109. doi: 10.1016/j.ijpp.2018.03.001.

[73] Acute and prolonged effects of ammonia on haematological variables, stress responses, performance, and behaviour of nursery pigs. E. von Borell, PhD; A. Özpinar, PhD; K. M. Eslinger; A. L. Schnitz; Y. Zhao, PhD; F. M. Mitloehner, PhD. EVB: Institute of Agricultural and Nutritional Sciences, Martin-Luther-University Halle-Wittenberg, Halle, Germany. AO: Western Institute for Food Safety and Security, University of California, Davis, California. KME, YZ, FMM: Department of Animal Science, University of California, Davis, California.

antibiotics as FA and by the safety assessment done during the authorisation process[74]. The withdrawal from the market of 1,743 FA may also be assumed to have contributed to protect consumers from potentially unsafe products, though this cannot be definitively established.

For workers and users

Risks for workers and users are strictly assessed and authorisations may include specific protection measures to be respected. If the use of a FA gives rise to unacceptable consequences that cannot be mitigated by protection measures, then it will not be authorised. This was the case with the denial of the authorisation of formaldehyde in 2018[75].

Environmental benefits (EM 3.1.11)

The environmental risk assessment of FA used for farmed animals (food- and non-food producing animals) ensures that they do not have any adverse effects on the environment. Labelling requirements are also important in this respect. For example, if a maximum limit is established for a FA in order to prevent any adverse effects on the environment, the indication of this level on the label will help operators use the FA properly throughout the feed chain.

In addition, certain FA have beneficial effects on the environment, for example, by reducing nitrogen or phosphorous excretion through the use of phytases that improve the assimilation of phosphorus by animals, or by using essential amino acids to promote better assimilation of proteins. FA may also help reduce feed losses. FA may have qualitative environmental benefits that can be summarised as follows[76]:

- Better use of resources reduces environmental footprint of animal-sourced products, considering that more than 50% of the animal production footprint is related to feed ingredients (Wideman et al., 2012). Feed materials that are generated at local level may increase their quality by reducing the indigestible nutrients (e.g., fibres), thereby increasing either their energy, amino acids and/or mineral values or by ensuring the necessary level of essential FA. Enzymes, amino acids and microorganisms may facilitate those actions.
- Modification of emissions that have a negative impact on the environment, thus reducing pollution and mitigate climate change impacts.

  There are three main sources of emissions from animal production:
  - enteric methane emissions;
  - gaseous emissions from manure storage (ammonia and nitrous oxide);
  - nutrients, minerals, FA metabolites concentrations in the manure.

  Livestock systems, particularly ruminants, contribute to greenhouse gas emissions, and particularly in the form of enteric methane. A review of mitigation options for enteric methane from ruminants showed some of the effective strategies including the increase forage digestibility for which some FA have been proved efficacious. Also, the

[74] For example, the denial of authorisation in 2012 of one microorganism as silage additive "Lactobacillus *pentosus* (DSM 14025)" and two microorganisms in 2014 "*Pediococcus pentosaceus* (NCIMB 30068) and *Pediococcus pentosaceus* (NCIMB 30044)". Those FA spread resistance to antibiotics used in humans.

[75] Commission Implementing Regulation (EU) 2018/183 of 7 February 2018 concerning the denial of authorisation of formaldehyde as a feed additive belonging to the functional groups of preservatives and hygiene condition enhancers.

[76] Environmental performance of FA in livestock supply chains. Guidelines for assessment. FAO 2019.

authorisation of a specific FA reducing the methane emission in milking cows is an example of this mitigation effect for reducing the impact on climate change.

Manure management, including storage, handling, and field application can be a source of emission of nitrous oxide and ammonia. Methane emissions from manure accounts for 12-41% of total agricultural CH4 emissions for most countries (Chadwick et al., 2011) and emissions depend on the storage duration, temperature and manure composition. The modification of the physico-chemical characteristics of the manure through FA enables the reduction of ammonia and N_2O emissions.

- Reduction of pollution: for example, the addition of phytase to feed results in a lower excretion of phosphorous in manure, contributing to reduce eutrophication in waters (meaning a reduction of dissolved oxygen in water bodies caused by an increase of mineral and organic nutrients that increase algae production).
- Reduction of feed losses: feed production is one of the most impacting aspects of animal production. Hence, it is important to ensure that the large majority of the feed ingredients and feeds produced are delivered to the animal. For this purpose, the use of FA such as antioxidants, preservatives and silage additives provide tools to reduce feed losses along the feed chain and contributes to reduce the environmental effect of livestock production. Reduction of feed loses has a positive effect on the environment as the disposal or destruction of products may require, for example, consumption of energy to treat the feed for those purposes.

Benefits for businesses (EM 3.1.6)

The benefits for FeBOs (producers of FA, producers of premixtures and feed compounders) stem from the comprehensive risk and efficacy evaluation of FA and the implementation of clear labelling rules that facilitate the use of those FA along the feed chain[77]. Certain FA which help preserve the quality of FA and premixtures thus minimise the risk of disposal or destruction of products (e.g., Vitamin A must be placed on the market in combination with an antioxidant to prevent oxidisation). The efficacy assessment ensures a level playing field amongst operators reducing the possibility that fraudulent FA would be placed on the market. Greater clarity in the authorisation process is another element that benefits FeBOs when they seek authorisation. The withdrawal from the market of 1743 FA that were potentially unsafe or inefficacious also has a positive impact on FeBOs. The safety evaluation and banning of antibiotics as growth promoters contribute to minimise AMR threats. FeBOs also benefit from easy access to non-EU markets[78] and from a high variety of FA that can meet market demand in terms of innovation, presentation of FA (e.g., liquid, pellets, etc.) or specific animal needs (e.g., specific FA for lactating sows or piglets).

The qualitative benefits <u>for farmers</u> can be summarised as follows:

- reduction of losses resulting from animal diseases or AMR;
- availability of innovative FA;
- more balanced diets for animals;
- better use of resources;

[77] FA Final Report _FCEC, pages 77 and 78.
[78] FA Final Report _FCEC, page 64.

- increase of animal performance or of animal resilience to heat or stress;
- contribute to reducing the negative impact of livestock farming on the environment (phytases, amino acids and methane reduction);
- protection of the farmers' economic interests as FA are efficacious for the intended purpose.

Benefits for MS

The centralised authorisation process and the establishment of clear rules for authorisation have reduced the administrative burden for MS, in particular, because they do not need to perform the risk assessment. Labelling and traceability rules facilitate MS' control activities.

Benefits for pets and pet owners (EM 3.1.8)

Pet owners benefit from having safe and more efficacious FA on the market that take into account the specificities of pet animals. The comprehensive risk assessment on animal health, covering chronic toxicity, mutagenicity and carcinogenicity aspects is very relevant to those animals that have a long lifespan.

The qualitative benefits for pet owners and pets can be summarised as follows:

- Reduction in the occurrence of diseases and intoxications. An example is the denial to authorise titanium dioxide in 2021, mainly for use in feed for cats and dogs, due to its mutagenic and carcinogenic effects.
- Reduction in the risk of spreading AMR to pets and pet owners.
- Protection of pet owners' economic interests as only FA which are efficacious for the intended purpose may be authorised.
- Availability of efficacious and innovative FA that meet the nutritional needs of pets.

In general, the authorisation process under the 2003 FA Regulation can be seen to have been efficient as demonstrated by: 1) the high number of applications submitted, with an upward trend since 2015; 2) the large number of FA authorised, including innovative FA (34% of applications); 3) the low number of RASFF notifications (Rapid Alert System for Food and Feed) concerning FA and acceptable results of Commission Audits; 4) the recognition of the value of EU authorisations in third countries; and 5) the global position of the EU FA market (35% of the world FA market by value).

The benefits for FeBOs can be seen throughout the food chain. In general, stakeholders (mainly FeBOs) consider that the FA Regulation has benefits for FA producers (including applicants) and for compound feed producers (82% and 80% of respondents see benefits for FA producers and compound feed producers, respectively).

Nevertheless there are elements of the 2003 FA Regulation that are viewed by stakeholders as reducing the efficiency of the authorisation process and increasing the costs of applications: 1) the insufficient use of extrapolation procedures and of non-animal models as an alternative to animal testing; 2) the failure to implement data sharing to help avoid the need for toxicological tests on vertebrates; 3) the insufficient understanding of some elements of EFSA guidance concerning applications for authorisation and in particular in relation to the definition of clear endpoints to demonstrate efficacy; and 4) the short duration of the authorisation period. Only

12% of respondents to the SH survey find the costs of applications for getting a FA authorised in the EU market as really proportionate to the benefits (EM 3.2).

A majority of FeBOs considered that the safety/efficacy requirements of the re-evaluation were not proportionate to the benefits. The burden of the new safety and efficacy requirements for re-evaluation has been proportionate to the benefits, according to 15 and 13 NCAs out of 24, respectively for safety and efficacy (EM 8.2.5 and 8.2.6).

The guidance prepared by the EURL for the validation of the method of analysis has been a very efficient instrument for stakeholders (mainly FeBOs). As a result, the validation of the method of analysis, except for a few complex cases (e.g., some botanical flavourings and a few colourants), is ready before EFSA finalises the assessment; therefore, this requirement does not interfere negatively with progress through the authorisation process. In general, the EURL has been very efficient in implementing all its tasks.

The European safety assessment system for FA is widely recognised in Europe and third countries and has been little challenged before the Courts or under the procedures set by multilateral international agreements (WTO).

4.1.5 Comprehensive and harmonised labelling rules

There is a consensus that appropriate labelling prevents the misuse of FA along the feed chain, which thereby contributes to food and feed safety (ensuring in particular that appropriate doses and the proper use in the animal species concerned are respected)[79]. The results of the controls performed by the MS authorities do not raise major concerns in this regard. From the PC (efficiency /costs benefits), 36% of the respondents, including a majority of NCAs, consider that the labelling costs are justified. Those that do not agree argue that the obligation to indicate all information on the physical label is a burdensome requirement. In the SH survey, 53 out of 110 respondents consider that labelling requirements are fit for purpose but 45 disagreed and pointed to the need to modernise the labelling provisions by conveying the information through other means (currently, the FA Regulation only provides for a physical label), such as electronic means, QR Code trademark, separate documents, etc., as it is already the case for some compound feeds and feed materials. In the case studies, the same arguments were articulated by FeBOs who consider this obligation to be disproportionate (vi Case studies, page 20). In addition, three MS authorities consider that it is necessary to change the system (NCA Survey).

The absence of harmonised and specific labelling requirements for FA only intended for export to third countries in accordance with Article 12 of the General Food Law, in order to indicate that they are only intended for such purpose, can be another element of distortion. According to the industry, the diverse national approaches that currently exist lead to competitive disadvantages between companies within the EU (see 1.4.3.7 Annex III).

The absence of labelling tolerances (see glossary) for FA in premixtures adds more room for interpretation of the labelling rules. This situation creates a certain burden for FeBOs when the

[79] vii Consultation Synopsis Report, point 3.4.2.3.
FCEC Final report, 7.2, EQ5 Judgement criteria: "Lack of contradiction / inconsistency between the FA Regulation and the CLP".

FA circulate within the EU, since the conditions in relation to labelling tolerances may be different from one MS to another, and they therefore need to change the labels used in order to accommodate these variations.

In summary, the labelling provisions laid down in the FA Regulation have been effective in ensuring a safe and efficient use of FA and premixtures along the feed chain, but their efficiency has been slightly reduced due to an absence of harmonisation in certain specific areas.

The efficiency of the labelling system considers the costs associated with compliance with the labelling requirements.

The costs for labelling considered are those that are triggered by a change in the authorisation of a FA, which then requires that the labelling of that FA also be changed.

The factors that affect labelling costs are the linguistic regime, as labels have to be translated at least into the national language(s) of the MS(s) where the product is placed on the market; regulatory changes; certain specific requests from MS; and market-driven factors.

The costs of labels for FA are negligible. The estimated costs for manufacturers of premixtures range from €80,000 to approximately €223,000 per plant, per year. This is most likely an overestimation as it is not possible to separate costs triggered by regulatory changes from those made due to other reasons. The increasing use of automatic labelling systems further reduces those costs, which may explain the differences between costs at different plants.

The transitional periods provided for in the authorisation acts for the re-evaluation of "existing" FA allow time for the labels to be adapted to fit the new authorisation. These time periods are considered adequate by FeBOs.

Labelling rules are, in general, efficient as the costs derived from regulatory changes are not significant compared to the benefits provided, especially in terms of providing information to minimise safety risks along the feed chain. This analysis is supported by a majority of respondents in the PC. Nevertheless, three relevant concerns have been identified that create some degree of burden, thereby reducing the efficiency of the system: the obligation to indicate all the information on a physical label; the absence of labelling tolerances in premixtures; and the simultaneous implementation of the FA Regulation and CLP Regulation, in particular for premixtures of FA.

4.1.6 Information to feed business operators, other users of FA and consumers.

To FeBOs

As regards workers' safety provisions, the combination of CLP labelling requirements with the specific requirements set out in the authorising Regulation has created different understandings amongst MS authorities, and this in turn has affected the circulation of FA and premixtures (on this, see 1.5.2 Annex III).

To consumers

In addition to being safe and efficacious, FA must not "*harm the consumer by impairing the distinctive features of animal products or mislead the consumer with regard to the distinctive*

features of animal products". Specific criteria were set up to address all possible consumer concerns and assess whether a FA could give the food derived from the animal a misleading feature regarding its expected properties, e.g., a flavouring that gives the meat a flavour that is not characteristic of that meat. This aspect has been raised by EFSA in a few cases, all of which led to a positive conclusion in favour of the authorisation.

Though FeBOs have indicated that consumers are not aware that FA can modify the organoleptic (i.e., qualitative-sensory) characteristics of food, no evidence could be gathered to confirm this due to the very low response rate of consumers and their representatives to the consultations carried out, despite the efforts made to involve them in surveys and interviews.

To FeBOs and users of FA

The Register of FA is considered by a majority of stakeholders (59 out of 110) to be an efficient tool to ensure FeBOs are aware of all the FA that have been authorised. Nevertheless, for 26 operators out of 110, the Register could be improved to make it more informative and user-friendly (see PC). The pdf format does not allow them to easily find the information they need, and for certain aspects, there is no direct link to the relevant information (e.g., EFSA opinion) permitting its rapid retrieval.

4.1.7 Control, traceability and enforcement rules

The Rapid Alert System for Food and Feed (RASFF) shows the level of compliance regarding the presence of FA or their residues in food of animal origin. During the period 2004-2020, 82 notifications out of 16,634 were linked to the presence of unauthorised FA or a high level of FA residues in food from animal origin, representing only 0.5% of the total number of notifications over the period. Twelve RASFF notifications for FA and premixtures were reported during the period 2004-2017 out of a total of 517 notifications on feed (i.e., 2.3% of the total number of feed notifications (EM 1.2.7)).

The 2020 Commission Audits on Official Controls of FA and Traceability[80] found that robust and risk-based systems are in place for the planning of official inspections and sampling in the FA/premixtures sector. Inspectors generally adhered to this planning and were able to adequately verify operators' fulfilment of the main requirements concerning hygiene, facilities, equipment, maintenance and traceability. Some weaknesses were identified for labelling that did not affect in general the safe use of FA and premixtures, and for retained samples of the manufactured products that FeBOs must keep.

As regards the audits performed to FeBOs producing compound feed and feed materials, the report entitled "Overview report - Hazards and Management of Risks in the Feed Sector"[81] states "*In the majority of Member States (12) relevant requirements were satisfactorily or largely satisfactorily taken into account during official controls. In these Member States, similarly to the above section, a number of arrangements (namely, guidelines and checklists) had been put in place by competent authorities. These contributed to ensuring that feed*

[80] https://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=139
[81] https://ec.europa.eu/food/audits-analysis/overview_reports/details.cfm?rep_id=100

ingredients (feed materials and feed additives) and compound feed (complete or complementary) were labelled in compliance with relevant requirements. However, in seven Member States the audit teams noted that the label on some feed materials did not include the required indication of "feed material". It can be assumed that instructions on the use of FA are followed correctly as the report did not refer to any problem on this issue.

One of the questions raised during the evaluation was whether the method of analysis of a FA which is used for official controls should be updated when the authorisation of a FA is renewed, as this is not required by the 2003 FA Regulation. MS authorities consider this necessary, but FeBOs did not express a clear position, while pointing out that the Official Controls Regulation allows MS authorities to use more updated methods which are validated at international or EU level, where necessary.

A clear majority of both MS authorities and business stakeholders perceive that the role of the EURL, which is in charge of the validation of the method of analysis, is adequately defined in the 2003 FA Regulation (EM 1.4.9). The EURL, supported by the network of National Reference Laboratories (NRLs), can effectively carry out its tasks despite their complexity. A majority of NCAs and a small majority of FeBOs considered that the method of analysis must be updated on the occasion of the renewal of authorisations. A majority of both also consider that the role of the EURL is still properly addressed in the FA Regulation (EM 8.4.1 and 8.4.2).

The 2003 FA Regulation allows EFSA to propose a Post-Market Monitoring (PMM). At present, there is only one FA (lantharenol) for which EFSA has assessed its PMM plan, along with additional evidence provided by the applicant, confirming that this FA was safe. As this was the sole case of a PMM being required and assessed, no solid conclusion on this subject can be drawn. As indicated before, the PMM is on-going for all coccidiostats (EM 1.4.12).

Traceability is also an important element of effective enforcement of the legislation. No significant criticism on the relevance of traceability requirements emerged from the stakeholder consultation. Some manufacturers and business associations observed that other Regulations (especially the Feed Hygiene Regulation and the General Food Law) play an important role in ensuring FA traceability. Some FeBOs also stated that traceability is fully ensured by the systems and codes of practices already in place. In the roadmap consultation, one NCA considered that traceability requirements should be laid down in the FA Regulation instead of in the General Food Law.

MS authorities highlighted that traceability is not sufficiently ensured for imports of FA/premixtures and for FA/premixtures only intended for export to third countries. There are several reasons which account for this: a) the lack of a clear identification of imported products (no import code); b) the difficulties for MS to control establishments in third countries, c) the lack of harmonisation of control requirements for the third-country establishment's representatives in the EU, and d) the absence of harmonised labelling to identify FA only intended for export to third countries. The absence of specific relevant provisions in the Feed Hygiene Regulation aggravates this situation for both imports and exports.

There is no customs code that enables the identification of FA and premixtures on their entry into the EU. These products might be imported as chemical substances because the exporter

does not know the final destination of the product or because more advantageous customs codes can therefore be used (lower tariffs). Although there is a generic customs code "2309 preparations of a kind used in animal feeding", it is not always used. This point has been highlighted by the NCAs (ii FA Final Report FCEC, page 46). A majority of respondents (40 out of 62 – excluding 17 'do not know' responses) considers imports of FA into the EU to be adequately controlled, while 14 respondents disagree (SH survey). 11 MS authorities consider imports of FA into the EU to be adequately controlled, while 14 partially controlled (EM 1.4.1).

In addition, the current definition of "placing on the market", determining the scope of application of the FA Regulation (including the authorisation requirement), basically excludes the intended export to third countries of products provided that they have a limited circulation in the EU that does not imply transfer of ownership. These restrictions may result in a burden for FeBOs and could negatively impact their competitiveness, especially for SMEs for which this is a very important market (EM 2.2.2 and 2.2.3). See more information in section 1.4.3.7 of annex III, in the SH survey and the NCA Survey).

MS authorities and other stakeholders (mainly FeBOs) also pointed out a possible inconsistency between the Feed Hygiene Regulation and the FA Regulation (see FCEC Final Report, Section 7.3.1), as in practice controls of the FA requirements applicable to EU establishments would be more stringent than for establishments in third countries and than for the control of FA intended for export in relation to the implementation of the provisions of the General Food Law. See more information in 3.2.2 Annex III and in 1.4.3.7 Annex III.

In summary, controls and traceability of FA are, in general, satisfactory (see EM 1.4.3, 1.4.4, 1.4.5, 1.4.6, 1.4.7, 1.4.11) although some weaknesses have been identified for imports and for FA only intended for export. Enforcement of the 2003 FA Regulation is mainly ensured through controls and penalties imposed in case of infringements. The available data also noted the high compliance of sampling and analysis in the context of official controls, despite some weaknesses that have been identified in Commission Audits. The limited number of RASFF notifications specifically concerning FA may indicate that the enforcement is effective in general, except for imports (no import code for FA) and for FA only intended for export (no specific labelling indication / no harmonised rules for tracing and control). The fact that no list of third country establishments has been established under the Feed Hygiene Regulation nor specific requirements to trace and control FA only intended for export, may undermine the effectiveness of certain aspects of the FA Regulation.

4.1.8 Specific interests for pet owners and their animals

1,017 FA were authorised in 2017 for pets. The FA legislation, including the Commission Rules for Applications, establishes specific provisions concerning FA intended for pets, and EFSA subsequently developed specific guidance (EM 1.28 to 1.2.10).

Nearly all respondents to the stakeholder survey who provided an opinion agree that FA are efficacious and safe for pet animals (74 and 76, respectively, out of 78 respondents), excluding 28 and 30 respondents, respectively, who did not provide an answer as pet food is not relevant for their organisation (SH survey) (EM 1.2.11 and 1.2.12).

For a majority of stakeholders (mainly FeBOs), the 2003 FA Regulation provides benefits for pets and pet owners (SH survey) though it should be noted that animal welfare organisations did not contribute to the survey, despite the efforts to involve them. One citizen indicated that there is an increasing consumer demand for "aesthetic" appearance of pet food that needs to be considered (many compound feeds are grey in colour and this is not accepted by pet owners).

45 out of 107 respondents consider the authorisation procedure to fall short in addressing scientific and technical developments in feed for pets and livestock, due to the time period incurred during the authorisation process (EM 8.1.3). This contrasts with a majority of MS authorities which consider that the 2003 Regulation does a good job in addressing those technical developments (for both livestock and pets)[82] (EM 8.1.2). If there is a point to be considered here, then, it is probably not connected to FA intended for pets specifically, but rather to the authorisation process in general.

To conclude, the FA Regulation has considered the specificities of pet owners and their animals by setting up a comprehensive set of rules. FA are also regarded as safe, efficacious and relevant to provide benefits for pets and their owners.

4.1.9 Innovative and efficacious FA

Innovation may affect the evolution of different aspects of FA, including FA that can be better digested by animals, and new preparations that can for instance increase storage capabilities, reduce dusting potential or facilitate specific uses (spray, drying, pelleting or liquid forms). However, the most important innovations are those that involve the discovery of new compounds with innovative actions or new effect mechanisms.

The promotion of innovation under the 2003 FA Regulation is not perceived as effective by the industry, especially in the case of new FA, although a majority of MS authorities disagree. Some MS authorities, however, noted that the authorisation period is too short to encourage innovation specifically by SMEs, as the period of market exclusivity is not long enough to recover the investment made. Applicants identified a difficulty of interpreting some EFSA guidance and an insufficient definition of endpoints (what needs to be measured to demonstrate an effect) as the most prominent barriers to innovation. Under current EFSA guidance, endpoints can be proposed, but applicants do not receive validation from EFSA to inform them that those endpoints are indeed appropriate.

There is a growing demand for new FA which would specifically support more sustainable farming methods through new functions that did not exist before. This does not mean that all sustainable FA are by definition innovative or that innovation does not exist for other types of FA. As sustainability was not an explicit objective of the 2003 FA Regulation when it was adopted, this issue is discussed further below under new needs (see section 4.3.3).

FA that can have favourable effects on the environment or on animal welfare can be authorised under specific functional groups which fall under the wider category "zootechnical additives".

[82] ii FA Final Report _FCEC, pages 47 and 48.

However, the criteria defining the 'zootechnical' category, which includes probiotics and enzymes, are generally linked to the performance or productivity of livestock production (e.g., substances or micro-organisms that increase digestibility of feed or positively influence gut flora). The sole FA authorised to date under the 2003 FA Regulation for its positive environmental effects is a FA that reduces methane emission by dairy cows (Bovaer®10). Here, the requirement was in particular the demonstration that it had no negative zootechnical effect (significant reduction in milk production). It would have been legally feasible to remove such a product from the "zootechnical additives" category and authorise it under another category but in that case, it would not have been possible to grant market exclusivity to the applicant, as holder-specific authorisations may only be granted for certain categories of FA, including the zootechnical FA[83]. These constraints might be seen as obstacles to innovation in the specific area of sustainability, though this case also shows that such FA can indeed be authorised under the existing legislation. To establish a holder-specific authorisation system for a new category of FA, a modification of the 2003 Regulation by ordinary legislative procedure would be needed.

The restrictions on the use of FA in water for drinking were also identified during the consultation as a potential barrier to innovation. Water could be an efficient route of administration for FA that could increase the performance of certain FA. Innovation in the form of new FA specifically designed for administration through drinking water would make it possible to take full advantage of this route. Such innovation has to date focused mainly on nutritional FA such as amino acids and vitamins.

The rules governing the renewal of authorisation of FA were initially designed to encourage technological progress, as it was assumed that applicants would not seek renewal for FA that have been replaced on the market by more innovative forms. However, stakeholders do not perceive these rules as promoting technological progress. They claim that such rules are not needed, as the market is self-regulating and works to remove those FA that are less efficient. The evaluation does not show a clear link between innovation (technological progress) and renewal of authorisation. In the case studies, FeBOs questioned the authorisation period of 10 years followed by a renewal of the authorisation for all types of products, and in particular for FA for which there is an extensive body of scientific knowledge on their adverse impacts and low identified risk. In such cases, according to operators, the renewal obligation creates unnecessary burden not only for operators but also for EFSA and the Commission. In their view, the short period for renewal reduces their capacity to invest in new FA and it is not justified on safety grounds. Only 29 out of 110 FeBOs consider that the 10-year authorisation promotes innovation. For NCAs, the response was more nuanced: 18 find this period good to promote innovation (EM 8.3.1 and 6.11). Most FeBOs do not agree that the 10-year period is necessary to ensure safety. Most NCAs (17), however, thought that this period is necessary, although three NCAs disagreed. For each of the above aspects, it is noted that several NCAs (4 to 6, depending on the aspect) did not provide a definite answer. FeBOs considered that for holder-specific FA and non-holder specific FA, the 10-year period is not adequate, while a small majority of NCAs felt that this period is adequate (EM 8.3.3 and 8.3.4).

[83] Holder-specific authorisations may only be granted for zootechnical additives, coccidiostats and histomonostats and FA that are genetically modified or produced from GMOs.

The establishment of a holder-specific authorisation status for certain FA has been a clear tool to improve innovation. The increasing number of applications and FA authorisations using this tool confirms this. Feed business operators claimed that non-holder specific authorisations reduce innovation and an extension of the holder-specific authorisation regime to other FA should be facilitated (see PC). In the SH survey, a majority of respondents (59%) want to keep the current regime, while 23% of respondents want holder-specific authorisation status extended to other FA. No significant difference in terms of the cost-benefit balance can be seen between SMEs and non-SMEs. However, the required upfront investment (R&D and authorisation costs) is high, and access to finance to support this is generally an issue for smaller companies, when these are not part of larger entities (EM 3.1.12). The results of the case studies and interviews revealed that SMEs are very active in placing on the market FA not linked to an authorisation holder as this reduces the costs they need to bear (EM 2.2.6). They are also active in submitting applications which are supported by available scientific literature. For holder-specific authorisations, SMEs are also active, but they tend to focus on a few species to reduce costs. There are currently 1,214 non-holder specific FA authorised in the EU, compared to 236 holder-specific FA authorisations. Although the major innovation occurs among those 236 FA (new functions and actions), innovation may also take place in non-holder specific FA. Nevertheless, the impact of this matter on SMEs needs careful attention (EM 3.2.7).

In addition, the concerns associated with a low supply of vitamins on the EU market and dependency on imports from third countries for certain FA (vitamins, amino acids and trace elements) raise the question whether it might be necessary to extend this exclusivity to other categories or functional groups of FA in order to incentivise applicants to apply for authorisation for those essential FA that are very important for animal welfare and health. Therefore, the possible extension of market exclusivity to other categories of FA should be considered in any future revision of the legislation, as it may have a positive influence on innovation, especially for more sustainable FA, as well as improving the availability of certain FA. Again, the impact of any changes to these provisions on SMEs needs to be carefully considered.

The barriers described above are real, but they did not prevent innovation from being pursued in the EU FA sector. Four new functional groups were established by the 2003 Regulation to allow new types of FA to be authorised, and a large number of innovative FA (210) were authorised under the "zootechnical additives" group. However, few FA have been authorised with positive effects on animal welfare (three applications by December 2021) or on the environment (only one FA authorised). The number of patent applications for FA submitted to the European Patent Office doubled under the 2003 Regulation compared to the previous period (207 applications were received between 2004 and 2019 compared to 104 applications between 1979 and 2003). The share of EU applicants *versus* non-EU applicants remained almost the same for the two periods (44% EU applicants and 56% non-EU applicants).

Though no evidence could be collected on the amount and trend of R&D investments by EU-based companies to develop new FA since the 2003 FA Regulation came into force, some respondents from the industry sector noted that costs have been reduced by investing in non-

EU research facilities or sub-contracting R&D[84] activities (including trials) to facilities based in non-EU countries (EM 2.2.4).

4.2. How did the EU intervention make the difference?

All stakeholder groups perceive a harmonised authorisation procedure at EU level as achieving better results than national level authorisations. This view was confirmed in all consultation activities; by 101 out of 110 respondents (mainly FeBOs) in the targeted consultation, 96% of respondents covering all stakeholder groups in the public consultation, and 26 out of 27 national authorities in the targeted consultation (EM 9.1).

The smooth operation of the EU's Single Market was seen as the key advantage by business stakeholders and supported by the views of two national authorities considering that the intra-EU trade of FA is facilitated by a central approach. In addition, this system is considered more economic as there is no need to replicate the scientific assessments by different national authorities across more than one authorisation process. It also prevents applicants from "authorisation tourism" where they make applications to what they perceive as the least rigorous MS.

The added value of harmonised labelling rules was recognised by stakeholders (mainly FeBOs) (105 out of 110) as well as by all national authorities. This harmonisation is perceived as an element that facilitates the smooth operation of the EU market by reducing complexity and costs for both FeBOs and national authorities (EM 9.2).

A wide but not so clear consensus prevailed among all stakeholder groups that the EU-level intervention in the FA area is still warranted and needs to continue (unanimity for MS competent authorities, and support from 71 out of 110 mainly business stakeholders, with 31 respondents, mainly manufacturers of FA/premixtures and traders, not providing an opinion) (EM 9.3).

The result of the evaluation shows that the EU intervention is perceived positively by all stakeholders, including MS authorities. This intervention has reduced costs and facilitated the smooth functioning of the EU single market.

4.3. Is the intervention still relevant?

The objectives identified in the FA Regulation continue to be pertinent to the evolving needs, problems and issues related to the placing on the market and use of FA and premixtures.

4.3.1. Relevance of the objectives

The objective "*reduce AMR threats*" is still relevant, as the EU is fully committed to further strengthen the EU's response to AMR risks. The reduction of AMR threats to citizens, animals and the environment is still considered relevant by 26 MS authorities out of 27 and by 104 out of 111 other stakeholders (mainly FeBOs)[85] (EM 7.1).

[84] ii FA Final Report _FCEC, pages 68 and 69.
[85] vii Consultation Synopsis Report, pages 14 and 22.

The objective "*simplify and harmonise the authorisation process*" is still relevant according to a majority of MS authorities (24) and a majority of stakeholders, mainly FeBOs). The positive responses accounted for 91% (EM 7.2).

The objective "*ensure a rigorous risk assessment*" is still considered relevant by all the MS authorities and by 88% of other stakeholders (mainly FeBOs)[86]. A sound scientific assessment is the basis to ensure a high level of food and feed safety as well as to reinforce public health (EM 7.4). As regards the relevance of ensuring the protection of human health, animal health and the environment, there is a majority of FeBOs in favour (96%) of that general objective while support from MS authorities was unanimous (26) (EM 7.3).

The objective "*establish clear/comprehensive rules for authorisation and labelling of additives*" is still relevant for 97 % of stakeholders[87]. There is a quasi-unanimous consensus among MS authorities (24) and stakeholders (mainly FeBOs) on this matter (EM 7.6).

The objective "*improve FA control, traceability and enforcement rules*" is still relevant for the majority of MS authorities (25) and for 93 % of stakeholders (mainly FeBOs) (EM 7.5).

The objective *"addressing specific interests for pet owners and their animals"* is relevant for a majority of MS authorities (23). For other stakeholders (mainly FeBOs), this objective is widely seen as still relevant (63% of respondents), although some of them did not express any opinion, as this was not their area of expertise (34%). We can conclude that this objective is still relevant and of growing importance, taking into account the increasing market for pet food (EM 7.7).

As regards the objective "*encouraging placing on the market of FA that are innovative and efficacious*", there is a wide consensus among MS authorities (26 out of 26). For most stakeholders consulted via interviews (FeBOs), this objective remains relevant (103 out of 107). Nevertheless, many industry respondents also claimed that further efforts are required to promote the authorisation of innovative FA, in particular by SMEs[88](EM 7.8).

The objective "*ensuring that FA do not mislead consumers on food quality*" is still relevant for a majority of MS authorities (22 out of 26). 61% of stakeholders (mainly FeBOs) agreed on the relevance of this objective whereas 31% did not express any judgement (EM 7.9).

4.3.2. Are the current rules still adequate to support scientific and technological progress?

A majority of NCAs considers that the rules and definitions used in the 2003 Regulation are still appropriate to the current state of scientific and technical knowledge, while FeBOs are divided with a slight majority disagreeing (EM 8.1.2). The authorisation procedure is considered to be suitable to address scientific and technological progress by a majority of NCAs while a majority of FeBOs disagrees (EM 8.1.3). The criteria for authorisation are still relevant for scientific and technological progress for a majority of NCAs but not for the FeBOs (EM 8.1.3). A majority of FeBOs and NCAs considers that the re-evaluation process gives flexibility to adapt to scientific and technological progress (EM 8.2.2).

86 vii Consultation Synopsis Report, pages 14 and 22.
87 vii Consultation Synopsis Report, page 14.
88 ii FA Final Report _FCEC, page 114.

4.3.3. New needs

The majority of respondents to the surveys -- 16 MS authorities (out of 27) and 66 % of other stakeholders (mainly FeBOs) -- considered that new needs that had emerged since the 2003 Regulation was adopted need to be addressed by a revision of the legislation (EM 8.5.3 and 7.10).

However, analysis of the new needs identified revealed that very few of those identified could be regarded as genuinely new.

The concept of 'sustainability' was not as central to EU legislation in 2003 as it is today and was not explicitly included in the 2003 Regulation since it had not then been defined at EU level. Nevertheless the 2003 FA Regulation did include some aspects related to this concept such as positive effects on the environment or animal welfare. The FAO has defined sustainable agriculture development as "*the management and conservation of the natural resource base, and the orientation of technological and institutional change in such a manner as to ensure the attainment and continued satisfaction of human needs for present and future generations. Such sustainable development (in the agriculture, forestry, and fisheries sectors) conserves land, water, plant and animal genetic resources, and is environmentally non-degrading, technologically appropriate, economically viable and socially acceptable*[89]".

The revision of the FA Regulation is listed amongst the actions of the Farm to Fork Strategy, where it is stated that: "*to help reduce the environmental and climate impact of animal production, avoid carbon leakage through imports and to support the ongoing transition towards more sustainable livestock farming, the Commission will facilitate the placing on the market of sustainable and innovative FA*". A revised FA Regulation should be coherent with the emerging definitions of sustainability by providing the necessary flexibility to take into account a possibly new framework and should therefore consider other sustainability effects beyond the animal welfare or environmental effects, e.g., better use of resources.

According to all groups of stakeholders, FA have the potential to improve the sustainability of EU livestock farming by reducing the sector's carbon footprint, including methane emissions, as well as water pollution (nitrates and phosphates)[90]. The FA Regulation already refers to objectives and criteria related to the sustainability of livestock farming, such as protection of animal welfare or protection of the environment. Nevertheless, the FA Regulation does not encompass the broad concept of sustainability which can be regarded as only partially addressed in that Regulation (EM 7.11).

The possibility of claims for FA was a new need identified by FA producers[91] in the PC. Claims are allowed for feed materials and compound feed under the conditions of the Feed Marketing Regulation, but not for FA and premixtures (see 4.2 Annex III). This point was further explored as the EFSA assessment on efficacy regulates the specific function that can be claimed on the label, e.g., a preservative. The current FA Regulation only allows the labelling of the functional group for the FA as laid down in the authorisation. In the case, for example, of the recent

89 https://www.fao.org/3/u8480e/u8480e0l.htm
90 ii FA Final Report _FCEC, page 85.
91 FEFANA contribution to the PC.

authorisation of the FA that reduces methane emissions, it would be possible to say that it provides "reduction of methane emission" but not that it "contributes to the reduction of greenhouse gases" or "contributes to mitigate climate change", a language that would be more easily and more widely understood. This limitation in the FA Regulation reduces the possibility to convey messages more effectively along the feed chain. Such claims could be a good tool to raise awareness of the sustainable benefits of FA and could be considered in any future revision of the FA Regulation.

Under the Common Agricultural Policy, farmers are encouraged to adopt or maintain practices that benefit environment and climate (under the first Pillar "Direct payments" and the second Pillar "support of rural development") and groups of farmers may commit to a collective implementation of practices that reduce the impact of livestock farming on the environment -- for example by using an appropriate formulation of feed including certain amino acids that reduce nitrogen excretion. Providing clear and easily accessible information in this regard via claims would support the farmers in this regard.

Different alternatives could be envisaged to ensure that those claims are not misleading (see 4.2 Annex III).

The capacity of the 2003 FA Regulation to adapt to scientific and technological progress is questioned by the SH (SH survey) and by some MS authorities, though most MS authorities consider the FA Regulation is suitable to address scientific and technological progress. The arguments raised by FeBOs were: 1) science evolves faster than the FA Regulation can timely adapt; 2) the demonstration of efficacy for FA having environmental or animal welfare effects requires generally the demonstration of performance functions in addition to those effects, thus discouraging applicants; and 3) some definitions should be better adapted to the current state of art.

4.3.4. Societal expectations

About half (49%) of the respondents in the PC considered that societal needs were sufficiently taken into account by the 2003 FA Regulation, compared to 25% who thought they were not. Citizens were more inclined to indicate that societal factors are not sufficiently taken into consideration (8 responses out of 16 citizens that responded). Despite the efforts made to gather the views of consumers, animal welfare organisations and environmental organisations, in particular on societal expectations, it was not possible to get their contribution[92].

The development of new products (especially by SMEs) is considered an important tool to address evolving societal needs, in terms of further reducing the preventive use of antibiotics, improving meat quality, addressing animal welfare and conditions of breeding, improving sustainability, and reducing the environmental impact of livestock farming[93].

The role of FA in providing affordable food is very limited, but they can contribute to a better use of resources and to an increase in the performance of animals, thus reducing production costs.

[92] ii FA Final Report _FCEC, page 22.
[93] vii Consultation Synopsis Report, page 30-31.

FA can have a clear and positive effect on animal welfare through several different channels: by improving the physiological status of animals, reducing the stress due to adverse climate conditions, and facilitating the transition to different production stages in the life cycle.

All these positive benefits will reduce the production costs/losses for farmers and modestly contribute to providing affordable food of animal origin.

The direct contribution of FA to provide healthy and nutritious food is difficult to establish, although there are some elements that should be noted. Healthy aspects of food of animal origin are linked to minimum levels – or zero, if possible – of pathogens, toxins, contaminant residues and other agents that can cause foodborne disease. The safety assessment of FA ensures that FA will not cause hazards in food from animal origin and will not contribute to increase the level of contaminants or residues in that food.

FA have not successfully improved the nutritional profile of food of animal origin, e.g., by reducing saturated fats in monogastrics, or bio-fortification of food of animal origin. The 2003 Regulation does not have any specific functional group to which additives pursuing this type of effects could be allocated. In any case, this possibility would require much more examination, as such actions might also have serious negative effects on animal health, animal welfare and may raise ethical considerations. The promotion of those additives intended to improve the nutritional profile of food of animal origin cannot be regarded as a sustainable practice in the global context of the food chain. The shift to healthier diets should be facilitated by stimulating product reformulations and improving consumers' information.

The protection of natural resources is very relevant in animal farming, mainly due to the effect that livestock farming may have on the terrestrial and water compartments (freshwater, groundwater and marine water). Furthermore, the protection of biodiversity through the protection of non-target plant and animal species, microbes, and protozoans is an additional aspect to consider. During the implementation of the 2003 FA Regulation, the environmental risk assessment has been improved to cover all these elements and to prevent FA or their metabolites from harming the soil, water and biodiversity. In addition, many authorised FA having positive effects on the environment have been authorised under functional groups not directly related to these actions. One example is FA which are authorised as nutritional additives, but also serve to reduce phosphorous excretion (phytases), or nitrogen excretion (amino acids).

As regards climate action, FA can contribute to reducing greenhouse emissions of methane and nitrous oxide and have other environmental benefits by mitigating the negative effects of livestock production.

Factors linked to agricultural production are better management of soil and water quality, or an improvement in biodiversity. The effects of FA described above may have a moderate impact on this objective and so help ensure a more attractive environment for farmers and citizens in rural areas.

Any revision of the 2003 FA Regulation should ensure that FA having positive effects on sustainability can be authorised without the requirement to also demonstrate an animal performance effect.

5. WHAT ARE THE CONCLUSIONS AND LESSONS LEARNED?

In general, the **objectives** of the 2003 FA Regulation, underlying in particular the authorisation system and the labelling requirements provided therein, were found **still relevant** to the evolving needs and practical issues related to the placing on the market and use of FA and premixtures.

The evaluation found that sustainability in animal farming could maybe be better addressed through the Regulation, though there was room for improvement in this regard. In particular, the potential of FA to contribute to a reduction in the negative impacts of livestock farming on the environment or to improve animal welfare is presently under-exploited. However, the potential of the Regulation to contribute to more sustainable farming in these areas already exists, though it is maybe not fully realised. The main obstacle is the limitation of the categorisation system for FA, which is focused exclusively on performance. The existing categorisation system should ideally be modified so as to encourage the marketing of safe FA that are shown to have a favourable impact on sustainability, for example by creating a specific category of additives promoting sustainability.

The FA Regulation **contributed positively to the fight against antimicrobial resistance (AMR),** a major public health objective, by banning antibiotics as growth promoters and by introducing pre-market assessment to identify any potential risk of AMR effect. The evaluation shows the potential of the FA Regulation to reduce AMR further and acknowledges that this objective still has a high level of relevance and should therefore continue to be pursued, in particular by facilitating and encouraging the authorisation of innovative FA that can provide an alternative approach to the use of antibiotics.

The evaluation also finds that the **authorisation system, including the** independent **risk assessment** by EFSA and the **risk management process**, is both **credible and effective**, thus providing the means to assure a high level of protection of human health, animal health and the environment**,** and effectively increasing the level of safety all along the food and feed chain.

The efficiency and effectiveness of the authorisation system were demonstrated by the very small number of complaints and legal actions lodged against authorisation measures, and the low number of RASFF notifications concerning FA. These are even more impressive when set against the high number of applications for authorisation submitted under the FA Regulation, and the large number of authorised FA, including innovative FA. These quantitative indicators are reflected at a more qualitative level by the recognition in third countries of the value of EU authorisations of FA, and the strong global position of the EU FA market.

Although the **authorisation of FA is now harmonised and simplified** in comparison to the previous 1970 FA Directive, stakeholders continue to find that the authorisation procedure is in some cases not fully predictable and that the system overall remains too complex, costly and time consuming. This is mainly due to a small number of specific points:

- **Some delays in the authorisation** of FA occur during the assessment carried out by EFSA and to a lesser extent during the adoption procedure of the authorisation measures by the Commission. The main cause of delay is the fact that many application dossiers submitted are incomplete. This may be due to a different interpretation by

applicants of EFSA guidance documents, regular updates of those documents to adapt to new scientific knowledge or failure to take up the possibility of meetings with EFSA before the application is lodged.

While updates to requirements on data that should be submitted by applicants may not be avoided, so as to ensure the safety of the FA, improvements have already been implemented such as the possibility of pre-submission advice from EFSA provided for in the 'Transparency Regulation'[94] and other mitigation measures. Any benefits from those recent measures and provisions are expected to manifest in the medium term.

- The establishment of a **10-year authorisation period** allows for a timely safety/efficacy re-assessment of FA, as scientific/technical knowledge evolves. The renewal process for FA authorisations was also designed to encourage technological progress as applicants would not be interested in seeking a renewal if the FA has meanwhile been replaced on the market by a more innovative product that fills the same market need. However, this is not perceived by stakeholders as a measure promoting technological progress. They claim that the market is self–regulating and removes the less efficient or less innovative FA. The evaluation suggests that the renewal process for authorisations is not clearly linked with positive effects on innovation. While a prolongation of the authorisation period would reduce administrative and regulatory burden, this needs to be balanced against a possible impact on safety.
- The effectiveness of the authorisation system and of specific related provisions of the FA Regulation could be improved in terms of **clarity and coherence**, including coherence in relation to other legislation, which may have impacted somehow both the successful implementation of some measures, and the general effectiveness and efficiency of the authorisation process as such. In this regard, the following areas for improvement have been identified:
  - Establish clear rules on data sharing in order to avoid duplication of toxicological tests on vertebrates. The setting up of alternative testing methodologies that could help reduce the need for animal testing should also be explored further.
  - Improve clarity of the rules on the use of FA in water for drinking, so as to facilitate their practical implementation by operators and their coherence with the legislation on biocidal products.
  - Further specify the definition of 'FA' so as to better distinguish them from other types of feed, and define certain terms used, such as 'preparations'.
  - Provide for transitional periods in case of withdrawal of an application for renewal, in order to allow operators to adapt to the expiry of the authorisation.
  - Clarify the legal status of 'recommended or maximum recommended levels of use' of FA, which are provided for in certain authorisation acts.
  - Clarify the requirements for the environmental risk assessment of FA intended specifically for farmed non-food producing animals.

Certain provisions of the FA Regulation are considered as not sufficiently efficient, due to some administrative burden or complexity involved in their implementation. The following areas for

[94] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019, which amended the General Food Law and several legislative acts in the food safety sector. That Regulation entered into application on 27 March 2021.

simplification and reduction of administrative costs and regulatory burden have been identified:

- Establish a simpler procedure when the authorisation holder changes, with respect to holder-specific authorisations.
- Extend the duration of the authorisation period, at least for certain types of FA.
- Facilitate the extrapolation of study results from major to minor species and from food to feed.
- Review the existing restrictions on the circulation of FA only intended for export to third countries, in the context of a possible harmonisation of the applicable rules.

The FA Regulation is resulting in substantial costs for business and public authorities which however seem to be justified by the resulting benefits.

Costs for businesses mainly stem from the preparation of application dossiers. Certain simplification or clarification measures as indicated above may reduce costs to a certain but limited extent. Extending holder-specific authorisations to more categories of FA may provide market exclusivity to those applicants, improving the availability of certain essential FA. Nevertheless, this change would need to be carefully considered as it might negatively affect SMEs. In addition, ensuring better coherence with the CLP Regulation as regards the labelling of FA and premixtures concerning users' safety may further reduce costs and burden.

Costs for the risk managers could be reduced through a simplification of the procedure in case of modification of an authorisation holder, the extension of the duration of the authorisation period, and the clarification and/or better definition of concepts used in the FA Regulation.

Benefits of the provisions of the FA Regulation have been identified for human health, animal health and the environment and also for consumers, pet owners, farmers and feed business operators along the feed chain.

The FA Regulation was successful in conveying necessary safety messages and allowing the safe and appropriate use of FA. However, the simultaneous implementation of the FA Regulation and the CLP Regulation has led to different interpretations by MS, creating a possible burden and a potential negative impact on workers' safety, although the evaluation was not able to identify any concrete instance of such negative impact. More coherence with the labelling provisions applicable to feed materials and compound feed, by creating the possibility of using *modern alternatives* to the physical label, such as electronic means, could be a significant improvement. Furthermore, a demand exists to harmonise the labelling of safe FA only *intended for export* to third countries and the establishment of *labelling tolerances* for FA contained in premixtures.

An adaptation of the *Register of FA*, by making it more informative and more user-friendly, would improve the information on the authorisation status of FA.

Enforcement of the FA legislation is mainly ensured at MS level through official controls and penalties imposed in case of infringements. Available data from MS' official controls, Commission Audits and the limited number of RASFF notifications in relation to FA point to a good level of compliance with the FA Regulation and may indicate that enforcement is generally

effective. In this context, the role of the EURL-FA in contributing to the effective control of FA is essential.

Nevertheless, some weaknesses in **enforcement and traceability** of imports from third countries have been identified. A problem arises due to the lack of a specific import code to identify FA/premixtures. The fact that such harmonised traceability rules, but also lists of third country establishments of dispatch have not been established under the Feed Hygiene Regulation negatively impacts enforcement and traceability.

As indicated above, another area for improvement concerns the situation of FA/premixtures only intended for export to third countries, due to a lack of appropriate labelling indications and of harmonised rules for tracing and control of such products.

The FA Regulation has addressed **the specific needs of pet animals and their owners** by setting up a comprehensive set of rules that are adapted to this somewhat different context, in particular during the FA risk assessment phase. The evaluation shows that FA for pet food are regarded as safe, efficacious and relevant and that they thus provide real benefits for pets and their owners. The FA Regulation has thus achieved its objective of addressing the specific needs and interests of this sub-sector, but it should be noted that animal welfare/pet animals organisations did not contribute to the different consultation activities, despite the efforts to involve them.

The FA Regulation allows the **placing on the market of efficacious FA** where efficacy is defined in relation to their functional group classification.

The FA Regulation achieved a high level of **innovation** in FA that are used as an alternative to antibiotics, and in FA improving the digestibility of feed (better use of resources) and increasing animal performance. However, the FA Regulation was perceived as failing to keep pace with innovation in sustainability effects, such as reducing the environmental impact of livestock farming or improving animal welfare. This was attributed to the limitations of the categorisation system for FA. In addition, many authorised FA (such as amino acids) have positive effects on the environment but there is a lack of "visibility" of this effect as they are authorised under functional groups which are not related to those environmental effects (e.g., as nutritional additives).

Other identified barriers to innovation include an insufficient understanding of certain elements of EFSA guidance, in particular in relation to the definition of clear endpoints to demonstrate the efficacy of new FA, and the fact that some FA may not be administered via drinking water. Water could be an efficient route of administration of FA that could increase the performance of certain FA, and any revision of the FA Regulation should help promote innovation. In this regard, the current restrictions on certain FA should be re-examined.

The 10-year duration of the authorisation period is considered too short and discourages industry from investing resources in developing new FA. It should be assessed whether it is always justified on safety grounds. Finally, the establishment of holder-specific authorisations for a wider range of FA has been identified as a measure that might foster innovation. The increasing number of applications for authorisations of this type confirms this finding, though the impact on SMEs also needs to be considered.

Feed business operators may have no interest in investing in non-holder specific authorisations as they bear the authorisation costs while others may place the products on the market once they are authorised. This has generated a number of unintended negative effects, including notably a shortage in the supply of certain essential FA such as vitamins that are very important for animal health and welfare.

Accordingly, potential areas for improvement to promote innovative FA, notably related to sustainability aspects, could include:

- A review of the classification of FA into categories/functional groups, so as to allow the authorisation of FA with positive effects on sustainability aspects and animal welfare and provide more flexibility for potential future modifications of that classification.
- The introduction of a claims system for FA, highlighting innovative and sustainable characteristics thereof.
- An extension of the holder-specific authorisation status to more FA, in order to encourage the submission of applications for innovative or sustainable FA contributing to improve the supply of certain FA that are important for animal health and welfare and may reduce dependency on third countries.
- A clarification of the use of FA in water for drinking.
- A consideration of the extension of the duration of the authorisation period (the resources currently invested in obtaining a renewal of authorisation could then be allocated to the development of new FA).

The EU intervention in the area of FA is considered as bringing **added value** through the harmonised EU-level authorisation procedure and labelling rules.

The evaluation showed that additional harmonisation as regards the rules concerning labelling tolerances of FA in premixtures, labelling of FA or premixtures intended for export only, and new labelling means for FA and premixtures could bring further benefits.

ANNEX I: PROCEDURAL INFORMATION

1. Lead DG, Decide Planning/CWP references

The evaluation of the FA Regulation ('the evaluation') was prepared under the lead of the Directorate-General for Health and Food Safety. In the Decide Planning of the Commission, the process is referred to under item PLAN/2017/988. The evaluation was mentioned in the 2017 Regulatory Fitness and Performance Programme REFIT and the 10 Priorities of the Commission[95] accompanying the Commission Work Programme for 2017. The evaluation is also linked to the Fitness check on the General Food Law mentioned in the Commission Work Programme for 2015[96], which was carried out in 2017.

2. Organisation and timing

The evaluation started in 2017 with the publication of the Evaluation Roadmap on 28 August 2017[97]. The evaluation is based on a Public Consultation which run from 12 December 2018 to 3 April 2019, with the factual summary report of the PC published in November 2019. The evaluation is also based on a study performed by an external contractor which was finalised in June 2020.

An Inter-Service Steering Group (ISSG) assisted DG Health and Food Safety in the evaluation process, which was created in February 2017 and included Commission services of Directorate-Generals GROW, AGRI, ENV, EMPL, MARE and JRC, together with the Commission's Secretariat General and Legal Service. The ISSG met 4 times during the evaluation process from March 2017 to February 2019.

The draft Staff Working Document ('SWD') on the evaluation and all supporting documents were submitted to the Regulatory Scrutiny Board ('RSB') on 4 March 2022, in view of a meeting on 6 April 2022. The RSB issued a positive opinion on 8 April 2022.

3. Consultation of the RSB

The draft SWD on the evaluation was reviewed by the RSB which issued a positive opinion. The opinion includes recommendations on how the SWD could be further improved and which were addressed as explained below:

Table 1: How recommendations of the RSB have been addressed.

Recommendations of the RSB	**Modifications in the SWD on the evaluation in response to the Board's recommendations**
(1) The report should improve the data and information used to support the conclusions of the evaluation, e.g., in relation to the evaluated time period, the costs and	Data and information improved: • Updating of statistics on FA, premixtures, compound feed, feed materials and livestock production. • Clarification of the structure of the market and differences between FA and specialty feed ingredients. Limitations and caveats have been included (point 3.1 and new Annex VII on market data).

[95] REFIT – making EU law simpler, less costly and future proof - European Commission (europa.eu)
[96] Commission Work Programme for 2015. A New Start. COM (2014) 910.
[97] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1483-Evaluation-of-the-feed-additives-Regulation_en

benefits, and the potential for burden reduction. It should better justify the use of relatively old data (2004-2017) and how this is still representative. Where new data is added, it should be clarified if this data is supporting or contradicting the conclusions, and to what extent. In the absence of more quantitative data, the report should provide a more robust qualitative analysis, in particular in support of the benefit assessment, clearly outlining the limitations and uncertainties.	• Consequences of increasing development of FA production in the Asian Pacific region (3.2.1). • Additional information on R&D (3.1.2). Justification of the period 2004-2017 used to analyse and explain that this period is still representative and that this does not contradict the conclusions (section 1). As for benefits, a qualitative analysis has been done with references to studies or documents supporting it where possible (4.1.4.2 and Annex III). Caveat has been introduced to explain limitations in order to establish causal links and lack of data on actual use of FA (Annex II). The methodology of costs calculations has been included in Annex II and more detailed information has been specified in the main part of the report, including the overall costs of the Regulation (4.1.4.1), as well as in point 2.1.1 of Annex III. Some parts have been summarised to avoid too many technical details and repetitions.
(2) The report should ensure coherence between the data and conclusions in Annex III and in the main text, outlining the difficulties related to isolating specific causal relationships and, consequently, better calibrating the conclusions that can be drawn from the available evidence. The evaluation matrix in Annex III should be completed, making clear the difference between formal compliance and verifiable or verified outcomes. It should be clear where the answers to the evaluation questions can be found in the report.	Some data of Annex III have been transferred to the main text ensuring coherence between the data/conclusions of the main text and the Annex. The intervention logic ('IL') has been modified to indicate the general objectives, to disentangle drivers, problems and needs, to indicate how the intervention was expected and the expected outcomes. The links to the IL were clarified by separating the authorisation process from aspects related to labelling (section 2). The evaluation matrix has been completed and all references to the evaluation matrix have been included in the main text where appropriate. The evaluation matrix includes the sources of data and makes a distinction between formal compliance and verified outcomes. The authorisation process has been clarified: the definition of different steps and the reasons for the delays have been pointed out. (4.1.2.3 and Annex VIII). Further explanations have been provided for: ✓ How the re-evaluation process worked and how additives were assessed (Annex VIII). ✓ When the second opinion from EFSA is requested (3.1.3). ✓ The labelling rules and how they contribute to the safety of FA and how operators follow the label instructions (3.1.3 and 4.1.7). The link with CLP is described better (3.1.3). ✓ The restrictions on administering additives in water and the reasons why such restrictions were introduced (4.1.3). ✓ The difference between applications, authorisation and number of additives (Annex VIII). ✓ The performance of the EU system compared to third countries (4.1.2.5). ✓ A specific section for internal and external coherence (4.1.3). ✓ Import codes (4.1.7).

	✓ Claims (4.3.3). ✓ Relationship between animal health and animal welfare benefits (4.1.4.2).
(3) The report should distinguish between innovative and sustainable FA and clarify the different bottlenecks encountered for these types of additives. It should clarify how different aspects influence the rate of innovation, e.g., the trade-off behind extension of the length of the authorisation period or the differences between holder and non-holder-specific authorisations.	The report includes several explanations to distinguish innovation from sustainability and to explain the bottlenecks encountered for this type of additives (4.1.9). The report explains what the elements that influence the rate of innovation are and how innovation succeeded in some aspects but not in others. The length of the authorisation period is also analysed comparing the expected results when the 2003 FA Regulation was adopted and the real effect of this period in relation to innovation and burden (4.1.9). The differences between holder and non-holder-specific authorisation have been included (3.1.3).

4. Evidence and sources

The evaluation is based on an external support study conducted by the Food Chain Evaluation Consortium ('FCEC') - Brussels from May 2018 to June 2020. This support study answered 10 evaluation questions linked to the five evaluation criteria. Several reports and documents recently published have also been considered in the evaluation process:

- The REFIT evaluation of the General Food Law[98].
- The Farm to Fork Strategy[99], which was adopted on 20 May 2020 as one of the key actions of the European Green Deal[100].
- FAO and WHO 2019 Sustainable healthy diets – Guiding principles[101].
- Non-animal Methods in Science and Regulation, Non-animal Methods[102].
- EU aquaculture report: sales value goes up while the volume remains steady[103].
- WEBINAR Innovation to tackle climate change. Generating facts about FA and livestock production[104].
- The Green Deal and the CAP: policy implications to adapt farming practices and to preserve the EU's natural resources. European Parliament Think Thank[105].
- Farm to Fork strategy - An overview of Parliament's positions. European Parliament Think Thank[106].
- What if we could fight antibiotic resistance with probiotics? European Parliament Think Thank[107].

98 European Commission (2018) the REFIT Evaluation of the General Food Law (Regulation (EC) No 178/2002) SWD (2018) 38.
99 https://ec.europa.eu/food/horizontal-topics/farm-fork-strategy_en
100 https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en
101 http://www.fao.org/home/en/
102 EU SCIENCE HUB. https://ec.europa.eu/jrc/en
103 EU SCIENCE HUB. https://ec.europa.eu/jrc/en
104 http://www.fao.org/partnerships/leap/news-and-events/news/detail/en/c/1312668/
105 http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL_STU(2020)629214
106 http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL_BRI(2020)658206

ANNEX II. METHODOLOGY AND ANALYTICAL MODELS USED

This Annex presents the methodological approach used in this evaluation, including the general approach followed in the study supporting the evaluation.

Evaluation Matrix

The development of an Evaluation Matrix ('EM'), which linked Evaluation Questions ('EQs') to a series of judgement criteria and indicators, is a well-recognised approach and ensures that appropriate methodologies are used to gather the required data to form the evaluation evidence base. The EM was fine-tuned through discussion with the Steering Group.

Data collection

For the enforcement of the Regulation by the MS authorities, the period for the analysis was based on the Multiannual Control Plan of the years 2011-2015. For many other aspects, the data-gathering and analysis was extended until the end of 2019, where possible.

In the case of renewals of authorisation, the data collected covered the period 2017-2020, as the majority of the renewals were requested during this time frame. The reason is that the first authorisation act adopted under the FA Regulation was in 2005, followed by 5 authorisation acts in 2006 and increasing Regulations subsequently. Taking into account that the process leading to the adoption of the first authorisation took more than 16 months, the first renewal processes were concluded in 2017.

For specific issues that were relevant for the evaluation, information up to 2021 was included: Rapid Alert System for Food and Feed concerning residues in food of animal origin, results of the Commission Audits on Official Controls of FA and Traceability. The new information did not change the conclusions of the report but provides additional information.

The following methodologies were used and implemented:

- First, an extensive desk research and literature review was performed. All relevant literature and databases were screened to establish a list of relevant material, which was then mapped to the indicators in the EM. Nearly 5,000 initial results were reduced to 500 upon screening for relevance to the EQs, and these were further reduced when screened for relevance to the indicators.

- In addition, the data collection comprises targeted consultation activities, including targeted surveys, interviews and case studies, which are presented into details in the synopsis report annexed to this SWD (vii Consultation Synopsis Report). The targeted consultation activities were conducted by the contractor performing the evaluation study:

    - The three surveys were addressed, respectively, to NCA, to stakeholders involved in the FA field and to stakeholders from third countries.

    - The interviews were developed to complement the data gathered in surveys.

    - Case studies were performed in order to understand the concrete application of the FA Regulation, identify and justify the factors that underpin the observed impacts,

[107] http://www.europarl.europa.eu/thinktank/en/document.html?reference=EPRS_ATA(2020)641545

and collect qualitative and quantitative data that cannot be collected from the other sources. The authorisation process and the labelling of FA were the two thematic areas covered.

External study

An external study[108] was commissioned to support this evaluation covering 2004 to 2017, a period that is largely representative of the experience encountered with the new authorisation and assessment process that had been introduced. This study was desk-based and supported by an extensive consultation strategy as described above.

Limitation and robustness of findings

The significant challenges outlined below are exogenous to the evaluation methodology and were identified from the outset. These were addressed by expanding the data collection exercise and broadening the consultation strategy to ensure that the study could gather an appropriate and objective evidence base in particular given the number of indicators used to address the evaluation questions. Specific caveats in the data and estimates presented in this Report are indicated and explained in the text.

More in detail, several challenges needed to be overcome or mitigated in carrying out this evaluation:

- Categorisation of FA: The classification of FA in the FA Regulation does not necessarily match with some commercial categories. This situation was addressed by developing a consolidated list of the commercial categorisation based on a variety of commercial sources and then mapping this consolidated list to the regulatory categories.

- The data on the market and market trends is very scarce. There is no official information available in EUROSTAT (no trade/industrial classification) on the market (e.g., level of production, turnover, production prices, labour input, import prices, market prices, or the quantification of imports or exports) allowing to characterise the sector and to know the level of competitiveness of the EU industries or the EU market share. Therefore, various other sources (Report by RM Associates Ltd, Mordor Intelligence, Allied Market Research, FEFANA, FEFAC FEDIAF or FAO) were examined in order to estimate the market of FA in the EU and worldwide, the relation to compound feed and feed materials and to identify key market trends. The classification of additives is different depending on the source, some sources include “prebiotics” that are normally regarded as “speciality feed ingredients“ but in fact are feed materials. Also, microorganisms are called “probiotics” in some sources. There is no data since the implementation of the FA Regulation in 2004 and some of the following years.

- Due to the lack of identification at the entry point in the EU, it is not possible to estimate how many additives are produced in third countries, considering the increasing production in those countries and the delocalisation of the production sites.

- The lack of data required additional primary and secondary data collection from a wide range of sources, including commercial sources. Where quantitative data could not be identified or developed, qualitative approaches were used with extensive triangulation to produce the most reliable estimates.

[108] Conducted by the Food Chain Evaluation Consortium – FCEC and published together with this Staff Working Document

- Temporal scope of the study and baseline: The baseline for the study is the situation at the time of the entry into application of the FA Regulation in 2004. In 2004, the situation was related to the implementation of the former FA Directive. However, no impact assessment or evaluation of the 1970 FA Directive were performed for the adoption of the FA Regulation. Furthermore, the industry was not sufficiently organised as an association at European level[109]. In particular, the baseline was developed based on data from the EU Register of FA, the list of FA notified as existing products under the 1970 FA Directive, the list of authorised FA under that Directive[110], the list of products authorised under Council Directive 82/471/EEC[111], and limited documents from academic or/scientific publications. Qualitative approaches were used to fill quantitative data gaps.

- Estimation of costs and benefits: Providing estimates of costs and benefits in a uniform manner to allow unit cost comparisons required considerable input from stakeholders, especially FeBOs.
    - ✓ The efficiency has been particularly challenging to assess, given the absence of an impact assessment and the lack of precise data on current costs.
    - ✓ When it comes to authorisation costs, the data collection has met important confidentiality constraints, particularly for holder-specific authorisations, where a single company holds the authorisation for a product, and it was important to ensure that single companies could not be identified. To address this challenge, the Standard Cost Model was applied. This allowed us to isolate key obligations arising from the FA Regulation and then, to quantify these by using a combination of required staff time/grade and cost per unit. It was necessary to extend the data collection to a large range of companies, in order to address gaps, improve the estimations and overcome confidentiality concerns.

- Enforcement data: Evidence on enforcement from MS authorities was rationalised by aligning the survey to the results of the Multi-Annual National Control Plan (MANCP) 2012-2015 required by the Official Controls Regulation. Only 16 MS, out of the 25 who responded to the survey, were able to provide data. For the remaining MS, the results could not be specifically identified, as they were merged with other outcomes from different legislative provisions.

- Representativeness of stakeholder groups: The views of competent authorities and the feed industry are well reflected in this report due to their active participation in the consultations activities organised as part of the study. However, organisations representing pet owners, consumers, animal welfare and environmental NGOs, did not participate in the consultations despite the efforts developed by the study team and the Commission to involve them. Therefore, their views could not be considered in the analysis.

- Comparability of databases: The SANTE and EFSA databases were used to analyse the authorisation and evaluation procedures. Several shortcomings were identified:
    - ✓ It is not possible to match the SANTE and EFSA applications as they refer to different administrative procedures. This does not necessarily affect the analysis, as it is possible to analyse the different steps in the procedure. However, it may lead to some difficulties in processing the data and understand the tracking of an application.

[109] FEFANA was created in 1963 with five national associations of five countries. In 1990, associations from Spain and Scandinavian countries joined the organisation. In 2004, FEFANA established itself as a European association with direct affiliation of member companies.

[110] List of the authorised additives in feedingstuffs published in application of Article 9t (b) of Council Directive 70/524/EEC concerning additives in feedingstuffs (2004/C 50/01). OJ C 50, 25.2.2004, p. 1.

[111] Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition OJ L 213, 21.7.1982, p. 8.

- ✓ There is no accessible collection of data on the results of the EFSA opinions, whether they are positive, positive with restrictions, negative or inconclusive. An estimation based on different data has been made[112].

- Quantification of benefits: The actual benefits are generally not possible to quantify, and even less to monetise. This is due both to their non-quantifiable nature, and the presence of confounding factors which mean that lack of a basis for attributing causality cannot be isolated and attributed to the FA Regulation alone. This is the case for all of the expected benefits for human health, animal health and welfare, and the environment: for all these aspects, benefits were analysed qualitatively, in terms of the extent to which they are considered to have been achieved by the different groups of stakeholders, bearing in mind the need to attribute causality to the FA Regulation. Benefits generated by the FA Regulation could not be quantified because as they don't arise directly in monetary terms, expressing them in such terms would requires a two-steps process: a) quantifying them in physical terms; b) converting those physical quantities in monetary terms. Both steps of this process are unfeasible. To quantify in physical terms the effects of the FA Regulation, it would be necessary to take a 'with-and-without' approach comparing the relevant figures in the 'with' scenario (the actual scenario in which the FA Regulation and other relevant policy measures coexist), and in one 'without' the FA Regulation but with all the other relevant policy measures implemented during the period of implementation of the FA Regulation. Unfortunately, since the FA Regulation was actually implemented, figures for the latter scenario are not available. For instance, it is not possible to associate the significant fall in antibiotic use in food-producing animals with the FA regulation as several other measures have impacted this reduction such as: the Commission's Action Plans against the rising threats from AMR (2011-2016), the EU One Health Action Plan Against AMR adopted in 2017, the EU Guidelines on the Prudent use of Antimicrobials in Animal Health, and the different National Action Plans and Strategies. Furthermore, little or no relevant quantitative data are available.

- This analysis was supported, where possible, by evidence provided on an exemplary basis (i.e., best examples of benefits actually obtained). Efforts were also made to collect more quantitative indicators of the benefits of the FA Regulation for FeBOs and for MS Competent Authorities, in terms of potential costs savings and generated market value. Only in few cases, FeBOs provided data in terms of the share of regulatory costs as a percentage of production costs or turnover.

- Quantification of costs of human health, animal health and the environment: This is not possible as linking the use of an additive with a certain health or environmental effect having costs on health, welfare of animals or the environment is not feasible due to the lack of a basis for attributing causality. This causality cannot be isolated and attributed to the FA Regulation alone. In addition, to assess the costs of the FA Regulation using the usual 'with-and-without' approach is unfeasible because no impact assessment and evaluation of the former 1970 FA Directive were performed before the adoption of the FA Regulation. With regard to the comparison of costs and benefits of the FA Regulation, it is necessary to notice again that neither the impact assessment nor the evaluation of the previous 1970 FA Directive has been performed before the adoption of that Regulation. As a consequence, it is not possible to calculate its cost effects by comparing the costs of the FA Regulation with the costs of the previous 1970 FA Directive using the usual 'with-and-without' approach. As it is not possible to calculate the costs effects of the FA Regulation, obviously it is also not possible to compare in any way its costs and its benefits.

Methodology for the analysis of costs

[112] Details on the methodology to make this estimation in FCEC Final Report, 1, EQ 1.5.

The methodology for the analysis of the regulatory costs for the affected stakeholders, MS-MS authorities, EU institutions, and the analysis of benefits is described in document vii Cost methodology (Annex 6 to the FCEC Final Report).

- Costs for businesses:
  - ✓ The assessment of administrative and compliance costs stemming from the FA Regulation was based on the identification of relevant obligations and required actions, as defined in the standard cost model ('SCM').
  - ✓ Costs for applicants are calculated on 'business as usual' ('BAU') and on additional basis.
  - ✓ Labelling costs for BAU are negligible, so the calculation was made on the basis of additional costs (BAU excluded).
  - ✓ The obligations defined in the FA Regulation were classified in accordance with their importance. Costs were monetised using the Eurostat dataset on mean annual earnings by economic activity and educational attainment [dataset: earn_ses14_30][113] for industry (except construction), as an average across the EU-28 and for each of the staff categories 1 to 4 (adjusted for overhead costs). The use of the average EU-28 earnings neutralises the impact of the location of companies' operations on costs.
  - ✓ The direct costs of the obligations were estimated as an average over the last three years 2016-2018 on the basis of detailed information provided by the operators on the case studies and on the surveys for the main activities identified having relevant impact on costs.

- Costs for MS: The SCM was followed to identify the administrative obligations, identification of target groups within NCAs that perform the different actions (implementation of the FA Regulation and control activities), frequency of required action (attendance to meetings of SCoPAFF, number of inspections per year/establishment), identification of relevant costs and burdens (attendance to SCoPAFF meetings, control activities and other legal obligations). The performance was assessed by the staff time[114] devoted to these activities. It has been estimated as an average over the last three years by the NCA (2016-18).

- Costs for the European Commission: The SCM was followed to identify the administrative obligations, the frequency of certain actions (e.g. attendance to meetings of SCoPAFF), the identification of the cost parameters that refer only to labour costs, the data sources, i.e. SANTE database, Unit Management Plan to determine the allocated human resources, EFSA database, Register of FA and SANTE web for the meetings of the SCoPAFF. The costs cover BAU and additional costs.

- Costs for the EURL: The SCM was followed to identify the administrative obligations, the frequency of certain actions (SCoPAFF meetings), the identification of the cost parameters that refer only to labour costs, the data sources, i.e. EURL database, the unit resources dedicated to FA, and SANTE web for the meetings of the SCoPAFF. The costs cover BAU and additional costs.

- Costs for EFSA: The SCM was followed to identify the administrative obligations, the frequency of certain actions (EFSA panel and working groups meetings), the identification of the cost parameters that refer only to labour costs, the data sources, i.e. EFSA database, and the unit resources dedicated to FA. The costs cover BAU and additional costs.

Some important elements of the costs methodology are described in the tables below:

[113] Statistics | Eurostat (europa.eu)

[114] EUROSTAT average annual earnings in the public sector, by economic activity and educational attainment (staff categories 1 to 4), per Member State (latest data: 2014), adjusted for overhead costs (addition of 25%) in accordance with the Better Regulation toolbox #60.

Table 1: Identification of costs according to the Standard Cost Model (SCM)

A. TYPES OF OBLIGATION	*B. TYPES OF REQUIRED ACTION*
1. Notification of (specific) activities or events 2. Submission of (recurring) reports 3. Information labelling for third parties 4. Non labelling information for third parties 5. Application for individual authorisation or exemption, i.e., obligation to fulfil each time a particular task has to be carried out 6. Application for general authorisation or exemption 7. Registration 8. Certification of products or processes, i.e., obligation to deliver a certificate or to get a certificate 9. Inspection on behalf of public authorities 10. Cooperation with audits & inspection by public authorities or their appointees including maintenance of appropriate records. 11. Application for subsidy or grant 12. Other	*1. Familiarising with the information obligation* *2. Training members and employees about the information obligations* *3. Retrieving relevant information from existing data* *4. Adjusting existing data* *5. Producing new data* *6. Designing information material* *7. Filling forms and tables (including recordkeeping* *8. Holding meetings (internal/external with an auditor, lawyer etc.)* *9. Inspecting and checking (including assistance to inspection by public authorities)* *10. Copying (reproducing reports, producing labels or leaflets)* *11. Submitting the information to the relevant authority* *12. Filing the information* *13. Buying (IT) equipment & supplies to specifically used to fulfil information obligation.* *14. Other*

Table 2: Obligations for FBOs, as defined in Regulation (EC) No 1831/2003

The purpose of this table has been to provide an initial understanding of the importance of these costs for operators. Source: Agra CEAS, based on the SCM and exploratory interviews with the industry.

OPERATOR	OBLIGATION	REFERENCE (REG. (EC) NO 1831/2003) *(A)*	IMPORTANCE (COST-WISE) *(MAJOR/MINOR) (B)*
Any person seeking an authorisation	Submit an application	Authorisation	Minor
		Article 4	
Applicant	Adequate and sufficient demonstration of the conditions set out by the FA Regulation	Conditions for authorisation	Major
		Article 5	
Applicant	Deliver the necessary documents/data to EFSA	Application for authorisation	Major
		Article 7	
Applicant	Deliver the supplementary information to EFSA (if requested)	Opinion of the Authority	Major/Minor *(depends on questions or not from EFSA)*
		Article 8	

The holder of the authorisation	Ensure that post-market monitoring is carried out and submit reports to the Commission (rarely requested)	Supervision	Minor
		Article 12(2)	
The holder of the authorisation/applicant	Re-submit an application, if changing the terms of the authorisation + data supporting the request for the change	Modification, suspension and revocation of authorisations	Major
		Article 13	
Producer, packer, importer, seller or distributor (within the EU)	Responsibility for proper labelling actions	Labelling and packaging	Major/Minor *(depends on producer logistics)*
		Article 16	
Applicant	Take all necessary steps to reach agreement on sharing the use of information	Data protection	Minor
		Article 20	
Applicant	Contribute to supporting the cost of the tasks of the Community Reference Laboratory and the consortium of National Reference Laboratories	Reference laboratories	Minor
		Article 21	
Applicant	Adequate and sufficient information for renewal	Renewal of authorisation	Major
		Article 14	
MS	MS shall lay down the rules on penalties applicable to infringements of the FA Regulation	Penalties **Article 24**	*This is not a cost as such for operators. The analysis covered the extent to which penalties apply and severity of penalty.*

(a) Article 10(2) of the FA Regulation (re-evaluation of existing products) and Article 15 of the FA Regulation (urgent authorisation): these aspects were not considered to incur 'major' costs by the industry.

(b) Minor/major costs in this context is meant to provide the relative importance of the costs (i.e., whether they constitute 'major' or 'minor' costs for an operator).

Table 3 - Obligations for applicants

ARTICLE / OBLIGATION	SUBMISSION OF FEES	SUBMISSION OF APPLICATION	DOSSIER PREPARATION AND COMPLETION (TESTS / STUDIES)
4 (Submit an application)	X	X	
5 (Demonstration of conditions)			X
7 (Deliver documents/data to EFSA)			X
8 (Deliver supplementary info)			X
12 (Ensure monitoring)			
13 (Re-submit application and data)	X	X	X
14 (Renewal of authorisation)	X	X	X

Table 4: Activities related to costs

	INTERNAL COSTS *(A)*	EXTERNAL COSTS *(B)*
Applicants: • authorisation costs (Article 4+10) • renewal costs	Staff time, by staff category *(c)*: preparation of application dossiers	• Safety studies • Efficacy studies • External consultants • Other costs (including post-monitoring)
FeBOs: • labelling costs	Staff time, by staff category *(c)*: label translation, redesign and application per label change	• Purchase of equipment and services

ANNEX III. EVALUATION MATRIX AND, WHERE RELEVANT, DETAILS ON ANSWERS TO THE EVALUATION QUESTIONS (BY CRITERION)

This Annex is not exhaustive in the response to the evaluation questions and intends to complement the main part of the document, in particular section 4.

1. - EFFECTIVENESS

1.1 REDUCE ANTIMICROBIAL RESISTANCE (AMR) THREATS TO ANIMALS, CITIZENS AND ENVIRONMENT.

With the entry into force of the FA Regulation, the four remaining antibiotics still in use as growth promoters were taken off the EU market in January 2006.

Given the decreased use of specific antibiotics before and after the EU general ban from 1996 to 2008, some studies demonstrated a positive impact on the reduction of AMR, which has been documented in various EU countries (e.g., in Denmark from 1996 to 2008, or studies conducted by WHO). Specifically, an overall positive impact of the ban of antibiotics in feed, previously used as FA in farm animals and humans, has been reported in some Scandinavian countries – e.g., Denmark and Sweden (Grave et al., 2006; DANMAP, 2009a,b; SVA, 2009, 2010, 2011; DANMAP, 2011)[115].

After the ban, despite initial promising observations showing a reduction in the antibiotic resistance (Boerlin et al., 2001), larger data sets were not initially indicative of a decrease in multi-resistance of the livestock species of concern in the Netherlands (MARAN, 2012). Later, however, the same author reported some reductions (MARAN, 2015) in relation to changes in the use of antimicrobials, but mainly as veterinary drugs[116].

Although the antibiotics authorised by the former 1970 FA Directive were addressed to food-producing animals, companion animals due to their close contact with humans may contribute to spread AMR to humans. Use of antimicrobials that are critically important for human health in companion animals is an additional risk factor for emergence and transmission of antimicrobial resistance[117]. This risk is limited by the pre-market assessment.

In addition, the Commission has withdrawn or denied the authorisation of five additives and applicants withdrew applications for which they were unable to provide the necessary proof of absence of antimicrobial resistance development.

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115 https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4666

116 https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.4666

117 Reflection paper on the risk of antimicrobial resistance transfer from companion animals. 15 January 2015 EMA/CVMP/AWP/401740/2013.

Furthermore, although a post-market monitoring for microorganisms used as FA is not required for all microorganisms as such, EFSA examined carefully this aspect as they may have antimicrobial resistance effects. In the 15 renewals carried out from 2019-2021, no safety hazards or issues have been noticed by EFSA in relation to AMR. The effect of the more comprehensive and harmonised post-market monitoring for certain FA[118] to prevent the development of antimicrobial resistance could not yet be assessed. Applicants have to provide information on post-market monitoring in their application for renewal of the authorisation (which has to be submitted at the latest 1 year before the end of the 10-year period of authorisation). At present, the renewal process for the concerned additives is ongoing or has not started yet. For all coccidiostats authorised, a post-market monitoring the PMM is ongoing, but the results are not yet available.

The ban of antibiotics as FA encouraged innovation in FA by developing alternatives, acting, in the majority of cases, on the beneficial interaction between the microbiota (mainly gut bacteria) and host. During the 2004-2021 period, 99 new additives (84 "gut flora stabilisers" and 15 "other zootechnical additives") were authorised for this purpose.

Some important insights have already been gained about how the microbiota might have an influence on a number of disease processes, both within and distant from the gut.

In addition, the ban of antibiotics as FA is accompanied by a general trend in the reduction of antibiotic sales for therapeutic use, as proved by the data from ESVAC (European Surveillance of Veterinary Antimicrobial Consumption). Back in the 2005-2009 surveillance, a certain decrease in the antibiotic sales was evident, although not for all active substances and homogenously in all EU countries. This trend was confirmed in the following years[119]. The FA Regulation has been effective in banning antibiotics as growth promoters, in reducing the risks of placing additives having AMR effects on the market through pre-market assessment and renewals of authorisations, in encouraging innovation reducing the need for antibiotics for therapeutic use. The results of the Public Consultation recognised the suitability of the FA Regulation, for its contribution to reduce AMR has been confirmed.

1.2 SIMPLIFY AND HARMONISE THE FA AUTHORISATION PROCESS

The new measures defined by the FA Regulation were addressed to modify the 1970 FA Directive's procedures which were considered too complicated and not always predictable. Furthermore, the need for simplification, harmonisation, and better predictability of the procedures were addressed to reduce administrative burden. The FA Regulation aimed at setting an EU authorisation procedure and detailed common rules for applications so as to permit a comprehensive assessment of all aspects that may affect safety and efficacy of FA.

[118] To trace and identify any direct, indirect, immediate, delayed, or unforeseen effects applies in particular to all coccidiostats and histomonostats. For the time being, no request for authorisation of histomonostats have been submitted or authorised.

[119] https://www.ema.europa.eu/en/documents/report/trends-sales-veterinary-antimicrobial-agents-nine-european-countries_en.pdf

The FA Regulation introduced a series of provisions to set:

- single and harmonised procedures for the authorisation, renewal and modification of authorisation of FA,
- an EU-level centralised and independent risk assessment performed by EFSA,
- the definition of timelines and steps to be respected in the procedures,
- more comprehensive and detailed rules to prepare application dossiers, including an application form[120],
- a well-structured system to categorise FA according to their properties and the functions that they perform, i.e., safety and efficacy criteria accompanied by a precise definition of categories and functional groups (e.g., nutritional additives as a category that includes different functional groups: vitamins, amino acids or trace elements).

In addition, the FA Regulation introduced a comprehensive set of safety/efficacy criteria which are defined according to clear categories and functional groups. This seeks to provide clarity to applicants on classification and facilitate safety and efficacy assessment by designing specific requirements adapted to each specific functional group or category, when required.

The new provisions have some clear positive effects on the achievement of the objectives:

- extend the assessment to new functional groups (Evaluation Matrix (EM)1.1.1)).
- ensure full assessment for 432 applications (EM 1.1.2) of which, 140 corresponded to silage additives, urea and amino acids.
- ensure that 1,743 additives, which were placed on the market by the former FA Directive, are totally or partially withdrawn as there is not comprehensive safety/efficacy assessment performed (EM 1.1.4 and 1.1.5).

Commission Regulation (EC) No 429/2008 includes detailed rules concerning the preparation and the presentation of applications. EFSA developed guidance documents to further assist applicants in the preparation of dossiers by introducing more detailed information and requirements. Technological and scientific progress triggered the adoption of new or revised EFSA guidance over the time (including new requirements), which however may have

[120] Commission Regulation (EC) No 429/2008.

increased the complexity of the process, and ultimately, could lead to increased delays in preparing dossiers for some applications (see table 1 on EFSA guidance changes and related impact). This is the case in particular of the EFSA Guidance on the assessment of the safety of FA for the environment and the Guidance on the characterisation of microorganisms used as FA or as production organisms, which impacted many applications. However, other EFSA guidance documents were revised in order to reduce the number of required studies or data, resulting in a beneficial impact for applicants.

Table :1 Overview of the changes in EFSA guidance and their consequences:

GUIDANCE	DATE OF ADOPTION OF THE NEW MODIFIED GUIDANCE	MODIFICATIONS INTRODUCED IN RELATION TO THE FORMER GUIDANCE	NUMBER OF FAD APLICATIONS AFFECTED BY GUIDANCE CHANGES
Guidance on the assessment of the safety of FA for the target species	26/09/2017	The modifications done in the guidance were clearly focused on trying to reduce the number of studies generated by the applicant in the target species either by establishing a clear list of exceptions (some of those where already considered in the previous guidance, e.g., QPS micros), including approaches to use already existing data, toxicological data or by broadening the extrapolation rules (with the exception of fish). There is a benefit in terms of reduction of studies for the applicants (overall).	Around 160 applications[121] since implementation of the guidance (around 40% of the total number of applications)
Guidance on the assessment of the safety of FA for the consumer	27/09/2017	No major modifications regarding the dataset needed, some more waivers for data were considered (e.g., enzymes produced by a QPS) Nearly no impact compared to the previous guidance or reduction in the need for studies.	Around 160 applications since implementation of the guidance (around 40% of the total number of EFSA applications)

[121] This refers to applications processed by EFSA ('FAD' applications). These applications do not correspond to the administrative applications (SANTE applications) as for one SANTE application there may be more than one FAD numbers. Each time the Commission asks for an opinion to EFSA for a specific SANTE application, EFSA allocates a new FAD number. The current informatics system does not allow to systematically link EFSA (FAD) applications with SANTE applications.

GUIDANCE	DATE OF ADOPTION OF THE NEW MODIFIED GUIDANCE	MODIFICATIONS INTRODUCED IN RELATION TO THE FORMER GUIDANCE	NUMBER OF FAD APLICATIONS AFFECTED BY GUIDANCE CHANGES
Guidance on the identity, characterisation and conditions of use of FA	27/09/2017	Nearly no impact compared to the previous guidance.	Around 400 applications since the implementation of the guidance (all EFSA applications)
Guidance on the characterisation of microorganisms used as FA or as production organisms	21/02/2018	The major modifications done affected three main aspects, introduction of the WGS based data for the characterisation of bacteria and yeasts (recommended for fungi) and need to use the data to the relevant chapters of the guidance, namely: identification, characterisation of the strain in terms of AMR and toxins and virulence factors, structure of the genetic modification and provision of the raw data, the update on the MIC values for the antimicrobial susceptibility and the modifications related to the testing on the absence of cells and DNA. Increased requirements in the generation of the data which may address relevant aspects of the safety of the products (e.g., AMR).	Around 200-230 applications (60-70% of all dossiers) since the implementation of the guidance
Guidance on the assessment of the efficacy of FA	17/04/2018	Reduce the amount of studies/data by establishing clear rules on the use of already existing data/authorisations (some already taken in previous guidance documents) and broadening the extrapolation rules. There is a benefit in terms of reduction of studies for the applicants (overall).	Around 190 (around 60%) of EFSA applications since the implementation of the guidance
Guidance on the assessment of the safety of FA for the environment	27/02/2019	The tiered approach is considered. The new guidance may have increased the requirements in the generation of the data.	Around 25 (10%) EFSA applications since the implementation of the guidance

The major business organisations raised this issue of updated guidance in the Roadmap consultation and also in the context of re-evaluation of FA (Article 10(2))[122]. Mitigation measures set up by EFSA to reduce the negative effects of those revisions are:

- procedures set up by EFSA to engage FeBOs during the development of guidance documents contributing to facilitate better understanding of new demands and to provide inputs by FeBOs.
- the pre-submission advice mechanism (Article 32a of the GFL) allows EFSA to explain any novelties before an application is submitted (since 27 March 2021).
- access to dedicated support for SMEs from EFSA when preparing, submitting and monitoring their applications.

Timelines set up by the FA Regulation were considered appropriate by a majority of MS authorities (see Annex V), whereas there was a low response rate from other stakeholder groups and their opinions were divided (see Annex V).

A large majority of the respondents agreed on the effectiveness of the new simplification and harmonisation rules, especially due to the centralised procedure (PC, NCA survey), however a loss in the procedural smoothness [123] has been noted.

1.3 ENSURING A RIGOROUS RISK ASSESSMENT

The immediate consequence of developing a rigorous risk assessment is the placing on the market of safe additives.

The new elements improving risk assessment introduced by the FA Regulation are the independent assessment carried out by EFSA, the separation between evaluation and management and the general principles and procedures laid down in the General Food Law. Altogether, the implementation of those elements led to the achievement of specific objectives related to a rigorous FA risk assessment. This is supported by the results of the surveys[124] , not only for food-producing animals, but also for pets. (See PC, SH survey and NCA survey). More specifically, a strong consensus (80% or more) was identified for a rigorous assessment for consumers, animals, workers and environmental safety. As regards efficacy, a majority of users of FA (53 out of 63) consider that FA are efficacious.

The FA Regulation lays down a comprehensive set of safety requirements to fill the gaps of the previous 1970 FA Directive affecting all additives or certain groups of additives:

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[122] FCEC Final report, Judgment criteria: EQ9.2: "A majority of stakeholders consider that the reauthorisation (Article 10 2) process has helped adapt future renewal of authorisations to new requirements".

[123] FCEC Final report, EQ 7, Judgment criteria: "Relevance of the simplification of the feed additive authorisation process in comparison to the previous process under the directive".

[124] vii Consultation Synopsis Report sections, pages 8, 19, 26 and 27.

- amino acids (were partially evaluated by Directive 82/471/EEC[125]) and silage additives were not evaluated before. Both were not under the scope of the former 1970 FA Directive.
- as for enzymes and microorganisms, some gaps were addressed by requesting more data to complete the safety assessment, in particular concerning transfer of resistance to antibiotics, risk to consumers and risk for the environment and workers.
- as for all the vitamins, except vitamin A and D, there were no safety assessment in the former FA Directive. The same applies for many colourants and the majority of flavourings.
- as for coccidiostats and histomonostats, the FA Regulation introduced new criteria to assess the risk of antimicrobial resistance.
- as for FA intended for pets, the FA Regulation introduced the obligation to carry out studies for chronic toxicity, mutagenicity and carcinogenicity. This concerned 1.017 additives.
- comprehensive worker safety requirements for all additives.

The achievement of the objective is supported by several indicators. The most relevant are listed below:

- few RASFF[126] notifications (EM 1.2.7);
- the presence of safe FA on the market has increased: new substances are fully evaluated as FA (EM 1.2.1), this corresponds to 458 applications (EM 1.2.2) and 1,136 additives (EM 1.2.4);
- the presence of efficacious additives has increased on the market: substances are fully evaluated as FA (EM1.1.1), this corresponds to 300 applications of existing additives under the former 1970 FA Directive (EM 1.1.2);
- 1,623 additives are out of the market as they were not assessed for safety and/or efficacy according to the new requirements (EM1.1.4 and 1.1.5);
- eight Regulations were adopted to achieve this aim (EM 1.1.6). In addition, 120 additives were totally or partially withdrawn by applicants. In total 1,743 additives;
- five requests of administrative review of EFSA evaluation were dismissed (EM 1.5.1);
- 1,017 additives intended for pets are now fully evaluated for safety and efficacy (EM.1.2.8).

During the period 2004-2020, the RASFF notifications showed the level of compliance as for the presence of FA or their residues in food of animal origin. 82 notifications – out of 16,634 – were linked to the presence of unauthorised additives or a high level of residues. This represented 0.5% of the total number of notifications. As regards RASFF notifications for the period 2004-2017, out of a total of 517 notifications on feed only seven relate to FA and five to premixtures. These represented 2.3´% of the total number of feed notifications (EM 1.2.7).

[125] Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition. Official Journal L 213, 21/07/1982, p. 8.
[126] ii FA Final Report _FCEC page 31.

Some elements of the safety assessment performed by EFSA are recognised in the authorisation process carried out by some third countries such as Chile, Canada or China. The industry also indicated that EU approvals are generally a major advantage for fast-track registration of EU products imported in many other parts of the world, particularly in the SE Asian and in African regions[127]. The main element in EU authorisation lies on the credibility of the safety and efficacy assessment performed by EFSA, which is recognised not only at EU level but at international level as well.

1.4 SET UP CLEAR /COMPREHENSIVE RULES FOR THE AUTHORISATION AND LABELLING OF FA (OBJECTIVE 4)

1.4.1 Duration of authorisation period

The unlimited authorisation period and other types of authorisations set up in the former 1970 FA Directive has been replaced by a 10-year authorisation that simplified the authorisation process and allows for a timely reassessment of the safety of FAs, as scientific knowledge of their effects and impacts evolves. It was expected that this time limit would also encourage the development of FAs with a better safety and/or efficacy profile. As to the 10-year authorisation being efficient in promoting the placing on the market of innovative additives with a better efficacy profile[128], the majority of MS authorities (17 out of 27) considered to be adequate, although some comments, from those that disagree or did not provide response (don't know), noted that this period could not encourage innovation for SMEs. Stakeholders are divided but business associations and feed additive producers deemed that this period is too short for innovative additives that entailed a high investment. The 10-year authorisation period was perceived as effective for safety purposes by a slight majority of MS authorities (17 out of 27). Six MS authorities did not respond and 4 disagree. Stakeholders (mainly FeBOs) were divided on the adequacy of this period. Some MS authorities, business associations and companies mentioned the possibility to extend the period for additives with a long history of safe use.

To summarise, the 10-year authorisation period was perceived as effective for a slight majority of MS authorities, although for stakeholders (mainly FeBOs) opinions on this issue were divided. In both groups, there are voices claiming for a longer period in the case of additives with a high safety profile. The promotion of innovation is not perceived as effective for the industry, especially in the case of new FA. In addition, for some MS authorities the period reduces innovation for SMEs for which the effort to invest in getting authorisation for novel FA does not compensate the revenues.

1.4.2 Authorisation procedures

As regards effectiveness **of the different authorisation procedures**, the following elements should be considered.

[127] ii FA Final Report _FCEC, page 69.
[128] ii FA Final Report _FCEC pages 122-123.

The different steps in the authorisation procedure were analysed to identify what elements drive or hinder effectiveness. In some cases, there is a segregation of data depending on whether we refer to applications for a new authorisation (Article 4) or for re-evaluation Article 10(2). The consequences on possible delays in the authorisation are different since as regards applications under Article 4, the additive is not yet on the market whereas for those under Article 10(2), the additives are already on the market as they had been authorised by the former 1970 FA Directive. For FeBOs, the impact on effectiveness is much higher if some delays occur for an application under Article 4 as they may lose competitiveness.

1.4.2.1 The authorisation procedure in the context of Article 4 (new authorisation) and Article 10(2) (re-evaluation of existing products)

The main steps in the authorisation process are summarised below[129].

- **Completeness check (30 working days to validate the dossier by EFSA):** 31 working days for nearly half of dossiers submitted under Article 4(1); and one third of dossiers submitted under Article 10(2). For the remaining dossiers, the completeness check is carried out within 41 working days **(EM 1.3.3).** The completeness check is in general effective as no major delays are incurred.

  Completeness check is the time from the date of reception of the mandate from the Commission until the consideration that **the application is valid**. EFSA verifies that all the information has been submitted by the applicant. It is a formal verification (the quality of the information is not verified). If there is missing information, EFSA requests the applicant to provide it. 30 working days is the period established by EFSA for this verification. This is not a legal deadline but an administrative deadline. In practice, the period runs from 31 working days to 41 working days (EM 1.3.3).

  Table 2: Time for completeness check

PERIOD FOR COMPLETENESS CHECK	ARTICLE 4(1) APPLICATIONS	ARTICLE 10(2) APPLICATIONS
31 days	47%	32%
32-35 days	34%	39%
31-35 days	81%	71%

  The time periods are not too impactful and are closed to the 30 working days administrative deadline.

[129] FCEC Final report and SANTE database.

– **Assessment period by EFSA (6 months)**: The average period taken for EFSA to issue its opinion was 438 days for Article 4(1) applications and 830 days for Article 10(2) applications. Only 20% of all opinions issued under Article 4(1) and 12% of all opinions issued under Article 10(2) are in accordance with the six-month deadline. The average time period does not reflect the situation for a large number of applications.

Assessment period is the time since the application is considered valid until the opinion is adopted by the FEEDAP panel. The legal deadline for this period is 6 months, which is extended whenever EFSA seeks supplementary information from the applicant. 78% of applications for **new FA** and 88% of applications for **re-evaluation** of authorised FA suffered delays during this process caused by missing and/or incomplete information presented in the application dossiers. Incomplete dossiers triggered the request for additional information by EFSA[130] (IL1.3.4).

Table 3: Time for adoption of EFSA opinion

EVALUATION PERIOD (EM 1.3)	ARTICLE 4(1) APPLICATIONS	ARTICLE 10(2) APPLICATIONS
6 months	22%	12%
>6-8 months	13%	4%
>8-12 months	19%	9%
>12-18 months	20%	16%
>18 months	27%	59%

Despite these time periods, applicants consider that they have sufficient time to respond to the questions from EFSA (EM1.3.7).

– **Commission decision issued within a reasonable deadline (6 months**). On average, the time taken extends by about additional 189 days (roughly 6 months) for Article 4(1) applications and additional 379 days (roughly 12 months) for Article 10(2) applications. The average period thus is 12 months for Article 4(1) and 18 months for Article 10(2). The average time period does not reflect the situation for a large number of cases: as for Article 4(1) applications, 37% of the decisions are published in the Official Journal of the EU within 180 days since the moment EFSA opinions are issued and 41% within ≥6-10; for Article 10 (2) applications, the 6 months deadline is met in 31% of authorisations and 15% of the cases within ≥6-10. The time periods may be explained by the frequency level of the PAFF Committee meetings, besides, some authorisations are complex and require several discussions at the PAFF Committee and the procedural steps for the publication and adoption by

[130] "Stop the clock" mechanism, referred to in Article 8(2) of the FA Regulation.

the Commission are time consuming[131]. For Article 10(2) applications, the Commission grouped different ones for the same additive to reduce administrative burden and this may explain part of the longer time periods of Article 10(2) applications compared to those under Article 4(1) (EM 1.3.6).

The time periods in the re-evaluation of FA are also explained by the implementation of the provision set out in Article 10(2) by which the Commission sets out a detailed calendar (in consultation with EFSA) listing in order of the priority the different classes of additives to be re-evaluated. This measure was included in the FA Regulation as the deadline to present the applications for re-evaluation of FA authorised without a time limit was 8 November 2010 and it was expected that the majority of the applications would occur around that date. This would not allow EFSA and the Commission to process all the applications in this short period of time. This prioritisation differed the authorisation period for some additives such as colourants or flavourings that were not considered as first priorities.

There is no legal deadline for the time between adoption of the EFSA's opinion and publication in the EFSA Journal, but an administrative deadline of 25 working days has been established.

Table 4: Time publication in the EFSA Journal

PUBLICATION PERIOD	ARTICE 4(1) APPLICATIONS	ARTICLE 10(2) APPLICATIONS
25 working days	90%	87%

Overall, these time periods are not considered limiting the effectiveness of the authorisation process and EFSA complies satisfactorily with the expected deadlines.

In the **risk management process,** there are three steps:

1.- The period since the application is submitted until EFSA's opinion is requested by the Commission. For this period there is no statistical information available, but an estimation was made and in the majority of the cases the letter to request complementary information is sent within one month. Sometimes there are delays if the applicant does not send the complete application or there are formal aspects not respected (e.g., application not signed). There is no legal deadline for this period.

[131] 7-21 days after positive conclusion at the SCoPAFF to process the outcome of the vote, 25-37 days translations and Cabinet agreement, 12-13 days adoption by the College and publication in the Official Journal of the EU.

2.- The period since the Commission receives the opinion from EFSA (normally two or three days before its publication in the EFSA Journal) until it prepares a draft authorisation Regulation, the Commission has in principle a legal deadline of three months, which is respected in more than 95% of cases. The time period beyond the three months may result from the fact that during the Christmas and summer period the SCoPAFF is not convened so frequently.

3.-The period since the draft proposal is discussed for the first time in the SCoPAFF until the authorisation Regulation is published in the Official Journal of the EU. This information is not available, therefore, the reference to calculate the time periods is the period from the publication of the EFSA's opinion in the EFSA Journal until the authorisation Regulation is published in the Official Journal of the EU (see below).

A reasonable time period since the EFSA opinion is published until the authorisation Regulation is published in the Official Journal is six months. For 37% of new applications the 6 months period is respected and for 41% the period is ≥ 6-10 months (see table below). In addition to the discussions at the SCoPAFF, the time required for the procedural steps between voting in the Committee meeting, adoption by the Commission and publication in the Official Journal, is 5 to 7 weeks on average[132].

Table 5: Time for the publication of the authorising Regulation in the Official Journal

PERIOD	ARTICLE 4(1) APPLICATIONS	ARTICLE 10(2) APPLICATIONS
6 months	37%	31%
≥6-10 months	41%	15%

Time periods for the whole process

The time periods in the authorisation procedures are very relevant for the assessment process as the missing and/or incomplete information presented in the dossiers triggered the request of additional information by EFSA ("stop the clock"). A substantial majority of dossiers submitted by applicants (78% of applications for new authorisations under Article 4(1) and 88% of applications for re-authorisation under Article 10(2)) present important missing

[132] 7-21 days after positive conclusion at the SCoPAFF's meeting to process the delivery of the formal opinion of the Committee, 25-37 days for the translations of the draft act and obtaining the Cabinet's agreement, 12-13 days for the adoption by the College and publication in the Official Journal of the EU.

and/or incomplete information during the assessment. This triggered the clock stopping process 1,320 times in the 2004-2017 period, with an average of 1.73 requests for complementary information per finished dossier during this period[133].

The FA Regulation allows an extension of the authorisation period until the adoption of the renewal measure, provided that the application for renewal has been submitted in due time and that the applicant cooperates properly during the process (cfr. EFSA's requests for complementary information).

Missing and/or incomplete information in application dossiers can be explained by the following:

- Applicants are not familiar with the EFSA guidance or with the changes of EFSA guidance. That guidance can provide a strong support in the development of studies but cannot substitute the interpretation of the guidance itself and the appropriate study design made by the applicant. These issues tend to be more common in the case of efficacy studies, due to the complexity involved, especially for innovative FA where the design of studies and end points to consider are challenging.
- Applicants claimed that the lack of pre-submission meetings with EFSA to clarify uncertainties or queries limited their capacity to prevent future shortcomings. In this regard, the 2019 amendment of the General Food law (Regulation (EU) 2019/1381, so-called "the Transparency Regulation") provided for the possibility of pre-submission advice (Article 32a of the General Food Law) on the rules applicable to, and on the content required for, the application, and prior to its submission. This should mitigate the concerns expressed by applicants although it is premature to know the results of that new mechanism.
- Lack of experience in preparation of dossiers for additives that were never evaluated is another reason considered for this issue. It can be the case for the re-evaluation of several colourants or botanical flavourings that were not previously assessed as they were authorised by the former 1970 FA Directive under a generic entry including many substances that were not identified (e.g., other colourants). For example, characterisation of botanical flavourings required a huge effort to applicants as those substances may contain more than 30 components and there was not much data in literature on the composition of those additives. As a consequence, a full analysis needs to be performed by applicants. For colourants, the method of analysis was a big challenge due to its complexity.

Even though the timelines for the different steps were considered reasonable, it was noticed that the authorisation procedure suffered from some delays, especially in the assessment process, but also, to a lesser extent, in the management procedure.

1.4.2.2 Renewal of authorisation (Article 14)

Almost all applications (for the period 2017-2021[134], 64 out of 65) required an extension beyond the one-year deadline provided in the FA Regulation for their authorisation. The average time for the EFSA assessment period was 314 days, which exceeds the normal period of 6 months by 134 days. The

[133] ii FA Final Report _FCEC, page 37.

number of “stop the clock” set up for 65 applications was 91 times, with an average of 1.4 times per application. Only 5 out of 65 applications did not require a “stop the clock” (EM 1.3.8 and 1.3.9).

1.4.2.3 Incentivise applicants regarding minor species and extrapolation to minor species.

The procedure for extrapolation from major to minor species allows to extrapolate the results of data generated for a major species (e.g., chicken) to a minor species (e.g., quail), avoiding duplication of relevant tests. The FA Regulation provides also for incentives to applicants requesting an authorisation for minor species to extend the data protection period by one additional year for each minor species for which a use extension authorisation is granted. The extrapolation however presents limitations since it cannot be considered for species that are physiologically different. The extrapolation is possible, for example, from a chicken for fattening to a guinea fowl for fattening but it is not possible from a chicken to a rabbit. There are minor species that do not have a counterpart as “major species” (snails species, insects species or rabbits). In that case, a complete set of studies is required as regards the minor species considered and the sole incentive is related to the extension of the data protection period.

The extension of the use of additives from major to minor species is an important aspect to give full coverage to additives intended for animals of low economic interest (see glossary). This extension was promoted in the FA Regulation:

- by extending the data sharing protection one additional year for each minor species for which the authorisation is granted
- by setting up the principle of extrapolation to facilitate that extrapolation in the Commission Rules for Applications (Regulation (EC) 429/2008) and EFSA guidance. This extrapolation has limitations as it is only possible for species that are physiologically comparable (e.g., laying hens can be physiological comparable to other laying poultry animals from the following species guinea fowl, geese, quail or pigeons).

The procedure to request extrapolation from major to minor species did not work well[135], according to stakeholders -mainly FeBOs- (SH survey and EM 1.3.11) The reasons are the following:

- the target market is limited and the needs to extend the use of additives to those species are not well understood, there is a lack of involvement of users further down the chain in the process to ensure that minor species of interest are covered by an application.
- it requires investment in data generation and the users does not contribute to the costs.
- the return on investment is not clear, in particular for small markets.

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[134] The period 2017-2021 has been selected as the majority of renewals occurred as from 2017.
[135] ii FA Final Report _FCEC, page 43.

Some MS authorities (NCA survey) share some SH views, although the extrapolation worked well according to 18 MS authorities. Some MS authorities noted that extrapolation is difficult for some pets as they are physiologically different from other species or for those species *that do not have a 'major species' counterpart (so-called 'orphan species', e.g., insects, snails, rabbits). For some species such as rabbits, there is consequently a limited number of specific FA (e.g., zootechnical additives) available.* One NCA indicated that the assessment of efficacy should not be an obstacle to extend the authorisation to minor species, as long as safety is ensured.

The FA Regulation was not successful in promoting the authorisation of additives intended to those minor species, considering that where extrapolation was not possible, applicants were not sufficiently incentivised by the one-year extension of the data protection period, lacking a guarantee of return on investment. The extrapolation as such has not been either successful and there is room for improvement in the Commission Rules for Applications for increasing the possibilities of extrapolation for efficacy. Applications in order to facilitate the extension of applications for certain species or categories of animals to physiologically similar minor species having equivalent age or type of production (fattening, laying etc.).

1.4.2.4 Extrapolation from food to feed

A majority of applicants (23 out of 43) consider that the extrapolation from food to feed does not work well (EM 1.3.10, SH Survey). On the contrary, for MS authorities a small majority consider that it works well (16), whereas eight remain neutral and one is against this statement (NCA Survey). The major exposure of animals to the additive compared to the human exposure does not allow, for safety reasons, to make extrapolation from food to feed in many applications[136]. This is an aspect for which there is no room for manoeuvre. For efficacy studies, the extrapolation works well for flavourings but there is room for improvement for other functional groups, providing that the specifications of the additive and the function that the additive performs in food and feed are the same.

1.4.3 Other provisions that may create some burden and/or may reduce effectiveness in the authorisation and placing on the market of FA

1.4.3.1 Water for drinking

The coherence of the provisions related to the use of additives in drinking water should be assessed on the one hand, the definition of FA refers to this use for all additives but on the other hand this use is restricted to certain functional groups in Article 6 and in Annex I of the FA Regulation, which set the definitions of the categories and functional groups of additives. In the definition of certain functional groups, the function of the additive refers only to its effect on feedingstuffs but not on water, such as acidity regulators which are described as substances which adjust the pH of feedingstuffs, while nothing is mentioned about their effect on drinking water. For 789 flavourings, the applicants withdrew the application for use in water for drinking. The different feeding/drinking systems introduced technical challenges in its implementation. The distinction in the routes of administration for liquid feed (to use

[136] ii FA Final Report _FCEC, page 40

complementary feed) and for water for drinking (to use additives) is not evident in some feeding systems and this may create different interpretations in the MS[137]. During the 2004-2017 period, those questions were raised several times (35), directly or indirectly, at the level of SCoPAFF. Those aspects have been noticed by some MS authorities and by stakeholder –mainly FeBOs- (PC).

1.4.3.2. Data sharing

Data sharing between applicants will reduce tests and costs of applications and will be consistent with the EU policy on animal welfare. The FA Regulation lays down requirements for data sharing to prevent repetition of toxicological tests on vertebrates (Article 20). The applicants must take all the necessary measures to reach an agreement. If such an agreement is not reached, the Commission *may decide* to disclose the information while ensuring a reasonable balance between the interests of the parties concerned. The FA Regulation does not provide the Commission with tools or mechanisms to ensure a reasonable balance between the parties. Consequently, few requests of data sharing occurred (three) and it was not possible to draw any conclusions. In the PC two thirds of respondents were not able to indicate whether or not data sharing rules are effective in reducing costs and animal testing. Those that have a negative view, have three different arguments: data sharing is not fully exploited, there is room for reduction of costs or the market should decide. Nonetheless, some of these respondents argued that data sharing is a useful concept for reducing costs[138].

1.4.3.3 Applicant's withdrawal of application during the renewal process

There is no sufficient information for FeBOs about the renewal process – e.g., if an applicant has withdrawn the application during its assessment. This created a certain level of unpredictability for the feed chain on the availability of FA. The applicant for renewal must introduce the application for renewal at the latest one year before its expiry, FeBOs know if this application has been submitted once EFSA processes the application (Register of questions) or where an indication is introduced in the Register of FA that an application for renewal has been submitted (this could take some time). In addition, if an applicant withdraws the application during the assessment process, the additive must be immediately withdrawn from the market, but FeBOs are not informed in advance, so they do not have time to react. On the occasion of certain SCoPAFF meetings, some MS have also raised this issue.

1.4.3.4 Recommended levels

Levels and maximum recommended levels. Clarity on how to establish recommended levels could be improved. Whilst for some FA levels are established as conditions for authorisation, for others, recommended levels are established within the labelling provisions. The possibility to establish recommended levels should be re-examined, so that those levels are set as conditions for authorisation but not as labelling provisions. Some area for

[137] ii FA Final Report __FCEC, pages 74 and 75.
[138] vii Consultation Synopsis Report, page 28.

improvement should be considered in terms of coherence. For some additives, the recommendation is to use "Maximum Recommended Levels". These are limits for the use of FA providing a certain flexibility as opposed to maximum limits, which are mandatory and should be indicated on the label of the premixtures, compound feed and feed materials. Those maximum recommended levels have been recently set as the labelling provisions for some FA, for example for flavourings. The Feed Marketing Regulation lays down the obligation to indicate the level used on the label of the compound feed/feed material if the respective Maximum Recommended Level has been exceeded. If this level is not exceeded, then the level used is not required to be indicated on the label of the premixture, compound feed or feed material. This is very important for premixtures of flavourings as the disclosure of their composition may harm the competitiveness of the company. The know-how about the composition of those premixtures is very important and it requires a lot of experience and investment. A clarification of this concept would ensure a harmonised implementation across the EU and could reduce some burden for FeBOs and MS authorities that have to ensure enforcement of the legislation. MS authorities signalled the necessity to improve the definitions of processing aids in relation to FA, as well as to establish a harmonised definition for maximum recommended levels or recommended levels.

1.4.3.5. Preparations

The FA Regulation has established the requirements for preparations (see glossary) and labelling provisions. According to MS authorities, a definition is necessary to ensure harmonised implementation that reduces disparities in the implementation of the legislation and to increase clarity in the FA Regulation when those preparations are authorised[139] .

1.4.3.6. Modification of non-holder specific authorisations

Article 13(3) of the FA Regulation only covers the modification process introduced by the holder of an authorisation but does not foresee rules for requests for modifications of a non-holder specific authorisation. In such cases, a full evaluation is not required, but instead only a verification if the modification may rise a safety concern or may undermine the efficacy. This situation has been largely mitigated by using Article 13(1) and (2) of the FA Regulation that permits the Commission to modify any authorisation (including non-holder specific authorisations) on its own initiative, after consultation of EFSA. A clarification of the FA Regulation should be considered as it affects around 1,214 additives that are not linked to an authorisation holder.

1.4.3.7 Additives only intended for export

FA only intended for exports to third countries are subject to the provisions of Article 12 of the General Food Law, which imposes compliance with the relevant requirements of food law, unless otherwise requested by the authorities of the importing country or established by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country. In other circumstances, except if

[139] ii FA Final Report _FCEC, page 107

the products are unsafe, they can be exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the products concerned could not be placed on the market in the EU. The current definition of "placing on the market", determining the scope of application of the FA Regulation (including the authorisation requirement), basically excludes the export to third countries of those products from the producing establishment provided that they have a limited circulation in the EU that does not implies transfer of ownership[140]. The limitations in the circulation may produce a burden for FeBOs as they cannot process/incorporate the additives to premixtures or compound feed using different establishments of the EU that can be more effective or economically advantageous. This may reduce competitiveness and may not be fully coherent with the objective of the FA Regulation for a better functioning of the internal market. This limitation to the circulation in the EU needs to be addressed in the FA legislation in conjunction with the labelling of those products.

The absence of harmonised labelling for those products, indicating that they are only intended for export can be another element of distortion. According to the industry, there are diverse national approaches, which leads to competitive disadvantages amongst companies in the MS[141]. Nineteen MS authorities have taken measures to control those exports.

Control measures are framed within the scope of the Feed Hygiene Regulation and the Official Controls Regulation (registration, notification, random controls etc). The FA Regulation does not regulate the requirements applicable for the control of importers. The fact that the Feed Hygiene Regulation does not establish a list of third countries' establishments or specific requirements to trace and control additives only intended for export, undermines the effectiveness of certain aspects of the FA Regulation. MS did not identify major problems, even though this matter was not specifically harmonised. Nevertheless, several NCAs (Spain, France, Belgium and The Netherlands) requested harmonisation in the context of exchanges within the SCoPAFF with a view to harmonise the requirements for all EU FeBOs and improve communication between competent authorities. Although those control requirements are related to the Feed Hygiene Regulation, this request shows that this issue needs to be better addressed. For FA and premixtures intended for export, 19 MS have taken preventive measures to control that those products do not end up on the EU market. However, the approach varies considerably between MS. One MS stated that additives not authorised or withdrawn in the EU for safety purposes should not be exported to third countries even though they are accepted by those countries. As regards FeBOs, a small majority of respondents (35 out of 65; excluding 19 'do not know' responses) consider the rules applicable to the export of FA to be properly addressed in the FA Regulation, while 20 consider them not (EM 8.4.3).

1.4.3.8 Change of the authorisation holder

[140] The determining criterion to ascertain that there is no intra-EU transfer should be the existence of a sale contract between the EU operator concerned and an operator established in the third country of destination. Other contracts concluded by the EU operator concerned with another EU operator, for instance with a transporter, exclusively for the execution of that sale contract and thus leaving no room for the latter operator to decide to change the destination of the products (i.e., to the EU or to third countries) should not be regarded as implying a transfer. The notion of transfer does not refer to the physical movement of goods, but to the transfer of ownership of goods to another person within the EU.

[141] ii FA Final Report _FCEC, pages 66-67.

The current system requires the adoption of an implementing Regulation (including a request to EFSA for an opinion) for any change of the authorisation holder of an additive (mergers or acquisitions). Therefore, some internal administrative arrangements between EFSA and the Commission have been set up as the Commission only informs EFSA of this administrative change without the need to issue a new EFSA opinion as it is not related to a safety assessment. The change of the authorisation holder represents 10% of the Regulations adopted in relation to holder-specific authorisations. However, the obligation to adopt an implementing Regulation remains. It entails a certain burden for the Commission, EFSA and MS. In the NCA Survey, 11 MS authorities agree that this simplified approach is necessary although 12 did not express an opinion and three did not agree.

1.4.3.9 Requirements for environment applicable to farmed non-food producing animals

This aspect was raised after the evaluation study during the discussion for the revision of Commission Rules for Applications. It refers to non-food producing animals, such as fur animals. Although there are not applications specifically addressed to those animals and the authorisation for all animal species including those animals have been carried out with an environmental risk assessment, the FA Regulation would need to be modified to clearly state that those animals are covered by the environmental risk assessment.

1.4.3.10 The Register of FA

Although the register has been an excellent tool for FeBOs to be aware of all additives authorised and their conditions of authorisation, the Register of FA is not considered sufficiently "user-friendly". A majority of respondents to the PC consider that this is an efficient tool, but it needs to be improved to become more informative and user friendly. For instance, the current pdf format does not allow to search information in a straightforward manner (e.g., the EFSA opinion).

1.5 ADEQUATE, CLEAR AND COMPREHENSIVE LABELLING RULES, INCLUDING ADEQUATE RULES FOR SAFE HANDLING OF FA

In relation to labelling, there are several aspects to consider:

- Whether the labelling rules have been effective to protect human health, animal health and the environment along the food chain.
- Whether there are aspects not addressed or not sufficiently addressed that may reduce the effectiveness

1.5.1 Labelling provisions

There is a consensus that labelling prevents the misuse of FA along the food chain (doses and the proper use in the species concerned are respected).[142] The results of the controls performed by the MS authorities do not rise major concerns in this regard. From the surveys and the case studies emerged the necessity to modernise the labelling provisions by conveying the information through other means (currently it is only possible through the physical label) such as electronic means, QR Code trademark, separate documents, etc. This demand is to a certain extent in line with the labelling provisions applicable to compound feed and feed materials. This issue has been raised by a majority of stakeholders but also by some MS authorities (see SH survey, NCA Survey).

1.5.2 The Classification, Labelling and Packaging (CLP) Regulation

The CLP Regulation harmonises the criteria for classification and the rules for labelling and packaging of chemical hazardous substances and mixtures. The combination of CLP labelling requirements and specific requirements set out in the authorising Regulation, created different understandings amongst MS authorities. The authorisation of FA does not usually introduce labelling provisions for workers' safety but generally provide for workers' safety requirements to be respected, as conditions of use of the authorised additives. However, some MS authorities require the introduction of those safety requirements on the label. In addition, these labelling indications are not harmonised in the different MS. Furthermore, it is being considered that the CLP Regulation applies also to FA and premixtures, thereby introducing additional labelling requirements for workers' safety. This introduces complexity on the labels, in particular for premixtures. Although the surveys did not reveal a high rate of positive response on whether the CLP Regulation is coherent with the FA Regulation, the case studies[143] provided a clearer picture on the effects of the simultaneous application of both Regulations, especially in premixtures. On the one hand, MS have different understandings on how worker safety provisions can be indicated on the label to ensure respect for both Regulations; on the other hand, labelling requirements for user safety might be redundant or even conflicting in both Regulations. This could be aggravated in premixtures, where different additives are incorporated. As regards workers' safety provisions, the simultaneous implementation of the CLP Regulation and of the FA Regulation has been reported as one aspect that may undermine workers' safety (in case of contradictory directions of use), although no clear evidence has been provided (for more information see PC).

1.5.3 Other aspects related to labelling rules

Another aspect that reduced the effectiveness of the FA Regulation is the absence of labelling tolerances for FA in premixtures. This situation creates a certain burden for FeBOs (change of labels to accommodate to MS requirements) when the additives circulated within the EU, since tolerances may be

[142] vii Consultation Synopsis Report, page 29
ii FA Final Report _FCEC, page 104

[143] vi Case studies, pages 20,21 and 23

different from one MS to other. Nevertheless, this issue was not raised in the study which emerged from the discussions at the SCoPAFF and from some events organised by stakeholders.

Finally, as indicated above, the absence of a harmonised labelling for FA and premixtures only intended for export is another concern that does not bring lightness to the system.

1.6 IMPROVE FA CONTROL, TRACEABILITY AND ENFORCEMENT RULES (OBJECTIVE 5)

The FA Regulation seeks to improve control and traceability by establishing validated methods of analysis to be used for official controls, by linking certain additives to an authorisation holder and extending the scope of the PMM.

1.6.1. Method of analysis

One of the points raised during the evaluation was the necessity of updating the method of analysis in the renewal. Updating the method of analysis for the renewal is considered necessary for 22 MS authorities – while only one of them disagrees. A majority of respondents do not consider the update of the method of analysis for the authorisation renewal to be necessary (51 out of 101); whereas it is considered necessary by 26 respondents. Some FeBOs pointed that the Official Controls Regulation allows MS authorities to use more updated methods which are validated at international or EU level, where necessary. On the other hand, the role of the EURL is adequately defined in the FA Regulation according to the majority of respondents.

More information is included in the FCEC Final study[144]. The available evidence indicates that the EURL for FA can effectively carry out its tasks, supported by the network of NRLs, despite its complexity and challenges. A clear majority of both MS authorities and business stakeholders perceive that the role of the EURL is properly addressed in the FA Regulation.

1.6.2 Post-Market Monitoring

Another element introduced in the FA Regulation is the possibility that EFSA decides, upon assessment, the establishment of a post-market monitoring (PMM) to ensure surveillance. However, it cannot be fully evaluated since the results of the PMM are submitted by the applicant to EFSA, when the renewal takes place. Currently, there is no data to assess if the PMM has been useful to identify any unforeseen effect or to confirm that the initial authorisation was adequate to protect health. There is only one additive (lantharenol) for which the PMM has been evaluated by EFSA. After examination of the PMM and additional evidence provided by the applicant, EFSA concluded that this additive was safe.

[144]ii FA Final Report _FCEC pages 48 and 49.

1.6.3 Traceability

No significant criticism was raised by stakeholders on the relevance of traceability provisions. Some manufacturers and business associations observed that other Regulations (especially the Feed Hygiene Regulation and the General Food Law) play an important role in ensuring FA traceability. Some FeBOs also stated that traceability is fully ensured by the systems and codes of practices already in place. In the feedback to the evaluation roadmap, one NCA also considered that traceability requirements should be laid down in the FA Regulation rather than in the General Food Law.

MS authorities however consider that traceability is not fully accomplished[145] when it comes to additives/premixtures for imports and additives/premixtures only intended for export. There are several reasons which account for it:

a) the absence of a clear identification of imported products.
b) the difficulties for MS to control establishments in third countries.
c) the absence of harmonisation of control requirements for the third country establishment's representatives in the EU.
d) the absence of harmonised labelling to identify additives only intended for export.

The absence of specific provisions in the Feed Hygiene Regulation aggravates this situation for both imports and exports.

1.6.4 Enforcement

Enforcement of the FA legislation is mainly ensured through controls and sanctions imposed in case of infringements. The data on controls performed in 16 MS indicated an average frequency of one control of FA and premixtures per year/per establishment. The available data also showed the high compliance of samples and analysis. All MS have put in place sanctions applicable to infringements that went from a financial penalty to the withdrawal of approval or registration of the establishment. This suggests that the controls worked well in general although, due to the different administrations/procedures involved, the data collected could not provide a complete picture of the situation. Information on controls is provided in the context of the Official Controls Regulation, which does not make always segregation for FA and premixtures in relation to other feeds.

The limited number of RASFF notifications may indicate that the enforcement is effective in general except for imports (no import code) and for feed additive only intended for export (no labelling indication / no harmonised rules for tracing and control). It should be noted that despite the concerns expressed by the MS authorities for control of imports, there were only few RASFF notifications. In the period 2004-2017 only 7 notifications were reported for imports of FA and premixtures from third countries.[146]. For FA and premixtures intended for export, 19 MS have taken preventive measures

[145] ii FA Final Report _FCEC, pages 98-99 and 102
[146] ii FA Final Report _FCEC, pages44-46.

to control that those products do not end up on the EU market, however, the approach varies considerably between MS. The FA Regulation does not regulate the requirements applicable for the control of importers. The fact that the feed Hygiene Regulation does not establish a list of third countries' establishments or specific requirements to trace and control additives only intended for export, undermines the effectiveness of certain aspects of the FA Regulation.

1.7 ADDRESS SPECIFIC INTERESTS FOR PET OWNERS AND THEIR ANIMALS

The FA Regulation introduced a comprehensive set of requirements compared to the previous Directive. Taking into account that pets have a long lifespan, the evaluation takes new aspects into consideration, in comparison to the previous Directive, the assessment of chronic toxicity, mutagenicity and carcinogenicity effects so as to prevent any negative impact on pets' health. The efficacy/safety assessment were also improved by introducing statistical power limits to reduce the possibility of having erroneous results in experiments. EFSA adopted a specific guidance for pet animals to address their specificities in the assessment. These comprehensive set of rules affect 1,017 FA, which were not evaluated or were insufficiently evaluated under the previous 1970 FA Directive (EM 1.2.8, 1.2.9, 1.2.10).[147] In addition, labelling requirements ensure that these additives are used in accordance with the conditions of authorisation (e.g., maximum doses) along the feed chain. Safety of owners is also considered in the Regulation insofar as FA cannot be given directly to the animals by pet owners, they should always be incorporated in a compound feed or in a feed material by a professional operator.

For a majority of respondents across all stakeholder groups, the Regulation provides benefits for pets and pet owners (SH survey); however, it is noted that animal welfare organisations did not contribute to the survey, despite the efforts to involve them. One citizen expressed the view that there is an increasing consumer demand for cosmetic appearance of pet food that needs to be considered. This issue may be related, for example, to the use of colourants so as to meet the requirements of pet owners (many compounds feed is grey colour, and this is not accepted by pet owners). Nearly all respondents agree that FA are efficacious and safe for pet animals (74 and 76, respectively, out of 78 respondents); excluding 28 and 30 respondents, respectively, who did not provide an answer as pet food is not relevant for their organisation).

1.8 INNOVATION

As regards the capacity of the FA Regulation to address scientific and technical developments for pets, a majority of respondents (45 out of 107) across all stakeholder groups consider the authorisation procedure not to be suitable to address scientific and technical developments for pets and livestock production, due to the time periods incurred during the authorisation (suitability of the Regulation). This contrasts with a majority of MS authorities that consider that the FA Regulation is suitable to address those technical developments in general (livestock and pets)[148] This is not an issue that can be

[147] ii FA Final Report _FCEC, page 32.
[148] ii FA Final Report _FCEC, page 47.

attributed to pet additives but to the authorisation process in general and does not change the fact that specific interests of pet owners and their animals have been considered in the Regulation.

This objective is driven by different provisions that were intended to encourage innovation and the placing on the market of safe and efficacious FA.

1.8.1 R&D

Innovation may occur in all additives, for example by looking at new forms of additives that are better digested by animals (trace elements are linked to an organic molecule, such as an amino acid), at preparations of FA that protect against thermal of physical treatments, increase storage capabilities, improve safety handling (reducing dusting potential) or by facilitating specific uses (spray drying, pelleting or liquid forms). Nevertheless, the most important innovations are those that entails the discovery of new compounds with innovative action/effect mechanisms that may trigger, in some cases, the necessity to create a new functional group and to establish new end points to measure those actions or effects. The number of patents applications for FA submitted to the European Patent Office doubled compared to the previous period: 207 applications were received between 2004 and 2019 compared to 104 applications between 1979 and 2003. The share of EU applicants *versus* non-EU applicants remained almost the same for the two periods (44% EU applicants and 56 non-EU applicants). This suggests that innovation occurred and that it had some positive effect for both EU and non-EU applicants.

Despite the extensive consultation undertaken for the FCEC study, there is no indication (quantitative or qualitative) of the R&D trend by EU-based companies active in the FA sector. It is therefore not possible to establish with certainty whether R&D investment to develop new FA has increased or decreased since the Regulation came into force. It was also noticed by some respondents from the industry that costs are reduced by investing in non-EU research facilities or sub-contracting R&D[149] activities (including trials) to facilities based in non-EU countries. More information is available in the FCEC Final study.

1.8.2 Functional groups and categories

The largest number of innovations during the period 2004-17 are in the zootechnical additives category and functional group ‘other zootechnical additives’ as well as in the new 4 functional groups created after the adoption of the FA Regulation, which are:

- 1(m) substances for reduction of the contamination of feed by mycotoxins (Commission Regulation (EC) No 386/2009).
- 1(n) hygiene condition enhancers (Commission Regulation (EU) 2015/2294) ;
- 1(o) other technological additives (Commission Regulation (EU) 2019/962).

[149] ii FA Final Report _FCEC, page 68

– 4 (e) physiological condition stabilisers (Commission Regulation (EU) 2019/962).

In May 2021 there were 9 additives authorised for those groups. There were 18 applications for the period 2004-2017. For the last adopted functional groups the applications are very few. In particular, as for the physiological condition stabilisers EFSA is in discussion with the FA sector to examine what are the most adequate end points that should be considered in the assessment of the efficacy. The adoption of new functional groups entails further research for EFSA and FeBOs in order to establish clear requirements that allow to performing studies intended to demonstrate that the additive is efficacious for a specific function.

As for the functional group "other zootechnical additives" there were 61 applications during the period 2004-2017 and there were 34 additives authorised in May 2021.

The data suggests that the FA Regulation has enabled innovation compared to the previous 1970 FA Directive in new emerging segments of FA, and in general, in the design of new forms of additives that improve their efficiency and are more adapted to the changing conditions of the market. Nevertheless, some aspects of the Regulation did not achieve the expected results in terms of innovation.

1.8.3 Classification system for FA

The classification system of FA and provision to be taken into account to favour technological progress:

FA used to affect favourably animal welfare or the environment may only be allocated within the category 'zootechnical additives'. The FA Regulation does not allow the creation of other categories of additives for which the authorisation is issued to a specific holder[150]. The applicant is requested by EFSA guidance to demonstrate a zootechnical effect of the additive (e.g., improvement of performance- increase egg/meat production). However, the actions performed by these additives are not related to an increase of performance in animals, but to a specific improvement in the well-being of animals (e.g., reduction of stress) or positive effects on the environment. This discrepancy discourages applicants from applying for those kinds of additives.

[150] Regulation (EU) 2019/1243 of the European Parliament and of the Council of 20 June 2019 adapting a number of legal acts providing for the use of the regulatory procedure with scrutiny to Articles 290 and 291 of the Treaty on the Functioning of the European Union, (OJ L 198, 25.7.2019, p. 241) permitted to adopt delegated acts to amending Annex I, to adapt the categories and functional groups as a result of technological progress or scientific development. A new category not linked to an authorisation holder can may therefore be created. Indeed, the provision to determine the categories of additives that are linked to an authorisation holder is placed in Article 3(3) of Regulation (EC) No 1831/20039(6). Any modification of this provision would require the modification of the Regulation. Consequently, although new categories were possible, they could not be linked to a holder authorisation.

Article 6(1) of the FA Regulation, refers, in the definition of "zootechnical additives", to their use to affect favourably the performance of animals in good health or to affect favourably the environment. Article 5(3) of the same Regulation, listing the possible effects of FA, provides in particular that they may affect favourably the environmental consequences of animal production (Article 5(3)(e)) or that they may affect favourably animal welfare (Article 5(3)(f)). In addition, Commission Regulation (EC) No 429/2008 recognises those favourably affecting animal welfare under the category of zootechnical additives. Despite the fact that the legislation does not link the zootechnical effect exclusively to the improvement of animal performance, but also to other effects (on the environment or on animal welfare), there might be some room for interpretation as EFSA requires the demonstration of animal performance even where the additive is intended to affect favourably the environment or animal welfare.

This situation is relevant also to the innovation aspect[151]. In comparison with the previous Directive, specific measures were introduced to meet the new needs of modern animal production. This was achieved through the introduction of elements that affect favourably both the environmental consequences of animal production and animal welfare (Article 5). In addition, the possibility to update the additive categories when necessary was foreseen (Article 6), based on technological or scientific development. The absence of FA authorisations for environmental and animal welfare effects shows that the objective was not fully achieved due to certain provisions in the FA Regulation open to some clarifications and possibly leading to misinterpretation, insufficient guidance and insufficient mechanisms for communication applicant-assessor in the assessment of efficacy, especially for innovative FA. This aspect of innovation emerged in the consultations and case studies. Innovation is not perceived for stakeholders (mainly FeBOs) as sufficiently achieved while the survey showed no definite answer for many MS authorities and only 12 agree that the Regulation promoted innovation. The Regulation is not considered sufficiently flexible by an important share (38%) of the PC respondents[152], especially among business associations (41%) and companies/business organisations (52%).According to disagreeing respondents, science and technology evolves at a much faster pace than regulatory developments, with the industry research and development efforts focusing on innovative new products to meet current challenges (e.g. alternatives to use of antibiotics, more sustainable food production, reducing the impact of farming practices on the environment, improving animal welfare, etc.). The current framework lacks the flexibility to adapt to scientific and technological advancements.

1.8.4 The use of additives in water for drinking.

One of the most important innovations introduced in the FA Regulation was the possibility to use additives in water for drinking. The innovation in the use of additives in water for drinking has occurred mainly in nutritional additives such as amino acids and vitamins, increasing their efficiency and contributing to improving animal welfare, as the distribution of certain additives via water can be more efficient. In general, innovation in water for drinking could have been affected due to the fact that many additives may not be used in water for drinking and the technical aspects related to their implementation created divergent views amongst MS authorities.

[151] vii Consultation Synopsis Report, pages 14,15,22 and 23
[152] vii Consultation Synopsis Report, pages 30-31

1.8.5 Renewal of authorisation

The renewal was intended to allow technological progress and scientific development. Applicants should consider whether the investment for a renewal is worthwhile or not in case that more efficient or safer additives are already placed on the market. According to the data of renewal of applications provided by EFSA (end of 2021), at least 12 applications for renewal out of 65, were introduced in combination in accordance Article 4 (new authorisation) or with Article 13 (modification). This means that the additive application may extend the initial authorisation to further species/animal categories, that there is a more efficient/safer method of production of the additive to be evaluated, that the composition of the additive may change to become more efficient or safer etc. It should be highlighted that 10 of those applications corresponded to zootechnical additives. Nevertheless, due to the low number of renewals, it is not possible to draw a clear conclusion from the existing data. For a majority of MS authorities, the renewal is adequate to promote innovation (17 in favour). For stakeholders (mainly FeBOs) the opinions are divided: is considered adequate by 29 and not adequate by 27 out of 99 respondents (43 neither agree not disagree).[153]. It is not possible to establish a link between innovation and the renewal process.

1.8.6 Market exclusivity for innovative FA.

This refers to those additives linked to an authorisation holder (see glossary and EM) The number of authorisations granted for FA linked to an authorisation holder showed that this measure was effective in promoting innovation. The concerns associated to low supply of vitamins on the EU market raised the question whether it is necessary to extend this exclusivity to other categories or functional groups to incentivise applicants to apply for those authorisations. Under the existing regime for non-holder specific authorisations, the costs of obtaining an authorisation are borne by one applicant while others may benefit from the "generic" authorisation, provided that their products comply with the authorisation's specifications. This issue was raised in the case studies in the context of the renewal: FeBOs have to assume the burden of renewal for the benefit of the wider industry. For a majority of respondents (59%), non-holder-specific authorisations for nutritional additives, technological additives and sensory additives should not be replaced by authorisations linked to a specific holder; whereas, for 23% of respondents, they should (8% don't know). Non-holder specific authorisations are particularly important for SMEs, as this allows them to place their products on the EU market, while making important savings in terms of the investment for preparing the required research and studies in view of applications for authorisation[154]. Although the possible extension of market exclusivity to other additives may have positive influence on innovation and may improve the availability of certain additives, this issue needs to be carefully considered as it may affect the activity of SMEs.

1.9 ENSURE THAT FEED ADITIVES CANNOT MISLEAD CONSUMERS ON THE QUALITY OF FOOD

[153] vii Consultation Synopsis Report, pages 11and 21.
[154] ii FA Final Report _FCEC, page 87

The FAs are addressed to all animals, but certainly, the impact is mainly on food-producing animals. Article 5 of the Regulation established the conditions to be met to get the authorisation. In addition to being safe and efficacious, they must not mislead the consumer by impairing the distinctive features of animal products. The implementation of the rules led to the development of specific criteria to address all possible consumer's concerns.[155]. Stakeholders and MS authorities widely recognised the ability of the FA Regulation to ensure safety for consumers (EM 1.2.6). This is also supported by RASFF notifications. During the period 2004-2020, the RASFF notifications showed the level of compliance as for the presence of FA or their residues in food of animal origin. 82 notifications – out of 16,634 – were linked to the presence of unauthorised additives or a high level of residues. These represented 0.5% of the total number of notifications (EM 1.2.7).

In addition, the feed additive assessment must consider whether an additive could give the food a misleading feature regarding its expected properties – e.g., a flavouring that gives the meat a flavour that is not characteristic of that meat. This aspect has been raised by EFSA in very few cases with a positive conclusion in favour of the authorisation.

Feed business FeBOs have indicated that consumers are not aware of the role of FA in modifying the organoleptic characteristics of food from animal origin. This aspect has not been sufficiently analysed, as the consumers' participation in different surveys and interviews was too low. No consumer organisation participated in the consultations, despite the efforts developed by the study team.

As regards those labelling provisions that may have impact on the safety or quality of food (e.g., the indication on the label of the level authorised for a colourant giving colour to poultry meat), the Regulation has been effective in the implementation of labelling provisions. This is supported by the high rate of conformity reported by the MS authorities during the controls.

2.-.EFFICIENCY

2.1. COST-BENEFITS ANALYSIS FOR FEED BUSINESS FEBOS

FeBOs need to fulfil two main legal obligations stemming from the FA Regulation that have significant impacts on the costs for the industry:

- Authorisation process
- Labelling of FA and premixtures of additives (Article).

[155] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of FA (OJ L 133, 22.5.2008, p. 1–65) and Guidance for establishing the safety of additives for the consumer (EFSA Journal 2012;10(1):2537)

The analysis has been extended to the implications for compound feed and pet food (compound feed intended for pets). The information on the additives that need to be included in the labelling of compound feed may also impact on the production of the compound feed. For example, if we change the maximum dose of an additive, this triggers changes in the labelling of compound feed.

The section on the authorisation process includes the costs for a new authorisation (Article 4) and costs for re-evaluation of those additives authorised by the former 1970 FA Directive (Article 10(2)).

2.1.1 Costs for the authorisation process:

The **major obligations** generating costs were identified as follows:

a) Payment of fees is a fixed cost: €6,000 paid to the EURL, plus the cost of sample (which has been indicated by the industry as relatively 'minor').

b) The submission of an application is an administrative obligation which can be quantified on the basis of staff time, staff category and unit costs.

c) The extent of costs for dossier preparation and completion is driven by (i) the number of tests / studies requested, and (ii) the complexity of tests / studies required. In order to quantify this, efforts were made to determine the average unit cost of studies and identify the average number of requested studies. This included the additional costs created by requests for supplementary data.

The costs for businesses to prepare an application for new authorisation or re-evaluation depend on the type of additive, on whether the additive supports an important innovation and on the type of species covered by the application.

- type of additive: new additives, such as those on the category "zootechnical additives", for which new substances or new uses are requested, entail a number of high-cost efficacy and safety studies as there is no previous experience or scientific publications to support the request. Coccidiostats is another category that requires very demanding safety and efficacy studies. For other additives, such as vitamins, the costs tend to be much lower as there is extensive safety/ efficacy data and the innovations introduced are less sophisticated.
- species and categories covered by the application: For example, for ruminants the costs of efficacy studies are much higher than for poultry or fish.

The costs involved vary considerably between FeBOs. To some extent, this reflects the type of feed additive in which the operator specialises.[156] .

[156] ii FA Final Report _FCEC, pages 74 and 75

The costs examined are the costs for different studies (safety and efficacy studies), internal staff time costs, costs of consultants and other costs such as EURL fee for the validation of the method of analysis, identity and characterisation of the additive (e.g., analysis to determine chemical composition and impurities).

Table 6: Number of tests and range of costs necessary to perform the study (FCEC elaboration, based on stakeholder survey and case studies) [157]

TYPE OF STUDIES	NUMBER OF SAFETY STUDIES	COSTS RANGE FOR ALL SAFETY STUDIES (€)
IN VITRO	1-8	≤10,000 - 50,000
LABORATORY ANIMALS	1-7	≤10,000 - 400.000
RUMINANTS	1-6	18,000 – 200,000
PIGS/POULTRY/FISH	1-6	≤ 10,000 - 400,000
OTHER SPECIES	1-6	≤ 30,000 - 150,000
TYPE OF STUDIES	**NUMBER OF EFFICACY STUDIES**	**COSTS RANGE FOR ALL EFFICACY STUDIES (€)**
RUMINANTS	1-12	50,000 – 200,000
PIGS/POULTRY/FISH	1-18	20,000 – 120,000
OTHER SPECIES	1-6	20,000 - 150,000

The average costs estimated for an applicant to obtain an authorisation is €1.1 million across all applicants that provided complete data to the survey (n=31) and all types of FA for which an authorisation dossier was submitted in 2016-18. This cost includes the initial application and the administrative cost of replying to supplementary EFSA questions during the authorisation procedure. The costs per year for an average of 57 applications is €62,700,000.

The major component of the authorisation costs (i.e., direct costs) is safety and efficacy studies (37% and 32%, respectively), followed by internal staff costs (22%). No significant differences in average costs for SMEs vs large companies were identified. Costs vary over a very wide range of values: €50,000 for some additives with a substantial history of consumption for feed use, €373,000 for additives requested by a consortium of companies under Article 10(2), €2.6 million for a zootechnical additive and €3.4 million per application for coccidiostats. [158]

[157] vi Case studies
[158] vi Case studies pages 3-15.

The costs for SMEs are the same as those for large companies. The high expenses derived from an authorisation have impact on SMEs applications (SMEs not part of a larger entity) that tends to focus on fewer animal species in the case of innovative additives (linked to an authorisation holder) or for *generic* additives (see glossary), for which scientific literature is available. In this case, new trials on target animals (see glossary) or laboratory animals are not required, as scientific literature may provide the necessary information.

Applicants raised that the cost increase is mainly due to the EFSA request of complementary information ('stop the clock') and the delays in the SCoPAFF. [159]

The time periods in the authorisation process (management procedure) only have business impact on new applications, as the applicant cannot place the additive on the market. 37% of applications are processed within the expected deadlines. Those periods may reduce the efficiency of the process. Although some longer time periods affect few applications, it has a big impact on the calculation of the average period for the adoption of the authorising Regulations. The discussions in SCoPAFF meetings, normally convened every two months, are one of the reasons for some longer periods.

The use of non-animal tests (e.g., *in vitro* tests using human/animal cells and tissues or computer-modelling techniques) has been identified as a factor that may reduce costs in the applications, especially for the demonstration of efficacy. This was pointed in the case studies by one NCA and some applicants.[160]

Extrapolation from major to minor species[161]: This may contribute to reduce costs for authorisation and address the shortage of additives for those species. The 1-year extension of data protection for each minor species has not been successful in promoting the authorisation of FA for minor species.

Extrapolation from food additives to feed for additives performing the same functions in food and feed is one of the aspects that can reduce costs. The major exposure of animals to the additive compared to the human exposure does not allow, for safety reasons, to make this extrapolation in many applications. For efficacy studies, the extrapolation works well for flavourings but[162] there is room for improvement for other functional groups[163].

FA are authorised for a 10-year period. One year before the expiration of the authorisation, the applicant has to apply for a renewal (Article 14)

[159] ii FA Final Report _FCEC, page 75
[160] ii FA Final Report _FCEC, page 60
[161] See definition in glossary.
[162] ii FA Final Report _FCEC, page 40
[163] ii FA Final Report _FCEC, page 40-41

The average cost for the renewal of an authorisation is €216,000, which represents 20% of the authorisation costs. The bulk of this is spent on safety studies followed by internal staff costs (9%).

The duration of the authorisation is considered too short for some additives having a safety record of use. The renewal of an authorisation entails costs for the Commission, EFSA and for applicants. There is potential for reduction of costs if the duration of authorisation is extended for certain additives so that the costs for renewal are spread evenly over a larger number of years.

It is possible to conclude that the process for authorisation of FA has been efficient. The following evidence confirms this statement.

- The highest number of applications during the period 2004-2017 correspond to zootechnical additives (34% of all applications[164]), the most expensive applications, with an upward trend since 2015.
- The large number of additives authorised in the 2004-2017 period with an upward trend over that period.
- The RASFF notifications for FA are low, 12 notifications on 2004-2017 and no significant feed safety crisis having negative effects on stakeholders along the food chain has been reported.
- The recognition of some elements of the EU authorisation procedure by some non-EU countries. This is identified as an important strength for the competitiveness of EU products in world markets (see EQ2.3 of FCEC final report).
- Although there are no statistical data on the increasing value of the feed additive market, the EU position is relevant (approximately 35% of the world FA market value).
- The return of investment for the most expensive dossiers (zootechnical additives) is high[165].
- The benefits for FeBOs are spread along the food chain. In general, FeBOs consider than the FA Regulation have positive benefits for feed additive producers (including applicants) and for compound feed producers (82% and 80% of respondents see benefits for FA producers and compound feed producers, respectively).

Nevertheless, some issues that reduce the efficiency of the process and subsequently increase the costs of the applications, have been identified:
- extrapolation for major to minor species was not sufficiently exploited.
- applications for minor species were not sufficiently incentivised.
- extrapolation from food to feed, especially for the demonstration of efficacy, could be implemented more widely.
- data-sharing rules to reduce tests on vertebrates were not implemented.

[164] Considering administrative applications (SANTE applications).
[165] ii FA Final Report _FCEC, page 88.

- Some extra-time in the assessment of some additives due to a lack of understanding by applicants of the guidance or not sufficient information in the guidance to establish endpoints for certain new actions. This applies especially for demonstration of efficacy in innovative additives.
- some extra-time in the adoption of authorisation Regulations by the Commission.
- insufficient development and use of non-animal models as an alternative for tests using animals.
- the duration of authorisation period increases the costs as the costs for renewal must be borne after 9 years of the authorisation.

For SMEs the high costs of some applications are a significant barrier, so they tend to focus on holder–specific additives for specific categories of animals rather than for all species. Generic (non-holder specific) authorisations are also important for SMEs as their additives can be placed in the EU market without bearing the costs of applications[166].

2.1.2 Labelling costs

The costs considered are the administrative costs that are triggered by the changes in the authorisation of a feed additive, which requires modification of labels. The specific information on this issue was provided through the case studies[167].

For FA and premixtures, the information needs to be included in a label attached to the product. This fact reduces flexibility and increases the labelling costs *vis-à -vis* other types of feeds (for compound feed and feed materials, relevant provisions allow for some flexibility in certain cases).

The factors that affect labelling costs are the number of additives contained in the premixture and the linguistic regime. Labels for FA have to be translated into all EU languages while premixtures have a more limited distribution and they are translated into 3-4 languages. A majority of consulted FeBOs (22 out of 30 respondents to the survey and all FeBOs interviewed) find that changes in the authorisation of FA mainly refer to the species covered or to the conditions of use. Other reasons, not related to regulatory changes, are requests by MS authorities and market-driven factors.

The costs of labels for FA are negligible. For premixtures, the estimated average costs for manufacturers of premixtures range from €80,000 to approximately €223,000 per plant, per year; this is an overestimation as it is not possible to separate costs triggered by regulatory changes from other reasons. The increasing use of automation labelling systems reduce those costs, which may explain the differences between different plants. These costs include costs of labels, translation services, design and printing of labels and reformulation when required.

[166] ii FA Final Report _FCEC, page 88
[167] vi Case studies, pages 17-23

Indirect costs are the **compliance costs due regulatory changes.** Those regulatory changes are normally: changes in the level of use of the additive, change in the identification number of the additive (for additives re–evaluated a new number is assigned under the new classification system), the specification of the substance may change (e.g., purity). Normally those changes must be introduced after a transitional period that is always granted if there are no safety reasons that justify the contrary. This transitional period (6 months for additives and premixtures, 12 months for compound feed/feed materials intended for food-producing animals and 24 months for compound feed/feed materials intended for non-food producing animals) suffices to ensure a smooth transition for FA already on the market (Article 10(2) of the FA Regulation),[168] as it significantly reduces the need to change the labels. Those measures are considered adequate for FA. Only for premixtures, few FeBOs have indicated that the period is too short as they need 3-4 months for stock clearance. For compound feed, including pet food, the case studies have not identified significant problems with the usual transitional period of 12 months for food-producing animals and 24 months for non-food producing animals. Costs are around €2,000 for the disposal of labels for premixtures applying the usual transitional period. The compliance costs can be estimated between €24,000 and €40,000 per product and €13,500 in labels for premixtures when the change affects an important additive widely used and the transitional period is shorter than the usual transitional period. However, the occurrence of this possibility is very low (see vi Case studies, page 24).

Stakeholders appear divided on whether labelling requirements are fit for purpose or not, with a majority of manufacturers of FA and premixtures considering them not fit[169]. They are also divided as to the negative impact of labelling costs, although there is a majority considering that there is no impact. For those indicating a negative impact, one of main problems mentioned is the necessity to include the information on the physical label and the necessity to regularly review this information, particularly in premixtures[170].

MS authorities have identified issues that led to different interpretation of labelling rules across the EU, which triggered changes on the labelling at MS level. The issues reported are the use of claims (only the claims stated in the authorising regulations are possible), the use in water for drinking and the declaration of carriers in premixtures[171]. Nevertheless, those issues were not related to EU regulatory changes.

Another issue that may increase costs is the absence of harmonised labelling tolerances of FA in premixtures. This causes different interpretations by the MS and may trigger additional costs related to the change of label or the refusal to place the premixture on the market by a MS authority.

Stakeholders largely think that the current labelling rules are informative and help to prevent misuse (e.g., exceed the maximum level permitted) along the food chain. As regards the role of labelling to ensure worker protection, the opinions are more divided 55% agree and 24 % disagree[172]. The reason

[168] vii Consultation Synopsis Report Re-evaluation of additives authorised by the former Directive that remains on the market until the re-evaluation is completed and a new authorisation is granted. This new authorisation may entail changes in relation with the previous authorisation.

[169] vii Consultation Synopsis Report, page 8

[170] vii Consultation Synopsis Report, pages 13 and 35

[171] ii FA Final Report _FCEC, page 77

for this is that the simultaneous application of the FA Regulation and CLP Regulation may reduce efficiency, as this could result in different or even conflicting provisions, which can have major impact on premixtures[173].

Labelling rules are, in general, efficient, as the costs derived from regulatory changes are not significant compared with the benefits provided, especially on their role to provide information to minimise safety risks along the food chain. Furthermore, this claim is substantiated by the high level of conformity (96-98%) of the samples and analysis performed by the MS in FA and premixtures. Nevertheless, three relevant concerns have been identified that created a burden, thus reducing the efficiency of the system: the obligation to indicate all the information on a physical label, the absence of labelling tolerances in premixtures and the simultaneous implementation of the FA Regulation and CLP Regulation, in particular as for premixtures of FA.

2.1.3. Regulatory costs compared to production costs

The total costs of authorisation as % of total regulatory costs and/or as % of total cost of production of this product or product price were not possible to estimate. Two companies indicated that the total regulatory costs stemming from the Regulation, of which the main component are the authorisation costs, are estimated at 2% and less than 5%, respectively, of the cost of production for this product. This estimation was based on a 10-year authorisation period. As a comparison, another company that is a major FA and compound feed manufacturer indicated that regulatory costs stemming from all legislation are 15% of all costs of the entire company's animal nutrition portfolio (EM 2.1.6)

2.2 COSTS FOR EU INSTITUTIONS AND AGENCIES AND PUBLIC ADMINISTRATIONS (COMMISSION (DG SANTE AND EURL), EFSA AND MS NCA).

2.2.1 Costs for DG SANTE

The costs refer to the staff costs and cover all the activities required for FA approval and maintenance the FA Register. Those activities are summarised as follows for the period 2004-2017:

a) Administrative procedure related to FA approval:
   - Verification of the compliance of applications: 791 [174] applications.
   - Mandates to EFSA: 1,066
   - Evaluation of EFSA opinions: 613 opinions.

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[172] vii Consultation Synopsis Report, page 29
[173] ii FA Final Report, page 104
[174] Administrative applications for Article 4(1) and Article 10(2).

b) Adoption of legal decisions:

- Regulations for the obligations derived from the FA Regulation: 444[175]
- Confidentiality decisions: (515) Applicants may ask for confidentiality of certain parts of the dossier when they submit the application but also when submitting complementary information ("stop the clock" by EFSA or possibility to submit complementary information to the Commission if the EFSA opinion is inconclusive). For each request of confidentiality, the Commission needs to take a formal decision and verify if this request complies with the provisions of the FA Regulation. As there is some information that may not be kept as confidential; the examination of the requests may require a technical knowledge. This may also create some extra-time in the adoption of EFSA opinions (no synchronisation between the decision on confidentiality and the EFSA opinion). Regulation (EU) 2019/1381 ("the Transparency Regulation")[176], which applies to applications submitted since 27 March 2021, has transferred this obligation to EFSA. It provides for specific rules on confidentiality decisions, standardises the procedure for such decisions and allows synchronicity of the decision on confidentiality with the EFSA opinion.

- Meetings of the SCoPAFF section Animal Nutrition: 235 days (period 2004-20017)

c) Maintenance of the Register of FA. Number of versions published: 259.

The performance is calculated over the 2004-2017 period, these tasks have involved a total of 15,426 working days of AD[177] staff (or 1,102 working days/year, of which 46 working days per year are dedicated to participation in SCoPAFF meetings) and 4,000 working days of AST staff (or 250 working days per year). These inputs have involved, on average, 4.6 FTE[178]s of AD staff and 1.1 FTE of AST/SC1 staff per year over the period. The daily cost of the European Commission staff below is considered equal to € 620 for AD staff and € 255 for AST staff.[179]

The table below shows that the **total cost of the administrative obligations of the European Commission**, calculated using the cost parameters specified above, amounts to € 10,584,000. Average yearly costs over the 2004-2017 period for all the above-mentioned tasks are estimated at €756,000, 90% of which covers AD staff and 10% AST staff.

[175] According to the date of publication

[176] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC. OJ L 231, 6.9.2019, p. 1.

[177] AD: administrators. AST: assistants. AST/SC: secretaries and clerks.

[178] Full time equivalent. One full time equivalent is equal to 8 working hours/day.

[179] Monetised on the basis of 2019 rates of remuneration of EU officials, OJ C 420/09, Volume 62, 13 December 2019, adjusted for overhead costs. AD rate is based on AD/AST, grade 10, step 1; AST rate is based on AST/SC, grade 4, step 1. The same rates are assumed for all institutions (Commission, EFSA and EURL).

Table 7: Total Costs for the European Commission

TYPE OF COST	DESCRIPTION OF ESTIMATED EFFORT	ESTIMATED COST
Commission total costs of the Regulation	15,426 working days AD STAFF	€ 9,564,120
	4,000 working days AST STAFF	€ 1,020,000
TOTAL ESTIMATED COST		€ 10,584,000

Considering that the **application** is the most relevant step that triggers all the different actions (791 applications were processed by SANTE during the period 2004-2017 (on average 56 applications per year), a calculation is made to estimate the staffs' costs per application, which rises to €13,400.

Table 8: Commission average cost per application

TYPE OF COST	DESCRIPTION OF ESTIMATED EFFORT	ESTIMATED COST
Commission average cost per application	19.5 working days AD STAFF	€ 12,091
	5 working days AST STAFF	€ 1,290
TOTAL ESTIMATED COST		€ 13,400

The number of working days spent on the tasks has been relatively stable year-on-year, since the main phase of the implementation period (2012-2017) i.e., processing mainly applications for new authorisations, having increased by about 10% since the previous phase (2007-2011) when applications for re-authorisations peaked (see section 3.1.1). The same human resources have borne the increase of applications, which shows an increase of efficiency in the applications management.

The Commission's participation in meetings of the SCoPAFF (average 16.7 days/year) has involve on average 46 working days/year of AD staff time. The number of applications during the period 2012-2017 increased efficiency in the application management. In order to reduce costs on travel expenses and other costs derived from the organisation of meetings (interpretations and administrative support of meetings), in 2017 the Commission started to reduce the number of meetings extending its duration, so the number of days per year remains stable.

On the one hand, the system has been efficient as the authorisations granted were not contested (only one case at the Court of Justice), a few cases were reported in the RASFF system (12 cases) and there were only five cases of administrative review (Article 19). This allowed to allocate almost all the resources to the authorisation process.

On the other hand, several issues hampered the Commission's efficiency diverting resources to actions that could be improved:

- Decisions on confidentiality of application dossiers (515 decisions)
- The modification of authorisation Regulations when the authorisation holder changes, as regards holder-specific authorisations (see EM).
- The complexity of certain applications.
- The adoption of inconclusive EFSA opinions that triggers a new request of supplementary information by the Commission to the applicant.
- The too short duration of the authorisation.

FeBOs claim that the need to have physical discussion within the SCoPAFF might delay the adoption of some authorisation Regulations. The Commission considers that the discussions within the SCoPAFF are necessary due to the complexity of many applications.

There are three areas for improvement identified:

- Establish a simple administrative procedure for the change of authorisation holder.
- Extend the authorisation for certain additives if there are not safety grounds that justify keeping the existing authorisation period.

Costs for the standard authorising Regulations and for Regulations changing the authorisation holder:

Regulations where the authorisation holder changes represent 10% of the Regulations linked to an authorisation holder. During the period 2004-2017, this accounts for 28 Regulations for which the authorisation holder changed. The administrative costs are lower than the one for an authorising Regulation because it does not require any further elaboration of the Regulation, there is no EFSA opinion and the discussions at the SCoPAFF are minimum.

Although it is difficult to quantify the costs, an estimation can be done considering that the time and resources dedicated to this activity are about 60% of the resources dedicated to a standard authorising Regulation.

Table 9: Commission average cost per standard authorising Regulation

TYPE OF COST	DESCRIPTION OF ESTIMATED EFFORT	ESTIMATED COST
Commission average cost per standard authorising Regulation	32.7 working days AD STAFF	€ 20,274
	8.5 working days AST STAFF	€ 2,168
TOTAL ESTIMATED COST		€ 22,400

For the **standard authorising Regulations, the costs are €22,400 per Regulation**. **In case of change of authorisation holder, the costs are estimated at €13,400 per implementing Regulation**.[180] For the Commission during the period 2004-2017, the total costs of Regulations changing the authorisation holder amount to €375,200 which accounts for €26,800 per year (2 Regulations per year).

Table 10: Commission average cost per Regulation changing the authorisation holder

TYPE OF COST	DESCRIPTION OF ESTIMATED EFFORT	ESTIMATED COST
Commission average cost per Regulation changing the authorisation holder	19.5 working days AD STAFF	€ 12.091
	5 working days AST STAFF	€ 1,290
TOTAL ESTIMATED COST		€ 13,400

2.2.2. Costs for the EU reference laboratory (EURL)

The duties and tasks of the EURL are assigned by the FA Regulation, in particular Article 21 thereof. The main obligation of the EURL for FA is the evaluation of the analytical methods proposed by the applicant to determine the active substance(s)/agent(s) in the feed additive (as finished product), in

[180] There are for the whole period 482 Regulations adopted, 454 standard Authorising Regulations and 28 Regulations changing the authorisation holder If the costs of Regulations changing the authorisation holder are 60% of the costs of a normal authorising Regulation: 454 x Y+28 x 0.6Y=€10,584,000; Y= €22,400 (where Y is the average cost of a standard authorising regulation). The reference here is the number of authorising Regulations that is lower than the number of applications, this explains why this figure is higher than the €13,400 cost per application. In case of change of authorisation holder, the costs are estimated at 0.6 x €22,400 = €13,400.

premixtures, in feed, and in water (if applicable). Other important task is to maintain in their facilities a bank of reference samples of all the authorised additives. Other tasks considered for the estimation of the costs is the participation in the SCoPAFF meetings and the annual coordination meeting with the National Reference Laboratories (NRLs) organised by the EURL.

The performance is calculated over the 2004-17 period, these tasks have involved a total of 14,008 working days of AD staff (or 1,000 working days/year) and 3,500 working days of AST staff (or 250 working days per year). These inputs have involved 4 FTEs of AD staff and 1 FTE of AST staff per year over the period. The number of working days spent on all the above describe tasks has been relatively stable year-on-year throughout the period. Average annual costs over the 2004-2017 period are estimated at €684,000, 90.5% of which is the cost of AD staff and 9.5% of which is the cost for AST staff. The majority of the time is devoted to the preparation of the validation reports and keeping of samples (94%). On the other hand, the EURL participation in meetings of the Standing Committee and the annual coordination meeting with NRLs have involved on average 34 and 22 working days/year, respectively, of AD staff time.

Table11: EURL costs

TYPE OF COST	DESCRIPTION OF ESTIMATED EFFORT	ESTIMATED COST
EURL average annual costs	1,000 working days AD STAFF	€ 620,000
	250 working days AST STAFF	€ 63,750
TOTAL ESTIMATED COST		€ 684,000

Considering the evaluation report as the main output that triggers the majority of the actions performed by the EURL, 37 evaluation reports per year were prepared on average during the 2004-2017 period, at an estimated cost of €18,500 in staff costs per validation report. This cost is justified as the validation process entails on some occasions the organisation of an inter-laboratory comparison study.

Table 12: EURL costs per validation report

TYPE OF COST	DESCRIPTION OF ESTIMATED EFFORT	ESTIMATED COST
EURL average cost per validation report	27 working days AD STAFF	€16,740
	7 working days AST STAFF	€ 1,785
TOTAL ESTIMATED COST		18,500€

The guidance prepared for the validation of the method of analysis has been a very efficient instrument for FeBOs. As a result, the validation of the method of analysis, except for few complex cases (e.g., some botanical flavourings and some few colourants), is ready before EFSA finalises the assessment, therefore it does not interfere negatively in the authorisation process.

A majority of stakeholders and competent[181] authorities agree that the role of the EURL is adequately defined in the Regulation[182]

In general, the EURL has been very efficient in implementing all its tasks.

2.2.3 Costs for EFSA

The EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP-Panel) provides scientific advice on the safety and/or efficacy of additives and products or substances used in animal feed. It is composed of 17 scientists from across Europe.

The costs related to the EFSA tasks during the period 2004-2017 [183]involved:

a) the cost of the FEEDAP Panel/working groups (WG) meetings; and,

b) staff time to meet the legal and administrative obligations related to the risk assessment of FA. EFSA has processed 969 applications during the period 2004-2017.

Those costs were estimated on the basis of the costs for which EFSA had data 2014-2018 for the categories AD, AST/FG staff categories. No data was available for the period 2004-2013. During the period 2004-2013 human resources were quite stable and increased in 2014 for the AST/FG staff while the AD staff remained relatively stable.

Average annual costs for EFSA over this period are estimated at €1.9 million of which, €1.1 million per year are staff costs.

During the period of 2014-2018 EFSA has processed **346 applications**, corresponding to 69.2 applications per year on average at **an estimated cost of €27,450 per application** (new and re-evaluation), €15,900 of which are internal staff costs. The average **cost for a renewal is estimated to be around €16,470** (60% compared to a standard application for authorisation).

[181] A total of 969 applications for Articles 4(1), 10(2) 13, 14 and 15 of the FA Regulation and 71 applications for Article 29 of the GFL.
[182] vii Consultation Synopsis Report page 11 and 21
[183] Due to major system changes, EFSA were not able to provide data for the period 2004-13.

Table 13: EFSA costs

	2014	2015	2016	2017
Annual cost of FEED Panel/WG meetings	€ 861,159.47	€ 864,168.89	€ 819,368.94	€751,778.14
No. of expert days/year	1,279.9	1,284.5	1,225	1,077.2
Total staff hours/year	9,873.75	11,819	26,477.75	24,713.5
EFSA AD staff involved	14 (proxy)	14	16	16
EFSA AST/FG staff involved	7 (proxy)	7	10	14

Over the 2014-18 period, the cost of the FEEDAP Panel/WG meetings has fallen by 40%, from €861,000 in 2014 to €515,000 in 2017 This is due to a decrease in the number of expert days per year, from 1,280 in 2014 to 824 in 2018, which resulted in a reduction in the costs involved (the cost of expert days themselves and also reimbursable). This task has involved 5,690 expert days over the five years, or 1,138 working days/year on average. Dividing this number by the 69.2 applications per year processed it is possible to obtain an average work effort of 16.5 expert days per application. An average total labour cost (travel included) of the external experts of € 700 is considered. The significant cut in the budget dedicated to feed-related activities, particularly between 2017 and 2018, is in line with the overall EFSA budget cut and reflects efforts to streamline costs by:

- using digital tools to work (i.e., phone meetings, web conferences) which is more cost-effective and time efficient. The physical meetings were reduced by 40%; and,

- centralising some aspects of the work, e.g., costs covering experts' flights were transferred to a different, common budget line dedicated only to flights for all EFSA.

On the other hand, during the same period, the requirements for internal staff time to fulfil the legal and administrative obligations related to the risk assessment of FA have increased by nearly 2.5 times: from an estimated 1,234 working days in 2014 to 3,153 days in 2018. This task has involved a total of 12,263 working days over the five-year period, or an average of 2,453 working days/year. Dividing this number by the 69.2 applications per year processed it is possible to obtain an average work effort of 35.4 working days per application. An average total labour cost (overheads included) of € 450 per working day is considered.

Although the required internal staff time has increased substantially, the increase was for the AST/FG staff was from 7 in 2014/15 to 15 in 2018, while the number of AD staff has remained relatively stable through the period (14 AD staff in 2018, the similar as in 2014/15).

Table14: EFSA cost per application processed

TYPE OF COST	DESCRIPTION OF ESTIMATED EFFORT	ESTIMATED COST
EFSA average cost per application processed	35.4 working days internal staff	€ 15,900
	16.5 working days external experts	€ 11,550
TOTAL ESTIMATED COST		€ 27,450

Again, the shift towards a higher share of AST/FG staff involved in feed-related activities reflects efforts to reduce costs, e.g., some administrative tasks have been taken away from the scientific units and are now performed at the central level. Furthermore, the increase in internal staff time reflects a shift from using external experts towards in sourcing some of the work to EFSA staff. The benefits of this strategy include:

i. increases in quality and harmonization of outputs.

ii. shorter timelines.

iii. improved control of the entire process.

iv. increased number of adopted outputs per year.

The increase of quality and harmonisation of outputs reduced the number of publications with errata or editorial corrections, from 9 publications in 2014 to two in 2018. The harmonization of outputs has been improved by increased preparation of opinions by staff members who ensured the use of the same approaches and same wording across the opinions wherever possible, based on a so purposed designed opinion template. Also, the creation of cross-cutting meetings across EFSA units helped to streamline the assessment methodologies and implementations for substances used in different food & feed domains.

The timing between accepting a mandate and the adoption of the corresponding scientific output (opinion) has been reduced from 640 days on average in 2014 to 342 days in 2018. In order to improve the entire process, draft opinions have been elaborated by assigning staff members and Panel experts, who are knowledgeable on the topic but not involved in drafting the assessment, for a deep review of draft opinions before they are discussed by the Panel for possible adoption. This involvement of ‘fresh eyes’ allows an increased identification of errors and/or items so as to be clarified, which often can be addressed before the upcoming Panel meeting.

Further efficiency of the process is expected to be achieved through increasing digitalisation. Improve electronic submission of data using agreed data formats would facilitate the automation of some administrative steps and the development of algorithms for data extraction and analysis. In addition, improving EFSA's expert capacity to draft risk assessments would be needed to further increase the efficiency of the process. This is expected to be achieved by establishing collaborations with individual experts and partnerships with scientific institutions who could support EFSA staff, the working groups and Panel in performing preparatory work.

With this strategy, the staff costs increased by 2.2 times between 2014 and 2018, i.e., at a lower rate than the increase in required staff time due to the increasing number of opinions.

Total annual costs for EFSA over the 2014-18 period are, on average, at €1, 9 million per year (staff costs + travel costs for panel and experts).

2.2.4 Costs for MS

The standard cost model was followed to identify the administrative duties, identification of target groups within NCAs that perform the different actions (implementation of the Regulation and control activities), frequency of required action (attendance to meetings of SCoPAFF, number of inspections per year/ establishment), identification of relevant costs and burdens (attendance to SCoPAFF meetings, control activities and other legal obligations). The performance was assessed by the staff time[184] devoted to these activities. It has been estimated as an average over the last three years by the NCA (2016-18).

The costs in terms of staff time[185] related to the MS CA tasks involve:

a) participation in the meetings of the Standing Committee in Brussels. This includes preparation of meetings and any administrative procedure related to the participation in those meetings.

b) control activities carried out for inspections and verification checks; and,

c) other legal and administrative obligations, *e.g.*, setting administrative procedures.

The staff time dedicated to a) c) activities (participation in the meetings of the Standing Committee and other legal and administrative obligations) has been calculated for MS CAs[186] over the period 2016-2018 (60 working days per MS per year for preparation/attendance of the meetings of the Standing

[184] EUROSTAT average annual earnings in the public sector, by economic activity and educational attainment (staff categories 1 to 4), per Member State (latest data: 2014), adjusted for overhead costs (addition of 25%) in accordance with the Better Regulation toolbox #60.

[185] Other Member States cannot estimate the costs of the Regulation *versus* other feed legislation.

Committee in Brussels and 92 working days per MS per year for the fulfilment of legal and administrative obligations.) Multiplying this work effort by an average cost of € 190 per working day is possible to obtain an average total cost per MS of € 29,000.

Table 15: costs for NCAs

TYPE OF COST	DESCRIPTION OF ESTIMATED EFFORT	ESTIMATED COST
Meetings of the Standing Committee in Brussels	60 working days per year	€ 11,450
Legal/administrative obligations	92 working days per year	€ 17,550
TOTAL ESTIMATED COST		€ 29,000

Considering that the application is the most relevant step that triggers all the different actions, the costs (791 applications processed by SANTE during the period 2004-2017= 56 applications per year) for each MS per application amount to €500 both per application for new authorisation and renewals (calculated based on the € 29,000 per year per MS). For the whole EU, this amounts to €14,000 per year per application.

The number of Regulations where the authorisation holder changes represent 10% of the Regulations linked to an authorisation holder (281). During the period 2004-2017, this accounts for 28 Regulations for which the authorisation holder changed (EM 3.2.6 and 6.7). The administrative costs are lower than that for an authorising Regulation because it does not require further elaboration of the Regulation, there is no EFSA opinion and the discussions at the SCoPAFF are minimum. Furthermore, during the same period 454 standard authorising Regulations have also been adopted.

Although it is difficult to quantify costs, an estimation can be done considering that the time and resources dedicated to this activity are about 60% of the resources dedicated to a standard authorising Regulation. The cost for a standard authorising Regulation is €860[187] and for a Regulation changing the authorisation holder is €500 per MS. Therefore, the average total cost for a standard authorising Regulation is €860x28=€24,088, while the average total cost for a Regulation changing the authorisation holder is €500x28=€14,000. The costs associated with the latter procedure were €14,490 per MS for the whole period.[188]. For all MS during the period 2004-2017, this amount to €405,600 which accounts for €28,900 per year for all EU MS.

[186] Other Member States cannot estimate the costs of the Regulation *versus* other feed legislation.
[187] The reference here is the number of authorising Regulations that is lower than the total number of applications, explaining that this figure is higher than the €500 cost per application.
[188] €29,000 per year x 14 years=€406,000 total costs per MS. There are for the whole period 482 Regulations adopted, 454 standard authorising Regulations and 28 changing the authorisation holder. If the costs of Regulations changing the authorisation holder are 60% less than a standard authorising Regulation: 454 x Y+28 x 0.6Y=€406,000; Y= €862.

Several MS could not provide estimates of time spent on legal/administrative obligations for controls for FA and premixtures as this information was available for all feed in general but does not distinguish additives and premixtures from other feeds. To allow for the differences in the estimates provided by MS, the staff time has been calculated for all the task 'b') as an average across those MS that provided complete data (14 MS).

The staff time dedicated to enforcement control tasks (b) has been calculated for MS CAs[189] over the same period 2016-2017 in 344 working days per MS per year. Multiplying this work effort by an average cost of € 215 per working day[190] is possible to obtain an average total cost per MS of € 74,000.

Table 16: costs of enforcement and control tasks

TYPE OF COST	DESCRIPTION OF ESTIMATED EFFORT	ESTIMATED COST
Enforcement and control tasks	344 working days per year	€ 74,000
TOTAL ESTIMATED COST		€ 74,000

In total, the costs for each MS CAs are €103.000 (29,000+74,000) euros per year on average which amounts to €2,884,000 per year for all EU MS.

2.3 BENEFITS FOR HUMAN HEALTH

Benefits for human health refer to three main aspects:

- Additives are safe because food from animal origin does not contain feed additive's residues that may compromise consumer safety. FA cannot contain microorganisms, toxins or other substances that may be transferred to food.
- FA do not contribute to increase AMR.
- Workers/users of FA are safe.

(Where Y is the average cost per MS of a standard authorising regulation); average total cost of Regulations changing the authorisation holder for the whole 2004-2017 period: 28 x 0.6 x 862=€14,490

[189] Other Member States cannot estimate the costs of the Regulation *versus* other feed legislation.

[190] The average daily cost of the staff involved in the implementation of the control activities (€ 215) is different from the one of the staff involved in the attendance of Standing Committee meetings and in the execution of the administrative/legal obligations (€ 190) due to the different staff category mixes involved in these activities.

Those three aspects are evaluated by EFSA to ensure that no health concerns arise when an additive is authorised. In addition to the rigorous EFSA assessment, the labelling provisions ensure that the relevant information to protect consumers or workers is transmitted along the feed chain. This role of EFSA is widely recognised, 90% of respondents consider that the safety assessment carried out by EFSA makes FA safe for human health[191]. 75% of respondents see benefits of the FA Regulation for human health. FA are safe for consumers according to 92% of respondents[192].

The reduction of AMR goes beyond consumers or users and provides benefits for the society in general. 72% of all respondents agree that the ban on the use of antibiotics introduced by the Regulation played an important role in preventing AMR[193].

As regards worker/user safety, 84% of respondents agree that FA are safe for users. A majority of MS authorities agree on this although three MS authorities, did not provide a definite answer.[194].

In the PC, 15 respondents (from the FA industry, consultants and one citizen) indicated in the open fields that there is a lack of coherence with worker safety regulations (FA Regulation and CLP), leading to overlapping labelling requirements. For some industry respondents the rules laid down in the CLP Regulation are sufficient[195]. This is pointed in the NCAs survey, where 4 MS indicated that there were at least one or two contradictions/inconsistencies between both Regulations (CLP and FA Regulation). Although the SH survey did not indicate such contradictions/inconsistencies for the specific question (28 out 35 indicate "don't know", 6 do not see contradictions/inconsistencies and 1 see contradictions/inconsistencies), the same survey shows that one of the main reasons for changing the labels is the request for additional worker safety requirements from MS authorities. Although the surveys did not reveal a high rate of positive response on whether the CLP Regulation is coherent with the FA Regulation, the case studies provided a clearer picture on the effects of the simultaneous application of both Regulations. The duplication of worker safety requirements increases costs, especially in premixtures, which normally contain many additives for which the indication of all the safety requirements for the individual additives and for the mixture as a whole may be a problem for small packages. In general, this duplication of rules can possibly lead to complex directions for users. CLP applies horizontally to feed additives and other sectors (including medicinal products, food additives or food flavourings) for substances and mixtures of such products that are not in the final state for the final user. Workers' requirements should therefore be set according to consistent criteria across all the sectors in order to provide clarity and avoid inconsistencies, at least for premixtures of feed additives,

191 vii Consultation Synopsis Report, page 27.
192 SH Survey
193 Public consultation
194 vii Consultation Synopsis Report, pages 8 and 19
195 vii Consultation Synopsis Report, page 29.

where a problem has been identified due to the simultaneous implementation of the FA Regulation and CLP Regulation[196]. In addition to the increasing costs for some premixtures, insufficient clarity may undermine the proper understanding of the worker safety directions on the label.

For the worker safety requirements there is room for simplification, for instance by applying only CLP Regulation for premixtures of additives while keeping the implementation of both Regulations for FA.

2.4 BENEFITS FOR ANIMAL HEALTH AND ANIMAL WELFARE

The benefits for animal health are clear for all FeBOs and MS authorities and is one of the elements of the current framework that is not questioned.

The surveys indicated that 85% of respondents considered that FA have benefits for animal welfare, although those benefits have not been fully exploited according to some feed additive producers and pet food industry. There are many additives that have indirect effects on animal welfare, such as vitamins, trace elements, gut flora stabilisers or coccidiostats, but there was no authorisation of additives with the specific purpose of having a direct effect on animal welfare.

FA favourably affecting animal welfare can only be allocated under the category 'zootechnical additives'. EFSA requests the applicant to demonstrate a zootechnical effect (e.g., improvement of performance - increase egg/meat production). However, the actions performed by these additives are not related to an increase of the animal performance, but to a specific improvement in the well-being of the animal (e.g., a stress reduction). This discrepancy discourages applicants from applying for those kinds of additives. Furthermore, the establishment of endpoints (see glossary) to demonstrate animal welfare effects requires additional input in EFSA guidance to facilitate those applications.

Despite the establishment of a specific functional group in 2019 – 'physiological condition stabilisers', which are intended to develop additives having beneficial effects on animal welfare – no additives have been authorised so far[197].

In general, a majority of respondents see benefits of the FA Regulation for animal welfare, for instance, 78% of respondents consider that FA help to improve animal welfare and several respondents showed the importance of having additives intended to improve animal welfare in the future. One MS authorities responsible for animal feed neither agree nor disagree with the statement that FA help to improve animal welfare. This MS authorities expressed the views that very few additives have been developed expressly to promote animal welfare, in line with some other respondents. It also

[196] See also the relevant Occupational Safety and Health legislation and in particular Council Directive of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work and Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (89/391/EEC)

[197] FA Register updated on 19/05/2021.

indicated that increasing the performance and growth of animals does not contribute necessarily to improve animal well-being. Another MS authorities of the same country contradicted this position and responded that they agree that additives help to improve animal welfare.

A citizen that neither agrees nor disagrees with the statement that FA help to improve animal welfare, indicated: *"animal welfare is a societal concern. Additives which are used must not have a negative effect on welfare. It is perhaps worth noting that in the case of non-food animals, e.g., pets there is a consumer demand on cosmetic appearance of feeds which also needs to be taken into consideration*".

After several years of discussion, the functional group '*physiological condition stabilisers*' was created, that is to say, substances or, when applicable, microorganisms, which, when given as feed to animals in good health, favourably affect their physiological condition, including their resilience to stress factors. The Regulation authorising this functional group also seeks to respect good farming practices that ensure the wellbeing of animals and the respect of animal welfare provisions, by including a specific recital on the matter.

The FA Regulation needs to be more efficient so that the authorisation of FA has positive effects on animal welfare by excluding the demonstration of performance. The costs incurred to demonstrate efficacy will be limited to those positive effects on animal welfare, excluding those aspects related to the demonstration of performance. The authorisation should not undermine the respect for good farming practices and animal welfare provisions.

2.5 BENEFITS FOR THE ENVIRONMENT

Many additives, not authorised under the functional group having benefits on the environment, have clear positive effects mitigating the impact of livestock farming on the environment, in addition to effects under the functional group for which they were authorised. More details on this point are in the main text.

EFSA performs a risk assessment to evaluate the impact of FA on the environment and may include restrictions on their use, e.g., maximum limits, and if necessary, a post-market monitoring plan.

The benefits on the environment have been recognised by the stakeholders (mainly FeBOs) 71% of respondents see benefits for the environment[198].

The post-market monitoring, which also includes the unforeseen effects on the environment, depends on the EFSA outcome performed on a case-by-case basis. Other environmental monitoring is not under the remit of the Regulation. The controls performed by MS cover all the aspects related to safety and placing on the market, including labelling, to ensure that additives/premixtures comply with safety requirements (for animals, consumers, workers and the environment) and with directions for their use, and to subsequently prevent a misuse along the feed chain.

[198] SH survey

The effects on the environment are considered adequately assessed and the level of compliance of additives and premixtures is high. This means that, where applicable, the maximum levels are respected and the information on the label is passed properly throughout the food chain.

2.6 BENEFITS FOR FARMERS

The benefits for farmers stem from the placing of safe and efficacious FA on the market. Those benefits are related to their specific functions. 83% of respondents noticed benefits of the FA Regulation for farmers. The details on those benefits are in the main text.

2.7 BENEFITS FOR CONSUMERS.

There are two elements to consider when dealing with benefits for consumers:

- Additives are safe because food of animal origin does not contain FA or its residues, which may compromise consumer safety.
- FA contribute to reducing AMR.

The EFSA evaluation must ensure that no health concerns arise when an additive is authorised. In addition to the rigorous EFSA assessment, the labelling provisions ensure that the relevant information to protect consumers is conveyed along the feed chain. During the period 2004-2020, the RASFF notifications showed the level of compliance as for the presence of FA or their residues in food of animal origin. 82 out of 16,634 notifications were linked to the presence of unauthorised additives or high level of residues, representing 0.5% of the total number of notifications.

This role of EFSA is widely recognised, 92% of respondents consider that FA are safe for consumers[199].

The reduction of AMR goes beyond consumers or users and provides benefits for the society in general. 72% of respondents agree that the ban on antibiotics introduced by the Regulation played an important role in preventing AMR.

2.8 BENEFITS FOR WORKERS/USERS

The benefits for workers are related to the evaluation performed by EFSA on worker safety and the measures that are adopted in the authorising Regulation to protect workers[200]. An appropriate labelling with the directions of use of the additives/ premixtures ensures that the information is conveyed along the feed chain.

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[199] SH survey.

[200] See also the relevant Occupational Safety and Health legislation and in particular Council Directive of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work and Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (89/391/EEC)

This role of EFSA is widely recognised, 90%[201] of respondents consider that the safety assessment carried out by EFSA make FA safe for human health. In this regard, 84% of stakeholders also consider that FA are safe for workers/users and 11% neither agree nor disagree with this statement.

The current system demanding the inclusion of all the information on a physical label in relation to worker/safety directions of use reduces the efficiency as it increases costs. One of the factors identified that triggers the costs increase of changing labels is the difference in interpretations of worker safety information by MS. The information about worker/safety requirements is quite extensive as two Regulations apply: the FA Regulation and the CLP Regulation; the latter requires information to be put on the label and in the Safety Data Sheet (Annex II to REACH). As for premixtures, the information required by the FA Regulation and CLP legislation may cause concerns related to available room on the labels and readability of the information. Generally, the complexity/cost is expected to be proportionately higher for smaller packs than for larger packs. Another element raised during the evaluation[202] that may reduce the efficiency in the implementation of worker safety provisions is related to the coherence with worker safety provisions (FA and CLP) leading to possible overlapping or complex labelling requirements. This issue is more detrimental to premixtures.

2.9. BENEFITS FOR PETS AND THEIR OWNERS

The benefits for pets and their owners can be summarised as follows:

- Additives are safe for pets. The Regulation introduced a comprehensive set of requirements compared to the previous 1970 FA Directive to ensure that they are safe. Taking into account that those animals have a long lifespan, the evaluation takes into consideration chronic toxicity, mutagenicity and carcinogenicity effects to prevent any negative effect on pets' health.
- Labelling requirements ensure that those additives are used in accordance with conditions of authorisation (e.g., maximum doses) along the feed chain.
- The safety of the owner is considered in the assessment. Since FA cannot be given directly to the animals by pet owners, they should always be incorporated in a compound feed or in a feed material. In addition, additives will not pose risks of AMR for pets and their owners as they are subject to pre-market assessment to eliminate any AMR effect. Although the antibiotics authorised by the former 1970 FA Directive were addressed to food-producing animals, companion animals, due to their close contact with humans, may contribute to spread AMR in humans. Use of antimicrobials that are critically important for human health in companion animals is an additional risk factor for emergence and transmission of antimicrobial resistance. Although the contribution of FA is negligible, the premarket assessment will ensure that FA intended for companion animal will not have any AMR effects.

[201] SH survey.
[202] PC. FEFANA response

For a majority of respondents from all stakeholder groups, the FA Regulation provides benefits for pets and pet owners. However, animal welfare organisations did not contribute to the survey, despite the efforts to involve them. One citizen expressed the view that there is an increasing consumer demand for cosmetic appearance of pet food that needs to be considered. This issue may be related, for example, to the use of colourants so as to meet the requirements of pet owners (many compound feeds are grey colour and this is not accepted by pet owners)

Nearly all respondents agree that FA are efficacious and safe for pet animals (74 and 76, respectively, out of 78 respondents); excluding 28 and 30 respondents, respectively that did not provide an answer as pet food is not relevant for their organisation) [203].

As regards the capacity of the FA Regulation to address scientific and technical developments for pets, a majority (45 out of 107 respondents) consider the authorisation procedure not to be suitable to address scientific and technical developments for pets and livestock production, due to the time periods incurred during the authorisation.

3. - COHERENCE

3.1 INTERNAL COHERENCE

The effectiveness of certain provisions of the FA Regulation could be improved in terms of internal coherence, which may also have affected the simplification and harmonisation of the authorisation process:

The information collected during the study identified some possible gaps in the definitions; in particular, MS authorities signalled the necessity to improve the definitions of "processing aids" in relation to FA, as well as to establish a harmonised definition for "maximum recommended levels" or "recommended levels".

3.1.1 Preparations

MS authorities also noticed the necessity to establish a definition of "preparations" of FA (a feed additive composed by different substances). Preparations are not defined as such although their compositional and labelling requirements were specified in the FA Regulation by the adoption in 2015 of implementing rules modifying Annex III of the FA Regulation[204]. A formal definition of "preparation" would be useful, as this would allow a better

[203] vii Consultation Synopsis Report, page 9.

[204] Commission Regulation (EU) 2015/327 of 2 March 2015 amending Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards requirements for the placing on the market and conditions of use of additives consisting of preparations OJ L 58, 3.3.2015, p. 46.

distinction between preparations of FA and premixtures (mixtures of FA or of FA with feed materials or water). Both are intermediate products that cannot be given directly to animals, but which are incorporated in compound feed or feed materials (e.g., wheat).

3.1.2 Drinking water

The coherence of the provisions related to the use of additives in drinking water should be assessed: the coexistence of the definition of FA, which allows the use of additives in water for drinking, and the limitations of the use for certain categories and functional groups as referred to in Article 6 and Annex I of the FA Regulation, has reduced clarity in relation to the possible scope of the applications. Some applicants requested the authorisation of use in water for drinking for the majority of chemical flavourings and for certain preservatives, but the FA Regulation does not allow this use. In the case of 789 flavourings and eight preservatives, the applicants withdrew the application for their use in water for drinking. In addition, the different feeding/drinking systems introduced technical challenges for the correct implementation of the rules laid down in the FA Regulation. For example, premixtures may have a composition similar to a complementary feed that is allowed as liquid feed. The distinction in the routes of administration for liquid feed (to use complementary feed) and for water for drinking (to use additives) is not evident in some feeding systems and this may create different interpretations in the MS. During the 2004-2017 period, these issues were raised several times (35), directly or indirectly, at the level of SCoPAFF. Those aspects have been noticed by some MS authorities and by stakeholders –mainly FeBOs- (PC and NCA Survey).

Technical questions about the practical implementation of the use of additives in water for drinking are relevant for the MS authorities and stakeholders -mainly FeBOs- (ii FA Final Report _FCEC, page 77) as it may create different understandings across the EU.

3.1.3 Data sharing

Data sharing between applicants should reduce tests and costs of applications and be consistent with the EU policy on animal welfare. The FA Regulation lays down requirements for data sharing to prevent repetition of toxicological tests on vertebrates (Article 20). The applicants must take all the necessary measures to reach an agreement. If such an agreement is not reached, the Commission *may decide* to disclose the information while ensuring a reasonable balance between the interests of the parties concerned. The FA Regulation does not provide the Commission with tools or mechanisms to ensure a reasonable balance between the parties. Consequently, few requests of data sharing occurred (three) and it was not possible to draw any conclusions. In the PC two thirds of respondents were not able to indicate whether or not data sharing rules are effective in reducing costs and animal testing. Those that have a negative view, have three different arguments: data sharing is not fully exploited, there is room for reduction of costs or the market should decide. Nonetheless, some of these respondents argued that data sharing is a useful concept for reducing costs[205].

3.1.4 Withdrawal of the application during the renewal process

[205] vii Consultation Synopsis Report, page 26.

The FA Regulation provides for a procedure for the renewal of authorisation of FA. If the application for renewal is presented in due time, the feed additive will remain on the market until a decision on the renewal is taken by the Commission, provided that the reasons for the possible delay for granting the renewal of authorisation are beyond the control of the applicant. It may happen that the applicant withdraws the application for renewal during the process. In this case, the additive is no longer authorised if the original authorisation has already expired. The FA Regulation is not consistent in this regard, as FeBOs must face a "sudden" expiry of the authorisation, without any transitional period allowing an adaptation of the products concerned on the market.

3.1.5 Change of the authorisation holder

The current system requires the adoption of an implementing Regulation (including a request for an EFSA opinion) for each change of the authorisation holder concerning holder-specific authorisations (due for instance to mergers or acquisitions of companies). In order to address this administrative burden, the Commission and EFSA agreed on some internal administrative arrangements allowing EFSA to be informed on the modification of the authorisation holder rather than to be requested to deliver an opinion on a purely administrative issue. This represents 10% of the Regulations adopted in relation to holder-specific authorisations (see FCEC Final Report: section 6.1.1, EQ3.2 and section 7.3.1). The obligation to adopt an implementing Regulation entails a burden for the Commission, EFSA and MS.

3.1.6 The category of "zootechnical "does not necessarily match with the expected functions

One of the issues raised during the evaluation was the fact that some categories of FA did not necessarily match with the expected functions of such additives. This affects certain innovative additives intended to have benefits for animal welfare or the environment. These additives were allocated in the category 'zootechnical additives' and applicants were required to demonstrate performance, in addition to the beneficial effects for animal well-being or the environment. Some additives may however have positive effects on animal welfare/environment, without necessarily leading to an increased performance or productivity of the animals (see FCEC Final Report, section 5.1.1, EQ 1.4). This finding needs to be further explored as in principle the FA Regulation provides for the possibility to demonstrate an environmental effect or an animal welfare effect, but the fact that those functional groups are under the category "zootechnical additives" triggered different interpretations by EFSA, according to the applicants.

3.1.7 Environmental risk assessment for non-food producing animals

The safety criteria and data requirements introduced in the FA Regulation were effective to ensure a comprehensive environmental assessment. Nevertheless, it is necessary to introduce some clarification regarding the environmental safety requirements applicable to farmed non-food producing animals (e.g., fur animals) in order to accommodate the requirements related to the safety criteria laid down in the FA Regulation. Although no application specifically addressing this type of animals was submitted and authorisations granted for all animal species (including non-food producing animals) have considered the environmental impact of the additives concerned, the FA Regulation would need to be modified in order to clearly state that those specific animals are covered by the environmental risk assessment.

3.1.8 Additives only intended for export

The FA Regulation does not provide specific labelling provisions to identify additives and premixtures intended only for export, nevertheless, some MS have imposed labelling obligations – *e.g.*, 'only for export'. In addition to the absence of harmonised labelling, the definition of the FA Regulation of "placing on the market" only allows the export from the producing establishment and very limited circulation within the EU to the third country. This reduces the circulation of those products, and it is not necessarily consistent with the normal activity of FeBOs, which may require, for example, producing certain additives in one or several establishments with a view to incorporate those additives in a premixture manufactured in another establishment. A large number of respondents to the MS authorities and stakeholders surveys were aware of those products, which are produced in the EU only for export[206]. For the specific sector of FA, 33% of manufacturers and traders of FA and premixtures exported those additives. Several of the consulted companies (including SMEs) indicated that the export of those products is an important segment of their business. In cases where the authorisation/approval process in the non-EU country is less burdensome than in the EU, this market option enables EU companies to maintain their global competitiveness, particularly SMEs producing a diverse product range, for which the burden of authorisation costs can be particularly dissuasive in view of their small scale of business.[207].

3.1.9 Imports of FA

As regards imports, the lack of a code permitting to identify FA at the time of import reduces the capacity of MS to control imports, as additives are often imported as chemical substances using different customs codes. FeBOs do not have a specific code or system in place that allows to classify their products as FA at custom level. A significant share of stakeholders considers imports not to be adequately controlled and a majority of MS authorities consider them only to be partially controlled (see ii FA Final Report _FCEC, page 45).

3.1.10 Modification of non-holder specific authorisations

The modification of non-holder specific authorisations is not sufficiently clear in the FA Regulation. Whereas for additives linked to an authorisation holder, the FA Regulation specifically mentions the possibility to request a modification of the authorisation, it is not so evident for additives not linked to an authorisation holder. Greater clarity and coherence in relation to this matter would therefore be appropriate.

3.2 COHERENCE WITH OTHER FEED LEGISLATION

3.2.1 Feed marketing Regulation. The Feed Marketing Regulation covers feed in general, without prejudice to specific rules concerning FA:

[206] vii Consultation Synopsis Report pages 16 and 23)
[207] ii FA Final Report, page 67

- provides for general safety and labelling requirements (in line with the General Food Law) and for specific labelling rules concerning feed materials and compound feed, including detailed rules where they contain FA (references to the authorisation acts where appropriate).
- distinction between feed materials and FA may be subject to some uncertainties for certain products, despite the respective legal definitions; Guidelines clarifying this distinction have been adopted (Commission Recommendation 2011/25/EU of 14/01/2011 – legal basis in the Feed Marketing Regulation) and regulations may be adopted by the Commission to decide on the status of certain products as FA (legal basis in the FA Regulation).

One of the major findings identified is the coherence with the Feed Marketing Regulation in relation to the **distinction between feed materials and FA**. This is a recurrent issue in the discussions at the SCoPAFF meetings (see FCEC Final Report, section 7.1.1). Several MS authorities and manufacturers of FA and feed materials indicated that the classification of a substance as a feed material or a feed additive is one of the biggest challenges posed by the current EU regulatory framework for feed. The situation may undermine the level playing field as the authorisation of FA entails a high regulatory burden, whereas no pre-market authorisation procedure is required for feed materials. As the legal requirements for feed materials in the Feed Marketing Regulation are substantially lower (no pre-market authorisation) than for FA, in case of doubt FeBOs may tend to categorise them as feed material. This may pose a threat when actually a risk assessment and the more stringent rules of the FA Regulation would be required. In case of products considered on the borderline between the feed material and FA status, a clarification of that legal status can be sought via the SCoPAFF (e.g., if a sugar beet extract rich in betaine is an additive or not, taking into account that betaine is regarded as a nutritional feed additive). However, this takes a long time and resources from national and EU authorities. This topic was discussed 50 times at the SCoPAFF meetings during the period 2004-2017. Therefore, MS and stakeholders (mainly FeBOs) are of the opinion that more clarification in the products' regulatory definitions could minimise any possible inconsistency/insufficient certainty.

The Feed Marketing Regulation makes a distinction between **the concept of 'label'** (information present on the packaging) **and 'labelling'** (information present on any medium and in any form accompanying the product, including e.g., on the internet and advertising). The FA Regulation provides that the information must be contained on the label on the package or container of the FA or premixture; the possibility to pass the information by other means e.g., electronic means is excluded. A majority of manufacturers and also some MS did not consider those requirements to be fit for purpose and well aligned with the provisions of the Feed Marketing Regulation (ii FA Final Report _FCEC, page 44). This situation prevents manufacturers of FA and premixtures from using state-of-the-art technologies to pass the information, which results in some costs/burden, especially for premixtures.

Unlike provided for in the Feed Marketing Regulation (cfr Article 11(5)), the absence of **labelling tolerances** (see glossary) for FA in premixtures adds some room for interpretation of the labelling rules laid down in the FA Regulation. This situation creates a certain burden for FeBOs (change of labels to accommodate to MS specific requirements) when the additives circulate within the EU, since the conditions in relation to labelling tolerances may be different from one MS to another.

3.2.2 Feed Hygiene Regulation

The Feed Hygiene Regulation lays down general rules on feed hygiene also covering FA: traceability conditions and arrangements; rules on registration and approval of establishments; imports and exports requirements. It also covers activities of feed business operators related to FA, from the production stage, while the FA Regulation applies to the placing on the market and use of FA.

As regards imports, the MS authorities and FeBOs pointed out a possible inconsistency between the Feed Hygiene Regulation and the FA Regulation (ii FA Final Report FCEC, pages 98 and 99). No list of third country of dispatch nor of feed establishments of dispatch in third countries (including FA and premixtures) has been established in accordance with Article 23(1) of the Feed Hygiene Regulation. Interim measures set up in Article 24 of the Feed Hygiene Regulation, referring to Article 6 of Directive 98/51/EC, provide that establishments in third countries must have a representative established within the EU in order to be allowed to import products. This person must ensure that these establishments have implemented measures at least equivalent to those applicable in the EU. The FeBOs identified a possible lack of coherence between the two Regulations as in practice the controls of the feed additive requirements applicable to the EU establishments would be more stringent than for establishments in third countries. There are different approaches in the MS on how to assess whether an imported feed additive and the commercial documentation accompanying it (product specifications, certificates of analyses, etc.) provide sufficient guarantees that the imported product satisfies EU requirements. All those different approaches have been reported in the Commission Audits (EM 4.15).

As regards additives only intended for export, MS authorities did not identify major problems although this matter was not specifically harmonised (MS apply different measures to set up requirements for establishments producing additives/premixtures only) intended for export. This issue could be harmonised at EU level by including additional requirements in the Feed Hygiene Regulation. The FeBOs identified a possible lack of coherence between the two Regulations as the controls of the feed additive requirements applicable to the EU establishments would be more stringent than for establishments in third countries. MS authorities recognised that they do not have the capacity to control establishments in third countries. This undermines the level playing field for EU FeBOs. Although this matter concerns the Feed Hygiene Regulation, the establishment of a specific import code in the FA Regulation for FA and premixtures at the point of entry in the EU, may facilitate a better traceability and control of these products, thus slightly improving the coherence between the two Regulations.

Industry has identified the circulation of FA/premixtures only intended for export as another inconsistency with the Feed Hygiene Regulation. However, this point is void, as this is an aspect related to the definition of "placing on the market" in the FA Regulation and not to any provision on feed hygiene.

3.2.3 Medicated feed and veterinary medicinal products Regulations

In general, MS authorities and feed business FeBOs did not point out any inconsistency with the medicated feed and veterinary medicinal products legislation. Veterinary medicinal products (VMPs) exclude FA from their scope (ii FA Final Report _FCEC, pages 100). There have been some few cases where doubts about the nature of a specific substance were raised but they were solved. For some FeBOs, the notion of VMPs as products contributing to the prevention of animal diseases was too vague in the former Directive, thus not allowing a clear distinction of VMPs from FA with nutritional functions

that help maintain animals in good health. This issue has been clarified with the new definition of VMPs included in Regulation (EU) 2019/6 that replaces the former Directive. The use of zinc oxide has been also reported as an inconsistency, due to the fact that this substance is going to be phased out in 2022 for the negative impact on the environment. Its use as an additive is necessary, as it is an essential trace element for animals that cannot be replaced, whereas in the case of VMPs alternatives to this use with a lower environmental impact exist. The use of new chelated forms (zinc bounded to an organic substance) permits a high assimilation by the animals reducing the disposal on the manure, and consequently, the impact on the environment.

3.2.4 GM Food Feed Regulation

No inconsistencies have been identified between the FA Regulation and GMO legislation.

3.2.5 Directive on Undesirable Substances

The information collected during the study did not point to any major inconsistency or contradiction between the FA Regulation and EU legislation on undesirable substances. Undesirable substances are substances or products, apart from pathogenic agents, present in and/or on the product intended for animal feed, which may constitute a danger to human or animal health, to the environment or adversely affect livestock production. Those substances are, for example, heavy metals, mycotoxins, plant toxins, organochlorine compounds and dioxins and PCBs that may be found in feed (including FA and premixtures). Maximum limits are laid down for each of the listed substances, which, if exceeded, do not allow the placing of the feed product on the EU market.

3.2.6 Biocidal Products Regulation

Finally, another point has been raised as regards the coherence with the Biocidal Products Regulation. The use of certain substances in water, such as preservatives, is regarded as a "biocidal products" use. This use, having a preservative effect on water, is envisaged in the Biocidal Products Regulation and is not foreseen in the FA Regulation, while the Biocidal Products Regulation refers to the "disinfection" (and not "preservation") of drinking water (ii FA Final Report _FCEC, pages 104-105). The Biocidal Products Regulation concerns the making available on the market and use of biocidal products, which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product. The Biocidal Products Regulation excludes from its scope the products regulated under Regulation (EC) No 1831/2003 but this is limited by the provisions of Article 2(2), second paragraph, of the Biocidal Products Regulation: *"Notwithstanding the first subparagraph, when a biocidal product falls within the scope of one of the abovementioned instruments (including FA Regulation) and is intended to be used for purposes not covered by those instruments, this Regulation shall also apply to that biocidal product insofar as those purposes are not addressed by those instruments*". For some MS, the use of preservatives in water is a use not included in the FA Regulation as the FA Regulation does not permit this use, therefore, this use is a biocidal use.

This different interpretation is regarded as an area for improvement concerning the interplay between the two Regulations. There are eight feed additive applications under the functional group of preservatives (within the category of technological additives) for use in drinking water. Those applications were not processed, as the current legislation does not provide for the use of technological additives in drinking water (as explained before, certain functional groups only refer to the use of additives in feedingstuffs in their definition). The extension of use of additives in drinking water to other categories or functional groups needs to be examined and clarified (40% of respondents agreed to that need). This clarification should also better define the distinction between biocidal products and FA for certain uses in drinking water. For 24% of the MS authorities, the two legislations are not coherent. During the 2004-2017 period, this issue was raised several times (35), directly or indirectly, at the level of the SCoPAFF.

3.2.7 General Food Law

The General Food Law establishes notably the definition of feed, the definition of placing on the market and the general obligations for FeBOs.

Considerations on the interplay with the General Food Law refer to the requirements applicable for additives only intended for export and the different approaches applied in MS. Those requirements are set up in Article 12 of the General Food Law. This Article establishes the obligations for the exporting country to ensure that the products comply with the General Food Law, unless otherwise requested by the laws, regulations, standards, codes of practice and other legal and administrative procedures as may be in force in the importing country. In other circumstances, except if the products are unsafe, they can be exported if the competent authorities of the country of destination have expressly agreed, after having been fully informed of the reasons for which and the circumstances in which the food or feed concerned could not be placed on the market in the EU. This may be the case of a vitamin that is authorised in the EU for certain species but not for others, as there has been no application for authorisation. It may be possible that the levels of use in the EU are different from the ones authorised in the exporting country, since those levels are regarded as safe in this country's legislation by limiting the export of certain FA and premixtures that may pose a global risk.

3.2.8 CLP

The CLP Regulation harmonises the criteria for classification and the rules for labelling and packaging of chemical hazardous substances and mixtures. This labelling concerns the environment and worker safety directions and applies to FA and premixtures. The combination of CLP labelling requirements and specific requirements set out in the authorising Regulation, created different understanding amongst MS authorities. This introduces complexity on the labels, in particular for premixtures. The authorisation of FA does not usually introduce labelling provisions for workers' safety but generally provide for workers' safety requirements to be respected, as conditions of use of the authorised additives. Some MS authorities require the introduction of those safety requirements on the label. Those labelling indications are not harmonised in the different MS. Furthermore, it is being considered that the CLP Regulation applies also to FA and premixtures, thereby introducing additional labelling requirements for workers' safety. This introduces complexity on the labels, in particular for premixtures. Although the surveys did not reveal a high rate of positive response on whether the CLP Regulation is coherent

with the FA Regulation, the case studies[208] provided a clearer picture on the effects of the simultaneous application of both Regulations, especially in premixtures. On the one hand, MS have different understandings on how worker safety provisions can be indicated on the label in order to ensure respect for both Regulations; on the other hand, labelling requirements for user safety might be redundant or even conflicting in both Regulations. This could be aggravated in premixtures, where different additives are incorporated. As regards workers' safety provisions, the simultaneous implementation of the CLP Regulation and of the FA Regulation has been reported as one aspect that may undermine workers' safety (in case of contradictory directions of use), although no clear evidence has been provided.

Considering that the CLP Regulation applies widely for any chemical substance placed on the market and taking into account that effects of the mixtures are also regulated as a whole by that Regulation, the possibility to apply only the CLP Regulation for worker safety labelling provisions in premixtures should be examined. This would contribute to passing clear messages to workers, to improving worker safety and to aligning the labelling with similar or the same substances used in other areas: food, cosmetics, biocidal products etc.

3.2.9 REACH Regulation

The information collected during the study did not point to the existence of any inconsistencies between REACH Regulation and the FA Regulation. The study supporting the Fitness Check on REACH (EFTEC, 2017) and the Commission's report (EC, 2018a) did not point to any issues of contradiction / inconsistency with the FA Regulation either (see ii FA Final Report _FCEC, pages 103-104)

4.- RELEVANCE

4.1 DO THE ORIGINAL OBJECTIVES OF THE FA REGULATION STILL CORRESPOND TO THE EU'S CURRENT NEEDS/PROBLEMS?

This question tries to determine if the objectives of the FA Regulation are pertinent to the evolving needs, problems and issues related to the authorisation, placing on the market and use of FA and premixtures. The objectives identified in the regulation were:

1. Reducing antimicrobial resistance (AMR) threats to citizens, animals and the environment.
2. Simplifying and harmonise the FA authorisation system.
3. Set up clear/comprehensive rules for the authorisation and labelling

[208] vi Case studies, sections 4.3.4 and 4.3.5

4. Ensuring rigorous risk assessment.
5. Improving FA control, traceability and enforcement rules.
6. Addressing specific interests of pet owners and their animals.
7. Encouraging the placing on the market of FA which are innovative and efficacious.
8. Ensure that FA cannot be used to mislead consumers on the quality of food

The relationship between the identified needs and the objectives are described in the Intervention logic (see section 2.1).

4.1.1 1. Reducing antimicrobial resistance (AMR) threats to citizens, animals and the environment.

This objective is still relevant. In June 2017, the European Commission adopted the EU One Health Action Plan against AMR. In May 2020, the European Commission adopted the Farm to Fork Strategy, a tool to help shape the EU's path towards sustainable food systems. Its objective is the reduction by 50% of the overall EU sales of antimicrobials for farmed animals and in aquaculture by 2030.

The revision of the FA Regulation, one of the actions of the strategy, will favour the placing on the market of FA having a positive effect on animal health by improving their physiological status, thus reducing the use of antimicrobials in animal farming. All public authorities responding to the PC and academia considered that the ban on the use of antibiotics in feed introduced by the FA Regulation plays an important role in preventing AMR. Literature shows the contribution of the EU's ban on antibiotics as FA in the global fight against antimicrobial resistance.[209]

The reduction of AMR threats to citizens, animals and the environment is still considered relevant by 26 MS authorities out of 27 and by 104 out of 111 other stakeholders.[210] The use of coccidiostats as FA in poultry does not pose any risk related to AMR. AMR is one of the aspects evaluated by EFSA in the authorisation process. A post-market monitoring plan is required to ensure that the authorisation of coccidiostats does not have unintended effects. The Commission's audits on official controls carried out by MS in feed, as well as the results of the monitoring of coccidiostats residues in live animals and animal products carried out by MS, showed an effective control of the use of coccidiostats. A substantial majority of stakeholders (other than MS authorities) also consider that the use of coccidiostats and histomonostats as FA is important to ensure health and welfare of poultry and rabbits (61 out of 71). In addition, their use is well adapted to current farming practices (65 out of 72) and effectively controlled (63 out of 70) (in all cases, excluding a significant number of respondents that did not answer as they did not have knowledge of the issue)[211]. Nearly all MS authorities consider that the use of coccidiostats and histomonostats as FA is important to ensure health and welfare of poultry and rabbits (24 MS authorities; no NCA disagreed) and that it

[209] ii FA Final Report _FCEC, page 112.
[210] vii Consultation Synopsis Report, page 14.
[211] vii Consultation Synopsis Report, page 9

is well adapted to current farming practices (20 MS authorities; 1 NCA disagreed) and effectively controlled (19 MS authorities; 2 MS authorities disagreed).[212]

4.1.2. 2. Simplifying and harmonise the FA authorisation system

A majority of MS authorities (24) and of other stakeholders (91%) consider this objective still relevant.

There is also a wide consensus amongst MS authorities and industry representatives that the authorisation process should be simple and predictable[213]. The simplification of the feed additive authorisation process, in comparison to the previous process under the Directive, is still considered relevant by 23 MS authorities out of 26, and by 89% of other stakeholders.[214] The authorisation process has been quite efficient in permitting the authorisation of an increasing number of additives over time. Nevertheless, some inefficiencies have been identified.

4.1.3 Set up clear/comprehensive rules for the authorisation and labelling.

For 97 % of stakeholders, clear rules for authorisation and labelling are still relevant[215]. There is a quasi- unanimous consensus between MS authorities and FeBOs on this matter. Although, in general, the FA Regulation provides clear rules on authorisation and labelling, some aspects lacked sufficient clarity and reduced the efficiency of the process.

Improving labelling was an essential element to ensure the proper use of FA and it is an objective that remains relevant. For 58% of stakeholders, the current labelling is informative along the feed chain and for 81% the labelling prevents misuse along the feed chain – the maximum doses and the species concerned are respected.[216]

As for worker safety, just over half of respondents considers that the information is clear and effective, while about a quarter considers that it is not, particularly amongst companies/business organisations, business associations, and EU citizens.

The information provided in the labelling is widely recognised as useful to prevent misuse of FA. Nevertheless, different elements may decrease the efficiency of the system: the obligation to indicate all the information on a physical label, the absence of labelling tolerances in premixtures, and the simultaneous implementation of the FA Regulation and CLP Regulation, in particular for premixtures of FA.

212 vii Consultation Synopsis Report, page 19
213 ii FA Final Report _FCEC, page 112
214 vii Consultation Synopsis Report, pages 14 and 22
215 vii Consultation Synopsis Report, page 15
216 vii Consultation Synopsis Report, pages 15 and 22

4.1.4 4. Ensuring rigorous risk assessment.

Providing a rigorous risk assessment of FA is still considered relevant by all the MS authorities responding to the survey and by 88% of other stakeholders.[217] A sound scientific assessment is the basis to ensure a high level of food and feed safety as well as to reinforce public health.

An extremely wide consensus about the current relevance of a rigorous risk assessment of FA emerged among all the categories of consulted stakeholders. The Farm to Fork Strategy stresses the importance of protecting health and safety in building fair, strong and sustainable food systems. The reliability of the EU risk assessment used as the basis for EU authorisations is considered by the FeBOs as a major advantage for fast-track registration in several third countries, particularly in SE Asia and in African regions. A survey carried out in six third countries showed that at least three third-countries consider the risk assessment and the technical data required in the EU applications as valuable elements for their own authorisation process[218]. The soundness of the risk assessment performed by EFSA is not questioned in the administrative reviews for EFSA's procedure and in the Commission's decisions based on the outcome of the risk assessment.[219] This objective is thus still relevant and it is the cornerstone for developing a more sustainable food system.

4.1.5 Improving FA control, traceability and enforcement rules.

Consensus on the matter is quasi-unanimous among MS authorities, and extremely wide among other stakeholders since 93 % of stakeholders consider that ensuring traceability of FA is still relevant.[220] *No significant criticism on the relevance of traceability emerged from the stakeholder consultation. Some manufacturers and business associations observed that other Regulations (especially the Feed Hygiene Regulation and the General Food Law) play an important role in ensuring traceability for FA.*

Improving FA control was one of the objectives that remains relevant. The validation of the method of FA analysis was one of the key measures introduced in the FA Regulation. Updating the method of analysis for the renewal is considered necessary for 22 MS authorities – while only one of them disagree. Other stakeholders do not have the same position: 23% agree that updating the method of analysis in the renewal of the authorisation is necessary, 21% do not have a position on this matter, and 38% do not agree. The different positions showed the relevance and the importance of having a method of analysis for control purposes, as well as the necessity to update such method when the authorisation is renewed, even if stakeholders do not

[217] vii Consultation Synopsis Report, pages 14 and 22
[218] ii FA Final Report _FCEC, page 133
[219] ii FA Final Report _FCEC, page 52
[220] vii Consultation Synopsis Report, pages 15 and 22

completely agree, as this entails additional costs for the renewal[221]. For a majority of MS authorities, the role of the EURL, which is in charge of the validation of the method of analysis, is still adequately defined in the Regulation.

Another element introduced in the FA Regulation is the possibility that EFSA decides, upon assessment, the establishment of a post-market monitoring plan (PMM) for nutritional, zootechnical, coccidiostats, histomonostats and additives consisting of, containing or produced from genetically modified organisms (GMOs). This traces or identifies unforeseen effects of the additives and contributes to control the effects of FA once they are placed on the market.

The PMM is always required for coccidiostats to allow the identification of unknown antimicrobial and coccidian resistance effects.

All the actions related to control (method of analysis and PMM) are still relevant to improve the control of FA. In general, the control performed by the MS is considered to be effective, except for imports.[222]

4.1.6 Addressing specific interests of pet owners and their animals

The FA Regulation recognised the specificities of pet food and the necessities associated with pet owners. The pet industry has been growing with an annual rate of 2.6% in the last 3 years.[223]

Europeans tend to humanise their pets. Pet owners try to find pet food that reflects their taste and are more concerned about the specific requirements of different life stages or situations; therefore, premium feeds and feed intended for particular nutritional purposes (e.g., support heart functions in dogs and cats) are very important in this market segment. This reality is supported by the increasing requests for authorisation of feeds intended to satisfy particular nutritional purposes for pets, as well as the availability of premium products in the pet food market.

Twenty-three (23) MS authorities considered this objective as relevant, whereas it was slightly relevant or irrelevant for three. It is important to note that one NCA highlighted that some additives such as colourants are used make the feed more attractive to pet owners by conferring organoleptic properties that are not present in the feed ingredients.

For other stakeholders, this objective is still relevant (63% of respondents), although some of them do not express any opinion, as this was not their area of expertise (34%).

[221] vii Consultation Synopsis Report, pages 15 and 22
[222] ii FA Final Report _FCEC pages 60 and 61
[223] FEDIAF European Facts & Figures 2019

We can conclude that this objective is still relevant and of growing importance, taking into account the increasing market for pet food.

4.1.7 7. Encouraging the placing on the market of FA which are innovative and efficacious.

There is a wide consensus for MS authorities (23 out of 26) and other stakeholders (94% of respondents) that this objective remains relevant.[224] Nevertheless, industry respondents largely claim that further efforts are required to promote the authorisation of innovative additives.

Innovation is regarded as the way to address societal needs by the industry, and in particular, by SMEs. Some needs have been identified in this regard: reduction of antibiotic use, improving meat quality, addressing animal welfare and conditions of breeding, improving sustainability, and reducing the environmental impact of livestock farming. For some MS authorities, there are aspects that reduce the capacity of innovation: outdated definitions, criteria for authorisation which are not adapted to address current needs (use in water for drinking, lack of endpoints (see glossary) to define efficacy, functional groups do not match with the expected functions). The EFSA guidance permit to propose endpoints, but the issue is that applicants do not have a validation from EFSA side whether those endpoints are appropriate or not. EFSA does not have the legal basis to give study-specific pre-submission advice as for instance EMA is doing.

While the FA Regulation has been in general efficient in permitting the authorisation of innovative additives, there is a consensus amongst stakeholders and MS authorities that innovation has not been sufficiently addressed by the FA Regulation.

4.1.8 8. Ensure that FA cannot be used to mislead consumers on the quality of food.

This objective aims at not misleading consumers on the quality of food of animal origin (e.g., a flavour that is not characteristic of such food).

For MS authorities, this objective is still relevant (22 out of 26); as for other stakeholders, 61% considered that this objective is still relevant, although 31% did not express any judgement. For those stakeholders who did not express a favourable opinion on the relevance of this objective (13%), different arguments supported their position. For instance, there is a weak or non-existing link between FA and the characteristics of food of animal origin, and consumers do not have any specific knowledge or understanding on the role that FA play and how they can modify the organoleptic characteristics of food of animal origin.[225]

This objective is still relevant for all stakeholders.

[224] vii Consultation Synopsis Report, pages 15 and 22
[225] ii FA Final Report _FCEC, page 114

4.2 ARE THERE NEW NEEDS/PROBLEMS EMERGING SINCE THE FA REGULATION WAS ADOPTED?

For 16 MS authorities (out of 27) and for 66 % of other stakeholders, there were new needs that emerged since the Feed Additive Regulation was adopted.

Amongst the new needs identified in the surveys, very few could be regarded as genuine new needs. Improving the sustainability of animal farming using innovative FA was one new need identified. The FA Regulation contained several aspects related to the sustainability of livestock farming, such as protection of animal welfare or protection of the environment. Nevertheless, the Feed Additive Regulation did not encompass the broad concept of sustainability which can be regarded as a new need partially addressed in the FA Regulation.

Claims was another of the new needs identified. The FA producers[226] ask for better coherence along the feed chain.

Claims are authorised for feed materials and compound feed, but not for FA. The only possible claim in FA is the claim related to the function performed by the additive following the corresponding authorisation. MS authorities noticed that this limited approach created different interpretations of the labelling rules by stakeholders. Claims are useful to communicate some benefits of the feed additive and to differentiate and highlight an innovative product. This is also applicable to premixtures of FA.

The industry supports the approach followed in the Feed Marketing Regulation: the person responsible for the labelling provides, at the request of the competent authority, scientific substantiation of the claim, either by reference to publicly available scientific evidence or through documented company research.

Several business stakeholders and some MS authorities refer to the environment and animal welfare issues as “new needs”, even though they were considered in the existing FA Regulation. They spotted those issues as not sufficiently addressed in the Regulation. For some respondents (some business stakeholders and some MS authorities), animal welfare and the environment were regarded as broadly related to the concept of sustainability and hence considered as new needs. Other MS authorities or business stakeholders considered that greater emphasis should be put on the environment and animal welfare issues, although they were not able to identify the environmental benefits of using FA.[227]

4.3 HOW WELL IS THE FA REGULATION ADAPTED TO SUBSEQUENT TECHNOLOGICAL OR SCIENTIFIC ADVANCES?

[226] FEFANA contribution to the PC

[227] ii FA Final Report _FCEC, pages 115-116

Several aspects are related to the capacity of the FA Regulation to adapt to scientific and technological progress: the existing definitions, the criteria for authorisation, and the authorisation procedure that requires allocating additives within pre-established categories and functional groups.

The results of the stakeholder survey showed that the Regulation was not considered totally suitable to address scientific and technological progress. For the suitability of the definitions, respondents were divided with a slight majority (44 out of 108) finding them not to be suitable (compared to 39 that consider them to be).

As for the criteria for authorisation, the majority against the suitability of the Regulation was more evident, since 28 out of 44 respondents considered that those criteria are not relevant nowadays (13 considered them still relevant).[228]

For most MS authorities, the Regulation is suitable to address the scientific and technological progress, but a few MS authorities expressed concerns about the definitions (3 MS authorities) and the criteria for authorisation (2 MS authorities).[229]

In the PC, a small minority (18%) of respondents consider that the Regulation is sufficiently flexible to adapt to new scientific and technical developments, while 38% of respondents disagree. Public authorities and academia (only one respondent) fully supported the suitability of the FA Regulation to adapt to scientific and technical developments. As for FeBOs and their organisations and associations, 38% of respondents consider the Regulation to be sufficiently flexible, especially among business associations (41%) and companies/business organisations (52%).

The arguments raised by those who disagree with the suitability of the FA Regulation can be summarised as follows:

- science and technology evolve faster than the Regulation to permit timely adaptation to new challenges.
- efficacy assessment of new products with a new mode of action included in the EFSA guidance is not fully reflected in the conditions for authorisation (Article 5) of the Regulation (no functional group is allocated to that function, or the requirements of the category in which the additive is located do not match the actions performed by the additive, e.g. additives intended to have benefits on the environment or animal welfare have to demonstrate an improvement of the performance);
- definitions not adapted to the state of the art of the FA sector.
- the establishment of new functional groups to allocate new additives takes a long time.

4.4 HOW RELEVANT IS THE FA REGULATION TO ADDRESS CURRENT SOCIETAL CHALLENGES?

[228] vii Consultation Synopsis Report, page 22
[229] vii Consultation Synopsis Report, page 22

One of the questions posed in the PC was the consideration of societal needs for the authorisation of FA. Just under half (49%) of the participants considered societal needs were taken into account, compared to 25% who thought they were not. Citizens were more inclined to indicate that societal factors are not sufficiently taken into consideration (8 responses out of 16 citizens that responded).

Innovation in the area of FA is seen as a tool to satisfy societal expectations. The development of new products (especially by SMEs) is considered to be important in order *to address evolving societal needs, in terms of further reducing the preventive use of antibiotics, improving meat quality, addressing animal welfare and conditions of breeding, improving sustainability, and reducing the environmental impact of livestock farming*.[230]

It is important to note that despite the efforts to consult a wider range of stakeholders, such as consumers, animal welfare organisations and environmental organisations that may contribute to give visibility to other societal expectations, it was not possible to have their contribution.[231]

The Farm to Fork Strategy is framed in the European Green Deal and aims at addressing comprehensively all the challenges of sustainable food systems.

The Farm to Fork Strategy introduces in a very explicit manner the importance of sustainable food systems and the social aspects of food products. It recognises the social dimension of reducing food loss and waste, the social benefits that a sustainable food system may bring, the increasing attention that people pay to social issues, such as concerns about antimicrobials, pollutants or food additives, the social impact that the production of commodities may have in third countries, the protection of health in workers and the social aspects of food products (labelling, claims or food information). FA are part of the food chain since they are used in the production of food of animal origin. They may have an impact on the wellbeing and health of pets and farmed animals, and their use may have an impact on consumers, workers and the environment. There are several aspects related to social expectations that should be considered concerning FA:

- supplying affordable, healthy and nutritious food in the face of a growing world food demand.
- ensuring sustainable management of livestock farming, natural resources and climate action.
- contributing to a balanced territorial development of the EU's rural areas and their communities.

Currently, the concept of 'sustainability' has not yet been defined, nor the criteria determining to what extent food is 'sustainable'. However, the concept encompasses various elements of environmental, social and economic nature, such as climate change mitigation, animal welfare, use of resources, reduction of waste, healthy diets and food affordability. In this context, FA play a role in improving the sustainability of food systems.

[230] vii Consultation Synopsis Report, page 30
[231] ii FA Final Report _FCEC, page 23

The accomplishment of the multiple objectives of sustainable livestock farming requires policy interventions that consider all the elements intervening in the process.

The role of FA to provide affordable food is very limited, but FA contribute to a better use of resources and to an increase in the performance of animals, reducing production costs. Farmers may use FA to reduce losses in the production by keeping animals in good health status. FA permit better assimilation of feed materials that can be closer to the farmer and contribute to reducing waste in livestock production by facilitating the preservation of crop products during storage.

The effects on animal welfare by improving the physiological status of animals, reducing the stress due to adverse climate conditions, or facilitating the transition to different production stages in the life cycle are additional factors that reduce losses in animal farming.

All these positive benefits will reduce the production costs/losses for farmers, modestly contributing to providing affordable food of animal origin.

The protection of natural resources is very relevant in animal farming, mainly due to the effect that livestock farming may have on the terrestrial and water compartments (freshwater, groundwater and marine water). Furthermore, the protection of biodiversity through the protection of non-target plant and animal species, microbes, and protozoans is an additional aspect to consider. Over the years, the environmental risk assessment has been improved to cover all these elements and to prevent FA or their metabolites from harming the soil, water and biodiversity. The option of PMM is considered in the case that negative effects of the feed additive on the environment could not be undoubtedly excluded.

FA may have some positive effects on the environment, for instance:

- reducing the potential contamination of livestock farming by reducing phosphorous and nitrogen excretion from animals, therefore, reducing risks of soil leaching and water eutrophication.
- Reducing manure deposition using additives that change feed composition, decrease soil and water contamination, and cut down emissions related to the storage and reuse of manure as organic fertilizer.

Many authorised additives having positive effects on the environment or on animal welfare have been authorised under other functional groups not related to these actions (e.g., amino acids as nutritional additives). The FA Regulation has not been effective in establishing authorisation criteria that match these effects and has contributed to reduce innovation in this area.

The contribution of FA to provide healthy and nutritious food is difficult to establish, although there are some elements that can be considered. Healthy aspects of food of animal origin are linked to minimum levels – or null, if possible –of pathogens, toxins, contaminants and other agents that can cause foodborne disease. Food production must also minimize the use of antimicrobials.

FA have not successfully improved the nutritional patterns of feed of animal origin, e.g., reducing saturated fats in monogastrics, or bio fortification of foods of animal origin. The FA Regulation does not have any functional group to allocate those additives. In any case, this aspect deserve full attention as those actions may entail negative effects on animal health that need to be seriously considered.

FA are assessed in order to prevent the presence of any substance or microorganism that may have a negative impact on consumer's health. FA also contribute to minimise the use of antimicrobials in animal farming.

As regards climate actions, FA can contribute to reducing greenhouse emissions of methane and nitrous oxide and have other environmental benefits by mitigating the negative effects of livestock production.

Factors linked to the agricultural production are better management of soil and water quality, or an improvement of biodiversity. The effects of FA described above may have a moderate impact on this objective to ensure an attractive environment for farmers and citizens in rural areas.

5 ADDED VALUE

5.1 WHAT IS THE ADDED VALUE OF REGULATING THE AUTHORISATION AND PLACING ON THE MARKET OF FA AT THE EU LEVEL?

This question seeks to determine if a harmonised procedure at the EU level is perceived as achieving better results than a national level authorisation process or labelling requirements, trying to understand whether harmonisation is perceived as being more advantageous than non-harmonisation and whether an EU level approach is still warranted.

All the parties consulted (citizens, MS authorities, industry and other private stakeholders) unanimously agreed that there is an added value in having a harmonised authorisation procedure.[232]

The reasons supporting this statement were:

- it facilitates intracommunity trade.
- it is economically advantageous for the scientific assessment in order to avoid duplication of assessment by different countries.
- it reduces "authorisation tourism" (FeBOs make an application to which they perceive as the least rigorous MS).

[232] vii Consultation Synopsis Report, page 17 and 24

The harmonisation of labelling rules is relevant to the placing on the market of FA. There was also a wide consensus amongst all consulted parties (citizens, MS authorities, industry and other private stakeholders) that harmonisation at the EU level is more advantageous than having different provisions in MS. This harmonisation reduces complexity, costs and facilitates EU trade.

Finally, there is also a wide consensus that the EU level of intervention in the feed additive area is still warranted and needs to continue.

5.2 ARE THERE ANY NEW ASPECTS NOT HARMONISED THAT REQUIRE AN EU INTERVENTION?

During the consultation process, the following aspects on which EU harmonisation is further requested, were identified:

- a definition of the concept of "preparation";[233]
- the establishment of labelling tolerances of FA in premixtures.
- the labelling of additives only intended for export.
- the labelling of workers' safety provisions. The authorising Regulations do not set labelling provisions for workers' safety but lay down requirements for this purpose, e.g., use of masks for breathing protection. Some MS requested to include on the label of additives and premixtures, those workers' safety requirements set out in the authorising Regulations. This creates different interpretations by MS on how to convey to the label those requirements and, consequently, can create market distortion within the EU and a burden for FeBOs.

EVALUATION MATRIX

Note: the data refer to the period 2004-2017. If the period is extended, then, it will be indicated.

Column headings		Sources	
FeBOs	Feed business FeBOs		
SH sv	Stakeholder survey	FAR	FA register[234]

[233] vii Consultation Synopsis Report, points 3.3.2.5 and 3.4.2.2.
[234] FA Register (FAR) :

- Reference 1: Register December 2006 (rev. 7)
- Reference 2: Register December 2017 (rev. 259) - since the implementation up to 31/12/2017

NCA sv	NCA survey	OJ	Official Journal of the EU-EURLEX
Int	Interviews	SAN-F	SANTE-F (reports or interviews; as applicable)
CS	Case studies	SAN-DB	DG SANTE database on authorisations
Lit	Literature review	EFSA	European Food Safety Authority
COM	Commission indicated they will provide data	EU-RL	EU reference lab for FA
		RSF	RASSF
		ECJ	European Court of Justice
		EPO	European Patent Office
		NCA-req	Specific request of DG SANTE to MS authorities
		TC-sur	Third country survey to be requested through SANTE international relations unit
		FEF	FEFAC data
		RM	RM associates report

Evaluation criterion: Effectiveness – EQ1

1.1To which extent did the efficacy assessment of FA ensure that FA are effective? How do the achievements compare to Directive 70/524? 1.2 To which extent did the safety assessment of FA ensure safeguarding human and animal health and the environment? How do the achievements compare to Directive 70/524/EEC? 1.3 What elements of the authorisation procedure of FA are key drivers for its effectiveness and what elements hinder its effectiveness? Why? 1.4 What role does the risk assessment versus other provisions play in meeting the objectives of the Regulation? Which other key

provisions/actions foreseen by the Regulation play a key role?

1.5 To which extent did the risk assessment allow sound decision-making?

1.6. To which extent did coccidiostats and histomonostats produce the best results for poultry/rabbits farmers (health and welfare ensured, adaptation to farming practices, control)?

Legislation concerned

Regulation (EC) No 1831/2003

Evaluation question 1:

To what extent did the Regulation meet its objectives (e.g., ensure that FA placed on the market are efficacious, safe and ensure the protection of animal health and welfare, human health and the environment)?

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
1.1 FA categories for which efficacy was not at all or partially evaluated are now fully evaluated.	1.1.1	Listing of such categories					RM; FEF	FAR	• Technological additives, silage additives; substances for reduction of the contamination of feed by mycotoxins; and hygiene condition enhancers. • Amino acids (an important category of nutritional additives) and most zootechnical additives (enzymes, gut flora stabilisers) and other zootechnical additives. In total 339 additives authorised. Reference: ii FA Final Report _FCEC pages 25-26).
	1.1.2	Number of applications for						SAN-DB	432 applications: 132 for article 4(new additives) and 300 article 10(2) re-evaluation

		authorisation (separate data for Article10 and 4) (Ref 2)							(ii FA Final Report _FCEC, page 26)
	1.1.3	Number of EFSA opinions (separate data for Article10 and 4) (Ref 2)						EFSA	EFSA opinions: – 102 for out of 116 FAD applications for article 4. – 231 out of 301 FAD applications for Article 10(2) Reference: ii FA Final Report _FCEC, pages 26 and 27)
1.1 FA for which efficacy/safety was not demonstrated under Regulation 1831/2003 (Art 10) were withdrawn from the market	1.1.4	Number of FAs notified under Art 10 for which no application was introduced at expiry date						SAN-DB; FAR	1,743 additives Reference: ii FA Final Report _FCEC, page 27
	1.1.5	Number of FA withdrawn or partially withdrawn (Ref. 2)						SAN-DB	120 additives partially withdrawn or totally withdrawn during the assessment. ii FA Final Report _FCEC, page 27
	1.1.6	Number of Com Regulations requiring withdrawal of FA from market (Ref 2)						SAN-DB; OJ	8 Commission Regulations period 2004-2017 Reference: ii FA Final Report _FCEC, page 27 footnote 50
1.1 New FA for which efficacy/safety is not demonstrated and the authorisation is denied, or the application withdrawn (Art 4).	**1.1.7**	Number of additives for which new authorisation was not granted because efficacy/safety was not demonstrated						SAN-DB	6 additives Reference SANTE WEB
	1.1.8	Number of FAs applications withdrawn or partially						SAN-DB	89 requests for total or partial withdrawal Reference: ii FA Final Report _FCEC, page 28

		withdrawn (Article 4) (Ref. 2)							
1.1 FA on the EU market are considered efficacious	**1.1.9**	Positive opinion of FA users	X	X					63 users* out of 59 have positive opinion. * Manufacturer of FAs/premixtures; manufacturer of compound feed; manufacturer of both FAs and compound feed. SH SURVEY- ix Accompanying document: survey and PC results[235], page 11.
1.2 FA categories for which safety was not at all or partially evaluated are now fully evaluated	1.2.1	Listing of such categories Ref1					FEF	FAR	**Sensory** additives (certain colourants; nearly all flavouring compounds); and **nutritional** additives (all vitamins, except A and D) were not assessed by the Directive Safety was **partially assessed for**: **amino acids** and **zootechnical** additives (enzymes, gut flora stabilisers). In the case of **coccidiostats and histomonostats**, antimicrobial resistance and Maximum Residue Levels were not fully addressed by the Directive. Reference: ii FA Final Report _FCEC, page 29.
	1.2.2	Number of applications for authorisation of such categories (separate data for Article10 and						SAN-DB	458 applications: 251for article 4(new additives) and 207 article 10(2) re-evaluations Reference: ii FA Final Report _FCEC, page 30

[235] This document is part of the study conducted by the Food Chain Evaluation Consortium ('FCEC') and contains raw data of the surveys. This document is not disclosed as the main conclusions from the surveys are included in the document "vii Consultation Synopsis Report".

<table>
<tr><td rowspan="4"></td><td></td><td>4) Ref 2</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>1.2.3</td><td>Number of EFSA opinions of such categories (separate data for Article10 and 4) Ref 2</td><td></td><td></td><td></td><td></td><td></td><td>EFSA</td><td>EFSA opinions:
- 202 for out of 233 FAD applications for article 4.
- 151 out of 208 FAD applications for Article 10(2)

Reference: ii FA Final Report _FCEC, page 30</td></tr>
<tr><td>1.2.4</td><td>Number of additives of such categories Ref 1</td><td></td><td></td><td></td><td></td><td></td><td>SAN-DB; OJ</td><td>1,136 additives
Reference: ii FA Final Report _FCEC, page 30</td></tr>
<tr><td rowspan="3">1.2 FA on the EU market are safe for humans(users/workers) of additives, animals and the environment</td><td>1.2.5</td><td>POSITIVE opinion of FA users</td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td><table><tr><td>Safety for</td><td>SH Survey:</td></tr><tr><td>Animals</td><td>46 out of 62</td></tr><tr><td>Workers</td><td>55 out of 62</td></tr><tr><td>Environment</td><td>49 out of 63</td></tr><tr><td>Consumers</td><td>65 out of 63</td></tr></table></td></tr>
<tr><td>1.2.6</td><td>Positive opinion of NCAs</td><td>X</td><td>X</td><td></td><td></td><td></td><td></td><td><table><tr><td>Safety for</td><td>SH Survey:</td><td>NCA Survey</td></tr><tr><td>Animals</td><td></td><td>27 out of 27</td></tr><tr><td>Workers</td><td></td><td>21 out of 27</td></tr><tr><td>Environment</td><td></td><td>24 out of 27</td></tr><tr><td>Consumers</td><td></td><td>26 out of 27</td></tr></table>Reference: ix Accompanying document: survey and PC results, page 56</td></tr>
<tr><td>1.2.7</td><td>Number of RASFF notifications involving FA/ compared to total feed notifications</td><td></td><td></td><td></td><td></td><td>RSF</td><td></td><td>During the period 2004-2020, the RASFF notifications showed the level of compliance as for the presence of FA or their residues in food of animal origin. 82 notifications – out of 16,634 – were linked to the presence of unauthorised additives or a high level of residues. These represented 0.5% of the total number of notifications.</td></tr>
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									As regards the notifications for the period 2004-2017 out of a total of 517 notifications on feed only seven relate to FA and five to premixtures. These represented 2.3´% of the total number of feed notifications. Reference: ii FA Final Report _FCEC, page 31 and further elaboration by the Commission
1.2 Pet food additives are safer and efficacious	1.2.8	Number of additives authorised for pet animals not evaluated for safety or not sufficiently evaluated) Ref. Register December 2017 (rev. 259)						SAN-DB; FAR	1,017 additives Reference: ii FA Final Report _FCEC, page 32
	1.2.9	Number and extent of revisions of EFSA scientific guidance for the assessment of pet food.			X		EFS		EFSA set up scientific guidance for applicants regarding the assessment of additives intended for use in pet food, including clear and comprehensive data requirements. The aim has been to reduce the need for testing on pets by implementing other testing strategies, and to take into account the potential hazards of additives for pet owners. EFSA first adopted the "Guidance on the assessment of additives intended to be used in pets and other non-food-producing animals" on 1 February 2011, updated on 18 January 2012. Following an analysis by EFSA of the need for a further update of the guidance documents (EFSA, 2016), new guidance documents were adopted; all aspects related to pets were included in these documents, thus replacing the specific guidance document for pets. Currently, five guidance

									documents covering different aspects of the EFSA assessment have specific provisions and/or apply for additives intended for pet animals. Reference: ii FA Final Report _FCEC, page 32
	1.2.10	Identification of specific provisions in the legislation addressed to pet food (Regulation (EC) No 1831/2003 and Regulation (EC) No 429/2008 – compared to Directive 70/524							Furthermore, the assessment is based on specific requirements for additives destined to non-food producing animals. More generally, compared to the previous legislation and guidelines, the current regulatory framework introduced specific provisions on FA for pet food in view of the specificities of this segment: • The Regulation established a definition of 'pet animals and other non-food producing animals', while in the 1970 FA Directive these two types of animals were included in one definition as "pet animals" except fur animals that were considered separately. • The specific requirements for pet animals and farmed non-food producing animals were allocated in a specific Annex. As regards the environment, (EC) No 429/2008 provides for the obligation to perform Phase I of the assessment to determine if there is a significant environmental effect. Non- food producing animals are exempted from Phase II assessment unless there is scientifically-based evidence of a concern. In that case, the exemption does not apply. For farmed non-food producing animals, the FA Regulation and Regulation (EC) No 429/2008 were not sufficiently accurate but the EFSA guidance clarified that those animals are considered as food producing animals for the

									environmental assessment. Therefore, this aspect needs to be clarified in the Regulation. • Specific requirements were set out for assessing certain safety aspects of additives destined to pet animals, as well as to non-food producing animals more generally. Studies on chronic toxicity, reproductive toxicity, mutagenicity and carcinogenicity are mandatory while in the 1970 FA Directive those studies were dispensed with the presentation of other data. This was not sufficient to ensure complete full safety. • The full demonstration of the efficacy of FA destined to pet animals is required under the Regulation. • Specific statistical power limits became a requirement. The statistical power limits minimised the possibility to lead to an erroneous indication of safety/efficacy, for experiments that are not sensitive enough to detect adverse effects. This ensures that the protocols for studies met the objectives. Reference: ii FA Final Report _FCEC, page 32
	1.2.11	Positive opinion of respondents	X	X					With regard specifically to pet food additives on the EU market, nearly all respondents agree that they are efficacious and safe for pet animals (74 and 76, respectively, out of 78 respondents; excluding, respectively 28 and 30 respondents that did not provide an answer as pet food is not relevant for their organisation) As regards specifically pet food additives on the EU market, nearly all respondents agree that they are efficacious and safe for pet animals (3

									MS authorities neither agreed nor disagreed that they are efficacious). Reference: ii FA Final Report _FCEC, page 32
1.2 FA are safe for consumers	**1.2.12**	Positive opinions of respondents	X	X					Consumers 103 out of 111- SH SURVEY Reference: ix Accompanying document: survey and PC results, pages 12 and 13 26 out of 27 NCA SURVEY Reference: ix Accompanying document: survey and PC results, page 56
1.3 The information to be provided by applicants in their dossier is fit to assess efficacy (e.g., enables EFSA to assess efficacy in an effective manner)	**1.3.1**	EFSA feedback in interviews			X				– "The information provided by applicants in their dossier to EFSA is fit to assess safety and efficacy" – "Fitness of information for efficacy assessment" – "Dossiers of applicants are complete" Reference: ii FA Final Report _FCEC, pages 34, 35 and 37
1.3 The information to be provided by applicants in their dossier is fit to assess safety (e.g., enables EFSA to assess safety in an effective manner)	**1.3.2**	EFSA opinion in interviews			X				– "The information provided by applicants in their dossier to EFSA is fit to assess safety and efficacy". – "Fitness of information for safety assessment" – "Dossiers of applicants are complete" Reference: ii FA Final Report _FCEC, pages 34, 35 and 37
1.3. Dossiers of applicants are complete	1.3.3	Dossiers fully corresponding to requirements at the submission (completeness check) Two different						EFSA	All of the 392 FAD applications submitted under Article 4(1) (new authorisations), and all of the 398 FAD applications submitted under Article 10(2) (reauthorisations), for which EFSA received a mandate from the Commission during the 2004-17 period passed the completeness

		calculations one for Article 4 and one for Article 10. Ref 2							check The completeness check is completed within 31 working days for: nearly half of dossiers submitted during 2004-17 under Article 4(1); and, one third of dossiers submitted under Article 10(2). For the remaining dossiers, the completeness check is carried out within 41 working days. Reference: ii FA Final Report _FCEC, page 37
	1.3.4	Dossiers pending due to missing/incomplete information during the assessment Two different calculations one for Article 4 and one for Article 10. Ref 2						EFSA	A substantial majority of dossiers (78% of applications submitted under Article 4(1); and, 88% of applications submitted under Article 10(2)), are pending due to missing/incomplete information. Reference: ii FA Final Report _FCEC, page 37
1.3. EFSA's opinions are issued within legal deadlines (6 months from valid application)	1.3.5	Dossiers within 6 months deadline Two different calculations one for Article 4 and one for Article 10. Ref 2						EFSA	20% of all opinions issued under Article 4(1) and 12% of all opinions issued under Article 10(2) In the case of Article 4(1) applications, 20% of EFSA opinions were adopted within ≥6-9 months 12% within ≥9-12 months and 21 % within ≥12-18 months. In the case of Article 10(2) applications, 13% of EFSA opinions were adopted within ≥6-12 months and 16% within ≥12-18 months The average period to issue the opinions was 27 months for Article 4(1) applications and 36 months for Article 10(2) applications. Reference: ii FA Final Report _FCEC, page 38
1.3 Commission's decisions are issued	1.3.6	Commission's decisions are issued						SAN-DB	37% and 31´% of authorisations were granted for Article 4(1) and Article 10(2), respectively

within reasonable deadlines (6 months from publication of EFSA opinion and publication of the Regulation)		within reasonable deadlines. Two different calculations one for Article 4 and one for Article 10. Ref 2							within six months of receipt of the opinion Reference: ii FA Final Report _FCEC, page 39
1.3 Applicants can ask questions and receive answers to complete their dossiers within reasonable deadlines	1.3.7	Positive opinion among FeBOs	X						Applicants did not complain of any significant delays in receiving answers More than 82% of FeBOs consider that applicants have sufficient time to complete dossiers when EFSA requires so Reference: ii FA Final Report _FCEC, pages 39 and 40
1.3 Commission acts within required deadlines on renewal (Art. 14) of authorisation	1.3.8	Number of cases with automatic extension of authorisation due to absence of Commission decision			X	X		X	Period 2017-2021 for 65 applications for renewal 64 applications out of 65 required extension A large number of renewals are expected for the following years based on the expiry date for their authorisation (2023: 32, and 2024: 56). Reference: SANTE database
	1.3.9	Timelines in the evaluation period: average time, number of clock stops, average of clock stops						EFSA	Period 2017-2021 for 65 EFSA applications The average time for the assessment period is 314 days, which exceeds the normal period of 6 months in 134 days. The number of clock stops for the 65 applications was 91 times with an average for application of 1.4 times. Only 5 out of 65 applications did not require to ask for additional information and to stop the clock. Reference: SANTE internal calculations
1.3 The simplified procedure for FAs already authorised in	1.3.10	Positive opinion among FeBOs applicants	X	X	X	X			A majority of applicants indicating that procedure does not work well (23 out of 42). A large number of don’t know responses.

food works well									Reference: – ii FA Final Report _FCEC, page 40 – vii Consultation Synopsis Report, page 10 – ix Accompanying document: survey and PC results, page 15
1.3 The procedure to extend authorisation to minor species works well	1.3.11	Positive opinion among FeBOs	X	X	X	X			A majority of applicants 18 out of 42 indicated that does not work but there was a high number 13 that do not know or do not have experience. FCEC Final Report, EQ 1.3., judgement criteria: "The procedure to extend authorisation to minor species works well" Reference: – ii FA Final Report _FCEC, page 41 – vii Consultation Synopsis Report, page 10 – ix Accompanying document: survey and PC results, page 16
1.4 Imports of FA are adequately controlled	**1.4.1**	Positive opinion among FeBOs and MS	X	X	X				A majority of respondents (40 out of 62 – excluding 17 'do not know' responses) consider imports of FA into the EU to be adequately controlled, while 14 respondents believe they are not 11 MS authorities consider imports of FA into the EU to be adequately controlled, and 14 MS authorities consider them to be partially controlled. The main concerns raised by the latter MS authorities are linked to the absence of an EU list of third countries from which FA can be imported and the lack of CN codes Reference: – ii FA Final Report _FCEC, page 45 – vii Consultation Synopsis Report, pages 16

									and 23.
	1.4.2	Number of RASFF notifications involving FA imported/ compared to total feed notifications					RSF		See 1.2.7
	1.4.3	Results of multi-annual national control plan and annual reports of MS (2011-2015) include control of imports of FA.		x				NCA-REQ	Data provided by authorities in 16 MS indicate that, each year during the 2012-15 period, an average 3,182 controls were performed in 2,979 registered establishments producing FA/premixtures (total for the 16 MS), i.e., average control frequency is just over once per year per establishment. There are some differences between MS, with 8 of the 16 MS having a control frequency higher than once per year. During controls performed in 17 MS in the period 2012-15, an average 7,980 samples were taken for analysis each year and 24,000 analyses were conducted. The conformity of samples and the conformity of analyses each year was generally high (median: 96-98%, for both). For imports, 11 MS authorities consider imports of FA into the EU to be adequately controlled, and 14 MS authorities consider them to be partially controlled. The main concerns raised by the latter MS authorities are linked to the absence of an EU list of third countries from which FA can be imported and the lack of CN codes. The controls performed by MS authorities shows a good level of control and high conformity of samples.

									Infringements and penalties have been established in all MS, but they diverge. Additional information. Reference: – ii FA Final Report _FCEC, pages 44, 45, 46 and 47.
1.4 MS have put in place adequate sanctions to address non-compliance.	**1.4.4**	Number of MS have established provisions on sanction and infringements		X					All MS Reference: Reference: ii FA Final Report _FCEC, pages 44, 45, 46, and 47.
	1.4.5	- Administrative or criminal – sanctions? - Minimum and maximum sanctions - Are sanctions enforced?		X					No data
1.4 Fraudulent/non-compliant FA are rapidly identified and withdrawn from market	**1.4.6**	Number of sanctions imposed for FA and feed additive premixtures Results of multi-annual national control plan and annual reports of MS Period 2011-2015		X				NCA-REQ	"No sufficient information on sanction enforcement due to different administrations involved that difficult to collect data Reference: ii FA Final Report _FCEC, pages 44, 45, 46, and 47.
	1.4.7	Number of cases where products have been withdrawn from the market		X					No sufficient information on sanction enforcement due to different administrations involved that difficult to collect data Reference: ii FA Final Report _FCEC, pages 44, 45, 46 and 47.
1.4 FA-EURL can effectively carry out its tasks (storing of	**1.4.8**	Number of validation reports					EU-RL		2004-19, the EURL issued 628 validation reports FCEC Final Report,

samples, validating method of analysis etc…)									Reference: ii FA Final Report _FCEC, page 48.
	1.4.9	Feedback from FA-EURL	X	X					The role of the EU-RL is adequately defined in the Regulation according to the majority of respondents (61 out of 92). The role of the EU-RL is adequately defined in the Regulation according to 22 MS authorities; only one NCA disagreed, commenting that the EU-RL competence could be enhanced, e.g., to support the national laboratories with the development and/or execution of analysis, as well as the MS authorities whenever needed Reference: vii Consultation Synopsis Report, pages 11 and 21
1.4 Conditions and restrictions imposed on the marketing of FAs are respected by FeBOs.	**1.4.10**	Ms control of the respect of the authorisation conditions and restrictions of FA in feed. Results of multi-annual national control plan and annual reports of MS Period 2011-2015						NCA-REQ	See 1.4.3, 1.4.4 and 1.4.5
	1.4.11	Number of non-compliance/ number of total controls. Of samples taken. Results of multi-annual national control plan and annual reports of MS Period 2011-2015						NCA-REQ	The conformity of samples and the conformity of analyses each year was generally high (median: 96-98%, for both). Reference: ii FA Final Report _FCEC, page 45

1.4 Post-market monitoring plans enable to identify negative impacts and to take corrective actions	**1.4.12**	Number of negative impacts identified by the monitoring plans						SAN-DB	The sole monitoring plan prepared is under EFSA assessment (date 17-11-2021) Reference: SANTE database
1.4 Labelling requirements are fit for purpose	**1.4.13**	Positive opinion among respondents	X	X	X				A majority of respondents (53 out of 111) consider labelling requirements to be fit for purpose, although, a large number of respondents (45), particularly manufacturers of FA and premixtures, followed by manufacturers of compound feed and FA do not agree with this statement. Most MS authorities (19) consider labelling requirements to be fit for purpose, only 3 MS authorities disagreed, and the remaining 3 MS authorities did not provide a definite answer. A key comment by the MS authorities who disagreed or did not provide a definite answer is that the labelling could be modernised, with certain indications potentially provided in a separate document (other than the label). Reference: vii Consultation Synopsis Report, pages 11 and 21
	1.4.14	Outcome of case studies				X			Reference: vi Case studies ii FA Final Report _FCEC, page 44
1.4 Innovative FA can be placed on the market	**1.4.15**	Positive opinion among respondents	X	X	X				Just over half of respondents believes that the Regulation does not make it easier to place new innovative additives on the market when compared with the former 1970 FA Directive. 12 MS authorities believe that innovative FA can be placed on the market, 4 MS authorities

									disagreed, and 9 MS authorities did not provide a definite answer. The cost and complexity of the authorisation procedure are the main issues raised, especially for new FA for which functional groups or performance criteria (endpoints) may not be readily available. Reference: ii FA Final Report _FCEC, pages 47 and 48 vii Consultation Synopsis Report, pages 14 and 21.
	1.4.16	Number of new categories/functional groups in the Regulation and added after the Regulation came into force					X		Period 2004-2021 New categories: none Functional groups: 4
	1.4.17	Number of applications and authorisations of FA for new categories (REF 2 total and per year)						SAN-DB; FR	Zootechnical additives category and functional group ‘other zootechnical additives’: 61 out of 79 applications and 28 out of 35 authorisations were in this category (functional group 4(d)). The other two innovative groups are: ‘reduction of contamination by mycotoxins’ (12 applications and 6 authorisations) and ‘hygiene conditions enhancers’ (6 applications and 1 authorisation). In May 2021 there were 206 zootechnical additives authorised, of which 90 were digestibility enhancers, 86 gut flora stabilisers and 34 other zootechnical additives. Reference: ii FA Final Report _FCEC, page 47

1.4 The Regulation contributes to reduce the likelihood of antimicrobial resistance	1.4.18	Number of antibiotics banned as growth promoters					OJ		22 of which 4 were banned in 2006 Reference: SANTE WEB
	1.4.19	Number of additives authorised that are alternatives to the use of antibiotics (gut flora stabilisers + other zootechnical additives) (Ref1)						SAN-DB; FR	Period 2004- May 2021 Gut flora stabilisers:84 Other zootechnical additives:15 Reference: SANTE database
	1.4.20	The assessment of additives examines any effect on AMR							Regulation 429/2008 includes the evaluation of antimicrobial effects for FA, this led to the withdrawal or denial of 5 additives in the period 2004-2021
	1.4.21	Use of antibiotics/reduction AMR					x		Mainly documents from EFSA, EMA, ECDC, WHO and ESVAC
1.5 EFSA opinions are not challenged (administrative reasons)	1.5.1	Cases of request of administrative review (Art. 19)/cases favourable to EFSA/total opinions (Ref 2)						SAN-DB	During the period 2004-17, there have been five requests for administrative review under Article 19. In all five cases, the Commission decided that EFSA's scientific opinion was validly adopted, and the allegations put forward by the requestor were dismissed. Reference: ii FA Final Report _FCEC, page 52
1.5 Commission decisions are not challenged	**1.5.2**	Cases at the court of Justice/ cases ruling in favour of the European Commission (Ref 2)					ECJ		During the period 2004-17, there has been one case at the Court of Justice of the EU, which ruled in favour of the European Commission: • T-201/13 ("Toyocerin"): judgment of the General Court of 21 May 2015 (Rubinum v. Commission). Application for annulment of Commission Implementing Regulation (EU) No 288/2013 of 25 March 2013 concerning the

									suspension of the authorisations of the preparation of Bacillus cereus var. toyoi (NCIMB 40112/CNCM I-1012). The action was dismissed by the Court (i.e., ruling in favour of the Commission). Reference: ii FA Final Report _FCEC, page 52
	1.5.3	Comments from third countries in the WORLD Trade Organisation (SPS Agreement) (Ref 2)					WTO		Comments in one notification. USA and India have submitted comments to the WTO - under the SPS Agreement. These comments were made in the context of SPS notification G/SPS/N/EU/190 of 6 February 2017 concerning the (draft) Commission Implementing Regulation suspending the authorisation of ethoxyquin as a feed additive for all animal species and categories. The EU replied to those comments on 15 May 2017 and the act was adopted by the Commission on 7 June 2017. Reference: ii FA Final Report _FCEC, page 52
1.5 EFSA has enough and adequate information to give an informed opinion	**1.5.4**	Number of inconclusive opinions/ total opinions (Ref 2)						EFSA	An estimation is made concluding that around 15 % of EFSA opinions are inconclusive. Reference: ii FA Final Report _FCEC, page 53
1.5 Elements other than risks related (social, economic, environmental) are enough taken into account by Commission	**1.5.5**	Positive opinions of respondents	X	X	X				FeBOs negatively perceived whether the authorisation took into account legitimate factors (58% of negative responses and only 24% of positive responses). Most MS authorities (16) believe that elements other than safety and efficacy (e.g., social, economic, and environmental) are sufficiently taken into account by the Commission during authorisation (e.g., transitional periods to adapt to changes)

									Reference: vii Consultation Synopsis Report, pages 10 and 19 ii FA Final Report _FCEC pages 53 and 54
	1.5.6	Authorisations taking into account legitimate factors (Ref. 2)						OJ-EURLEX	159 Regulations took into account legitimate factors, in the majority of the cases economic aspects linked to the cost of labelling for existing products that were re-evaluated
1.6 Use of coccidiostats and histomonostats as FA is important to ensure health and welfare of poultry and rabbits	**1.6.1**	Positive opinions from respondents	X	X	X				Nearly all MS authorities consider that the use of coccidiostats and histomonostats as FA is important to ensure health and welfare of poultry and rabbits (24 MS authorities; no NCA disagreed), the remaining few MS authorities did not provide a definite answer (i.e., neither agreed nor disagreed with the above statements. Reference: vii Synopsis Report, page 19
1.6 The use of coccidiostats and histomonostats as FA is well adapted to current farming practices	**1.6.2**	Positive opinions from respondents	X	X	X				Nearly all MS authorities consider that the use of coccidiostats and histomonostats as FA are well adapted to current farming practices (20; 1 NCA disagreed); the remaining few MS authorities did not provide a definite answer (i.e., neither agreed nor disagreed with the above statements. Reference: vii Consultation Synopsis Report, page 19
1.6 The use of coccidiostats and histomonostats as FA is effectively controlled	**1.6.3**	Positive opinions competent authorities		X	X				Nearly all MS authorities consider that the use of coccidiostats and histomonostats as FA is effectively controlled (19; 2 MS authorities disagreed); the remaining few MS authorities did not provide a definite answer (i.e., neither agreed nor disagreed with the above statements. vii Synopsis Report, page 19

		Positive opinions of FeBOs	X		X				A substantial majority of respondents, including farmers, also consider the use of coccidiostats and histomonostats to be important as FA to ensure the health and welfare of poultry and rabbits (61 out of 71); are well adapted to current farming practices (65 out of 72) and effectively controlled (63 out of 70) vii Consultation Synopsis Report, page 9

Primary sources			**Secondary sources**
Surveys	Yes		1. SANTE data base 2. FA Register (FAR) 3. OJ Publications 4. EFSA data base 5. Literature review 6. MS Multi-Annual National Control Plans (MANCPs) and Annual Reports (2011-15) 7. SANTE-F Audits Reports 8. FEFAC/Eurostat statistics 9. RASFF data base 10. EFSA guidance 11. FA-EURL data base 12. EURLEX/Court of Justice database 13. WTO data base 14. RM Associates Report
Interviews	Yes		
Case studies	Yes		
SANTE request to MS	Yes		

Methods for analysis.
The aspects covered by this EQ are multiple due to its wide, high-level scope (i.e., reference to the overall objectives). Hence the large number of sub-questions and indicators feeding into the analysis. The analysis involves the identification of the relative contribution of key provisions of Regulation (EC) No 1831/2003, in terms of meeting objectives. The key provisions are: authorisation procedure (safety assessment; efficacy assessment; decision-making); labelling; other provisions/ actions (imports; sanctions; role of EURL etc.). This requires:

- Quantitative analysis of available data from the various secondary sources, including at first level, official data sources (e.g., FAR, SANTE database, EFSA, MANCPs, ECJ decisions etc.) and at second level, unofficial data/estimates (e.g., FEFAC; RM associates).
- Stakeholder consultation analysis.
- Intervention logic analysis.
- Benchmarking against the achievements of Directive 70/524/EEC
- Analysis of the use of coccidiostats and histomonostats for poultry/rabbits

Approach to answering the evaluation question and potential limitations

The analysis will be based on:

- The FA register (FAR), SANTE database and EFSA database will be used to the extent possible to provide quantitative data to some indicators. This will include some quantitative benchmarking against the baseline, where such data exists.
- Some additional literature sourced will be used to provide additional data/ information. For the Multi-annual National Control Plans the period chosen is 2011-2015 (latest complete plan).
- Stakeholder consultation analysis will be used to feed into indicators for which quantitative data do not exist and/or their experience and opinions are important.

The large number of indicators is inevitable in view of the wide scope of this EQ; it allows a comprehensive approach to answering the EQ. On the other hand, this also poses some limitations.

Limitations are mainly posed in terms of data availability: some of the data required to feed certain indicators (in relation to number of additives) are not systematically recorded in SANTE database and it is not certain that all parameters are possible to establish the data required by the indicators.

Evaluation criterion: Effectiveness – EQ2

Evaluation question 2: How did the Regulation contribute to develop a competitive and innovative EU feed additive industry?
2.1 How does the authorisation procedure for FA affect the competitiveness between EU and non-EU feed business FeBOs? 2.2 What factors support or hinder the competitiveness? 2.3 Which Non–EU countries recognise the EU authorisation procedure to allow companies to directly enter their market and why?
Legislation concerned Regulation (EC) No 1831/2003

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
2.1 The Regulation has encouraged the development of innovative FAs to cover new needs of the livestock sector	**2.1.1**	Number of additive authorisations of such types of FA since 2004 (e.g., number of authorisation for new functional groups)					RM; FEF	FAR	Zootechnical additives category and functional group 'other zootechnical additives': 61 out of 79 applications and 28 out of 35 authorisations were in this category (functional group 4(d)). The other two innovative groups are: 'reduction of contamination by mycotoxins' (12 applications and 6 authorisations) and 'hygiene conditions enhancers' (6 applications and 1 authorisation). FCEC Final Report, EQ 1.4., judgement criteria: "Innovative FA can be placed on the market. Reference: ii FA Final Report _FCEC, page 49
2.1 The Regulation has encouraged the development of new FAs to replace growth promoters.	2.1.2	Number of additives of such types of FA since 2004 (e.g., number of authorisation for new functional groups).					RM; FEF	FAR	Period 2004- May 2021 Gut flora stabilisers: 84 Oher zootechnical additives:15 Reference: SANTE database
2.1 Identification of major factors affecting competitiveness of the FA	**2.1.3**	Identification and qualification of costs for major cost categories (inputs, capital, labour)	X		X				Reference: ii FA Final Report _FCEC, pages 61 and 62

industry (EU vs non-EU FeBOs)	**2.1.4**	Relative importance of non-monetary factors (technical and regulatory barriers)	X		X			x	Limited circulation for FA only intended for export Reference: ii FA Final Report _FCEC. Insufficient clarity of certain provisions creates a burden for FeBOs: – Definition of FA/ versus biocidal products Reference: ii FA Final Report _FCEC, pages 104-105 – Use of additives in drinking water – Labelling tolerances of FA in premixtures – Absence of definition for preparations Reference: ii FA Final Report _FCEC, page 110 – No clear status for recommended levels. Commission experience derived from insufficient clarity in the Regulation. They can be indicated only as a labelling provision. Reference: ii FA Final Report _FCEC, page 107 – Simultaneous application of CLP and FA legislation for worker safety provision in premixtures. Reference: ii FA Final Report _FCEC, page 102 and vi Case studies) – No possibility to use digital tools for labelling of FA (all information must be in a physical label. Reference: ii FA Final Report _FCEC, page 94 and vi Case studies) – No sufficient clarity on how to modify authorisations not linked to an authorisation holder
2.1 Impact of the Regulation on relative competitiveness of the FA industry (EU vs	**2.1.5**	Identification of impacts and qualitative assessment.	X		X				Authorisation costs Labelling costs Other regulatory requirements not linked to the FA legislation; labour costs, environmental requirements etc. Reference: ii FA Final Report _FCEC, Judgement criteria pages 63-66

non-EU FeBOs)	**2.1.6**	Relative contribution of regulatory costs to total cost of production or price.	X		X				The total costs of authorisation as % of total regulatory costs and/or as % of total cost of production of this product or product price were not possible to estimate. Two companies indicated that the total regulatory costs stemming from the Regulation, of which the main component are the authorisation costs, are estimated at 2% and less than 5%, respectively, of the cost of production for this product. This estimation was based on a 10-year authorisation period. As a comparison, another company that is a major FA and compound feed manufacturer indicated that regulatory costs stemming from all legislation are 15% of all costs of the entire company's animal nutrition portfolio. According to all companies, the costs of authorisation in the EU are considerably higher than in non-EU markets due to the high level of requirements in safety and efficacy studies. One company indicated that registration costs for this enzyme in non-EU countries vary from country to country, but in their experience costs range between €500 and €3,000 per dossier and each application process takes between 2 months and up to 18 months to be completed. Reference: vi Case Studies, page 7
2.1 Significance of FAs in the economic activity of FA FeBOs	**2.1.7**	% Of sales of FA in the overall turnover	X						According to industry data, large and medium size companies seem to be less specialized in FA than smaller companies: FA account for less than half of the turnover for 70% of large companies and 60% of medium size companies as compared to some 30% of small companies[236]. The same survey results also indicate a total investment on R&D ranging from 26% to 14% of the turnover for the small and the large companies, respectively,

[236] Source: FEFANA (2018) Caveats: there is an over-representation of large companies that responded to the FEFANA survey. Of the total FEFANA membership (94 companies), 59 replied to the survey. Of these, 32 are large (according to the EU classification of 'large company', based on annual turnover > €50 million; but 26, based on annual balance sheet > €43 million); 11 are medium and 8 small, despite the fact that SMEs account for >60% of members.

									compared to 8% for the medium-size businesses. Reference: ii FA Final Report _FCEC, page 65
	2.1.8	% Of volume /value of fa in relation to feed	X						In 2020, FA had a turnover of €15 billion. The compound feed production in 2019 amounts to 55.6 billion euros, FA represented around 25% of the value of compound feed in that year.
2.2 Relative importance of imports on the EU market	**2.2.1**	Importance of imports on EU market by category of FA.	X		X				Imports from non-EU countries play an important role, across all categories. In one commercially 'major' group (trace/micro minerals) only products from non-EU countries are present on the EU market. The main countries of origin differ per functional group, but across categories, six non-EU countries are identified to play a major role (USA, China, India, Brazil, Japan and Canada), with the USA and China the most commonly identified. Reference: ii FA Final Report _FCEC, page 18 Other additives imported in large extend are amino acids and vitamins. Reference Feed info insights Limitations: there are no official statistics to quantify the imports.
2.2 Relative importance of EU exports to non-EU markets	**2.2.2**	Importance of EU production destined for exports (volume & value; qualitative)	X		X				Although, no figures are presented in this report it is a known fact that significant quantities of premixtures, mineral feeds and some compound feeds are exported to for instance the Middle East. Reference Report RM associated Some additional information in 2.2.3 No more information is available as there are no official statistics available.
2.2 Some FAs not authorized in the EU are still produced for	**2.2.3**	Identification of non-authorised FA that are now exported outside the EU	X	X	X				Although no data exist on the actual volume/value of exports of NAFA products, several of the consulted companies (including SMEs), indicated that the export of NAFA products is an important segment of their business. This option, in compliance with applicable requirements in non-EU countries, allows EU-

exports.		(volume & value)							based companies to produce for non-EU countries in cases where the authorisation/approval process in the non-EU country is less burdensome than in the EU. This enables EU companies to maintain their global competitiveness; particularly SMEs producing a diverse product range, for which the burden of authorisation costs can be particularly important in view of their small scale of business. Reference ii FA Final Report _FCEC, page 67 The sole country having data is Spain that have 30 establishments registered for the activity of producing FA or premixtures intended for export, with approximately 4,000 t of those FA and premixtures in 2021 from 304 consignments. As there are not statistics on the production of FA and premixtures, the reference could be the production of compound feed in the EU, as this production is proportionate to the production of FA and premixtures that are incorporated in compound feed. An estimation based on the information from Spain is that this market may have a volume around 18,000 t. This is an estimation that cannot be confirmed statistically. Reference: Commission data based on Spanish information.
2.2 R&D invested to develop new FAs is increasing	**2.2.4**	Trend in share of R&D on FA in total R&D of companies active in the FA industry	X		X	X			Despite the extensive consultation undertaken for the study, there is no indication (quantitative or qualitative) of the R&D trend by EU-based companies active in the FA sector. It is therefore not possible to establish with certainty whether R&D investment to develop new FA has increased or decreased since the Regulation came into force. As already indicated under EQ2.1, the share of turnover earmarked to R&D varies between companies, largely depending on whether FA are a core sector of their business. Furthermore, some industry respondents indicated that, to curtail costs, they are increasingly investing or considering investing in non-EU based R&D facilities, or sub-contracting R&D activities (including trials) to facilities based in

									non-EU countries. Therefore, the trend in the value of R&D spending within the EU as such may not be capturing the actual total R&D effort. As explained in the authorisation case study (Annex 4), the start-up costs can be a significant barrier, particularly for SMEs (depending on the financial support a company may have). In the first few years of the investment the company needs to invest in the R&D and authorisation costs involved with no revenue. Hence, due to the considerable costs involved, it is rare for a company to have more than one product going through an application for authorisation process at any time. Ultimately, each company has to make a strategic decision based on its structure and funding support, e.g., to start with an application for authorisation covering fewer species to save on costs (as this requires fewer studies) and expand to more species when possible Reference: ii FA Final Report _FCEC, page 68
	2.2.5	Number of patents by EU vs non-EU FeBOs (REF 30/04/2019)					EPO		The number of patents applications for FA submitted to the European Patent Office doubled compared to the previous period (207 applications were received between 2004 and 2019 compared to 104 applications between 1979 and 2003). The share of EU applicants versus non-EU applicants remained almost the same for the two periods (44% EU applicants and 56% non-EU applicants). Reference: European Commission. Elaborated with the data of the European Patent Office. The data were updated up 2019
2.2 Extent to which the authorisation	**2.2.6**	How important have generic authorisations been for SMEs	X		X	X			No significant difference in terms of the cost: benefit balance can be seen between SMEs and non-SMEs. However, the required upfront investment (R&D and authorisation costs) is high, and

procedure more specifically affects SMEs		placing the products on the market?							access to finance to support this is generally an issue for smaller companies, when these are not part of larger entities[237]. For these reasons, SMEs - particularly the smaller companies - either tend to specialise in a few FA or a few categories/species of animals to reduce costs and develop a niche, or tend to rely on generic, non-holder-specific authorisations to save on costs. Therefore, to the extent that SMEs rely on the non-holder-specific authorisations, their drawbacks as a disincentive to apply for such authorisation may penalise more SMEs. Reference: ii FA Final Report FCEC, pages 88-89. The presence of SMEs in the FA/premixtures sector is important. As highlighted under EQ2.1, 60% of company members of FEFANA are SMEs. SMEs are actively involved in the authorisation process. For instance, 14 of the 38 respondents to the stakeholder survey that filed an application for a new authorisation under Article 4 are SMEs (of which, four are part of a larger company). Similarly, 9 of the 24 respondents that filed an application for renewal of authorisation are SMEs (of which, 2 are part of a larger company). Furthermore, of the 45 companies that responded to the survey, 25 have placed one or more generic FA on the EU market; of these, 11 are SMEs (of which, 3 are part of a larger company) and 14 are large companies. (SH SURVEY) As explained in the authorisation case study (Annex 4), the start-up costs can be a significant barrier, particularly for SMEs (depending on the financial support a company may have). In the first few years of the investment the company needs to invest in

[237] See Annex 4, authorisation case study.

									the R&D and authorisation costs involved with no revenue. Hence, due to the considerable costs involved, it is rare for a company to have more than one product going through an application for authorisation process at any time. Ultimately, each company has to make a strategic decision based on its structure and funding support, e.g., to start with an application for authorisation covering fewer species to save on costs (as this requires fewer studies) and expand to more species when possible. According to the industry, SMEs are active in the sector of holder-specific FA, such as zootechnical additives, but they tend to focus authorisation requests to a specific category of animals rather than all animal species, to reduce the costs of R&D and authorisation (case study on authorisation, Annex 4). Generic (non-holder-specific) authorisations are also important for SMEs placing their products on the EU market, as they do not have to bear the costs of an application. With the exception of zootechnical additives, for which the holder of the authorisation benefits from marketing exclusivity for the whole period of authorisation, most other additives are non-holder-specific. Reference: ii FA Final Report FCEC, pages 68-69.
2.3 Extent to which the EU authorisation process is recognized in non-EU countries (China, USA, Canada, Australia, Japan, Brazil, Argentina and	**2.3.1**	Identification of countries...			X	X	RM	TC-sur	Of the six countries that responded to the survey, two countries (Chile and Canada) recognise substantial parts of the EU authorisation procedure, largely because their approaches are relatively aligned. In particular China indicated that technical data of FA authorised in the EU are being used as a reference for the technical assessment of these substances by the authorities in China. Reference: ii FA Final Report FCEC, page 70.

Chile)									
2.3 Extent to which the EU authorisation system is attractive to non-EU FeBOs	**2.3.2**	Identification of applicants from third countries. Ref 2					SAN-DB		It is not possible to establish with certainty whether the EU authorisation procedure is attractive to non-EU operators. In particular, it is not possible to identify with sufficient detail from the Commission internal database the operators from non-EU countries involved in a request for authorisation, as they usually have an EU representative that acts as an applicant. Commission data (2004-2019) identified several non-EU company applicants, but not an exhaustive list. This information indicates that companies based in at least seven non-EU countries have requested an authorisation to place their products on the EU market. These countries are: the USA (13 companies), Japan (8), China (3), India (2) and Australia (2), Switzerland (1), Turkey (1) and Korea (1 These figures however do not reflect the level of attractiveness of the EU authorisation system for non-EU operators as many multinational companies have a direct access to the EU market through their subsidiaries located in Europe. Reference: ii FA Final Report FCEC, page 71
2.3 Major differences in the authorisation procedure in non-EU countries (China, USA, Canada, Australia, Japan Brazil, Argentina and Chile) compared	**2.3.3**	Time from application to authorisation					X	TC-sur	The time taken to process an application for authorisation can vary considerably from one country to another, from a few months (in the case of three countries) to about a year (in the case of two countries). Only in one country, the procedure can take up to several years. Reference: ii FA Final Report FCEC, page 71
		Identification of major differences in safety requirements					X	TC-sur	Authorisation process: All countries have a process in place for feed additive approval, which includes a scientific risk assessment. When compared to the EU authorisation process, the components of the process followed in non-EU countries have generally lighter requirements, which significantly vary per

with the EU (duration, safety requirements etc…)									country. One of the six countries appears to be the most aligned to the EU since all requirements for safety and efficacy assessment need to be met. It is followed by three countries. In most cases, these impose similar requirements as in the EU. The remaining two countries generally apply requirements based on the product's process monograph. One of these also applies more detailed requirements on safety, namely the identification and characterisation of the additive (e.g., purity, presence of impurities, contaminants, etc.), but no specific tests on the target animals. Furthermore, in all countries, applicants can submit additional information during the assessment process, and, with the exception of one country, they can hold meetings before formally submitting the application, mainly for clarification purposes. Reference: ii FA Final Report FCEC, page 71

Primary sources		**Secondary sources**
Surveys	Yes	1. SANTE data base 2. FA Register 3. Literature review 4. FEFAC/Eurostat statistics 5. RM Associates Report 6. European Patent Register 7. Company data *(to the extent available from external provider – arranged by SANTE*)
Interviews	Yes	
Case studies	Yes	
SANTE request to MS	Yes	
TC survey (via SANTE)	Yes - tbc	

Methods for analysis.

- Stakeholder consultation analysis
- Benchmarking against third countries authorisation procedure (China, USA, Canada, Australia, Japan, Brazil, Argentina and Chile), descriptive statistics, and analysis of company data (to the extent available).

Approach to answering the evaluation question and potential limitations

The identification of major factors affecting competitiveness of FA FeBOs in the EU and in main competing countries (China, USA, Canada, Australia, Japan Brazil Argentina and Chile) aims to provide an overview for comparison purposes, to identify the relative importance of the Regulation's impact on competitiveness of FA FeBOs. If available, company data will be used to assess the major economic factors impacting competitiveness in relation to costs and innovation.

Evaluation criterion: Efficiency – EQ3

3.1 What are the compliance costs and administrative costs linked to the requirements of the Regulation (labelling, monitoring, etc.…)?
3.2 To what extent are the risk assessment and the risk management process sufficiently cost-effective, efficient and flexible (e.g.: in terms of procedural timeliness)?

Legislation concerned
Regulation (EC) No 1831/2003

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
3.1. Benefits justified costs	3.1.1.	**Costs (direct and indirect) for FeBOs (applicants and others) including authorisation, labelling, monitoring**	**X**		**X**	**X**		X	Total direct costs on average per year €62,700,000 €1,100,000 per authorisation €216,000per renewal In terms of labelling costs, the direct costs for producers of FA are negligible however for premixtures these reach in average between €80,000 and €223,000 per plant per year. These costs include costs of labels, translation services, design and printing of labels and reformulation when required. For pet food manufacturers costs occur for a few cases when an additive is withdrawn, and the transitional period is shorter

									than the period of expiry of the feed. The estimations for re-labelling compound feeds are €1 million for 2,000 references. For food-producing animals, the costs are negligible The main costs analysed are additional costs of labelling when label changes due to regulatory changes: adaptation of packaging and/or labels/labelling process. This includes labelling, packaging and storage costs, stock management of labels/final packaged products, label/packaging waste. These costs include both time required (staff time; staff category; unit costs) and the costs of materials and equipment. In terms of labelling costs, the direct costs for producers of FA are negligible however for premixtures these reach in average between €80,000 and €223,000 per plant per year. These costs include costs of labels, translation services, design and printing of labels and reformulation when required. For pet food manufacturers costs occur for a few cases when an additive is withdrawn and the transitional period is shorter than the period of expiry of the feed. The estimations for re-labelling compound feeds are €1 million for 2,000 references. For food-producing animals, the costs are negligible. Indirect costs Operators indicated that indirect costs are derived from the time periods incurred during the authorisation process in the two steps: EFSA evaluation (stop the clock) and during the Commission decision for the authorisation.

									Operators were not able to estimate these indirect costs in monetary terms. The costs are around €2,000 for disposal of labels for premixtures applying the usual transitional period. The compliance costs can be estimated between €24,000 and €40,000 per product and €13,500 in labels for premixtures when the change affects an important additive widely used and the transitional period is shorter than the usual transitional period. However, the occurrence of this possibility is very low. References: ii FA Final Report _FCEC, pages 75-80 vi: Case studies, pages 5-11 viii Costs methodology, pages :7-9
	3.1.2	Costs for EFSA			EFSA			EFSA	Total costs on average per year are 1,900,000 During the period of 2014-2018 EFSA has processed 346 applications, corresponding to 69.2 applications per year on average at an estimated cost of €27,450 per application (new and re-evaluation), €15,900 of which are internal staff costs. References: ii FA Final Report _FCEC, pages 82-83vi:
	3.1.3	Costs for COM			COM			X	In total the costs on average per year are €756,000 Considering that the application is the most relevant step that triggers all the different actions, an estimate of the staffs' costs per application for new authorisations and renewals amounts to €13,400. The number of applications during the period 2012-2017 increased efficiency in the applications management. The number of meetings of the SCoPAFF has been reduced but

									their duration has been extended, resulting in a stable number of days of meetings per year. This has permitted savings in travel expenses, interpretations and administrative support of meetings. In case of change of authorisation holder, the costs are estimated at €13,400 per implementing Regulation. For the standard authorising Regulations, the costs are €22,400 per Regulation. For the Commission during the period 2004-2017, the costs of Regulations changing the authorisation holder amount to €375,200 which accounts for €26,800 per year (2 Regulations per year). Reference: ii FA Final Report _FCEC, pages 81-82 viii Costs methodology, page 19
	3.1.4	Costs for EURL			EU-RL			EU-RL COM	The total costs for the EURL per year on average are €684,000. During the period of 2014-2018 EFSA has processed 346 applications, corresponding to 69.2 applications per year on average at an estimated cost of €27,450 per application (new and re-evaluation), €15,900 of which are internal staff costs. Reference: ii FA Final Report _FCEC, pages 80-81 viii Costs methodology, page 10
	3.1.5	Costs for MS CAs (controls)		X		X		X	The total costs the EURL per year on average are €2,884,000 It is estimated that each MS CAs spent on average €74,000 per year for enforcement and administrative tasks (‘a’ and ‘c’). Several MS could not provide estimates of time spent on

									legal/administrative obligations and controls for FA and premixtures as this information was available for all feed in general but does not distinguish additives and premixtures from other feeds. To allow for the differences in the estimates provided by MS, the staff time has been calculated for all the tasks ('a', 'b' and 'c') as an average across those MS that provided complete data (14 MS). It is estimated that each MS CAs spent on average €74,000 per year for enforcement control tasks (b) over the 2016-17 period. In total the costs for each MS CAs are €103,000 (29,000+74,000) euros per year on average which accounts to €2,884,000 per year for all EU MS. ii FA Final Report _FCEC, pages 83-84 viii Costs methodology, page 10
	3.1.6	Benefits for FBOs (applicants and others) – mainly qualitative	X		X	X		X	The qualitative benefits for producers of FA and premixtures and feed compounders are: – Minimise disposal or destruction of products by additives permitting the preservation of the quality of additives and premixtures (e.g., an additive such as vitamin A must be placed on the market in combination with an antioxidant to prevent oxidisation) and by the pre-market the safety assessment and comprehensive labelling rules;(see ii FA Final Report _FCEC, see pages 77 and 78). – Good reputation of the EU companies as the products that they place on the market are safe and efficacious and have carried out a comprehensive safety and efficacy evaluation. – Easy access to non-EU markets (ii FA Final

									Report _FCEC, see page 64). – High variety of additives that allows to satisfy the market expectations in terms of innovation, presentation of FA (e.g., liquid, pellets, etc.) or specific requirements for certain types of animals (e.g., specific additives of lactating sows or piglets). Reference FA Final Report _FCEC, see pages 64, 77, 78, 84 and 86.
	3.1.7	Benefits for farmers - qualitative	X		X		FAO RM	X	The qualitative benefits for farmers can be summarised as follows: Reduction of losses resulting from animal diseases or AMR. Availability of efficacious and innovative FA More balanced diets for animals. Better use of resources. Increase of animal performance or of animal resilience to heat or stress. Contribute to reduce the negative impact of livestock farming on the environment (phytases, amino acids and methane reduction). Protect the farmers' economic interests as additives are efficacious for the intended purpose. Reference: ii FA Final Report _FCEC, page 85.
	3.1.8	Benefits for pet owners – mainly qualitative	X		X		FFDIAF	X	The qualitative benefits of pet owners and pets can be summarised as follows: Reduce the occurrence of diseases or intoxications FA are safe for pets. As an example, the authorisation of titanium dioxide in 2021, mainly used in cats and dogs, was denied as it was mutagenic and carcinogenic. Reduce the occurrence of spreading AMR to

									pets and pet owners. □ Protect the pet owners' economic interests as additives are efficacious for the intended purpose. □ Availability of efficacious and innovative FA that satisfy the necessities of pets. Reference: ii FA Final Report _FCEC, page 86
	3.1.9	Benefits for animal welfare and animal health – mainly qualitative	X		X		FAO RM		The qualitative benefits for animal health and animal welfare are related to the improvement of the physiological status of the animals and consequently animal health and welfare: – The necessities of animals for vitamins or trace elements can be satisfied via FA preventing diseases or deficiencies in animals. Animal welfare may be compromised for example if animals do not take sufficient levels of vitamin D: lameness, difficulty walking, a tendency to sit on their haunches will occur in growing pigs.[238] – Prevent the occurrence of coccidiosis in poultry one of the most important parasitic diseases. – Prevent the occurrence of intoxications with undesirable residues in feed from animal origin. – Prevent the occurrence of diseases as promotes a desirable gut ecosystem by giving to the animals' beneficial species of microorganisms.

[238] The pathology of vitamin D deficiency in domesticated animals: An evolutionary and comparative overview. Elizabeth W Uhl. Int J Paleopathol. 2018 Dec; 23:100-109. doi: 10.1016/j.ijpp.2018.03.001.

									– Prevent the occurrence of antimicrobial resistance via for example of microorganisms that improve the beneficial flora in the gut. Also, the safety evaluation to prevent any AMR effect of the additives contribute to this aim. In this regard, in 2015, the authorisation of *Bacillus toyonensis* (NCIMB 14858 was denied as posed a risk for the spread of genes coding for resistance to tetracycline and chloramphenicol, which are antibiotics of human and veterinary importance. – Improve animal welfare: some amino acids that reduce nitrogen excretion will contribute to reduce ammonia in urine and improve animal welfare of animals as ammonia may increase the respiratory stress.[239] ii FA Final Report _FCEC, page 86

[239] Acute and prolonged effects of ammonia on haematological variables, stress responses, performance, and behaviour of nursery pigs. E. von Borell, PhD; A. Özpinar, PhD; K. M. Eslinger; A. L. Schnitz; Y. Zhao, PhD; F. M. Mitloehner, PhD. EVB: Institute of Agricultural and Nutritional Sciences, Martin-Luther-University Halle-Wittenberg, Halle, Germany. AO: Western Institute for Food Safety and Security, University of California, Davis, California. KME, YZ, FMM: Department of Animal Science, University of California, Davis, California.

	3.1.10	Benefits for human health – mainly qualitative	X		X				The qualitative benefits for human health are: Prevent the occurrence of diseases or intoxications derived from the consumption of feed from animal origin, for example the establishment of maximum residue levels for a colourant astaxanthin prevent that residues of this colorant may affect the consumer health. Prevent the occurrence of AMR: indirectly by contributing to reduce treatments with antibiotics in animals and directly by the evaluation of additives to prevent that they transfer AMR to animals, the environment, and to humans, for example the denial of authorisation in 2012 of one microorganism as silage additive "Lactobacillus pentosus (DSM 14025)" and two microorganisms in 2014 "*Pediococcus pentosaceus* (NCIMB 30068) and *Pediococcus pentosaceus* (NCIMB 30044)". Those additives spread resistance to antibiotics used in humans. Prevent the occurrence of occupational diseases derived from the manipulation of additives. It was the case of the denial of formaldehyde for poultry in 2019. This additive was carcinogenic for workers. Reference: ii FA Final Report _FCEC, page 86
	3.1.11	Benefits for the environment – mainly qualitative	X		X				The environmental benefits are derived from the risk assessment performed and the labelling rules. The environmental assessment performed for additives used famed animals (food and no-food producing animals) ensures that they do not have adverse effects on the environment. Labelling requirements are also important to ensure a proper

									use; for example, if a maximum limit of an additive is established to prevent any adverse effect on the environment, the indication of this level on the label will facilitate that operators will use the additive properly along the feed chain. In addition, FA may have qualitative environmental benefits that may be summarised as follows[240]: – Better use of resources reduces environmental footprint of animal sourced products, considering that more than 50% of the animal production footprint is related to feed ingredients (Wideman et al., 2012). Feed materials that are generated at local level may increase their quality by reducing the indigestible nutrients (e.g., fibers), thereby increasing either their energy, amino acids and/or mineral values or by ensuring the level necessary of essential additives. Enzymes, amino acids and microorganisms may facilitate those actions. – Modification of emissions that have negative impact on the environment thus reducing pollution and mitigate climate change impacts There are three main sources of emissions from animal production: ✓ Enteric methane emissions ✓ Gaseous emissions from manure storage (ammonia and nitrous oxide)

[240] Environmental performance of FA in livestock supply chains. Guidelines for assessment. FAO 2019.

									✓ Nutrients, minerals, feed additive metabolites concentrations in the manure Livestock systems, particularly ruminants, contribute to greenhouse gas emissions, and particularly in the form of enteric methane. A review of mitigation options for enteric methane from ruminants showed some of the effective strategies including the increase forage digestibility for which some additives have been proved efficacious. The authorisation of a specific additive reducing the methane emission in milking cows is an example of this mitigation effect for reducing the impact on climate change. Manure management, including storage, handling, and field application can be a source of emission of nitrous oxide and ammonia. Methane emissions from manure accounts for 12-41% of total agricultural CH4 emissions for most countries (Chadwick et al., 2011) and emissions depend on the storage duration, temperature and manure composition. The modification of the physic-chemical characteristics of the manure through FA enables in particular the reduction of ammonia and N_2O emissions. The reduction of pollution: for example, the addition of phytase to feed results in a lower excretion of the phosphorous in manure, contributing to reduce eutrophication in waters. Eutrophication (a

									reduction in dissolved oxygen in water bodies caused by an increase of mineral and organic nutrients that increase algae production). – Reduction of feed losses. Feed production is one of the most impacting aspects of animal production. Hence, it is important to ensure that the large majority of the feed ingredients and feeds produced are delivered to the animal. For this purpose, the use of FA such as antioxidants, preservatives, and silage additives provide tools to reduce feed losses along the feed chain and contribute to reduce the environmental effect of livestock production. Reduction of feed loses have positive effect on the environment as the disposal or destruction of products may require, for example, consumption of energy to treat the feed for those purposes. Reference: ii FA Final Report _FCEC, pages 86-87
3.1 Extend to which the cost/benefit ratio discriminates against SMEs	**3.1.12**	Costs/benefits ratio for SMEs compared to costs/benefits ratio for non-SMEs. Qualitative.	X		X				No significant difference in terms of the cost: benefit balance can be seen between SMEs and non-SMEs. However, the required upfront investment (R&D and authorisation costs) is high, and access to finance to support this is generally an issue for smaller companies, when these are not part of larger entities. For these reasons, SMEs - particularly the smaller companies - either tend to specialise in a few FA or a few categories/species of animals to reduce costs and develop a niche, or tend to rely on generic, non-holder-specific

									authorisations to save on costs. Therefore, to the extent that SMEs rely on the non-holder-specific authorisations, their drawbacks as a disincentive to apply for such authorisation may penalise more SMEs Reference: ii FA Final Report _FCEC, page 90.
3.1 Transitional measures for existing products reduce the administrative costs for labelling	**3.1.13**	Number of additives (existing products Article 10(2) authorized compared with number of additives having transitional measures to adapt to labelling requirements Ref1						SAN-DB; FAR	All additives authorised under Article 10(2) "existing products "have transitional measures Beyond the risk assessment outcome (EFSA opinion on safety and efficacy of the additive), other legitimate factors including social and economic considerations, need to be taken into account by the Commission/PAFF in the final decision. This is for example manifested in the case of reauthorisations by the provision of sufficient transitional periods for pre-existing products (under the former legislation), to allow the market to adapt to a change in the authorisation status of an additive. According to the Commission, for Article 10 authorisations, it can be considered that 100% of the opinions take into account legitimate factors such as costs, as all opinions issued provide transitional periods for adaptation to the labelling rules. However, it is difficult to evaluate whether legitimate factors are taken into account for Article 4 authorisations. Reference: ii FA Final Report _FCEC, page 53
3.2 The procedure for placing new FA on the market (Art 4) is	**3.2.1**	% Of positive opinions (Costs/benefits ratio)	X		X	X			Only 12% of respondents find the cost of applications for getting a feed additive authorised in the EU market is proportionate to the benefits.

considered efficient									
3.2 The procedure for renewing an authorisation (Art 14) is considered efficient	**3.2.2**	% Of positive opinions (Costs/benefits ratio)	X		X	X			66% of FeBOs stakeholders ix Accompanying document: survey and PC results page 56
3.2 Majority of stakeholders consider the procedure for authorisation (article 4) does not need to be modified significantly	**3.2.3**	% Of positive opinions	X	X	X	X			68% NCAs 32% of FeBOs stakeholders ix Accompanying document: survey and PC results pages 56 and 60
3.2 The different deadlines foreseen by the Regulation in the authorisation process are proportionate	**3.2.4**	% Of positive opinions	X	X	X	X			74% NCAs 67% of FeBOs stakeholders ix Accompanying document: survey and PC results page 56 and 60
3.2 The deadlines applied in practice (Art 4) do not significantly	**3.2.5**	Time from application to authorisation (average, min) (Ref 2)						SAN-DB	Although the minimum period involved has been significantly lower in some cases (minimum 224 days), the average period across all applications during 2004-17 has been 3.3 years (1,218 days) Reference: ii FA Final Report _FCEC, page 91

deviate from the legal deadlines									
3.2 The procedure to modify an authorisation when the authorisation holder changes do not imply too much burden.	**3.2.6**	Number of Regulations adopted/ number of authorisations granted linked to an authorisation holder (Ref. 2)						FAR	482 period 2004-2017 28 period 2004-2017 Reference: ii FA Final Report _FCEC pages 108 For the number of Regulations, the data elaborated by the Commission on the basis of the publication in the Official Journal (EURLEX)
	3.2.7	Balance of costs vs benefits for authorisation holder(s) ***Based on analysis of previous indicators.***							The cost: benefit balance for applicants (i.e., the return on their investment, ROI) depends on the efficiency of the authorisation process, its outcome, and the market significance of the feed additive i.e., expected sales over the 10-year period. The ROI is particularly high for companies specialising in specific 'flagship' products that account for a significant share of a company's sales. However, in the case of non-holder-specific authorisations there are definite drawbacks for applicants as a 'free-rider' effect is observed, whereby other companies, not incurring authorisation costs, can benefit from the authorisation. The costs of authorisation/labelling and the Regulation's overall cost: benefit balance is not significantly different between SMEs and large companies as the underlying factors determining costs tend to be independent of company size. Reference: ii FA Final Report _FCEC, page 90

Primary sources		Secondary sources
Surveys	Yes	1. Company data 2. SANTE data base 3. SANTE internal assessment 4. RM associates Report 5. FA Register
Interviews	Yes	
Case studies	Yes	
SANTE request to MS, EURL and EFSA	Yes	

Methods for analysis

- Mapping of benefits and costs arising from the Regulation (Direct costs, enforcement costs, indirect costs) by type of stakeholder (cf toolbox N°58) including public authorities (EU and national).
- Assessment of compliance costs, administrative burden, implementation/enforcement costs (cf toolbox N°59)

Approach to answering the evaluation question and potential limitations

Costs and benefits will be identified and described, and their importance will be assessed over period 2014-2017. Two main areas of costs for FA FeBOs have already been identified: authorisation/re-authorisation process and labelling; the areas of major cost stemming from these have been identified in the inception report. The assessment of costs will mainly be based on quantitative criteria, following the methodology set out in the inception report; the assessment of benefits will mainly be based on qualitative criteria. Costs arising from the Regulation will be put in perspective with the economic benefits from the sales of FA.

Evaluation criterion: Coherence – EQ4

Legislation concerned:

Regulation on feed hygiene (R. (EC) No 183/2005)
Legislation on undesirable substances (D. 2002/32/EC)
Regulation on feed marketing and use (R. (EC) No 767/2009)
The Catalogue of Feed Materials (R. (EU) No 68/2013)
Regulation on genetically modified food and feed (R. (EC) No 1829/2003)
Legislation on medicated feed (D. 90/167/EEC).

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
Lack of contradiction between the Regulation and EU legislation on feed materials in general (EC No 767/2009 and EU No 68/2013)	**4.1**	Identification of contradictory requirements/measures – if any - between EC No 1831/2003 and EC No 767/2009 and EU No 68/2013, including inconsistency of definitions or key terms left undefined		X	X	tba	X		Several MS competent authorities and manufacturers of FA and feed materials indicated the classification of a substance as a feed material or a feed additive as one of the biggest challenges posed by the current EU regulatory framework for feed. The classification has important regulatory implications as FA must undergo an authorisation process at EU level to assess their safety and efficacy, whilst feed materials do not. While specific EU guidance on how to distinguish between feed materials and FA has been laid down by the Commission. MS and FeBOs confront the situation referred to above regularly and, in some instances, request a clarification at EU level The views expressed indicate inconsistencies deriving from the legal definitions of feed additive and feed material as currently set at EU level, which do not provide clear criteria to distinguish one from the other. Reference: ii FA Final Report _FCEC, pages 96 and 97
	4.2	Identification of items placed on PAFF agenda regarding such inconsistencies, taking into account whether and how they have been addressed						PAFF	For this reason, this issue has been discussed frequently at the level of SCOFCAH/PAFF Committee with a view to reaching a common position on specific products. In particular, the analysis of the issues discussed at SCOFCAH/PAFF level during the period covered by the study shows

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
									that out of 224 items that have appeared in the agenda of those committees, the largest number (61) concerned the interaction between the FA Regulation and the Feed Marketing Regulation and notably the classification of a given substance as a feed additive or a feed material. Accordingly, at EU level, specific provisions have been adopted during the application of the FA Regulation in order to facilitate the differentiation between these two feed product categories: these include Commission Recommendation 2011/25/EU and Commission Regulation (EU) No 892/2010. Nonetheless, based on the findings of the study, there is still area for improvement in terms of clarity in this matter. Reference: ii FA Final Report _FCEC, page 97 and 101
	4.3	Identification of such inconsistencies as highlighted by SANTE-F auditors, taking into account whether and how they have been addressed			SAN-F		SAN-F		Overview Report of Audits Carried Out in Certain MS In 2018-2019 In Order to Evaluate Official Controls On FA Their Ingredients And Traceability (DGSANTE 2020-7100). The scope of this report does not cover inconsistencies between the two Regulations and focus on how MS were implementing official controls on FA and premixtures, therefore it has not been highlighted between SANTE auditors. The issue is addressed in the SCoPAFF and resolved on a case-by-case basis
Lack of	**4.4**	Identification of		X	X	X	X		Views expressed by consulted parties point to the

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
contradiction between the Regulation and EU legislation on labelling of feed materials and compound feed (EC No 767/2009)		contradictory labelling requirements/measures – if any - between EC No 1831/2003 and EC No 767/2009, including inconsistency of definitions or key terms left undefined							existence of one major inconsistency. Several NCA and manufacturers of FA and feed materials identified an overall lack of alignment of labelling requirements under the two frameworks (notably, article 16 of the FA Regulation as opposed to Articles 11-23 of the Feed Marketing Regulation): • The FA Regulation only allows provision of information on the packaging of FA, while the Feed Marketing Regulation also foresees the use of modern communication (e.g., internet-based) tools for the labelling of feed materials and compound feed. • EU legislation on the marketing of feed provides for a legal basis for the development of Community Codes of good labelling practice, while a similar provision is not laid down for FA. Reference: ii FA Final Report _FCEC, page 97I Tolerances: the FA Regulation tolerances are not set up for premixtures that are incorporated into compound feed or feed materials. This is inconsistency with the Feed Marketing Regulation.
	4.5	Identification of items placed on PAFF agenda regarding such inconsistencies, taking into account whether and how they have been addressed						PAFF	Those issues cannot be addressed as it requires changes in the Regulation of FA to align the labelling provisions to the provision of the Feed Marketing Regulation
	4.6	Identification of such inconsistencies as			SAN-F		SAN-F		This has not been highlighted as it was not under the scope of F audits

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
		highlighted by SANTE-F auditors, taking into account whether and how they have been addressed							
Lack of contradiction between the Regulation and EU legislation on GMOs	**4.7**	Identification of contradictory requirements/measures between EC No 1831/2003 and EU GMO legislation, including inconsistency of definitions or key terms left undefined		X	X	tba	X		Information collected during the study did not identify inconsistencies between the FA Regulation and EU GMO legislation on food and feed. Reference: ii FA Final Report _FCEC, pages 99 to 100
	4.8	Identification of items placed on PAFF agenda regarding such inconsistencies taking into account whether and how they have been addressed						PAFF	1 item in the agenda for a clarification of the GMO feed legislation
	4.9	Identification of as such inconsistencies as highlighted by SANTE-F auditors, taking into account whether and how they have been addressed			SAN-F		SAN-F		Not highlighted as there are no inconsistencies and this issue was not under the scope of F audits
Lack of contradiction between the Regulation and EU legislation	**4.10**	Identification of contradictory requirements/ measures between EC No 1831/2003, EEC 90/167 and EC 2001/82, including		X	X	tbc	X		Views expressed by NCA and industry did not point to any major inconsistency or contradiction between the FA Regulation and EU legislation on medicated feed and VMPs. However, some respondents from the FA industry

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
on medicated feed (EEC 90/167) and VMPs (EC 2001/82)		inconsistency of definitions or key terms left undefined							indicated that further legal clarity would be desirable in relation to borderline cases with a view to determining whether a given substance / product is a feed additive or a VMP. According to industry, this is because the current notion of VMP as products contributing towards prevention of animal diseases is too vague, not allowing to clearly distinguish VMPs from FA with nutritional functions that help maintain animals in good health. Reference: ii FA Final Report _FCEC, page 100
	4.11	Identification of items placed on PAFF agenda regarding such inconsistencies, taking into account whether and how they have been addressed						PAFF	This issue of zinc, the sole case of inconsistency was discussed several times in the SCoPAFF on the occasion of the authorisations of different forms of Zinc as FA. The problem for the environment was addressed by authorising chelated forms that permit better assimilation by the animals and reduce its excretion and by reducing to the maximum the levels of Zinc authorised.
	4.12	Identification of such inconsistencies as highlighted by SANTE-F auditors taking into account whether and how they have been addressed			SAN-F		SAN-F		Not highlighted as this issue was not under the scope of F audits
Lack of contradiction between the Regulation and EU legislation	**4.13**	Identification of contradictory requirements/ measures between EC No 1831/2003 and EU legislation on feed hygiene		X	X	tbc	X		Views expressed by NCA and industry point to one inconsistency (in relation to imports) and one difference in approach (in relation to exports) between the FA Regulation and the EU legislation on feed hygiene.

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
on feed hygiene and safety		and safety, including inconsistency of definitions or key terms left undefined							In particular, the inconsistency pointed out by both NCA and industry stakeholders lies with **imports of feed**, including FA, as the lists of non-EU countries and establishments from which import of feed is permitted, pursuant to Article 23 of Feed Hygiene Regulation, have not been established to date. In that context, the application of interim measures pursuant to Article 24 of the same Regulation has led to the identification of several difficulties and divergences in the implementation of import requirements across MS[241]. The interim measures lay down that establishments must have a representative in the EU. This representative must ensure that the establishments comply with feed hygiene requirements at least equivalent to those established in the EU and must keep a register of products placed on the EU market. Under the current circumstances, it is for instance difficult to establish for which feed products – i.e., all or only some of them such as certain FA or premixtures or compound feed containing them - a representative in the EU is required. In addition to that, there is a lack of harmonised approach on how to assess the reliability of the feed representative's declarations on the

[241] This emerges from a series of fact-finding missions that the European Commission services have carried out in nine Member States over the period 2015-2016. See, in this respect, e.g., DG(SANTE) 2015-7618 Final Report Lithuania, DG (SANTE) 2016-8903 Final Report France and DG (SANTE) 2016-8906 Final Report Spain.

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
									compliance of feed manufacturing establishments in non-EU countries and as regards the guarantees needed to support those declarations. The other major issue, perceived to constitute an inconsistency from an industry perspective, lies with export rules. Notably, while Article 25 of the Feed Hygiene Regulation allows, under the conditions set out in Article 12 of the General Food Law (GFL), the export to non-EU countries of FA and premixtures not authorised to be placed on the EU market (NAFA products), the FA Regulation has no provisions laid down for export. Reference: ii FA Final Report _FCEC, pages 98-99 **There is no import code** for FA and premixtures and. Reference: Survey to NCAs and ii FA Final Report _FCEC, page 46
	4.14	Identification of items placed on PAFF agenda regarding such inconsistencies, taking into account whether and how they have been addressed						PAFF	The interaction between these two legal frameworks has been discussed and clarified by the European Commission on a number of occasions (15 times) at the level of SCOFCAH/PAFF meetings.
	4.15	Identification of such inconsistencies as highlighted by SANTE-F auditors, taking into account whether and how they have been addressed			SAN-F		SAN-F		Imported FA and premix res are subject to feed operators' own-checks and to official controls carried out by competent authorities on feed importers and/or manufacturers using imported feedingstuffs. MS' competent authorities have different approaches on how to assess whether an imported feed additive and

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
									the commercial documentation accompanying it (product specifications, certificates of analyses, etc.) provides sufficient guarantees that the imported product satisfies EU requirements. For example, when carrying out documentary checks, several MS do not check/require that the method used for the analysis is the one mentioned in respective Regulation for the authorisation of the feed additive and/or that the laboratory that provides the certificate of analyses is accredited to ISO/IEC 17025. Some MS only accept certificates of analysis if the laboratory and/or the method is accredited, and the feed business operator can provide adequate evidence. Finally, while some MS limit the controls on imported additives to checks of the accompanying commercial documents, others carry out physical checks and take samples for analysis. In six of the ten MS visited, there are relatively low numbers of establishments producing non-EU authorised FA/premixtures destined for third countries. Even though EU legislation does not expressly require feed business operators to inform the competent authority of this activity, when the competent authorities know about it, such establishments are approved and are subject to regular official controls. In one MS, the central competent authorities stated that they were aware about such activities but at the time of the audit did not have a list of relevant operators. However, there

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
									was an ongoing effort to obtain necessary information. The audit teams noted that the official controls on relevant establishments did not always verify whether the operator producing and exporting the non-EU authorised FA/premixtures established that the relevant requirements had been met. In one MS, the central competent authority had established a robust system specifically dedicated to controls on operators producing and exporting non-EU authorised products. The system included inspections carried out by joint teams from the central and the local competent authorities, significantly strengthening the effectiveness of the official controls. Reference: Overview report Official controls on feed additives, their ingredients and traceability points 5.1 and 5.2
Difference in interpretations made by MS CAs.	**4.16**	Identification of cases of divergent/ contradictory interpretations reported by stakeholders / MS CAs.		X	X		X	PAFF	Control of imports of FA is not a harmonised at EU level and trigger different interpretations by MS on how to control importers. Export of FA only intended for export is not harmonised at EU level creates different systems to control those exports. 19 Ms have established a system to control those exports. Those issues need to be addressed in the Feed Hygiene Regulation but affects the implementation of the FA Regulation. The absence labelling tolerances for FA in premixtures triggers different MS's interpretations on

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
									those tolerances.
Impact of lack of coherence in EU feed legislation	**4.17**	Identification of cases in which contradictions/ overlaps/gaps in legislation at EU level led to some possible unclarity.			SAN-F		SAN-F	PAFF	While most issues deriving from diverging national interpretations have been addressed following their identification, there are areas in which differences in interpretation and approaches across MS persist. This is mostly due to the absence of fully harmonised EU rules in commonly acknowledged complex areas (e.g., export of non-authorised FA to non-EU countries and feed import requirements). These issues have been discussed under EQ1.4 (with reference to import controls) and EQ2.2 (exports of NAFA products) Reference ii FA Final Report _FCEC, page 101.
	4.18	Identification of cases in which contradictions/ overlaps /gaps in legislation at EU level led to regulatory burden.			X			PAFF REFT	The obligation in the FA Regulation to indicate all the labelling information in the physical label while in the case of feed materials and compound feed some information can be conveyed by other means created a burden for FeBOs of FA. The absence labelling tolerances for FA in premixtures created a certain burden as operators must adapt the labels to the particular requirements of MS
	4.19	Identification of cases in which contradictions/overlaps/gaps in legislation at EU level create obstacles to achieving the objectives of EC No 1831/2003.							The issues indicated in 4.17 create obstacle in full achievement of the objectives.

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
		Based on analysis of previous indicators.							

Primary sources			**Secondary sources**
Surveys	Yes		1. All relevant EU legislation. 2. PAFF minute 3. SANTE F Audit reports[242] 4. Stakeholder survey 5. Documentary research
Interviews	Yes		
Case studies	Yes (tbc)		

Methods for analysis

- Mapping of legislation.
- Stakeholder consultation analysis
- Intervention logic analysis.

Approach to answering the evaluation question and potential limitations

The analysis should focus on the following aspects of 1831/2003: scope, definitions, authorisation procedure (risk assessment and risk management), and labelling. It should seek to determine in particular whether current EU feed legislation provides a clear distinction between different feed products which allows the appropriate legal regimes to be applied, and whether there are any definitions missing, whether any additional feed hygiene requirements are necessary to ensure the safety of FA, whether labelling provisions ensure the information needs of stakeholders throughout the feed additive chain, and whether the list of undesirable substances in D. 2002/32/EC is fit for purpose and sufficiently comprehensive. Experience of national authorities and industry stakeholders should be taken into account throughout. Cases of incoherence should be identified and described, and their causes and effects carefully analysed.

Issues relating directly to thematic case studies (such as coherence of labelling provisions) will be directly addressed through the case studies. Other issues will not be directly addressed, but it is expected that some findings will nonetheless be identified.

[242] The SANTE-F audit reports to be analysed are those relevant time wise for the specific act being considered, e.g., audits as of 2010 for Reg. (EC) 767/2009 and as of 2013 for Reg. (EU) 68/2013.

Evaluation criterion: Coherence – EQ5

Evaluation question 5: **To what extent are the provisions of the Regulation consistent with other related legislation on food and chemicals allowing for consistent assessment and management of risk (General Food Law, Regulation on classification, labelling and packaging of substances and mixtures (CLP) and Regulation on Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH))? What are the consequences of incoherencies, if any?**
5.1 Are there loopholes or grey zones to be addressed? How does this impact competitivity? 5.2 Are there overlaps or inconsistencies which hinder effective and efficient application of the regulation?
Legislation concerned – relevant provisions of: General Food Law (R. (EC) No 178/2002) CLP Regulation on classification, labelling and packaging of chemicals (R. (EC) No 1272/2008) REACH Regulation on the registration, evaluation, authorisation and restriction of chemicals (R. (EC) No 1907/2006) The provisions on worker/user safety (D. 89/686/EEC; D. 89/391/EEC; D. 98/24/EC; D. 2004/37/EC)

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
Lack of contradiction / inconsistency between the Regulation and the GFL	**5.1**	Identification of provisions (including definitions, feed safety provisions, and labelling requirements) in GFL that are inconsistent with provisions of EC No 1831/2003		X	X		X		There is a contradiction between Article 12 of the GFL that allows for export additives only intended for export and the limitations of the FA Regulation that only allows circulation from the production establishment or a limited circulation that does not implies transfer of ownership. Reference: ii FA Final Report _FCEC, page 99 In addition, the concept of safety of additives and premixtures only intended for export is not clear is not clear
	5.2	Identification of items placed on PAFF agenda regarding such inconsistencies, taking into						PAFF	The implementation of Article 12 of the GFL has been discussed 16 times.

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
		account whether and how they have been addressed							
	5.3	Identification of such inconsistencies as highlighted by SANTE-F auditors, taking into account whether and how they have been addressed			SAN-F		SAN-F		Not reported in Audits
Lack of contradiction / inconsistency between the Regulation and the CLP	**5.4**	Identification of provisions (including definitions, notification procedures, and labelling requirements) in CLP that are inconsistent with provisions of EC No 1831/2003		X	X		X		According to industry stakeholders, as labelling requirements regarding user safety or environmental risks can be laid down by both the CLP Regulation and authorisations of individual FA, this has occasionally resulted in redundant, different or even conflicting provisions[243]. Reference: ii FA Final Report _FCEC, page 104
	5.5	Identification of items placed on PAFF agenda regarding such inconsistencies						PAFF	Not raised
	5.6	Identification of such inconsistencies as highlighted by SANTE-F auditors, taking into account whether and how they have been addressed			SAN-F		SAN-F		Not raised in SANTE AUDITS
Lack of	**5.7**	Identification of provisions		X	X		X		The information collected during the study did

[243] COPA-COGECA, FEFAC, EMFEMA, FEFANA common principles for labelling FA through the supply chain, 2014.

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
contradiction / inconsistency between the Regulation and REACH		(including definitions, notification procedures, and labelling requirements) in REACH that are inconsistent with provisions of EC No 1831/2003							not point to the existence of any loopholes or grey zones in the interaction between REACH Regulation and the FA Regulation, or to any other major inconsistency. The study supporting the Fitness Check on REACH (EFTEC, 2017) and the Commission's report (EC, 2018a) do not point to any issues of contradiction / inconsistency with the FA Regulation. No specific overlap or inconsistency was raised and discussed at the level of SCOFCAH/PAFF meetings during the period covered by the study. The information collected during the study did not point to the existence of any loopholes or grey zones in the interaction between REACH Regulation and the FA Regulation, or to any other major inconsistency. The study supporting the Fitness Check on REACH (EFTEC, 2017) and the Commission's report (EC, 2018a) do not point to any issues of contradiction / inconsistency with the FA Regulation. No specific overlap or inconsistency was raised and discussed at the level of SCOFCAH/PAFF meetings during the period covered by the study. Reference: ii FA Final Report _FCEC, page 102.
	5.8	Identification of items placed on PAFF agenda regarding such inconsistencies, taking into account whether and how						PAFF	No items

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
		they have been addressed							
	5.9	Identification of such inconsistencies highlighted by SANTE-F auditors, taking into account whether and how they have been addressed			SAN-F		SAN-F		Not raised
	5.10	Stakeholder perceptions of coherence/usefulness of the REACH data sheet			X				This is a requirement set up for the application. Stakeholders did not raise any issues or incoherence on this request to provide the data sheet
Difference in interpretations made by MS CAs.	**5.11**	Identification of cases of divergent/contradictory interpretation reported by stakeholders.		X	X		X	PAFF	The authorisation of FA does not usually introduce labelling provisions for workers' safety but generally provide for workers' safety requirements to be respected, as conditions of use of the authorised additives[244]. Some MS authorities require the introduction of those safety requirements on the label. Those labelling indications are not harmonised in the different MS. In addition, the CLP Regulation, applies also to FA and premixtures, thereby introducing additional labelling requirements for workers' safety. This introduces complexity on the labels, in particular for premixtures. Reference:

[244] See also the relevant Occupational Safety and Health legislation and in particular Council Directive of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work and Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (89/391/EEC)

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
									ii FA Final Report _FCEC, page 104 vi Case studies, page 22, first paragraph
Impact of lack of coherence in legislation	**5.12**	Identification of cases in which contradictions/overlaps/gaps in legislation at EU level led to some possible unclarity.			X		SAN-F	PAFF	Overlaps between FA Regulation and CLP may create some unclarity. Some MS requires to label the of FA while other no. Different interpretation of the CLP rules in combination with the feed additive provisions of worker safety.
	5.13	Identification of cases in which contradictions/overlaps/gaps in legislation at EU level led to regulatory burden.			X			REFT	Some MS requires to label FA while other no. Different interpretation of the CLP rules in combination with the feed additive provisions of worker safety. Those issues create burden for operators that need to change the labels upon request of NCAs especially when additives and premixtures circulate within different MS that have different interpretations.
	5.14	Identification of cases in which contradictions/overlaps/gaps in legislation at EU level create obstacles to achieving the objectives of EC No 1831/2003. ***Based on analysis of previous indicators.***							Some MS requires to label the of FA while other no. Different interpretation of the CLP rules in combination with the feed additive provisions of worker safety. This is again the objective improve the functioning of the internal market

Primary sources			Secondary sources
Surveys	Yes		- All relevant EU legislation. - PAFF minutes - SANTE-F Audits reports - Stakeholder survey/ interviews - Documentary research
Interviews	Yes		
Case studies	tbc		

Methods for analysis

- Mapping of legislation.
- Stakeholder consultation analysis.
- Intervention logic analysis.

Approach to answering the evaluation question and potential limitations

The analysis should focus on the following aspects of 1831/2003: scope, definitions, authorisation procedure (risk assessment and risk management), and labelling. It should seek to determine in particular whether current EU feed legislation provides a clear distinction between feed products and additives on the one hand, and food and chemical products on the other, especially in cases where related substances may be involved in their production, which allows the appropriate legal regimes to be applied with certainty, and to prevent loopholes and grey zones from arising. It should examine whether there are any definitions missing, and whether labelling provisions ensure that the information needs of stakeholders throughout the feed additive chain are clearly met. Experience of national authorities and industry stakeholders should be taken into account throughout. Cases of incoherence should be identified and described, and their causes and effects carefully analysed.

Evaluation criterion: Coherence – EQ6

Evaluation question 6:

To what extent are the provisions within the FA legislation internally coherent? What are the consequences of incoherencies, if any?

Legislation concerned:

Regulation (EC) No 1831/2003

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SHSV	NCASV	INT	CS	LIT	COM	RESULTS
Lack of internal inconsistency in the Regulation	**6.1**	Identification of contradictory requirements/ measures within EC No 1831/2003		X	X		X		- Structure of categories and functional groups FA can only be authorised within certain categories defined by the Regulation. The current categories are not adequate for new functions of innovative FA supporting sustainable agriculture and having positive effects on animal welfare or the environment and there is no flexible process to modify or add such categories FA used to affect favourably animal welfare or the environment may only be allocated within the category 'zootechnical additives'. The FA Regulation does not allow the creation of other categories of additives for which the authorisation is issued to a specific holder. The applicant is requested by EFSA guidance to demonstrate a zootechnical effect of the additive (e.g., improvement of performance- increase egg/meat production). However, the actions performed by these additives are not related to an increase of performance in animals, but to a specific improvement in the well-being of animals (e.g., reduction of stress) or positive effects on the environment. This discrepancy discourages applicants from applying for those kinds of additives. Reference: ii FA Final Report _FCEC, page 47 las paragraph. -No transitional period for renewal of authorisations if the applicant withdraws the application. The FA Regulation provides for a procedure for the renewal of authorisation of FA. If the application for renewal is presented in due time, the feed additive will remain on the market until a decision on the renewal is taken by the Commission, provided that the reasons for the possible delay for granting the renewal of authorisation are beyond the

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
									control of the applicant. It may happen that the applicant withdraws the application for renewal during the process. In this case, the additive is no longer authorised if the original authorisation has already expired. The FA Regulation is not consistent in this regard, as FeBOs must face a "sudden" expiry of the authorisation, without any transitional period allowing an adaptation of the products concerned on the market. Reference: few discussions at the SCoPAFF. -Data sharing: The procedures have limited effect on reducing animal testing because of incoherent rules on data sharing. Even though the applicant needs to take all measures to prevent repetition of toxicological tests on vertebrates in case of disagreement between the applicant and the other party (previous applicant), the Commission is neither obliged nor has the tools to take decision, based on objective parameters Reference: PC -Drinking water: The definition of FA refers to the use of all additives in drinking water, but Article 6 and Annex I of the Regulation restrict the use of FA in drinking water to certain functional groups. Therefore, internal coherence between the provisions related to the use of FA in drinking water should be assessed. In addition, FeBOs and NCAs have requested more technical clarity on the practical implementation of the use of additives in drinking water. Reference: ii FA Final Report _FCEC, pages 77, 108, 109,110

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
									- Environmental assessment for non-food producing animals. The safety criteria and data requirements introduced in the FA Regulation were effective to ensure a comprehensive environmental assessment. Nevertheless, it is necessary to introduce some clarification regarding the environmental safety requirements applicable to farmed non-food producing animals (e.g., fur animals) in order to accommodate the requirements related to the safety criteria laid down in the FA Regulation. Reference: comments DG ENVIRONMENT to the roadmap. -Modification of authorisations not linked to an authorisation holder. Article 13(3) only covers the modification process introduced by the holder of an authorisation but does not foresee rules for requests for modifications of non-holder specific authorisations. In such cases, a full evaluation is not required, but instead only a verification whether the modification may rise a safety concern or may undermine the efficacy. This situation has been largely mitigated by using Article 13(1) that permits the Commission to modify any authorisation (including non-holder specific authorisations) on its own initiative. The possibility for an operator to introduce requests for modifications of a non-holder specific authorisation should be further examined.
	6.2	Internal consistency of definitions used in EC No 1831/2003, and number of		X	X		X		Recommended levels and maximum recommended levels. There is insufficient clarity on how to establish recommended levels. Whilst for some FA levels are established as conditions for authorisation, for others, recommended levels are established on the labelling provisions. This is due to divergent views that triggered different discussions over the time. For some additives,

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
		key terms not defined within the regulation itself							the recommendation is to use “Maximum Recommended Levels”. These are limits for the use of FA providing a certain flexibility as opposed to maximum limits, which are mandatory and should be indicated on the label of the premixtures, compound feed and feed materials. Those maximum recommended levels have been recently set as the labelling provisions for some FA, for example for flavourings. The Feed Marketing Regulation lays down the obligation to indicate the level used on the label of the compound feed/feed material if the respective Maximum Recommended Level has been exceeded. If this level is not exceeded, then the level used is not required to be indicated on the label of the premixture, compound feed or feed material. Reference: ii FA Final Report _FCEC, page 107. Discussions at the SCoPAFF (2). Definition of preparations: preparations are not defined as such as the introduction of such definition could not be done by Implementing Rules and required a modification of the Regulation. To mitigate this absence of definition, some provisions on the compositional and labelling requirements were introduced in 2015 by Implementing rules. Reference: ii FA Final Report _FCEC, page 6, 107, 110, 136

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
Low number of gaps identified in the provisions of the Regulation	**6.3**	Identification of gaps in the provisions		X	X		X		There are several gaps identified: -No transitional period for renewal of authorisations if the applicant withdraws the application. --Data sharing: no objective parameters to decide on data sharing - No rules on how to apply the use of additives in water for drinking - No rules for the modification of authorisation not linked to an authorisation holder. -No definition of preparations - No definition of maximum recommended levels or maximum levels.
Low number of legal complaints	**6.4**	Number of legal complaints brought against the regulation, taking into account whether and how they have been addressed			X		X	X	No complains
Few cases in which FA intended for export finds their way into the EU	**6.5**	Number of audits addressing this issue, having regard to their outcome			X		SAN-F		No reference to these issues in the Commission Audits There are no precise data on the number of cases in which FA not authorised to be placed on the EU market and intended for export eventually end up on the EU market. As referred to under EQ1.4, the number of RASFF notifications concerning unauthorised FA with EU origin detected by MS is limited during the period

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
market, in spite of lack of labelling									covered by the study. Overall, the type of national measures aimed at controlling FeBOs carrying out such export activities significantly vary across MS, taking also into account the number of such operators and the volumes produced on the national territory. National measures may involve: the granting of specific authorisations for the production and export of unauthorised FA; the performance of controls (by means of random or risk-based routine checks); the provision of assurances by the concerned FeBOs that products are properly labelled (e.g. 'only for export', 'not for use within the EU'); the issuance of official export certificates by competent authorities or the mandatory notification by FeBOs of export dates and respective quantities to such authorities. Reference: ii FA Final Report _FCEC, page 107-108
Few cases in which FA had to be withdrawn from market, because rules on use in water are not applicable to all additives	**6.6**	Number of cases in which FA had to be withdrawn from market due to rules on use in water		X	X			FAR; SAN-DB	789 flavourings Reference: ii FA Final Report _FCEC, page 106
Low number of regulations had to be	6.7	Number of regulations published because the						FAR	28 Regulations period 2004-2017 Reference: ii FA Final Report _FCEC, page 106

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SHSV	NCASV	INT	CS	LIT	COM	RESULTS
adopted because the authorisation holder had changed		authorisation holder had changed							
Difference in interpretations made by MS CAs	**6.8**	Identification of cases of divergent/contradictory interpretation reported by stakeholders / MS CAs.		X	X		X	PAFF	Use of additives in water for drinking: 35 times discussed at the SCoPAFF Preparations: 6 times discussed at the SCoPAFF Recommended levels: 2 times for clarification but also in the discussion of many Regulations where those levels are established Overall, the information collected during the study point out that the provisions of the FA Regulation have given rise on several occasions to diverging interpretations between MS. Discussions at the level of SCOFCAH / PAFF meetings confirm that, out of 224 items concerning the FA Regulation, 102 concerned, amongst others, issues stemming from diverging national interpretations over the provisions of the Regulation. While the majority of issues raised in those committees have been addressed over time mainly through the provision of clarifications by the European Commission, adoption of amendments of the Regulation or opinions by EFSA, there are, however, a number of issues that have not been solved yet. Reference: ii FA Final Report _FCEC, page 108-109
Lack of significant divergences between the penalties set	**6.9**	Extent to which all MS foresee penalties for non-		X	X				Sanctions applied by MS to infringements in the FA and premixtures sector (in application of Article 24 of the FA Regulation) are generally financial penalties with some countries also foreseeing other administrative penalties. National approaches on the type and level of penalties vary to a significant extent.

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SHSV	NCASV	INT	CS	LIT	COM	RESULTS
out at MS level for non-compliance		compliance with the Regulation and that the penalties foreseen vary from one MS to another.							Reference: ii FA Final Report _FCEC, page 109
Failure to update the legislation on renewal of authorisation is not perceived as a major problem	**6.10**	Number of additives due for renewal in next 5 years						SAN-DB	2017-2021: 65; 2022: 48; 2023: 32; and 2024: 56 Against this background, views over the need to update EU legislation on the renewal of the 10-year authorisation for FA slightly varies across consulted parties. Overall, FA manufacturers are generally more inclined towards the update of such a legislation with a view to reducing the regulatory and administrative burden on all parties involved (applicant, European Commission, MS and EFSA). A few MS also share this view. From an industry perspective, for certain FA (e.g., those used in food production or with a long history of safe use in animal nutrition) the requirement of the renewal does not appear to be fully risk-based. Also, in certain cases, the renewal procedure may create some uncertainty and unpredictability for the feed chain on the availability of FA, since there is no obligation for former applicant(s) to submit an application for renewal in the case of generic authorisations. Any person that places on the market the additive may present an application for renewal but not necessarily the former applicant. This is not the case for holder specific authorisations for which the request of renewal should be submitted by the former applicant or his successor.

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
									Reference: SANTE DATABASE Reference: ii FA Final Report _FCEC, page 109
	6.11	% Of positive/negative opinions expressed by CAs of Ms and FeBOs on current procedure	X	X	X				A majority of FeBOs (29 out of 110) does not consider that the 10-year authorisation promote innovation. Opinions on the 10-year authorisation period are more varied. Key comments provided by the MS authorities who disagreed or did not provide a definite answer include that a 10-year authorisation can be too short to encourage innovation, particularly for smaller companies. For FA of lower risk, a period of 20 years could be more appropriate. For FA of higher risk (coccidiostats), the current 10-year period is generally appropriate. The 10-year authorisation period was perceived as effective for safety purposes by a slight majority of MS authorities (17 out of 27). Six MS authorities did not respond and 4 disagree (NCA survey).
Impact of lack of coherence in legislation	**6.12**	Identification of cases in which inconsistency in the provisions of EC No 1831/2003 led to some unclarity			X		SAN-F	PAFF	The following issues are identified: -No transitional period for renewal of authorisations if the applicant withdraws the application. --Data sharing: no objective parameters to decide on data sharing - No rules on how to apply the use of additives in water for drinking. No clear framework to determine which additives can be used in water for drinking - No rules for the modification of authorisation not linked to an authorisation holder. -No definition of preparations - No definition of maximum recommended levels or maximum levels -Structure of categories and functional groups not consistent Environmental assessment of non-food producing animals

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
	6.13	Identification of cases in which inconsistency in the provisions of Regulation (EC) No 1831/2003 led to regulatory burden.			X				The following issues are identified: -No transitional period for renewal of authorisations if the applicant withdraws the application. - No rules on how to apply the use of additives in water for drinking. No clear framework to determine which additives can be used in water for drinking - No definition of preparations - No definition of maximum recommended levels or maximum levels
	6.14	Number (and identity) of cases in which inconsistency in the provisions of EC No 1831/2003 led to obstacles to achieving the objectives of EC No 1831/2003. ***Based on analysis of previous indicators.***							All the issues identified in this point 6 led to reduce the functioning of the internal market and create a certain burden

Primary sources			Secondary sources
Surveys	Yes		- All relevant EU legislation. - PAFF minutes - SANTE-F Audits reports - Stakeholder survey/ interviews - Documentary research
Interviews	Yes		
Case studies	tbc		

Methods for analysis

- Mapping of legislation.
- Stakeholder consultation analysis.
- Intervention logic analysis.

Approach to answering the evaluation question and potential limitations

The analysis should focus on the internal consistency, without regard to the wider legislative context, of R. 1831/2003, and in particular its scope, definitions, authorisation procedure (risk assessment and risk management), and labelling. In addition, it should seek to determine whether the Regulation provides a list of current functions and functional groups of FA that still reflect the state of play of the market and of technological progress with regard to FA; whether current distinctions for use in water between different categories of FA are still justified; whether current distinctions between general and specific labelling requirements for FA are still justified; and whether the current list of FA that may be covered by holder-specific authorisations is still justified. Experience of national authorities and industry stakeholders should be taken into account throughout. Cases of incoherence should be identified and described, and their causes and effects carefully analysed.

Evaluation criterion: relevance – EQ7 (EQ8 → EQ7.1)

Evaluation question 7:
To what extent are the needs/objectives identified at the time of the drafting of Regulation (EC) No 1831/2003 still relevant? Are there any new needs/objectives which have emerged since the original drafting of the Regulation, and (if any new needs/objectives exist) to what extent is the Regulation suitable for tackling these?

RESPONSE

Do the original objectives of the FA Regulation still correspond to the EU's current needs/problems?

7.1 To what extent is the Regulation suitable for addressing the current needs of fight against antimicrobial resistance, sustainable livestock production, animal welfare, protection of the environment?
Legislation concerned Regulation (EC) No 1831/2003 Directive 70/524/EEC

Judgement criteria	ID	Relevant indicators	SH sv	NCA sv	Int	CS	Lit	COM	
Relevance of the reduction of AMR threats to citizens, animals and the environment	**7.1**	Number of positive responses	X	X	X				104 respondents out of 111- .SH SURVEY (vii Consultation Synopsis Report, page 15) 26 NCA out of 27-NCA SURVEY (ix Accompanying document: survey and PC results, page 60) Other Reference: ii FA Final Report _FCEC, pages 111-114
Relevance of the simplification of the feed additive authorisation process in comparison to the previous process under the directive	**7.2**	Number of positive responses	X	X	X				91%- .SH SURVEY (vii Consultation Synopsis Report, page 15) 24 NCA out of 26-NCA SURVEY (ix Accompanying document: survey and PC results, page 60) Other Reference: ii FA Final Report _FCEC, pages 111-114
Relevance of ensuring the safety of FA for human health, animal health and the environment (*overarching need*).	**7.3**	Number of positive responses	X	X	X				106 respondents out of 110- .SH SURVEY (vii Consultation Synopsis Report, page 15) 26 NCA out of 26-NCA SURVEY (ix Accompanying document: survey and PC results, page 60) Other Reference: ii FA Final Report _FCEC, pages 111-114

Judgement criteria	ID	Relevant indicators	SH sv	NCA sv	Int	CS	Lit	COM	
Relevance of the rigorous risk assessment of FA (*specific objective*)	**7.4**	Number of positive responses	X	X	X				88%- .SH SURVEY (vii Consultation Synopsis Report, page 15) 26 NCA out of 26-NCA SURVEY (ix Accompanying document: survey and PC results, page 60) Other Reference: ii FA Final Report _FCEC, pages 111-114
Relevance of ensuring the traceability of FA (*specific objective*)	**7.5**	Number of positive responses	X	X	X				93%- .SH SURVEY (vii Consultation Synopsis Report, page 15) 25 NCA out of 26-NCA SURVEY (ix Accompanying document: survey and PC results, page 60) Other Reference: ii FA Final Report _FCEC, pages 111-114
Relevance of clear rules for authorisation and labelling (*specific objective*)	**7.6**	Number of positive responses	X	X	X				97% (vii Consultation Synopsis Report page 15) 24 NCA out of 26-NCA SURVEY (ix Accompanying document: survey and PC results, page 61). Other Reference: ii FA Final Report _FCEC, pages 111-114
Relevance of addressing specific interests of pet owners and their animals (*specific objective*)	**7.7**	Number of positive responses	X	X	X				63%SH SURVEY (vii Consultation Synopsis Report page 15) 23 NCA out of 26-NCA SURVEY (ix Accompanying document: survey and PC results, page 61) Other Reference: ii FA Final Report _FCEC, pages 111-114
Relevance of facilitating the placing on the market of FA that are safe, innovative and efficacious	**7.8**	Number of positive responses	X	X	X				103 out of 107 SH SURVEY (vii Consultation Synopsis Report page 15) 26 out of 26 -NCA SURVEY (ix Accompanying document: survey and PC results, page 61)

Judgement criteria	ID	Relevant indicators	SH sv	NCA sv	Int	CS	Lit	COM	
									Other Reference: ii FA Final Report _FCEC, pages 111-114
Relevance of ensuring FA cannot mislead consumers on the quality of food	**7.9**	Number of positive responses	X	X	X				61% (vii Consultation Synopsis Report page 15) 22 out of 26 -NCA SURVEY (ix Accompanying document: survey and PC results, page 61) Other Reference: ii FA Final Report _FCEC, pages 111-114
New needs / objectives which emerged since the drafting of the Regulation	**7.10**	Additional needs / objectives identified.	X	X	X				At the same time, a majority of respondents (75 out of 112) identify new needs/objectives for the EU feed additive legislation, which emerged since the Regulation was adopted. An analysis of the identified needs was performed to classify them by broad theme and the extent to which stakeholders considered these needs to be fulfilled (vii Consultation Synopsis Report page 15) The so-called "new" needs identified by the highest number of consulted parties are issues related to the authorisation process; need to consider environmental aspects and promote the sustainable use of additives and sustainable farming/food production; need to consider animal welfare aspects; need to promote innovation (in terms of speeding up the introduction of innovative FA and/or feed additive production processes). Since most survey respondents are directly linked with the FA industry, a separate analysis focused on the "new" needs highlighted by the two most significant categories of respondents not directly linked with it, i.e., manufacturers of compound feed that use FA; organisations/consultancies that complete/assist

Judgement criteria	ID	Relevant indicators	SH sv	NCA sv	Int	CS	Lit	COM	
									clients with applications for authorisation of FA. The "new" needs identified by manufacturers of compound feed are (in decreasing order of prevalence): i) consideration of environmental aspects; ii) consideration of animal welfare aspects; iii) promotion of the sustainable use of resources and sustainable farming/food production. By contrast, not clearly prevailing "new" needs could be identified among those highlighted by organisations/consultancies that complete/assist clients with applications for authorisation of FA. Other Reference: ii FA Final Report _FCEC, pages 115-117
	7.11	Extent to which additional needs/objectives are met by the regulation	X	X	X				As explained, only some of the "new" needs identified by stakeholders were not considered in the original FA Regulation: in the first place, the need to consider sustainability aspects in the development, approval and use of FA. By contrast, some of the "new" issues in the authorisation process were already considered (at least in part) in the FA Regulation; the same can be said for environmental and animal welfare aspects, as well as for the development of new FA as a result of scientific and technological progress. With regard to this group of "new" needs, they generally refer more to further improving the relevance, effectiveness, efficiency or coherence of the FA Regulation, than to taking into account needs that were not considered at the time of drafting.

Judgement criteria	ID	Relevant indicators	SH sv	NCA sv	Int	CS	Lit	COM	
									Reference: ii FA Final Report _FCEC, pages 115-117

Primary sources			Secondary sources
Surveys	Yes		
Interviews	Yes		

Methods for analysis

- Mapping of legislation.
- Stakeholder consultation analysis.
- Intervention logic analysis.

Approach to answering the evaluation question and potential limitations

The relevance looks at the relationship between the needs and problems of the FA sector and society and the objectives of the intervention (reduce AMR, harmonise the authorisation procedure, ensure rigorous assessment, with particular attention to the environment, set up clear labelling rules, improve control and enforcement, address specific interests of pet owners and pets, increase transparency, ensure technological and scientific progress (innovation) and not mislead the consumers). This question seeks to clarify: (1) to what extent are original objectives still relevant; and (2) are there any new objectives.

This exercise is somewhat subjective and dependent on the opinions of all different stakeholders. Based on their experience, the perception of national authorities and stakeholders along the supply chain will therefore form the basis of the analysis of this EQ. For any new needs/objectives identified, explanation and justification will be sought.

Evaluation criterion: relevance – EQ8

Evaluation question 9:

To what extent has the Regulation provided for the possibility and/or flexibility for adaptation to technical and scientific progress, to minimise administrative burden or to adapt to new issues or necessities since the adoption of the Regulation?

8.1 Are the definitions, procedures and criteria in the feed additive Regulation still clear and relevant in the light of scientific and technical developments, in the light of present needs of livestock production and pets?
8.2 What conclusions may be drawn from the experience so far concerning the re-authorisation process?
8.3 Is the provision for a '10-year authorisation period' considered to be still adequate?
8.4 Have there been new issues/developments since the adoption of the Regulation that are not properly addressed by the Regulation (e.g., role of EURL, export of non-authorised FA, etc.)?
8.5 Are there any provisions, which create too much administrative burden?

Legislation concerned
Regulation (EC) No 1831/2003

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
A majority of stakeholders perceive the definitions to be in line with current state of scientific and technical progress	**8.1.2**	High score of positive opinions	X	X	X				In particular, respondents are divided on whether the definitions in the Regulation are in line with the current state of scientific and technical progress, with a slight majority (44 out of 108) finding them not to be (compared to 39 that consider them to be). (vii Consultation Synopsis Report, page 16) 23 out of 27 ix Accompanying document: survey and PC results, page 61) The Regulation is considered by most NCAs sufficiently suitable in its current form to address scientific and technical progress. The aspect on which some concern was expressed by few NCAs was whether the definitions in the Regulation (3 NCAs) and criteria used for authorisation of FA (2 NCAs) are in line with the current state of scientific and technical progress (while 6 and 3 NCAs respectively did not provide a definite answer). Key comments provided by those NCAs that disagreed or did not provide a definite answer are: Definitions: updating the definitions in the Regulation to update reference to old legislation, align with other recently

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
									revised legislation (e.g., Regulation No.2019/6 on veterinary medicinal products) and with scientific and technical progress; clarifying definitions to better distinguish between FA, premixtures, feed material, processing aids and veterinary medicines; and, adding a definition for preparations vii Consultation Synopsis Report, page 22) Other Reference: ii FA Final Report _FCEC, pages 119
A majority of stakeholders perceive the authorisation procedure to be suitable to address scientific and technical developments for pets and livestock production	**8.1.3**	High score of positive opinions	X	X	X				Similarly, a majority (45 out of 107) consider the authorisation procedure to be not suitable to address scientific and technical developments for pets and livestock production, due to the time periods incurred (compared to 34 that consider it suitable); and, in the light of scientific and technological developments, the criteria used for authorisation of FA are not considered still relevant by 28 out of 44 respondents (compared to 13 that consider them still relevant). SH-SURVEY. (vii Consultation Synopsis Report, page 11) 28 out of 29 NCA –NCA SURVEY (ix Accompanying document: survey and PC results, page 61) In the views of business stakeholders, several limitations hamper the FA Regulation's possibility and/or flexibility to adapt to technical and scientific progress. These limitations would mainly derive from: i) lack of clarity/precision in some of the definitions provided by the FA Regulation, plus missing definitions for some key concepts (as discussed in EQ4 to 6); ii) the difficulties and the long time needed for creating new functional groups to respond to emerging needs, as well as slow adaptation of authorisation criteria vis-à-vis rapid evolution of technical progress and scientific developments in the field of animal nutrition (as discussed in EQ1.4 and EQ2.1); and, iii) lack of flexibility in the reauthorisation process. These limitations are generally not identified by the

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
									consulted NCAs. Also, the available evidence suggests that innovation in new types of FA (e.g., zootechnical category) takes place (EQ1.4 and EQ2.1). A clear majority of both NCAs and (especially) business stakeholders perceive that the administrative burden deriving from the FA Regulation can be reduced. Specific suggestions for burden reduction were put forward by business stakeholders: i) tailoring the duration of authorisation periods to the safety profile of functional groups/individual products; ii) not requiring or streamlining/fast tracking the renewal of authorisations for FA with a low risk profile; iii) providing information through other media than physical labels, such as electronically readable labels. A majority of business stakeholders perceive that the burden of the new safety-related and efficacy-related requirements for reauthorisation is not proportionate to the benefits, although NCAs largely considered it to be proportionate. These, and some other identified opportunities for burden reduction, are also discussed under EQ3.2 (ii FA Final Report _FCEC, page 128).
A majority of stakeholders perceive the criteria for authorisation of FA as still relevant in the light of scientific and technical developments	**8.1.4**	High score of positive opinions	X	X	X				In the light of scientific and technological developments, the criteria used for authorisation of FA are not considered still relevant by 28 out of 44 respondents (compared to 13 that consider them still relevant). SH-SURVEY. (vii Consultation Synopsis Report, page 16). 26 out of 27 NCA –NCA SURVEY (ix Accompanying document: survey and PC results, page 61)
A majority of stakeholders	**8.2.1**	High score of positive opinions	X	X	X				Of those that have applied for re-valuation under Article 10.2 (41 respondents), a majority agree that the re-evaluation

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
consider that the re-evaluation (Article 10 2) process has helped adapt future renewal of authorisations to new requirements									process has helped adapt the future renewal of authorisations to new requirements (25) SH-SURVEY. (vii Consultation Synopsis Report, page 11). MS also appear overall satisfied with the re-evaluation process (Article 10.2). In particular, the process has helped adapt the future renewal of authorisations to new requirements (21 NCAs). NCA SURVEY. (vii Consultation Synopsis Report, page 20). A clear majority of the consulted parties (NCAs and business stakeholders;) agree that the reauthorisation process has helped adapt future renewal of authorisations to new requirements for the presentation of the dossiers (operators gained experience on how to prepare the dossiers for applications and how to adapt to changes in the requirements during the evaluation when new guidance are adopted as a result of scientific progress). Although no NCA expressed a negative judgment on the matter, the overall judgment among business stakeholders, despite being also positive, was less favourable. Some business stakeholders reported issues deriving from changes to requirements (especially for what concerns set up of trials and quality of data, e.g. to provide full composition of a botanical extract instead of partial composition or provide a specific test on mutagenicity that was not requested before) introduced by EFSA guidance documents published in 2012 and 2018 : those changes in requirements also applied to reauthorisation dossiers as they were progressively entering into the assessment process (ii FA Final Report _FCEC, page 120).
A majority of stakeholders perceive that the	**8.2.2**	High score of positive opinions	X	X	X				Of those that have applied for re-valuation under Article 10.2 (41 respondents), a majority agree that the re-evaluation process has provided applicants with enough flexibility to

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
re-evaluation process has provided applicants with enough flexibility to adapt to technological and scientific progress									adapt to technological and scientific progress (23). SH-SURVEY (vii Consultation Synopsis Report, page 11). A majority of NCAs agree that the re-evaluation has provided applicants with enough flexibility to adapt to technological and scientific progress (20 NCAs; 1 NCA disagreed). NCA SURVEY. (vii Consultation Synopsis Report, page 20).
A majority of stakeholders/MS perceive that the re-authorisation process has helped place on the market safer additives for farm animals	**8.2.3**	High score of positive opinions	X	X	X				Respondents are more divided on whether the re-evaluation process has helped additives safer for animals (whether food producing or no-food producing animals) to be placed on the market. SH-SURVEY (vii Consultation Synopsis Report, page 11). A majority of NCAs agree that the re-evaluation has helped additives that are safer for farm animals and for pet animals to be placed on the market (22 and 20 NCAs, respectively). NCA SURVEY (vii Consultation Synopsis Report, page 20).
A majority of stakeholders perceive that the re-authorisation process has helped place on the market safer additives for pet animals.	**8.2.4**	High score of positive opinions	X	X	X				Respondents are more divided on whether the re-evaluation process has helped additives safer for animals (whether food producing or no-food producing animals) to be placed on the market. SH-SURVEY (vii Consultation Synopsis Report, page 11). A majority of NCAs agree that the re-evaluation has helped additives that are safer for farm animals and for pet animals to be placed on the market (22 and 20 NCAs, respectively). NCA SURVEY (vii Consultation Synopsis Report, page 20).
A majority of stakeholders perceive that the burden of the new safety requirements	**8.2.5**	High score of positive opinions	X	X	X				Overall, a majority of respondents do not consider the burden of new safety and efficacy assessment required for re-evaluation to have been proportionate to the benefits (19 and 20 respondents, respectively); only 4 and 5 respondents, respectively, consider the burden to have been proportionate.

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
for re-evaluation was proportionate to the benefits									SH-SURVEY (vii Consultation Synopsis Report, page 11). Furthermore, the burden of the new safety and efficacy requirements for re-evaluation has been proportionate to the benefits, according to 15 and 13 NCAs, respectively; although 1 NCA disagreed, and several NCAs (9 and 11, respectively) did not provide a definite answer. NCA SURVEY (vii Consultation Synopsis Report, page 20).
A majority of stakeholders perceive that the burden of the new requirements for the re-evaluation as regards efficacy assessment was proportionate to the benefits	**8.2.6**	High score of positive opinions	X	X	X				Overall, a majority of respondents do not consider the burden of new safety and efficacy assessment required for re-evaluation to have been proportionate to the benefits (19 and 20 respondents, respectively); only 4 and 5 respondents, respectively, consider the burden to have been proportionate. SH-SURVEY (vii Consultation Synopsis Report, page 11). Furthermore, the burden of the new safety and efficacy requirements for re-evaluation has been proportionate to the benefits, according to 15 and 13 NCAs, respectively; although 1 NCA disagreed, and several NCAs (9 and 11, respectively) did not provide a definite answer. NCA SURVEY (vii Consultation Synopsis Report, page 20).
A majority of stakeholders perceive that the 10-year authorisation period is adequate to promote innovation	**8.3.1**	High score of positive opinions	X	X	X				29 out of 110 SH SURVEY (ix Accompanying document: survey and PC results, page 17) NCA views were more varied on the 10-year authorisation period. Although a majority found this period adequate to promote innovation (18 NCAs) out of 25. NCA SURVEY (vii Consultation Synopsis Report, page 21).
A majority of stakeholders perceive that the 10-year	**8.3.2**	High score of positive opinions	X	X	X				24 out of 110 SH SURVEY (ix Accompanying document: survey and PC results, page 18) Also, the 10-year authorisation period is considered necessary to ensure safety by most NCAs (17), although 3 NCAs

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
authorisation period is necessary to ensure safety									disagreed. For each of the above aspects, it is noted that several NCAs (4 to 6, depending on the aspect) did not provide a definite answer. Key comments provided by those NCAs that disagreed or did not provide a definite answer are a 10-year authorisation can be too short to encourage innovation, particularly for smaller companies in view of the difficulties to secure funding; the period could be adapted by type of additive, e.g., level of scientific/technical progress and safety risk. For FA of lower risk, a period of 20 years could be more appropriate; for FA of higher risk, the current 10-year period is generally appropriate. NCA SURVEY (vii Consultation Synopsis Report, page 21).
A majority of stakeholders perceive that the provision for a 10-year authorisation period is still adequate for holder-specific additives	**8.3.3**	High score of positive opinions	X	X	X				20 out of 110 SH SURVEY (ix Accompanying document: survey and PC results, page 18) It is considered particularly inadequate for non-holder-specific additives (39 respondents; compared to 20 that consider it adequate out of 99). NCA SURVEY. (vii Consultation Synopsis Report, page 11) For holder-specific (18 NCAs) out of 27 agree and 3 disagree - NCA SURVEY (vii Consultation Synopsis Report, page 21 and ix Accompanying document: survey and PC results, page 57)
A majority of stakeholders perceive that the provision for a 10-year authorisation period is still adequate for non-holder-specific additives	**8.3.4**	High score of positive opinions	X	X	X				24 out of 110 SH SURVEY (ix Accompanying document: survey and PC results, page 19) For non-holder-specific additives 15 NCAs agree out of 27 and 5 NCAs (ix Accompanying document: survey and PC results, page 19)

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
A majority of stakeholders perceive that updating the method of analysis is necessary for the renewal of authorisation	**8.4.1**	High score of positive opinions	X	X	X				Updating the method of analysis is not considered necessary for the renewal of authorisation by a majority of respondents (51 out of 101), while considered necessary by 26 respondents. SH SURVEY (vii Consultation Synopsis Report, page 11) Updating the method of analysis is considered necessary for the renewal of authorisation by 22 NCAs; only one NCA disagreed, commenting that the aim is the standardisation of analytical methods, not a continuous adaptation to new analytical techniques when this does not serve a specific purpose e.g., to allow better controls. NCA SURVEY (vii Consultation Synopsis Report page 21)
A majority of stakeholders perceive that the role of the EURL is still properly addressed in the Regulation	**8.4.2**	High score of positive opinions	X	X	X				The role of the EURL is adequately defined in the Regulation according to the majority of respondents (61 out of 92). SH SURVEY (vii Consultation Synopsis Report, page 11) The role of the E-RL is adequately defined in the Regulation according to 22 NCAs; only one NCA disagreed, commenting that the EURL competence could be enhanced, e.g., to support the national laboratories with the development and/or execution of analysis, as well as the NCAs whenever needed. NCA SURVEY (vii Consultation Synopsis Report, page 21)
A majority of stakeholders perceive that the rules applicable to the export of FA are not properly addressed	**8.4.3**	High score of positive opinions	X	X	X				A small majority of respondents (35 out of 65; excluding 19 'do not know' responses) consider the rules applicable to the export of FA to be properly addressed in the Regulation; while 20 consider them not to be properly addressed. About a third of respondents (27 of 98), including manufacturers, traders, and associations/organisations in the sector, were aware of FA and premixtures not authorised for placing on the EU market, which are produced in the EU only for export to non-EU countries. SH SURVEY (vii Consultation Synopsis Report, page 16) 19 NCAs have taken action to prevent that FA and premixtures

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
									non authorised in the EU and intended for export end up on the EU market. These actions include: registration of operators handling such additives; monitoring production, use (incorporation in premixtures) and exports, e.g. through obligation for operators to report movement and/or risk-based routine controls and random checks; import controls; obligation to notify all additives/premixtures before placing on the market; notification to the NCA of destination when sending such products to other MS; and, obligation to label ('only for export'). The actions reported by NCAs were generally considered effective and no problems were identified, except in the case of import controls. It is noted, however, that the approach varies considerably between MS and that 6 NCAs indicated they have not taken any action to control these exports and their potential re-entry in the EU. NCA SURVEY (vii Consultation Synopsis Report, page 23)
A majority of stakeholders perceive that administrative burden (e.g., change of authorisation holder, modification of authorisation for additives not holder specific) can be reduced.	**8.5.1**	High score of positive opinions	X	X	X				According to a majority of respondents (37 out of the 38 applicants), the administrative burden (e.g., for obligations relating to change of authorisation holder, modification of authorisation for non-holder-specific additives) can be reduced. SH SURVEY (vii Consultation Synopsis Report, page 14) The administrative burden (e.g., for obligations relating to change of authorisation holder, modification of authorisation for non-holder-specific additives) can be reduced for 10 NCAs; although 12 NCAs did not provide a definite answer and 3 NCAs disagreed NCA SURVEY (vii Consultation Synopsis Report, page 22)
High number of issues not	**8.5.2**	Number of issues/description			X				Improve the Register of FA

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
mentioned before that may prevent the Regulation from meeting current needs		that are not very relevant							
High number of issues in the Regulation that have created new needs or problems in the FA sector	**8.5.3**	Number of issues/description that are not very relevant			X				Sustainability as a whole is a new need partially addressed

Primary sources			**Secondary sources**
Surveys	Yes		
Interviews	Yes		
Case studies	TBC		

Methods for analysis

- Mapping of legislation.
- Stakeholder consultation analysis.
- Intervention logic analysis.

Approach to answering the evaluation question and potential limitations

The relevance looks at the relationship between the needs and problems of the FA sector and society and the objectives of the intervention (if the Regulation is still relevant to address scientific and technical developments, what are the conclusions drawn up concerning the re-authorisation process, if the 10-year authorisation is still relevant, if there are issues not properly addressed in the Regulation or issues that have created unexpected needs or problems). This question seeks to clarify if the intervention (Regulation) addresses the current needs of the FA sector and society. In this case, the experience of national authorities and industry stakeholders should be taken into account throughout.

Interviews will be used, where relevant, to further elaborate on findings of the survey. Subsequently, they will focus mainly on collecting information on cases that relevance is not confirmed by the survey findings.

While we suggest asking all questions to MS authorities, it is likely that some will not be able to comment on certain aspects of relevance.

Therefore, we recommend offering a “Don’t know” answer for MS authorities for all questions.

Evaluation criterion: added value – EQ 9

Evaluation question 10:
To what extent has the Regulation achieved results which could not have been achieved by MS action alone and to what extent is EU level intervention still warranted?

Legislation concerned
Regulation (EC) No 1831/2003

JUDGEMENT CRITERIA	ID	RELEVANT INDICATORS	SH SV	NCA SV	INT	CS	LIT	COM	RESULTS
A majority of stakeholders perceive that the harmonised authorisation procedure at EU level achieves better results than a national level authorisation procedure	**9.1**	% of positive opinions	X	X	X				For a substantial majority of respondents, harmonisation of the feed additive rules at EU level achieves better results than action at national level. This is the case both with the centralised EU-level authorisation procedure and harmonised labelling rules (according to 101 and 105, respectively, out of 110 respondents). SH SURVEY (vii Consultation Synopsis Report, page 17) For nearly all NCAs, harmonisation of the authorization rules at EU level achieves better results than action at national level (26 out of 27). NCA SURVEY (vii Consultation Synopsis Report, page 24 and vii Consultation Synopsis Report, page 24 and ix Accompanying document: survey and PC results, page 63)
A majority of stakeholders perceive that harmonisation of labelling rules at EU level is more advantageous than	**9.2**	% of positive opinions	X	X	X				For a substantial majority of respondents, harmonisation of the feed additive rules at EU level achieves better results than action at national level. This is the case both with the centralised EU-level authorisation procedure and harmonised labelling rules (according to 101 and 105, respectively, out of 110 respondents). SH SURVEY (vii Consultation Synopsis Report, page 17) For nearly all NCAs, harmonisation of the authorization rules at

non-harmonised rules									EU level achieves better results than action at national level (27 out of 27). NCA SURVEY (vii Consultation Synopsis Report, page 24 and ix Accompanying document: survey and PC results, page 63)
A majority of stakeholders perceive that EU level intervention is still warranted	9.3	% of positive opinions	**X**	**X**	**X**				EU level intervention in the area of FA needs to continue, according to 71 out of 79 respondents (excluding 31 'do not know' responses). SH SURVEY (vii Consultation Synopsis Report, page 17) Hence, EU level intervention in the area of FA needs to continue, according to all 28 NCAs. NCA SURVEY (vii Consultation Synopsis Report, page 24 and ix Accompanying document: survey and PC results, page 63)

Primary sources			Secondary sources
Surveys	Yes		
Interviews	Yes		

Methods for analysis

- **Mapping of legislation.**
- **Stakeholder consultation analysis.**
- **Intervention logic analysis**

Approach to answering the evaluation question and potential limitations

This question considers arguments about the value resulting from the EU intervention. There are two aspects of the Regulation to which EU added value is most relevant: the labelling rules and the authorisation procedure. In this question, the experience of the national authorities and FeBOs should be taken into account throughout.

ANNEX IV. OVERVIEW OF BENEFITS AND COSTS AND TABLE ON SIMPLIFICATION AND BURDEN REDUCTION

Overview of costs – benefits identified in the evaluation[245]									
		Table 1 Overview of costs – benefits identified in the evaluation							
		Citizens/Consumers		Businesses		Administrations		[Others]	
		Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary
Costs: Authorisation of FA	**One-off costs** Economic cost for businesses (regulatory charges and compliance costs) in preparing a dossier: safety studies, efficacy studies, application fee for the method of analysis, consultancy, post monitoring, purchase of	.			Direct costs application for authorisation of an additive. On average of €1.1 million of which 37% are costs to demonstrate safety, 32% are costs to demonstrate efficacy and 22% staff costs.		Direct costs – Commission: €13,400 per application. – EURL: €18,500 per validation report for each application – EFSA: €27,450 per application of which €15,900 are internal costs – MS: €500		

[245] Identification of costs according to the Standard Cost Model (SCM). Methodology of costs can be found in the FCEC Final Report, Annex 5. Information about different costs is where obtained through the stakeholder survey, NCA_S survey, interviews and case studies. Information available in FCEC Final report, section 6 and Annex 4: Case Studies.

	equipment/ services and staff costs[246] For EFSA and EURL covers the assessment and validation of the method of analysis, respectively, For the Commission the management procedure for the authorisation and participation in the SCoPAFF meetings. For MS attendance to the SCoPAFF meetings and obligations derived from the implementation of the FA Regulation Expected						per application		
Costs for the studies	**One-off costs** Economic cost for businesses (compliance costs) for studies				Direct costs *In vitro* studies: €≤10,000 - 50,000 Laboratory				

[246] The staff time provided by operators was monetised using EUROSTAT data. Four categories of staff were considered: senior managers (category 1); professionals with university education (category 2); technicians with vocational education (category 3); administrative staff (category 4).

	necessary for preparing a dossier. Those costs are already included in the costs of application but due to their importance a breakdown is presented Expected.				animals: €≤10,000 – 400,000 Ruminants: €18,000 – 200,000 Pigs/ poultry/fish €≤ 10,000 - 400,000 Other species €30,000 - 150,000				
Cost: Renewal of authorisation	One-off costs Economic cost for businesses (compliance costs) in preparing a dossier, for renewal of authorisation: literature review, studies where necessary, analysis of batches, consultancy, report for post-market monitoring where necessary, purchase				Direct costs Renewal for an additive. Average €216,000		Direct costs – Commission: €13,400 per application – EFSA: €16,470 per application – MS: €500 per application for each MS		

	of equipment and services and staff costs[247]. Expected								
Cost: Delays in the authorisation (Article 4)	**Recurrent costs** Hassle costs Unexpected				Direct costs It is not possible for applicants to monetise the costs and losses of the delays produced for the authorisation of a new additive. 7% of applications are processed within the reasonable deadline (1 year): 19% between 12-18 months, 25% between 18-24 months and 50% more than				

[247] The staff time provided by operators was monetised using EUROSTAT data. Four categories of staff were considered: senior managers (category 1); professionals with university education (category 2); technicians with vocational education (category 3); administrative staff (category 4).

					24 months.				
Cost: Labelling FA/premixtures	**One-off costs** Economic costs for businesses (compliance costs). The costs considered in this case are those linked to label changes that are triggered by regulatory changes (i.e., changes in an authorisation under the FA Regulation requiring adaptations to labels). The costs include design labels, change formulation for premixtures, comply with traceability requirements, translate labels, print labels Expected				[248] Direct costs for producers of FA and premixtures For FA, the costs are negligible. For premixtures: €80,000-€223,000 per plant per year Direct costs relevant for pet food manufacturers for very few cases when an additive is withdrawn, and the transitional period is shorter than the usual period. The estimations for re-labelling compound feeds				

[248] vi Case studies

					are €1 million to change the label of 2,000 references. For food-producing animals, the costs are negligible				
Costs: Disposal	**One-off costs** Economic costs for businesses (compliance costs). This refers to regulatory changes that require to dispose labels or products. Unexpected				Direct costs [249]Disposal of labels €2,000- for premixtures applying the usual transitional period; €24,000- 40,000 in product value and €13,500 in labels for premixtures when the change affects an important additive widely used and the transitional				

[249] vi Case studies

					period is shorter than the usual transitional period – e.g., the suspension of the antioxidant ethoxyquin. The occurrence of this possibility is very low.				
Costs: Administrative burden	**One-off costs** Administrative burden. Costs to change the authorisation holder Expected				Direct costs Negligible just a notification to the Commission.		Direct costs - Commission: €13,400 per Regulation. - For the MS €14,000 per Regulation.		
Costs: Enforcement	**Recurrent costs** Enforcement costs to perform control activities by MS. Expected						Direct costs € 74,000 per year on average MS to control the implementation of the Regulation.		
Benefits: reduction of cases of AMR	**Recurrent benefits** Reduction of cases of specific antibiotic-resistant microorganisms in livestock farming. Expected	Direct benefits Consumers and pet owners and society in general, as they will face		Direct benefits Increased worker safety through less development				Direct benefits for animal health (reducing AMR in livestock farming and	Impossible to quantify in monetary terms in any widely accepted way.

		reduced AMR-related threats.		of AMR. Indirect benefits for farmers in preventing losses from animal diseases				companion animals) and the environment	
Benefits: authorization process	**Recurrent benefits** Simplification, harmonisation and predictability (not fully accomplished) of the authorization process Expected			Direct benefits for applicants. Reduced uncertainty related to the authorization process Direct benefits for farmers availability of safe efficacious FA	Impossible to quantify using accepted methodology.	Direct benefits Reduced administrative costs of the authorization process for MS.	Impossible to using accepted methodology.		
Benefits: risk assessment	**Recurrent benefits** Risk assessment performed by EFSA Expected	Direct benefits for consumers from EFSA making sure that FA will not contain microorganisms, toxins or	Impossible to quantify using accepted methodology, but presumably high.	Direct benefits for farmers in: Preventing losses from animal diseases Increasing			Direct benefits as MS do not need to perform risk assessment	Direct benefits on animal welfare. and animal health Benefits for consumers and workers	Impossible to quantify using accepted methodology

		other substances that may be transferred to food		animal performance. Better use of resources. Balanced diets. Direct benefits for FeBOs: -Prevent loses, due to recall or disposal, in particular, loses generated by 1,743 additives potentially unsafe or inefficacious out of the market - Ensure level playing field as only efficacious additives are placed on the market				Direct benefits for society from reducing the environmental impact of livestock production and ensure safe food.	

Benefits: risk assessment	**One-off benefits** 1,743 potentially unsafe or inefficacious additives out of the market as they were not assessed for safety and/or efficacy according to the new requirements Unexpected				Impossible to quantify using accepted methodology				
Benefits: labelling	**Recurrent benefits** Prevention of the misuse of FA along the food chain through labelling provisions Expected	Direct benefits for consumer protection from the labelling provisions which contribute to control the presence of FA residues in food of animal origin.		Direct benefits for worker safety and for animal welfare and animal health from the labelling provisions.	Impossible to quantify using accepted methodology			Direct benefits Reduce misused of FA lead to a reduced risk of environmental impact and food threats Direct benefits for animals from safe and appropriate use of FA	Impossible to quantify using accepted methodology

Benefits: Enforcement	**Recurrent benefit** Enforcement benefits to perform control activities by MS. Expected	Indirect benefits for consumers from increasing safety of food of animal origin		Indirect benefits for farmers in preventing losses from feed additive frauds and safety issues			Direct benefits		
Benefits: specific interests of pet owners and their animals	**Recurrent benefits** Assessment of chronic toxicity, mutagenicity and carcinogenicity effects of FA to prevent any negative impact on pets' health. Expected	Indirect benefits for pet owners who have the possibility to use safe and efficacious products to care for their companion animals						Direct benefits for pet welfare from safe, efficacious, and relevant FA available	Impossible to quantify using accepted methodology
Benefits: Holder Authorisation	**Recurrent benefits** Encourage innovation and improve traceability. Expected			Direct benefits to feed additive manufacturers in terms of exclusive profit.	Impossible to quantify using accepted methodology			Indirect benefits Facilitates traceability	

TABLE 2: Simplification and burden reduction (savings already achieved)								
	Citizens/Consumers/Workers		Businesses		Administrations		[Other…] _ specify	
	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Type: recurrent / Reduction of feed/panel /working groups meetings at EFSA	No quantification impossible				EFSA changes in the system to organise meetings. The costs in 2016 were € 819,368. In 2017 there was a reduction of € 67,590 and in 2018 of € 303,938			
Type: recurrent / Reduction of SCoPAFF meetings		.			Reduction of two meetings per year for the Commission: € 600 per meting For MS reduction of travel costs could be minimum € 27,000 per meeting. For a reduction of two meeting per year to amounts to €54,000 per year			

PART II: II Potential simplification and burden reduction (savings)								
	Citizens/Consumers/Workers		Businesses		Administrations		[Other…] _ specify	
	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment	Quantitative	Comment
Description:								
Type: One-off / recurrent (select)								
One-off Clarify the requirements to demonstrate efficacy for environmental and animal welfare effects Reduction of application costs.				X No quantification is possible				
One-off Improve extrapolation from major to minor species will reduce application costs				X No quantification is possible				
One-off Improve the extrapolation from food to feed will reduce application costs				X No quantification is possible				
One-off Clarify definitions will reduce discussion at the SCoPAFF						X No quantification is possible		
One-off Clarify the status of recommended levels, biocidal products *versus* FA in water for drinking and use of additives in				X No quantification possible		X No quantification possible		

water for drinking. Will reduce discussions at the SCoPAFF and application costs								
One-off Establish labelling tolerances for FA in premixtures will reduce costs derived from the necessity to change labels, additional storage costs if the circulation is impeded when problems arise in the circulation within the EU due to different interpretation by MS				X No quantification possible		X No quantification possible		
Recurrent Prohibit duplicative testing and explore new testing strategies to reduce animal testing may reduce application costs.				X No major savings are expected as there were only three cases occurred during the implementation of the Regulation				
Recurrent Extension of the authorisation period from 10 to 15 years						Average over 30 years: -if extended to all additives =€ 889,000 per year only for the		

						Commission -if extended only to additive having high level of safety: =€249,000 per year only for the Commission		
Recurrent Simplify the procedure to change the authorisation holder will reduce administrative burden for the Commission	l				X	Commission: €13,400 per Regulation. - For the MS €14,000 per Regulation.		
Clarify the labelling of worker safety provisions reduce costs derived from the necessity to change labels, additional storage costs if the circulation is impeded when problems arise in the circulation within the EU due to different interpretation by MS				X Not possible to quantify				

ANNEX V-STAKEHOLDERS CONSULTATION – SYNOPSIS REPORT

The synopsis report summarises the consultation activities carried out, the stakeholders who contributed, and their opinions and to inform stakeholders on how their views have been taken into account in the analysis.

1. - CONSULTATION STRATEGY

The consultation strategy was drawn up in the Roadmap launched in August 2017 and lately completed in the terms of reference of the support study. The consultation aimed at

- collecting information and data on the application of the Regulation.
- gathering information on the experience of different stakeholders with the implementation of the relevant rights and obligations,
- collecting views on the different provisions of the Regulation and their effects, including information on costs and benefits.

Different stakeholder groups were identified in the consultation strategy, including public authorities, Commission representatives, EFSA, FA industries (producers and users), farmers, veterinarians, consultants' associations, food additives' associations, citizens and consumers, NGOs (e.g., environmental, health, and animal welfare organisations), and the research and innovation community. Many stakeholders of the FA supply chain (including manufacturers, traders, and users) are represented by umbrella associations. These associations actively engaged in the consultation process. Environmental organisations, animal welfare organisations and consumers did not contribute despite the efforts to involve them. For animal health the FVE participated and for farmers COPA-COGECA. There were also 16 citizens responding the PC.

The consultation strategy included feedback to the Roadmap and to the Public Consultation. It also included the following activities conducted as part of the evaluation study: exploratory interviews carried out during the inception phase of the evaluation study, targeted interviews, a survey to stakeholders, a survey to competent authorities, a survey to competent authorities from non-EU countries and case studies.

In addition, there were three documents submitted out of the formal consultation: two from FEFANA and one from a group of nine FA/premixtures producers. The letters from FEFANA were very relevant to explain the claims issue that was not so evident from the study performed by the contractor although raised by this organisation during the PC.

No campaigns have been identified to massively respond with suggested responses.

The following sections summarise the outcomes of each consultation activity.

2.- METHODOLOGY AND ANALYSIS

For the ROADMAP and the Public Consultation, the EU Survey platform was used. The data of the PC were processed in excel files that contained the response to closed question and open questions. For the stakeholder Survey and the NCA Survey, the contractor used their own platform and provided the Commission the position papers, and responses to the different questions.

3. - RESULTS OF THE CONSULTATION ACTIVITIES

3.1. - ROADMAP

3.1.1. Overview of the evaluation Roadmap and respondents

The Roadmap was open for feedback from 28 August to 25 September 2017. Feedback was received from 13 stakeholders and published on the Have Your Say page[250].

3.1.2. Outcome

Overall, respondents focused on the shortcomings of the legislation rather than on the planned evaluation methodology.

Feedback covered the challenges related to definitions in the FA Regulation (e.g., distinction between feed materials and FA, premixtures, etc.) and to the different interpretation of the provisions of the FA Regulation by MS. Concerns were also shared on the authorisation period (too short), the duration of the renewal process, the demanding procedure of the modification of the authorisation and on the low predictability of the assessment process, including the frequent revision of EFSA guidance. The necessity to revise the labelling rules was also raised as well as the need to improve coherence with the Regulation on the classification, labelling and packaging of substances and mixtures. Finally, some objectives of the FA Regulation were supported, including the need to facilitate innovation and to combat antimicrobial resistance by developing new alternatives to the use of antibiotics.

3.2.- PUBLIC CONSULTATION

3.2.1. Overview of the Public Consultation

The Commission held a public consultation (PC) which ran from 12 December 2018 to 3 April 2019. The questionnaire was available in 24 languages and included 26 open and closed questions.

The PC targeted all stakeholder groups identified in the consultation strategy for this evaluation.

To ensure broad coverage, the Commission organised communications activities to encourage stakeholders to respond to the PC, in particular by contacting the EU umbrella organisations representing the different stakeholder groups. The targeted organisations were selected based on their outreach to the wider network of stakeholders they represent.

3.2.2. Respondents

110 responses were recorded and 7 of them provided additional documentation. The number of respondents to the PC, by stakeholder group, is as follows:

[250] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1483-Evaluation-of-the-feed-additives-Regulation_en

- 52 companies/business organisations (FA/premixtures producers, compound feed producers, pet food producers and feed materials producers).
- 24 business associations representing FA / premixtures producers, pet food, compound feed, feed materials and farmers).
- 16 EU citizens,
- 12 public authorities.
- 6 'other' organisations (2 consultants, 2 veterinarians, 1 academic/research organisation and 1 umbrella organisation representing veterinarians).

There is a relatively high share of responses received from business stakeholders (70% of the total). Amongst companies (manufacturers and traders), many responses were received from SMEs (29).

Contributions were mainly received from stakeholders from Belgium (22[251]), France (19), Germany (13), Spain (12) and the Netherlands (10) while stakeholders from other EU countries were less represented. 10 contributions from outside the EU were received: The USA (3), Japan and Switzerland (2 each) and Canada, China and Turkey (1 each).

Seven supporting documents were received, including five position papers on the use of coccidiostats as FA (submitted by 6 respondents), and two proposals for revisions of the Regulation (submitted by one respondent).

3.2.3. Outcome

The factual summary report summarising the outcomes of the PC was published on the Have Your Say page [252]

Safety and efficacy of FA

The majority of respondents find FA are safe and efficacious. 72% of all respondents agree that the ban on antibiotics introduced by the Regulation played an important role in preventing antimicrobial resistance (AMR).

Similarly, 90% of respondents agree that the safety assessment of FA carried out by the European Food Safety Authority (EFSA) has helped make FA safe for human health, animal health and the environment. One third of citizens responded "neither agree nor disagree" or "don't know"

For most respondents (59%) – mainly public authorities and business associations – the Regulation has been effective in preventing food/feed crises and losses.

Authorisation procedure and definitions of the FA Regulation

Respondents largely agree that there is an added value in having a harmonised, centralised authorisation procedure for FA at the EU level, however they are divided when dealing with some aspects of the implementation of the Regulation.

[251] This includes international and pan-European organisations based in Belgium.

[252] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1483-Evaluation-of-the-feed-additives-Regulation/public-consultation_en

Just over half of respondents find that the Regulation does not make it easier to place new innovative additives on the market when compared with the former Directive.

Respondents' views diverge on whether the definitions in the Regulation are clear, relevant and up to date. Almost half of the respondents find they are, whereas just under 30% disagree. Some definitions should be clarified and completed (e.g., preparations or use in water.), as well as better aligned with the feed catalogue and other feed regulations.

Views on the suitability of procedures set out in the Regulation vary. Almost 3/4 of respondents providing an answer consider that having a centralised authorisation procedure ensures equal treatment of all applicants and common requirements (only 5% consider it does not). Just under half find that the procedure for submitting an application is fit for purpose (14% consider it is not), with business associations particularly negative on the suitability of data requirements. Regarding the procedures for granting, modifying, suspending and revoking an authorisation, as well as the procedure for sharing data, the industry was much more equivocal on whether these are fit for purpose. A large number of "Don't knows" for these questions (16-34%, depending on the procedure). Around 10% of all respondents provided no answer.

Respondents generally find that the authorisation procedure set out in the Regulation involving EFSA and the Commission is still fit for purpose and the risk assessment carried out by EFSA allows for sound decision making.

The Register of FA is considered by a majority of stakeholders (59 out of 110) to be an efficient tool for FeBOs to be aware of all additives authorised; nevertheless, for 26 operators out of 110, it needs to be improved to become more informative and user-friendly. The main negative issue commonly identified by respondents is the format of the Register.

Data protection

Over half of respondents were not able to answer whether data protection rules are effective in relation to the cost of preparing dossiers and the benefits provided by the 10-year protection, and if data sharing rules are effective in reducing costs and animal testing. 2/3 of total respondents find the implementation of these aspects is not effective, with a particularly negative response from industry about data protection rules. The main issue identified by respondents expressing a negative view is that data sharing is not being used to its full potential.

Labelling

A majority of respondents find that FA and premixtures labelling is informative and helps prevent their misuse along the feed chain, but the Regulation should also allow for information through other channels. Those respondents that expressed negative views consider there is a need to make labelling requirements more practical, facilitating the information flow along the feed chain, to be coherent with other legislation, for instance the feed marketing legislation (Regulation (EC) 767/2009). Labelling rules for worker safety provisions were contested by a quarter of respondents, especially amongst companies/business organisations, business associations, and EU citizens.

36 industry representatives provided precise comments indicated the importance of setting up a claims system to raise awareness of the positive benefits of FA and premixtures and to align the FA Regulation with the Feed Marketing Regulation that regulate claims in fed materials and compound feed.

Efficiency: cost /benefits

Regarding the costs and benefits of the Regulation, respondents views vary, with business associations particularly negative. For most respondents (59%) – mainly public authorities and business associations – the Regulation has been effective in preventing food/feed crises and losses.

Only 36% of respondents find the cost of FA/premixtures labelling is justified including a majority of public authorities consider it. Business associations are divided and companies/business organisations tend to consider that the cost is not justified (no possibility to transmit the information by means other than a physical label).

Only 12% of respondents find the cost of applications for getting a feed additive authorised in the EU market is proportionate to the benefits. This is mainly due to the 10-year duration of the authorisation, which is considered insufficient, the challenges of completing the assessment of efficacy, and the non-holder-specific authorisations (costs borne by applicant/s and benefits enjoyed by all FeBOs when putting the authorised feed additive on the EU market).

EU added value

A harmonised authorisation procedure achieved better results at EU level than a national level authorisation according 96% of respondents. Respondents largely find that EU harmonised conditions for placing FA on the market ensure fair competition within the EU and facilitates trade and that the EU level intervention in this sector is still warranted.

Relevance

Respondents are divided as to whether the authorisation of FA should consider – and sufficiently considers – (a) societal needs and (b) economic aspects, as well as safety and efficacy. For both questions there is a relevant "Don't know" responses (25%). Citizens are slightly more inclined to indicate that societal factors are not sufficiently taken into consideration. Industry had a higher propensity, compared to other respondent groups to consider economic aspects being sufficiently taken into account. For both questions, there is a relevant number of 'Don't know' responses, mainly from business associations, public authorities, citizens and NGOs.

Needs identified by several respondents (across all types of respondents) as not sufficiently considered by the current authorisation process are:

- Ensuring innovation, especially by SMEs, on new product development aiming to address evolving societal needs.
- Enabling authorisations that do not have large commercial support (minor species).
- Avoiding the economic impact stemming from inconclusive EFSA opinions that requires to submit additional information.
- Avoiding unnecessary animal testing.

Innovation

– Only half of the respondents could answer certain questions on the scope of the Regulation. From those respondents a small minority (18% of respondents) find that the Regulation is sufficiently flexible to new scientific and technical developments. Also, 45% of those respondents think that new categories of FA and/or functional groups need to be considered by the Regulation. Almost 40% of those respondents find that the use of additives in drinking water needs to be clarified, especially for technological additives (e.g., preservatives with the legislation on biocidal products.

– 36 respondents from the industry were in favour of extending the holder authorisation to other additives to foster innovation. The main arguments were that the applicant bear the authorisation costs but other operators benefit from this authorisation when the additive is authorised. This reduces the interest of applicants to apply for the authorisation of those additives.

3.3. - STAKEHOLDERS SURVEY

3.3.1. Overview of the survey

A stakeholder survey was disseminated between July and September 2019 to all stakeholders affected directly or indirectly by the FA Regulation. The Commission directly invited 70 umbrella organisations representing the different stakeholder groups to respond to the survey, including from the fields of animal welfare, environmental NGOs, consumer organisations, farmer and trade associations. Information on the survey and the link to the survey were also available on SANTE webpage. In addition, EU umbrella organisations were asked to make the survey available to their members.

In some cases, a large number of respondents did not provide a definite answer (i.e., '*neither agreed nor disagreed'*). This may suggest that they do not have a strong opinion.

3.3.2. Respondents

Manufacturers of FA and premixtures account for the largest number of replies (36 out of 112) (e.g., specialty feed ingredients business, compound feed and premix industry, and the pet food industry. Users (e.g., farmers and cooperatives, the poultry sector and the lecithin industry) also participated in the survey. Consumers and animal welfare organisations did not contribute to this survey.

63 manufacturers produce FA and other feeds, of which, nearly half (30) produce FA and/or feed for both food producing and non-food producing animals.

Between 48% and 50% of manufacturers of FA, premixtures, and compound feed had more than 75% of increase of the company turnover and company benefits. This means that for the remaining FeBOs the importance of FA for the company is shared with other activities.

The sample of responses suggests that the manufacturing and trading operations of FA and/or premixtures tends to be conducted as a separate business, with only 3 manufacturers indicating they are involved in trading (even though, this question was answered by only 37 respondents out of the 63 manufacturers and 14 traders). Amongst

manufacturers and traders, almost equal numbers of responses came from larger companies and SMEs.

Few users (e.g., farmers and cooperatives, the poultry sector and the lecithin industry) also participated in the survey. Consumers and animal welfare organisations did not contribute to this survey.

Finally, three additional documents were shared by stakeholders to support their contributions.

3.3.3, Outcome

Safety and efficacy of FA

Stakeholders generally agree that FA are safe (108 out of 112 respondents) and efficacious (103 out of 112 respondents). Nonetheless, over 90% of responses came from the FA/premixtures and feed sector. A substantial majority of respondents agree that FA on the EU market are safe for animals (108 out of 110), users and workers (92 out of 109), the environment (92 out of 110), and consumers (103 out of 111).

With regard specifically to pet food additives on the EU market, nearly all respondents agree that they are efficacious and safe for pet animals (74 and 76, respectively, out of 78 respondents). Respectively 28 and 30 respondents did not provide an answer as pet food is not relevant for their organisation.

A majority of respondents, including farmers, consider the use of coccidiostats and histomonostats to be important as FA to ensure the health and welfare of poultry and rabbits (61 out of 71), well adapted to current farming practices (65 out of 72) and effectively controlled (63 out of 70). In all cases a significant number of respondents could not answer. Moreover, for farmers, this use is a prevention measure to control the potential spread of coccidiosis. This effectively leads to economic benefits for farmers by preventing the potential costs arising in terms of veterinary costs and antibiotic treatments.

A majority of respondents agree that FA on the EU market are safe for consumers (92%) and for users (84%)

Authorisation procedure

More than 82% of FeBOs consider that applicants have sufficient time to complete dossiers when EFSA requires so.

As regards the simplified procedure for FA authorised in food, a majority indicates that the procedure does not work well (54%).

Almost half of respondents indicate that the extrapolation to minor species does not work well (43%) but there is around a third of respondents does not know or does not have experience.

Applicants find that the authorisation procedure is more or less efficient. There are diverging views on the 10-year authorisation period and the re-evaluation procedure.

Operators negatively perceived whether the authorisation took into account legitimate factors (58% of negative responses and only 24% of positive responses).

Respondents present divided views on the adequacy of the 10-year authorisation period to promote innovation. The measure is considered adequate by 27% of respondents and not by 25% of respondents, with 39% of respondents who neither agree nor disagree. 22% of respondents find that the 10-year authorisation period is necessary to ensure safety; whereas 25% of respondents think the opposite (35% neither agrees nor disagrees).

A majority of respondents do not consider the update of the method of analysis for the authorisation renewal to be necessary (51 out of 101); whereas it is considered necessary by 26 respondents. On the other hand, the role of the EURL is adequately defined in the Regulation according to the majority of respondents.

For a majority of respondents (59%), non-holder-specific authorisations for nutritional additives, technological additives and sensory additives should not be replaced by authorisations linked to a specific holder; whereas, for 23% of respondents, they should (8% don't know).

Innovation and scientific/technological progress

A majority of respondents (45 out of 107) consider the authorisation procedure to be not suitable to address scientific and technical developments for pets and livestock production, due to the time periods incurred (compared to 34 that consider it suitable); and, in the light of scientific and technological developments, the criteria used for authorisation of FA are not considered as still relevant by 28 out of 44 respondents (compared to 13 that consider them still relevant).

For a majority of respondents (59%), non-holder-specific authorisations for nutritional additives, technological additives and sensory additives should not be replaced by authorisations linked to a specific holder; whereas, for 23% of respondents, they should (8% don't know).

Regarding scientific and technical progress, respondents – especially manufacturers of FA and premixtures, and organisations/consultancies assisting them – do not find that the Regulation is sufficiently suitable. Beyond definitions not being apt to the current state of scientific and technical progress for a slight majority of respondents, missing functional groups are the most common issues identified within the Regulation (EC) 1831/2003 (although, by less than a quarter of respondents).

Labelling

Almost as many respondents (53 out of 111) consider labelling requirements to be fit for purpose and not being fit for purpose (45) do (particularly manufacturers of FA and premixtures, followed by manufacturers of compound feed and FA). The obligation to indicate all the information in a physical label is perceived as a major constrain.

Costs, benefits and competitiveness

The majority (34 applicants out of 38) indicated that the regulatory costs of authorisation have a negative impact on **competitiveness**. For 20 of them, the negative impact is

strong. This opinion was confirmed by the interviews conducted during the case study on the authorisation. The main elements of the authorisation process, which are identified as affecting competitiveness, are costs, especially the **costs** of efficacy studies which are considered disproportionate to real market needs, and the time required from the application to the approval, including the unpredictability of the process.

The majority of respondents, across all groups, consider that the Regulation provides benefits for farmers, pet owners, animal welfare, human health, consumers and the environment, as well as for feed additive and compound feed producers.

On the other hand, applicants expressed some concerns over the efficiency of the current implementation of the procedures laid down in Articles 4, 10 and 13, and they stress that there is scope for reduction of administrative burden.

International trade

On exports, a majority of respondents (35 out of 65 – excluding 19 'do not know' responses) consider the rules applicable to the export of FA are properly addressed in the Regulation, while 20 respondents disagree.

On Imports, a majority of respondents (40 out of 62 – excluding 17 'do not know' responses) consider imports of FA into the EU to be adequately controlled, while 14 respondents disagree.

Relevance

Most needs identified during the drafting of the Regulation are considered to have a high level of relevance, even though some new needs are also identified. Reduction of AMR threats is also relevant for a majority of respondents (104 respondents out of 111). However, some of the "new needs" identified cannot be regarded as such since the FA Regulation already covers those aspects; it is the case of the environment, animal welfare. FeBOs identify some of them as "new needs" as they have high expectations placed upon those topics, which they considered were not fulfilled.

Coherence

Some contradictions and inconsistencies were identified with the Regulations on feed marketing (EC No 767/2009) and on the Catalogue of feed materials (EU No 68/2013). The points related to coherence mainly refer to the labelling provisions of the Regulations.

EU added value

The harmonised authorisation procedure achieved better results at EU level than a national level authorisation (101 positive responses out of 110). For the harmonisation of labelling rules at EU level, the opinion was also positive (105 positive responses out of 110). In addition, there is also a majority (71 positive responses out of 110) in favour of supporting that the EU level intervention in the FA area is still relevant.

3.4. SURVEY TO MS NCA

3.4.1 Overview of the survey

The survey was sent to the NCA from all 28 MS, EEA countries and Switzerland and was open from July to September 2019. The objective was to collect data and insights on the implementation of the Regulation, focusing on the enforcement of the Regulation by the NCAS. Among others, the Commission made a presentation on the survey during the Standing Committee on Plants, Animals, Food and Feed in July 2019 to inform delegations on the survey.

3.4.2. Respondents

Altogether, **27 replies** were received from 25 EU MS (Hungary, Romania and the UK not participating) as well as Norway and Switzerland.

The high rate of responses was considered very satisfactory, also taking into account that the completion of the questionnaire required coordination of the NCA in charge of the feed legislation with other official instances (e.g., feed controls).

5.3 Outcome

The feedback provided in the open questions has been taken into account and synthesised when addressing the relevant judgement criteria and evaluation questions.

Safety and efficacy

MS authorities generally find that FA are safe and efficacious.

Nearly all MS authorities consider important the use of coccidiostats and histomonostats as FA to ensure health and welfare of poultry and rabbits (24 MS authorities; no NCA disagreed), well adapted to current farming practices (20; 1 NCA disagreed), and effectively controlled (19; 2 MS authorities disagreed); the remaining few MS authorities did not provide a definite answer (i.e. neither agreed nor disagreed with the above statements).

As regards specifically pet food additives on the EU market, nearly all MS agree that they are efficacious and safe for pet animals (3 MS authorities neither agreed nor disagreed that they are efficacious). Two of these MS authorities commented that it is not so clear what efficacy means and what is being measured in the case of pet animals; adding that the efficacy of many additives used in pet food is extrapolated from their use in food.

A majority of MS agree that FA on the EU market are safe for consumers (26 NCA s) and one NCA does not agree neither disagree.

Authorisation procedure

The authorisation procedure and the re-evaluation procedure are seen as working in a better way than the Directive, but some issues and scope for improvements have been identified.

Opinions on the 10-year authorisation period are more varied. Key comments provided by the MS authorities who disagreed or did not provide a definite answer include that a 10-year authorisation can be too short to encourage innovation, particularly for smaller companies. For FA of lower risk, a period of 20 years could be more appropriate. For FA of higher risk (coccidiostats), the current 10-year period is generally appropriate. The 10-year authorisation period was perceived as effective for safety purposes by a slight majority of MS authorities (17 out of 27). Six MS authorities did not respond and 4 disagree.

The different deadlines foreseen by the Regulation are overall considered reasonable by a majority of MS authorities.

A majority of MS authorities (18 out of 27) consider that the extrapolation from major to minor species worked well, although 3 strongly disagreed with this statement and 3 did not have an opinion. As regards the procedure of extrapolation from food to feed, a majority agree that works well (16) although, 8 neither agree nor disagree and 1 disagrees.

The role of the EU-RL is adequately defined in the Regulation according to 22 MS authorities. Only one NCA disagrees, commenting that the EU-RL competence could be enhanced, e.g., to support the national laboratories with the development and/or execution of analysis, as well as the MS authorities whenever needed.

Labelling

Most MS authorities (19) consider labelling requirements to be fit for purpose, only 3 MS authorities disagreed, 3 MS authorities did not provide a definite answer. A key comment by the MS authorities is that the labelling could be modernised, with certain indications potentially provided in a separate document (other than the label).

Innovation

12 MS authorities consider that innovative FA can be placed on the market, 4 MS authorities disagreed, and 9 MS authorities did not provide a definite answer. The cost and complexity of the authorisation procedure are the main issues raised, especially for new FA for which functional groups or performance criteria (endpoints) may not be readily available.

Efficiency

Most MS authorities consider the current implementation of the Regulation to be efficient although, according to 10 MS authorities, there is scope to reduce administrative costs.

Relevance

Most needs identified during the drafting of the Regulation are considered to have a high level of relevance, although some new needs have been identified.

Coherence

Some inconsistencies between the FA Regulation and the legislation on feed materials/compound feed, the CLP legislation and the biocides legislation were found. Those shortcomings were also identified by stakeholders in the SH Survey and case studies. Within the FA Regulation, the main contradictions/issues identified by 9 NCAs were absent definitions and/or key terms.

International trade

Action has been taken by 19 MS to avoid that additives and premixtures not authorised in the EU, which are intended for export, end up on the EU market. Six (6) MS have not taken any action.

On imports, 11 NCAs consider imports of FA into the EU to be adequately controlled and 14 NCAs consider them to be partially controlled, raising concerns. The main concerns raised by the latter NCAs are linked on to the absence of an EU list of third countries from which FA can be imported and on the lack of Combined Nomenclature codes to identify products.

Control

The controls performed by MS authorities shows a good level of control and high conformity.

Infringements and penalties have been established in all MS, but they diverge. Few MS provided data on the number of penalties imposed and the number of cases where products were withdrawn from the market because of infringements during the 2011-2015 period. This is partly due to the different administrations involved and the fact that there is no readily available breakdown of sanctions specifically imposed in the FA/premixtures sector. (EM 6.9)

EU added value

All MS authorities agreed that harmonisation of the authorisation procedure at the EU level achieves better results than actions at the national level (26 MS authorities agreed and one did not provide definite answer). For the harmonisation of labelling rules, MS authorities unanimously agreed. There was also unanimity that the EU level intervention in the FA area is still warranted and needs to continue.

3.5 - NON-EU COUNTRIES SURVEY

3.5.1 Overview of the survey

The targeted survey was addressed to the NCAs of eight non-EU countries, which are major producers of FA. These included Argentina, Australia, Brazil, Canada, Chile, China, Japan, and the USA, as well as the representatives from the industry of these countries.

The objective of the survey is to collect information on the legal status of coccidiostats and histomonostats (C&Hs), how the procedure of authorisation and risk assessment is

conducted in third countries, and to what extent the EU system was recognised in these markets. The survey was open from July to September 2019.

3.5.2 Respondents

Six countries responded to the EU survey: Argentina, Canada, Chile, China, Japan, and the USA. These countries account for an estimated 40% of the world FA market, which is similar to the EU-28 share of the world market.

3.5.3 Outcome

The following aspects were examined:

Definition and classification of FA: FA are not always defined as a distinct category and tend to be classified less precisely than in the EU. In some countries some EU additives are regarded as feed materials and do not need authorisation. In relation to the legal status of coccidiostats and histomonostats, they are regarded as FA in one country but in the rest of the countries they are veterinary medicinal products. All countries classify additives but only 4 take into account the purpose of the additive (e.g., effect on the feed or on the animal) in the classification. Those different approaches on the scope of FA make the comparisons difficult as the evaluation and authorisation of FA may affect very different products depending on the jurisdiction.

Authorisation process: All countries have a process in place for feed additive approval, which includes a scientific risk assessment. When compared to the EU authorisation process, the components of the process followed in non-EU countries have generally lighter requirements, which significantly vary per country. One of the six countries appears to be the most aligned to the EU, since all requirements for safety and efficacy assessment need to be met. It is followed by three countries. In most cases, these three countries impose similar requirements to those in the EU. The remaining two countries generally apply requirements based on the product's process monograph. One of these also applies more detailed requirements on safety, namely the identification and characterisation of the additive (e.g., purity, presence of impurities, contaminants, etc.), but no specific tests on the target animals. As regards worker safety, only two countries made test for this purpose. Furthermore, in all countries, applicants can submit additional information during the assessment process, and, with the exception of one country, they can hold meetings before formally submitting the application, mainly for clarification purposes.

Table 1 Type of tests and aspects examined during the assessment

ASPECTS EXAMINED-TESTS	COUNTRIES						
	EU	1	2	3	4	5	6
Animal health	X	X	X	X	X	X	
Human health- consumers	X	X	X	X		X	X
Human health (workers)	X		X	X		X	
Environment	X	X	X	X		X	
Efficacy	X	X	X	X		X	
Identification and characterisation additive	X		X	X	X	X	X
Maximum residue levels in food when necessary	X	X	X			X	X

ASPECTS EXAMINED-TESTS	COUNTRIES						
	EU	1	2	3	4	5	6
Tests on target animals	X	X	X	X		X	
Tests for human safety	X	X	X	X		X	
Test for worker safety	X			X		X	
Tests for environmental safety	X	X	X	X		X	
In vitro studies	X	X		X		X	
Studies on Laboratory animals	X	X		X		X	
Studies on target animals	X	X	X	X	X	X	
Guidelines for applicants	X	X		X	X	X	X

Timelines: The time taken to process an application for authorisation can vary considerably from one country to another, from a few months (in the case of three countries) to about a year (in the case of two countries). Only in one country, the procedure can take up to several years. In this regard it seems that the EU system to get an authorisation is, in general, more time demanding, except in one country where the deadlines may be similar or even higher.

Renewal of authorisation: The authorisation is granted on an indefinite basis in three countries. In two of these countries, there is no such mandatory requirement, but the authorisation may be re-evaluated based on the applicant's request or new information becoming available. A procedure for renewal is foreseen in the remaining three countries.

Claims: three countries indicated that they permit claims that are proven by specific tests or scientific evidence during the evaluation. One country indicated that in addition to the clams evaluated during the authorisation they admit claims substantiated by the operator when the additive is placed on the market if they are in line with the regulated product. One country did not respond to this issue.

Recognition to the EU authorisation: - Two countries (Chile and Canada) appraise substantial parts of the EU authorisation procedure, largely because their approaches are relatively aligned. In the remaining four countries (Argentina, China, Japan, the USA), the differences are considered to be too important to allow the EU authorisation process to be recognised when registering EU approved products in their markets. Nonetheless, China indicated that technical data on FA authorised in the EU is used as a reference for the technical assessment of these substances by the authorities in China. (EM 2.3.1)

3.6 INTERVIEWS AND CASE STUDIES

. 3.6.1. Overview and participants of interviews

At the initial phase of the evaluation study, 8 exploratory interviews were carried out by the contractor with key stakeholders between June and September 2018 to ensure a good understanding of the important issues, identify data gaps, and identify any challenges related to the evaluation. These interviews contributed to the finalisation of the methodology and adjusting the data collection activities. Stakeholders taking part to these interviews were EU organisations: (EFSA, EURL, EC services) as well as three European umbrella organisations representing FA and compound feed producers and one representing veterinary professionals.

In addition, and in order to complement the evidence gathered through the surveys, 12 complementary interviews were conducted between September and October 2019. The interviews mainly aimed to collect further quantitative and qualitative data, especially on the costs and impacts of the FA Regulation**.** They also provided stakeholders with the opportunity to highlight their experience, raise key issues that may not have been covered throughout the online surveys, and clarify some information/data already provided. Stakeholders participating to these interviews were EU organisations (EFSA, EURL, and EC services), five European umbrella organisations representing producers and manufacturers of FA and compound feed: three organisations representing farmers, poultry meat and aquaculture and one organisation representing veterinary professionals.

Four additional interviews were made with four NCAs from Belgium, Germany, Spain and France).

3.6.2. Overview and participants to the case studies

The case studies covered two thematic areas:

- The authorisation process from the application to the market, covering all types of FA, focussing on three FA (selected from the Regulation's functional groups, to represent three of the most important categories).
- The labelling of FA, covering two FA and two pre-mixtures, focussing on four MS.

A total of 24 interviews were conducted with 20 applicants and with four selected MS (Belgium, Germany, Spain and France). Detailed information on the case studies is available in the FCEC Final Report, Annex 4.

3.6.3. Outcome

Generally, all interviewed stakeholders and MS Competent Authorities consider that the current FA Regulation has been effective in ensuring that FA placed on the market are efficacious and safe for animals, humans and the environment.

They also agree that, in comparison to the former legislation (Directive 70/524/EEC), the implementation of the authorisation procedure set out in the Regulation is central to the achievement of a high safety standard.

- The EU industry tends to consider that the competitiveness and capacity to innovate of the EU FA sector is undermined by the relatively strict requirements of the FA Regulation, the time periods and sometimes 'unpredictability' of the authorisation process. The functioning of the efficacy assessment was given as an example. The occurrence of some delays is supported by the quantitative data available from EC/EFSA data on the timelines of approvals. According to applicants, the requirements are too rigid to assess the efficacy and insufficient flexibility in the Regulation to adapt to scientific and technical progress (e.g., creation of new functional groups takes too long, the definition of endpoints is too focused on performance targets etc.). According to MS Competent Authorities, key reasons are applicants' insufficient understanding of the (efficacy) requirements and data availability/cost to perform the required studies.

Concerns for EU stakeholders to maintain its current level of competitiveness (e.g., livestock farmers and the aquaculture industry) fear that fewer products may be available for use in the future.

The absence of harmonisation and the limitations on the circulation of FA/premixtures only intended for export obstructs the level-playing field for all stakeholders.

In addition, according to both the industry and MS Competent Authorities, EU producers are particularly disadvantaged in the case of non-holder specific authorisations. Nevertheless, SMEs benefits from the non –holder authorisation as they do not bear authorisation costs. For additives linked to an authorisation holder SMEs try to focus on few species or categories of animals to reduce costs.

From an efficiency perspective, the industry highlighted that the potential benefits are not yet fully realised. 10-year authorisation period: the time periods and additional requests for information/data may lead to increased costs and undermine the final return on investment (ROI).

- Regarding the labelling rules (Article 16) and from a practical operational point of view, the amount of information required to be included on the product's physical label is not considered to be fit for purpose.
- Generally, there is consensus between Competent Authorities and business representatives that the Regulation is internally and externally coherent. However, some issues have been identified: status of FA *versus* feed materials, the interaction of FA legislation with CLP and Biocides legislation, and lack of resources in the Feed Hygiene Regulation to control imports (i.e., no list of Third-country establishments for the NCAS and lack of efficient control of imports for FeBOs).
- Stakeholders also agree that the Regulation plays a positive role in reducing/containing anti-microbial use, hence supporting the wider policy targeted to reduce AMR threats from livestock production. However, their opinions are different when dealing with the technical and scientific progress allowed by the Regulation. Business stakeholders remain sceptical on this last aspect, which is also in line with their views on the negative impacts of the authorisation procedure on competitiveness and innovation.
- Competent Authorities tend to have a more positive view on the implementation of the Regulation, including coherence and relevance of the objectives.
- There is unanimous agreement among MS Competent Authorities and business stakeholders that the current legislation adds a great value.

ANNEX VI- SUPPORTING TABLES OR DIAGRAMS

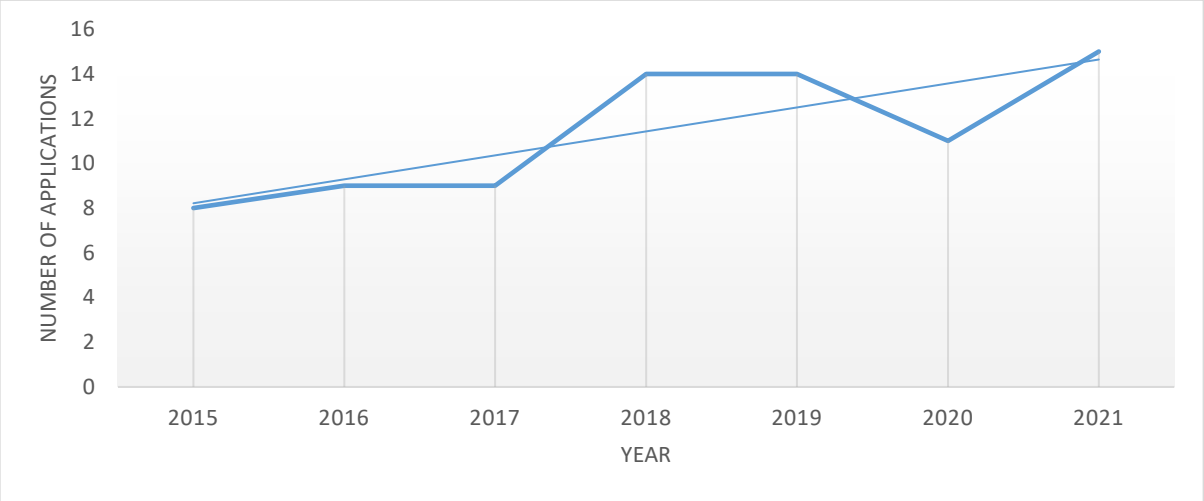
Table 1: list of categories and functional groups. The new functional groups introduced after the adoption of the FA Regulation are indicated in bold and underlined.

CATEGORY	FUNCTION	FUNCTIONAL GROUP
TECHNOLOGICAL ADDITIVES	*Substances added to feed for a technological purpose*	1. Preservatives 2. Antioxidants 3. Emulsifiers 4. Stabilisers 5. Thickeners 6. Gelling agents 7. Binders 8. Substances for control of radionuclide contamination 9. Anticaking agents 10. Acidity regulators 11. Silage additives 12. Denaturants **13. <u>Substances for the reduction of feed by mycotoxins</u>** **14. <u>Hygiene condition enhancers</u>** 15. **<u>Other technological additives</u>**
SENSORY ADDITIVES	*Substances that improve/change the organoleptic properties of feed or the visual characteristics of food derived from the animal*	1. Colourants 2. Flavouring compounds
NUTRITIONAL ADDITIVES	*Substances that improve the nutritional values of feed*	1. Vitamins, pro-vitamins and well-defined substances having a similar effect 2. Compounds of trace elements 3. Amino acids, their salts and analogues 4. Urea and its derivatives.
ZOOTECHNICAL ADDITIVES	*Substances that favourably affect the performance of animals in good health or the environment*	1. Digestibility enhancers 2. Gut flora stabilizers 3. Substances that favourably affect the environment **4. <u>Physiological condition stabilisers</u>** 5. Other zootechnical additives
COCCIDIOSTATS AND HISTOMONOSTATS	*Substances intended to kill or inhibit protozoa (parasites)*	

Table 2 EFSA guidance

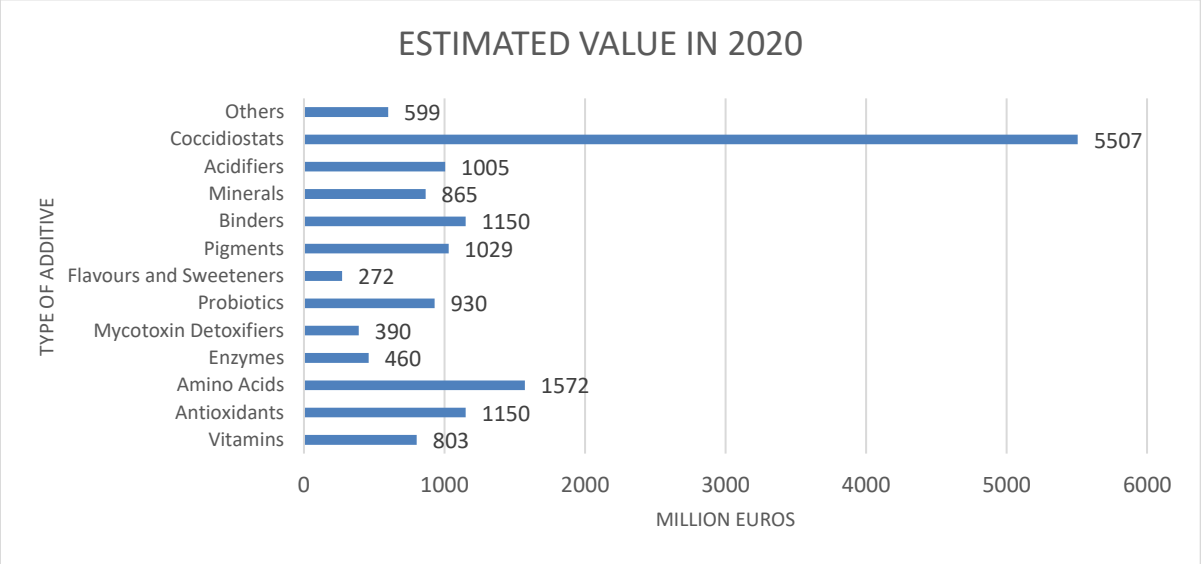
GUIDANCE	DATE OF ADOPTION
Guidance on the assessment of the safety of FA for the target species	26/09/2017
Guidance on the assessment of the safety of FA for the consumer	27/09/2017
Guidance on the identity, characterisation and conditions of use of FA	27/09/2017
Guidance on the characterisation of microorganisms used as FA or as production organisms	21/02/2018
Guidance on the assessment of the efficacy of FA	17/04/2018
Guidance on the assessment of the safety of FA for the environment	27/02/2019

Figure 1: number of applications for microorganisms



ANNEX VII- FA MARKET DATA

Figure 1: Estimated value for different types of FA in the EU in 2020.



Source: Mordor Intelligence, 2022. Note: Data provided by Mordor Intelligence have been converted from USD to Euro at the exchange rate of 1 USD = 0.87 Euro. Coccidiostats are estimated by the Commission as 35% value of all additives

Table 1. Estimate of the value of the EU feed additive market by type of animal, 2016-2026, EUR millions

Animal Type	2016	2017	2018	2019	2020	2021E	2026F
Ruminant	2,747	2,818	2,894	2,975	3,064	3,165	3,928
Poultry	3,352	3,484	3,624	3,775	3,938	4,117	5,034
Swine	3,050	3,167	3,292	3,425	3,570	3,724	4,640
Aquaculture	326	339	352	366	381	398	507
Other Animal Types	563	563	563	563	562	561	668
Total	**10,038**	**10,371**	**10,725**	**11,103**	**11,516**	**11,965**	**14,**777

Source Mordor intelligence. Note: Data provided by Mordor Intelligence have been converted from USD to Euro at the exchange rate of 1 USD = 0.87 Euro. Projection of 2021-2026 calculated based on the base year 2020.

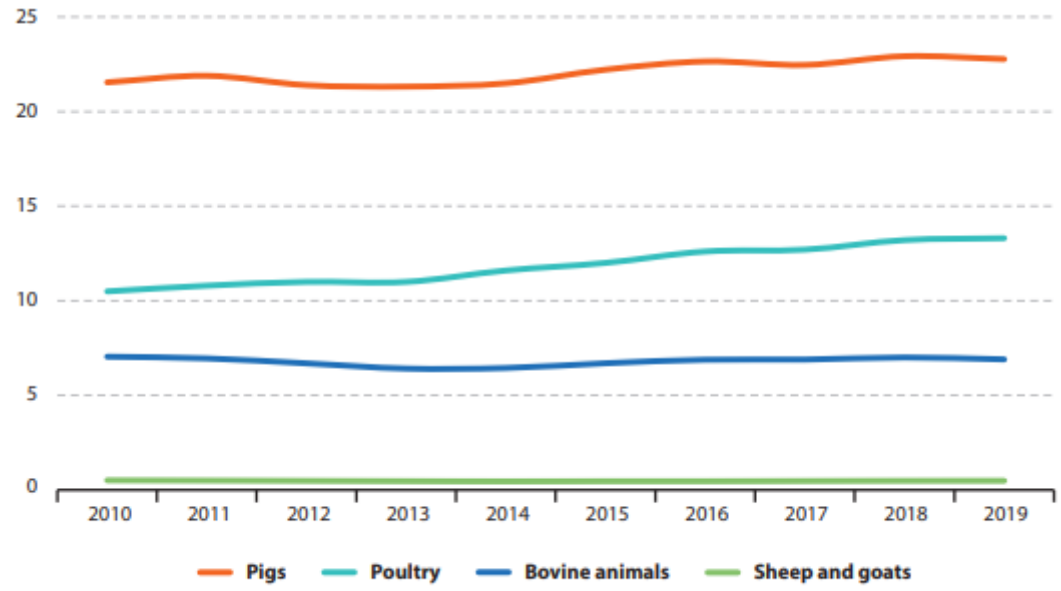
In the table above, the use of coccidiostats and histomonostats is not included, therefore the major consumption of FA is for poultry followed far behind by swine.

Based on different data as indicated above:

- In 2020, FA had a turnover of €15, 7 billion. The compound feed production in 2019 amounts to 55.6 billion euros[253], FA represented around 25% of the value of compound feed in that year.(EM 2.1.8) According to FEFAC, in 2020, the EU-27 compound feed industry produced 150.2 mt. (mio ton) of feed, consuming 76 mt. of feed cereals, 37.9 mt. of cakes and meals, 17.7 mt. of co-products from food & bioethanol industries, 5.1 mt. of minerals, additives & vitamins, 2.5 mt. of oils & fats, 2.3 mt. of dried forage, 2.2 mt. of pulses and 5.7 mt. t. of all other feed materials (e.g. former foodstuffs, straw, microbial biomass, etc.). If we made the assumption that the production of FA is around 5 mt., this represents 3, 3% in volume in relation to compound feed. If we considered that in 2020, 109 mt. of feed materials were used in the farm, the volume of additives represents 5% of all feed materials used in the farm in volume. The economic value of feed materials is not available and does not allow the calculation in relation to the value of FA.
- The current turnover of the EU-27 premixtures sector is estimated to be about €1.6 billion in 2021– this corresponds to about a volume 1 mt. of products. [254]. This represents around 0.5% in volume and 29´% in value in relation to compound feedingstuffs.

The feed market depends on the livestock products market. The value of livestock production in 2020 – amounting to €151 billion – accounts for 41% of the total value of farm production. More than half of its amount (82 bio €) is then created by beef & veal, and dairy animal products, followed by pigs, poultry & eggs and other animal products (i.e., sheep, goats, etc.). The overall EU-27 agricultural output production was €389 billion in 2020.[255:]

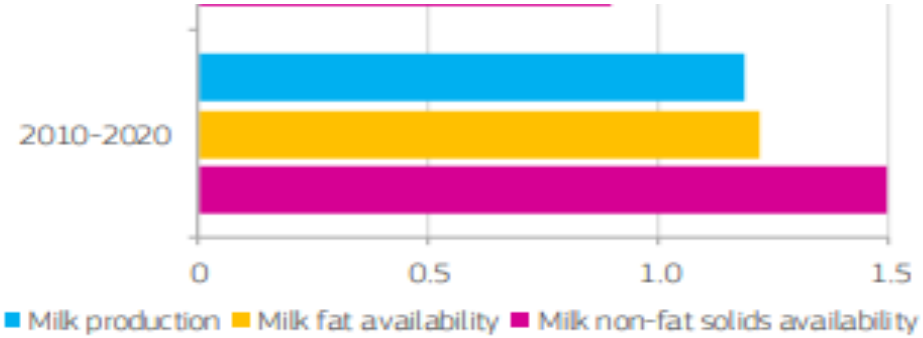
Figure 2: Production of meat from slaughterhouses, by species, EU27, 2010-2019 (million tonnes carcass weight)



Source: Eurostat (online data codes: apro_mt_lscatl, apro_mt_lspig, apro_mt_lssheep and apro_mt_lsgoat)

[253] Feed and Food. Statistical Yearbook 2021- FEFAC
[254] 2018 Report by RM Associates Ltd
[255] Feed and Food. Statistical Yearbook 2021- FEFAC

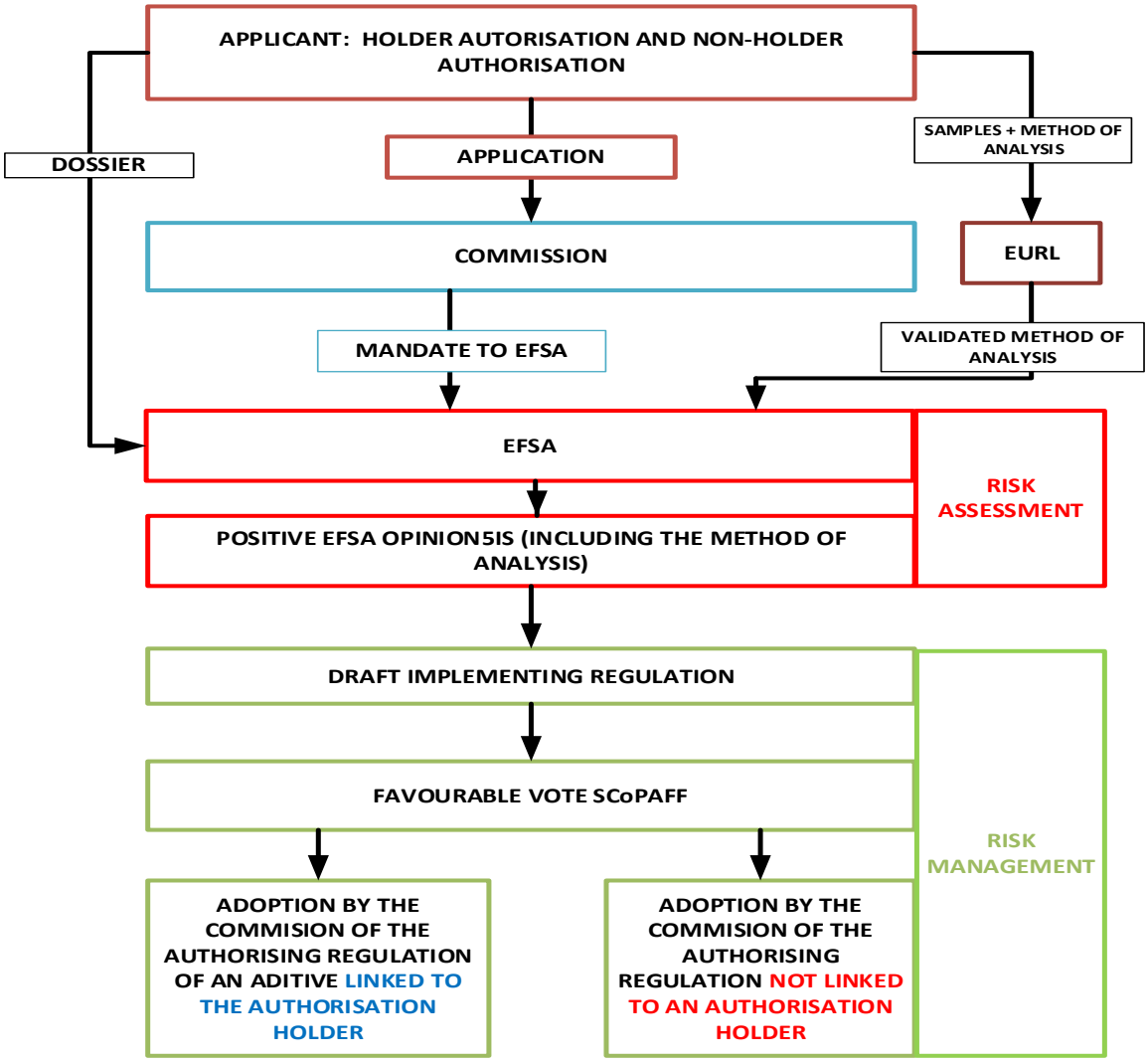
Figure 3 Annual growth rates of EU milk production, fat and non-fat milk solids availability. 2010 and 2020 represent the 2008-2010 and 2018-2020 averages.



Source EUROSTAT. EU AGRICULTURAL OUTLOOK 2020-2030

ANNEX VIII- AUTHORISATION PROCESS AND LABELLING REQUIREMENTS

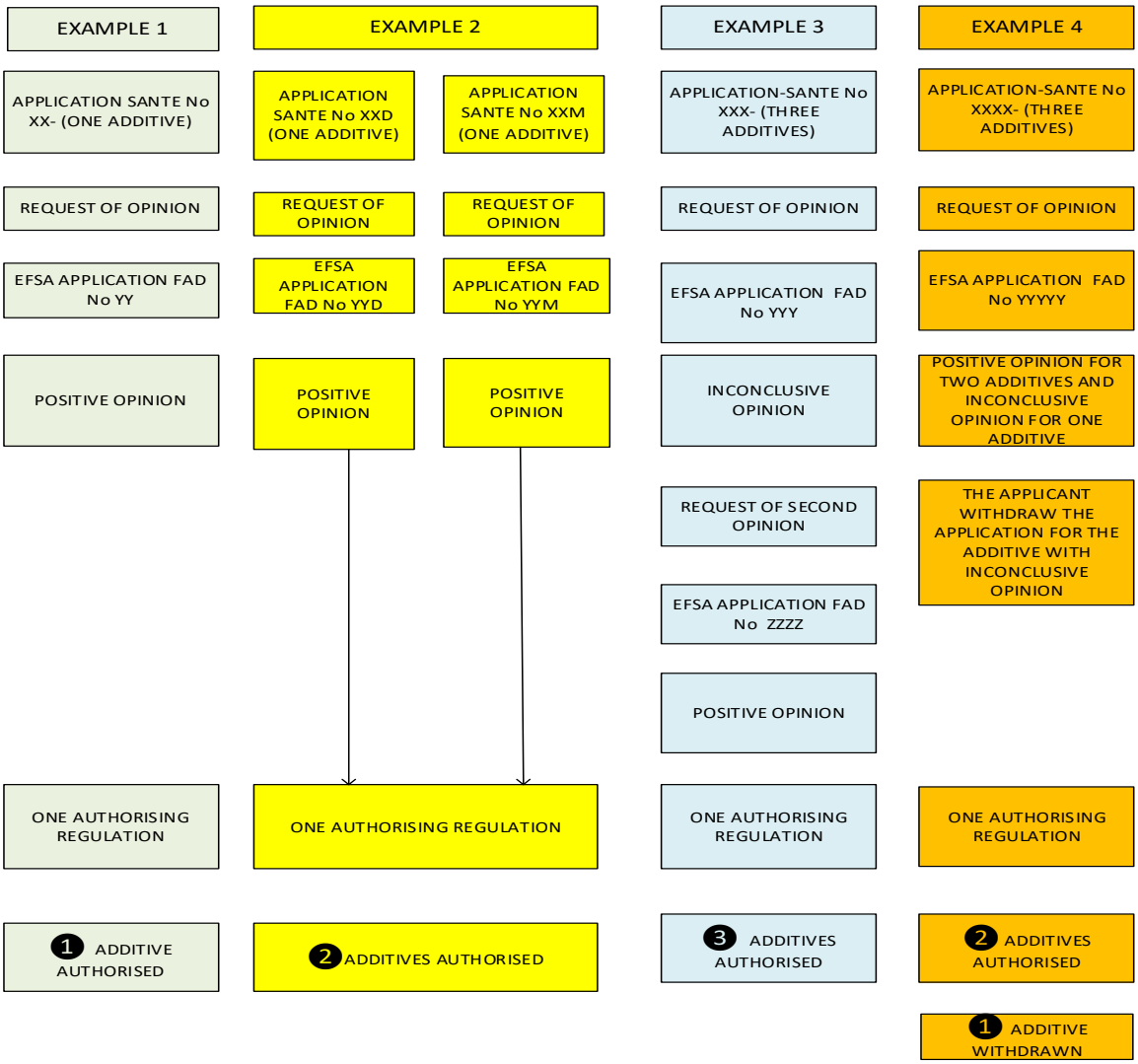
Figure 1: authorisation process



An application may contain one additive (example 1) or several additives (example 3). During the authorisation process, the applicant may withdraw the authorisation of one or several additives included in the application (example 4). It is also possible that several applications with different EFSA opinions are grouped and adopted through one Regulation (example 2). One authorising Regulation may, therefore, authorise one additive or several additives from the same application (example 1) or from different applications (example 2). The number assigned by the Commission to an application (SANTE number) is different from the number assigned by EFSA (FAD number). In addition, if there is a request for a second opinion, EFSA assigns a new number to the second request of opinion so that it regards this second request as a new application while for the Commission is the same application with the same SANTE number (example 3). See the figure below to understand the examples.

The EFSA database and the SANTE database are developed independently, therefore the data have been analysed separately.

Figure 2: examples of authorisation process



Re-evaluation of existing products:

The figure below illustrates the process for the re-evaluation of 'existing products'. The deadline to submit applications for the re-evaluation of most of the products (i.e., additives which were authorised without a time limit) was 8/11/2010. In consultation with EFSA, a detailed calendar listing in order of priority the different classes of additives to be re-evaluated was laid down, due to the high number of products to be re-evaluated. This prioritisation *de facto* extended the authorisation period for some FA such as colourants or flavourings that were not considered as first priorities. The re-evaluation process is now almost completed, except for some colourants and flavourings for which the re-evaluation started later.

Figure 3: re-evaluation process. Article 10(2) of the FA Regulation

DATA ON AUTHORISATIONS

Authorisations by type of authorisation: holder-specific or non-holder specific

236 of the additives authorised under the 2003 FA Regulation by May 2021[256] were issued to a holder. These were zootechnical additives, coccidiostats or additives that are genetically modified or produced from GMOs. Linking of authorisations of these critical additives to an authorisation holder significantly improved control and traceability by allowing the person responsible for placing the additive on the market to be identified at every step along the feed chain.

By May 2021, 1,212 additives had received a 'generic' (i.e., non-holder specific) authorisation under the FA Regulation. These generic authorisations covered the following categories: technological, sensory and nutritional additives.

Authorisation by type of purpose

1. **Authorisation of new FA or new uses covered by a 10-year authorisation period**: Over the period 2004-2017, there were 382 applications[257] for new substances (e.g., a new enzyme, a new vitamin etc.) or for a new use of a substance already authorised[258]. EFSA evaluated 398 applications for a new feed additive or for a new use of a feed additive.

   The authorisation procedure is the same for FA with or without holder-specific authorisation status. It is the responsibility of the applicants for authorisation to present a dossier with all the data required to demonstrate that the authorisation conditions are met, to be assessed by EFSA. The sole difference is that in the case of

[256] Register of FA. Edition 292 May 2021: 1 nutritional additive produced from a GMO, 210 zootechnical additives and 25 coccidiostats.

[257] As one authorisation may cover one or several additives, the yearly number of additives authorised may be higher than the number of authorisations. Among the 382 applications, 4% were applications for coccidiostats, 5% for sensory additives, 14% for technological additives, 18% for nutritional additives and 59% were zootechnical additives.

[258] Article 4(1) of the FA Regulation.

non-holder specific authorisations, any person complying with the specifications and requirements of the authorisation act, concerning that specific FA, is allowed to place the additive on the EU market and use it. If there is any issue with an ongoing application, the applicant is responsible (e.g., need to provide additional information to EFSA to clarify certain issues, deposit three samples in the EU Reference Laboratory for FA –EURL-etc.). If there is any issue with an authorised FA which is non-holder specific (e.g., in the authorising Regulation the purity is 95% but the additive placed on the market by an operator is 90%), the principle of primary responsibility of operators to comply with EU legislation applies (cfr. General Food Law and specific provision concerning the 'Supervision' in the FA Regulation).

2. **Re-evaluation of existing products**: 409 applications for re-evaluation of existing products were submitted during the period 2004-2017 to the Commission. In addition, 1,743 additives were totally or partially withdrawn from the market[259] as no application for their re-evaluation was submitted in time (1,623) or were totally or partially withdrawn during the re-evaluation process (120)[260] (EM1.1.4, 1.1.5).

3. **Modification of existing authorisations**[261]: During the period 2004-2019, 62 applications[262] for modifications covering 91 additives were submitted by authorisation holders, and 59[263] related Regulations were adopted.

4. **Inconclusive opinions:** 15% of EFSA opinions are estimated to be inconclusive (IL1.5.4). In those cases, the Commission informs the applicant about the outcome of the opinion and asks him if he wants to submit complementary information. If the applicant agrees, a second opinion is requested from EFSA on the basis of the new information submitted by the applicant. In this case, the legal basis for requesting this second EFSA's opinion is Article 29(1) of the General Food Law.

5. For 6 additives, the **authorisation was denied** following the EFSA opinion (EM1.1.7).

6. **Renewal of authorisations[264] after the 10-year authorisation period**: The applications for renewal started in 2017. During the period 2017-2021, 65 applications for renewal were submitted. The average time for the assessment was around 10 months (EM1.3.8). The authorisation procedure did not suffer from major

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259 'Partially withdrawn' means that the applicant withdraws for one or more additives (if the application contains several additives), withdraws for certain species/categories of animals or for certain uses (e.g., use in water for drinking).

260 Additives authorised before the entry into force of the FA Regulation ('existing products') had to be re-evaluated according to the conditions of the FA Regulation. To be kept on the market, an application for re-evaluation had to be submitted within 7 years after the entry into force of the FA Regulation or 1 year before the expiry date (for those authorised with a time limit) and could be kept on the market until their re-evaluation was completed. EFSA evaluated 423 applications for existing products (Article 10(2) of the FA Regulation). This exercise is almost completed for the majority of the functional groups.

261 According to Article 13 of the FA Regulation, the Commission - after examining the EFSA opinion - may decide to modify, suspend or revoke an authorisation, if the authorisation does no longer meet the conditions set out by the FA Regulation. In addition, a holder of authorisation may propose to change the terms of that authorisation.

262 Estimation based in EFSA database and data from EURLEX.

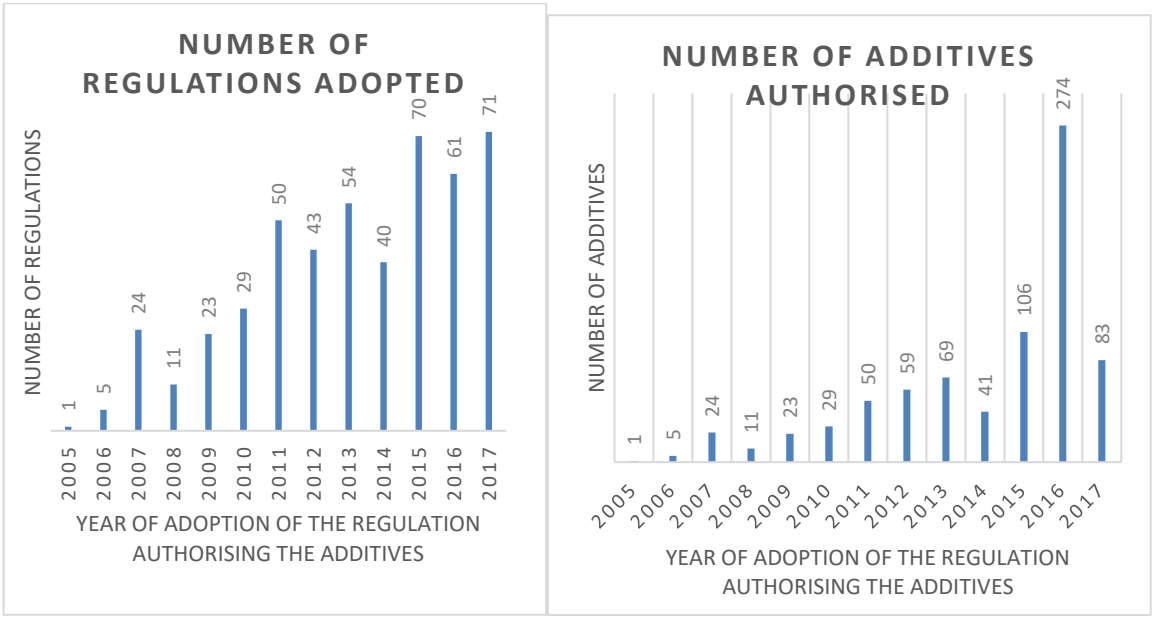
263 The reference is the date of adoption of the act.

264 Article 14 of the FA Regulation.

delays as normally there were no contentious issues to consider. A large number of renewals are expected to take place during the next few years given the expiry date of the existing corpus of authorisations (2023: 32, and 2024: 56).

7. **Urgent authorisations**[265]: 2 applications were received under the FA Regulation, which allows "in specific cases, where urgent authorisation is needed to ensure the protection of animal welfare, to provisionally authorise the use of an additive for a maximum period of 5 years" (e.g., lack of a vitamin that may have a negative impact on an animal's health of well-being). In both cases, MS rejected the request on the grounds that animal health and welfare were not deemed to be compromised.

Figure 4: Regulations adopted/additives authorised[266].



LABELLING RULES (Article 16 of the FA Regulation)

Labelling requirements for FA:

The labelling must be done by way of a physical label and is the responsibility of a producer, packer, importer, seller or distributor which must be established in the EU. It must contain the following information:

- Name of the additive and name of the functional group as mentioned in the authorisation
- Name and address of the business or person responsible for the label
- Weight or volume
- Approval number of the establishment[267] (where appropriate)

[265] Article 15 of the FA Regulation.

[266] As one authorisation may cover one or several additives, the yearly number of additives authorised may be higher than the number of authorisations.

[267] Some Feed establishments need to be approved by the Member State competent authority in accordance with the Feed Hygiene Regulation

- Directions for use, any safety recommendations on the use and specific labelling requirements mentioned in the authorisation
- Specific requirements mentioned in the authorisation, including animal species and categories for which the feed additive or the premixture is intended
- Identification number of the additive, batch reference and date of manufacture.

Additional requirements may apply depending on the type of additive (cfr. Annex III of the FA Regulation): for example, for microorganisms the number of colony-forming units per gram must be specified. When an additive may be affected by storage conditions over the time, an expiry date must be specified.

Labelling requirements for premixtures:

For premixtures, the same labelling obligations apply, but for additives incorporated into premixtures it is only necessary to indicate the name of the additive and of the functional group, the identification number of each additive and the weight or volume of each additive in the premixture. In addition, the word "premixture" must appear on the label. If the premixture contains feed materials as carriers, those carriers need to be declared. If the carrier used is water, the moisture content of the premixture is mandatory. Finally, only one minimum storage life may be indicated in respect of each premixture as a whole; such minimum storage life shall be determined on the basis of the minimum storage life of each of its components.

Relation between labelling and safety

The identification of the additive, the indication of the animal species for which the additive or premixture is intended, the level of incorporation of the additive in the premixture (related to the maximum level permitted for certain additives) and the safety recommendations on the use of the additive allow using those additives safely and guarantee that the maximum doses are not exceeded as this may impact on the health of animals, workers, consumers (cfr. more residues than permitted) or the environment (cfr. excretion of metabolites or the additives at levels that are not safe for the environment). The safety of animals is thus warranted through the indication of the animal species for which the feed additive may be used (e.g., xylitol is toxic for dogs, but it can be used in other species) and the doses permitted for each species.

ANNEX IX- DETAILED ANALYSIS OF MISSING DEFINITIONS AND PROVISIONS OPEN TO SOME CLARIFICATIONS

MS national authorities and FeBOs noted the absence of certain definitions and insufficient clarity of certain provisions namely:

- The correct categorisation of FA in relation to "processing aids".

- The establishment of additional conditions of authorisation regarding "maximum recommended levels" or "recommended levels*"* (see 1.4.3.4 Annex III).

- The legal status for certain additives: preparations are not defined as such and the introduction of such definition could not be done by implementing rules, requiring a modification of the FA Regulation. To mitigate this absence of formal definition, some provisions on the compositional and labelling requirements were introduced in 2015 by implementing rules (more information in 3.1.1 Annex III).

- Use of additives in drinking water: clarity on the use of FA in drinking water could be improved. The definition of FA refers to the use of all additives in drinking water, but Article 6 and Annex I of the FA Regulation restrict the use of FA in drinking water to certain functional groups. Consequently, applicants withdrew their applications for 789 flavourings for use in water for drinking that were only authorised in feed (EM 6.6). This unveiled a need to improve coherence between the definition and the provisions of Article 6 and Annex I. In addition, FeBOs have requested more technical clarity on the practical implementation of the use of additives in drinking water (see 1.4.3.1 and 1.8.4 of Annex III).

- Comprehensive evaluation of few additives that may be intended for farmed non-food producing animals: it could be necessary to introduce some clarification regarding the environmental safety requirements applicable to farmed non-food producing animals (e.g., fur animals) in order to accommodate the requirements related to the safety criteria laid down in the FA Regulation and in EFSA Guidance[268]. This situation did not affect the safety for the environment as EFSA already performed this assessment and no application specifically addressing this type of animals was submitted. The authorisations granted for all animal species (including non-food producing animals) have considered the environmental impact of the additives concerned. Nevertheless, for future possible applications addressed specifically to those animals this issue needs to be examined.

- Finally, the absence of harmonised and specific labelling requirements for FA and premixtures only intended for export is another element that does not bring lightness to the system (see 1.4.3.7 Annex III).

[268] Guidance on the assessment of the safety of FA for the environment. EFSA Journal 2019;17(4):5648.