European Commission

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

Final Report

Written by the Food Chain Evaluation Consortium – FCEC (Civic Consulting, Agra CEAS Consulting, Ltd, Arcadia International EEIG and subcontractor Areté s.r.l.)
17 June 2020

Directorate-General for Health and Food Safety
Evaluation of Regulation (EC) No 1831/2003 on additives for use in animal nutrition
2020 EUR [number] EN

EUROPEAN COMMISSION

Directorate-General for Health and Food Safety
Directorate E (Food and feed safety, innovation)
Unit E5: Animal nutrition, veterinary medicines

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European Commission
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List of Abbreviations and Acronyms

AH Europe	Animal Health Europe (ex IFAH-Europe; ex FEDESA)
AFIA	American Feed Industry Association
AMR	Antimicrobial resistance
ANAC	Animal Nutrition Association of Canada
BEUC	European Consumers Organisation
BR	Better Regulation
CA	Competent Authority
CAGR	Compound Annual Growth Rate
C&Hs	Coccidiostats and histomonostats
CLP	Regulation on the classification, labelling and packaging of substances and mixtures (Regulation (EC) No 1272/2008)
Copa-Cogeca	European farmers and European Agri-Cooperatives
COCERAL	Comité du Commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures
COM	European Commission.
CVMP	EU Standing Committee for Medicinal Products for Veterinary Use
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
EMA	European Medicines Agency
EMFEMA	European Manufacturers of Feed Minerals Association
ENSSER	European Network of Scientists for Social and Environmental Responsibility
EURL	European Union Reference Laboratory
EUVEPRO	European Vegetable Protein Association
FAO	Food and Agriculture Organisation
FAMI-QS	the worldwide Quality and Feed Safety Management System for the sector of Specialty Feed Ingredients
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
FEEDAP	Panel on Additives and Products or Substances used in Animal Feed (EFSA)
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
FVE	Federation of Veterinarians of Europe
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)
IPCC	The Intergovernmental Panel on Climate Change (United Nations)
LCA	Life Cycle Assessment
MA	Market authorisation
MCA	Multi-criteria analysis
MS	Member States
NAFA	'non-authorised' feed additives (for placing on the EU market)
NCA/s	National Competent Authority/ies (or Member State Competent Authority/ies, MS CA/s)
OIE	World Organisation for Animal Health
PAFF	Standing Committee on Plants, Animals, Food and Feed (ex SCOFCAH)
PMM	Post–marketing monitoring
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
SCM	Standard Cost Model
ToR	Terms of Reference
VMP	veterinary medicinal product
WHO	World Health Organisation
WTO	World Trade Organisation

Abbreviations to legal references:

Regulation (EC) No 1831/2003:	Feed Additives Regulation
Directive 70/524/EEC:	former legislation on feed additives
Regulation (EC) No 178/2002:	General Food Law
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 (GMO) 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:	Biocides 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)

[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) have been replaced by Regulation (EU) 2019/6 on veterinary medicinal products and Regulation (EU) 2019/4 on medicated feed; the new regulations will apply from 28 January 2022.

GLOSSARY of TERMS

Antimicrobials: substances produced either synthetically or naturally, used to kill or inhibit the growth of microorganisms, including bacteria, viruses or fungi, or of parasites, in particular protozoa.

Antibiotic: antimicrobials produced by, or derived from, a microorganism, which destroys or inhibits the growth of other microorganisms.

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), and of additives consisting of/containing/produced from genetically modified organisms (GMOs), no person can place the product on the market other than the authorisation holder named in the authorisation Regulation 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).

Categories/Functional groups: in accordance with the intended purpose, feed additives are classified in categories; within the same category additives are classified in functional groups, in accordance with the function that they perform. The classification (Article 6 of Regulation (EC) No 1831/2003) is as follows:

- **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, colorants
- **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 stabilizers

Coccidiostats and histomonostats: substances intended to kill or inhibit protozoa (parasites).

Compound feed: a mixture of at least two feed materials, whether or not containing feed additives, for oral animal-feeding in the form of complete or complementary feed.

Feed: any substance or products, including additives whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals (Article 3(4) of Regulation (EC) No 178/2002).

Feed additives: substances, microorganisms or preparations, other than feed material and premixtures, which are intentionally added to feed or water in order to perform, in particular, one or more of the functions mentioned in Article 5(3) (Article 2.2(a) of Regulation (EC) No 1831/2003). This refers to products used in animal nutrition to improve the quality of feed and the quality of food of animal origin, or to improve animal performance and health. Feed additives fall under the definition of feed set out in Article 3(4) of Regulation (EC) No 178/2002.

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 operators along the feed supply chain: feed additive producers and business operators that are

users of feed additives (manufacturers of compound feed and pre-mixes; and, pet food manufacturers).

Feed materials: products of vegetable or animal origin, whose principal purpose is to meet animals' 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 feed additives, 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;

Minor species: 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.

Post–marketing monitoring (PMM): after assessment, EFSA may propose to the applicant to carry a PMM plan in order to trace and identify any direct or indirect, immediate, delayed, or unforeseen effect resulting from the use of feed additives on human or animal health or the environment, using a product tracing framework similar to that which already exists in other sectors and in line with the traceability requirements laid down in food law. The PMM plan may be requested for nutritional additives, zootechnical additives and for additives falling within the scope of Community legislation relating to the marketing of products consisting of, containing or produced from GMOs. The design of the PMM plan shall be detailed on a case-by-case basis and identify who (e.g. applicant, users) will carry out the various tasks that the plan requires and who is responsible for ensuring that the plan is set into place and carried out appropriately. The Commission and EFSA will be informed of any observed adverse effects. The authorisation may impose the submission of reports during the monitoring. When the monitoring is concluded, a report on the results of the PMM plan must be issued and forwarded to the Commission. In the conditions of the authorisation of coccidiostats, field monitoring resistance of Eimeria spp. (the parasite causing coccidiosis) shall be undertaken, preferably during the latter part of the period of authorisation. For renewal of authorisation, the report on the results of the PMM must be submitted to EFSA as part of the dossier. EFSA must evaluate and take into account the results of the PMM. In addition, the Commission requests, in cases where the active substance is also a recognised antibiotic, studies to monitor for bacterial resistance to be undertaken as part of the PMM. The results of the PMM cannot be confidential.

Premixtures: mixtures of feed additives or mixtures of one or more feed additives with feed materials or water used as carriers, not intended for direct feeding to animals, additive concentrates intended for the industrial manufacture of compound animal feed.

Preparations: there is not definition but they can be described as feed additives composed by one or several active substances and other components (technological additives, feed materials or carriers) that are incorporated to facilitate the stability or administration of the active substance, e.g. vitamin A as active substance and one antioxidant to stabilise the vitamin and prevent its oxidation.

1. INTRODUCTION

1.1 Purpose of the evaluation

Feed additives are products used in animal nutrition to improve the quality of feed and the quality of food of animal origin, or to improve animal performance and health. Feed additives may not be placed on the EU market unless: (1) authorisation has been given following a scientific evaluation demonstrating that the additive has no harmful effects on human and animal health and on the environment; and (2) it is established that the additive in question is efficacious for the specific action indicated in the functional group for which it is requested. Feed additives fall under the definition of feed set out in Article 3(4) of Regulation (EC) No 178/2002[2] (the General Food Law - GFL): "any substance or products, including additives whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals".

Regulation (EC) No 1831/2003[3] (the Feed Additives Regulation) was adopted in 2003 as part of the actions set out in the White Paper on Food Safety (European Commission, 2000), which aimed to ensure the highest standards of food safety in the EU. To bring coherence to the EU legislation in a "farm to fork" approach, the White Paper announced new rules on additives in feedingstuffs to clarify and simplify the rules laid down in Directive 70/524/EEC on additives in feedingstuffs[4] as they were complex and subject to uneven implementation.

This study complies with the Better Regulation guidelines and toolbox. It supports the Commission's REFIT evaluation of the Feed Additives Regulation by providing a rigorous evidence base on which to build a report on the Regulation's effectiveness, efficiency, coherence, relevance, and EU added value.

The main purpose of the study is to evaluate the extent to which the feed additives legislation has achieved its objectives and whether it is still relevant. Identifying the factors that have helped or hampered the achievement of the objectives should give the Commission a better understanding of where, and why, the current EU legislation has worked well or not so well. It should show whether it still meets the needs of society and the Commission's priorities including the "farm to fork" strategy for sustainable food which is a key component of the European Green Deal.

The evaluation:

- assesses the progress made in attaining the objectives of the existing legislation;
- establishes whether the legislation has delivered the expected benefits;
- establishes whether the objectives remain relevant; and
- where appropriate, identifies potential areas for improvement.

[2] 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.

[3] 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 No 268, 18.10.2003, p. 29.

[4] Council Directive 70/524/EEC of 23 November 1970 concerning additives in feeding-stuffs, OJ L 270, 14.12.1970, p. 1

1.2 Scope of the evaluation

The evaluation examines the performance and impacts of the Regulation as a whole from its adoption in October 2003 until the present.

The evaluation covers all Member States and also non-EU countries if relevant for assessing the competitive position of the EU feed additives industry.

It focuses on:

- definitions of the Regulation;
- relevance and legal clarity of provisions and procedures;
- criteria and procedure to authorise feed additives;
- adaptation to technical and scientific progress;
- criteria and procedure for the modification of existing authorisations;
- procedure for confidentiality and data protection;
- quantification of costs and benefits including assessment of administrative burden;
- consistency with the relevant feed legislation;
- labelling of feed additives; and
- potential gaps and areas not sufficiently covered by existing provisions that lead to concrete problems on the ground.

The evaluation also assesses:

- the interactions between the Regulation and other relevant pieces of EU legislation on food and feed, chemicals and worker safety;
- the Regulation's relevance in the fight against antimicrobial resistance and in meeting objectives such as animal welfare, sustainable livestock production and protecting the environment;
- the costs linked to the implementation of the Regulation compared with the benefits achieved (as far as the data permit);
- the Regulation's impact on growth and jobs; and
- its enforcement by the Member States.

2. BACKGROUND

The background leading to the introduction of the Feed Additives Regulation is complex. This section summarises the various factors to provide context for the evaluation.

2.1 Situation in the EU before adoption of the Feed Additives Regulation

2.1.1 COUNCIL DIRECTIVE 70/524/EEC

The preceding legislation is Council Directive 70/524/EEC ('the Directive'). The Directive set out basic, harmonised rules for the authorisation, use and marketing of feed additives. This was necessary as: (1) feed additives were increasingly being used in animal feed; (2) only some Member States had rules in place and they were often only partial. The Directive covered functions such as enhanced taste and nutrition, feed conservation, anti-oxidant actions, and gelling effects or antimicrobial effects to promote growth or to fight against parasites (coccidiostats and histomonostats – C&Hs). It underwent five major amendments and its annexes were modified more than 100 times. These modifications were due to technological progress, new types of additives and the authorisation of additional additives (as listed in the annexes).

Except for antibiotics, coccidiostats, other medicinal substances and growth promoters, the authorisation of additives was not linked to an applicant company. The largest number of authorisations (n=210 for an unlimited period; and, n=95 for 4-5 years) related to additives not linked to an authorisation holder. Some categories of these additives (vitamins, provitamins, vitamin-like substances (except vitamin A and D), certain colourants, and the majority of flavourings) were authorised for an unlimited period on a generic basis. This means that the additive was not specifically authorised but it fell within a generic entry in the Directive that authorised a group of additives, e.g. "All vitamins other than vitamin A and D". For antibiotics, coccidiostats, other medicinal substances and growth promoters, the Directive required their authorisation to be linked to the applicant company. Only a few of these substances were authorised (n=10 for 10 years; and, n=2 for 4-5 years).

The Directive gave Member States the possibility to withdraw the authorisation of an additive, for example because one or more of the conditions were no longer met, due to new scientific evidence or following the use of safeguard measures (Article 11). In such cases, the Commission examined the grounds of the decision taken by the Member State and delivered an opinion after consultating the Standing Committee for Feedingstuffs.

2.1.2 SITUATION AT THE TIME OF INTRODUCTION OF THE FEED ADDITIVES REGULATION

As mentioned above, the Directive was already over 30 years old and had been extensively amended in line with technological progress and the emerging of new types of feed additives and feeding practices. However, these amendments had never been consolidated in a single version which created a complex legislative framework.

A comprehensive revision of all feed and food chain legislation also began after the White Paper on Food Safety[5] was adopted. The aim was to set out a "farm to table" approach in a coherent regulatory framework encompassing the whole food chain. Therefore, the General Food Regulation, which was adopted prior to the Feed Additives Regulation,

[5] COM (1999) 719 final, 12 January 2000.

formally separated the risk assessment and risk management functions, and established the European Food Safety Authority (EFSA) as an independent body responsible for risk assessments in the food chain with risk management falling under the responsibility of the Commission. Furthermore, Article 28(4) b of the General Food Law established the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP).

Prior to the adoption of the Regulation, the shortcomings fell under three broad areas:

1. Significant technological progress and market developments had not been sufficiently taken into account. In particular:
    - New types of additives, notably those used on silage or in water, had become available and were extensively applied, and new feeding techniques had emerged. Additives for use in water and on silage were therefore on the market in several Member States despite not having a community authorisation as they were out of the scope of the Directive.
    - The practice of mixing additives (premixtures) had also emerged while the Directive was in force and was frequent enough to require specific labelling rules.
    - The emergence of new types of additives had created an increasing variety and specialisation into the development of specific functions, which the list of the Directive did not fully address (e.g. zootechnical additives[6],[7]); furthermore, the number of amendments had created an unclear, or even confusing, list of authorised additives. This was perceived at the time to be fragmenting the feed additives market and posing challenges for the risk assessment process.
    - Authorisations of feed additives needed to be performed regularly and, where foreseen, the approval periods in the authorisations granted were not always sufficient.
    - The proliferation on the market of various products of unproven efficacy that claimed positive functions highlighted problems with the demonstration of the positive effect of an additive (on the feed or on the animal). This created concerns of unfair competition (between efficacious and non-efficacious products) and the potential for misleading users.
    - Although the Directive covered imports of additives from non-EU countries, it made no specific reference to imports or the equivalence concept. The concept was later introduced in other pieces of legislation[8] however. Imports into the EU from non-EU countries and new origins (e.g. China) had also increased.
    - There were no specific provisions for additives in pet food, though the market for additives in pet food had also increased.
2. Concerns expressed by experts and the public about feed safety and the protection of animal and human health and the environment increased. In particular:
    - Following the food and feed chain crises in the late 1990s there was a broader focus on feed safety. Several aspects of the authorisation process were considered to be weak, notably: (i) the possibility to identify the person responsible for the authorisation was limited to antibiotics, coccidiostats and histomonostats, even though new additives had emerged (zootechnical) that required holder identification; and (ii) a lack of clear rules on follow-up once the additive was authorised.
    - There were also increasing concerns about health threats stemming from anti-microbial resistance (AMR), as formally expressed in 1999 by the Scientific

[6] The importance of emerging groups of zootechnical additives, in particular digestibility enhancers and gut flora stabilisers, is well documented in literature (e.g. Simon and Klaus, 2008).
[7] Definition of the categories of feed additives is provided in the glossary.
[8] Council Directive 95/53/EC fixing the principles governing the organisation of official inspections in the field of animal nutrition included the concept of equivalence (Article 9b). The principle of equivalence was later generally enshrined in EU food law (Regulation (EC) No 178/2002, Article 11), meaning that the requirements of imported additives should be equivalent to additives produced in the EU.

Steering Committee Opinion on anti-microbial resistance (European Commission, 1999), with 15% of active ingredient antibiotics consumed during 1997 in the EU used in animal production. This raised concerns about the use of antimicrobials as growth promoters.

3. End users had raised concerns about the availability of clear information. In particular, the labelling provisions were complex and there was concern whether the information provided enabled the end user to make a choice with full knowledge of the facts. This created the potential for unfair competition and misleading of users. The Directive provided for the obligation to declare, in the feed materials and compound feeds, the additives and the active substance level for certain additives selected according to their function. When the Feed Additives Regulation was adopted, the rules governing the labelling of feed additives in compound feed and feed materials established in the Directive were transferred to Regulation (EC) No 767/2009. This Regulation established a new approach, compared to the Directive, based on safety criteria: those additives for which there is maximum dose need to be labelled. The end user is better informed and can use simultaneously different feeds or feed materials and prevent exceeding the maximum dose for certain additives for which the over dosage can be unsafe for animals, consumers or the environment.

Some more general procedural shortcomings were also identified including the risk of uneven implementation across the EU due to: the possibilities for derogations by Member States at national level (e.g. additive levels in complementary feedingstuffs, incorporation rates for additives and premixtures in feedingstuffs); those derogations might have food safety implications and also created unfair competition amongst operators. Member States acting as 'Rapporteurs' for the authorisation dossier which raised concerns over the extent to which assessments could be neutral; and, the complexity and lack of clarity in the rules (e.g. different types of authorisation available: provisional, for ten years or with no time limit, linked to the applicant company or no) which often resulted in uncertainty and undue delays for applicants. More generally, audits carried out by the European Commission in 2002-03 on the official inspection systems in the feed sector in 15 Member States found "*considerable differences in some areas and some common weaknesses in the design and implementation of these systems which hampered a uniform official supervision over the feed sector*" (European Commission, 2004).

2.1.3 BASELINE

When the single EU Register of feed additives was set up under the Feed Additives Regulation (first edition of Register, 7 November 2005), some additives were authorised further to the notification period foreseen in Article 10.1 of the Regulation for pre-existing products approved under the former legislation. This includes: products authorised under the former Directive on feed additives and products placed on the market on a generic basis; and, products that were out of the scope of the Directive but were now covered by the Regulation (silage additives, amino acids and urea); and, a relatively limited number of additives authorised under the Directive for which the applicant was not interested any more to place the product on the market.

As agreed with the Commission, the baseline used in this study for comparison to the current situation is the situation at the time of the First Register of 7 November 2005, without the pre-existing products (silage additives, amino acids and urea) in view of the fact that these were not considered as feed additives under the Directive, but were only subsequently notified (therefore falling under the scope of the Regulation).

The First Register lists a total of 2,657 additives, or 2,330 without the pre-existing products (silage additives: n=307; amino acids: n=16; and, urea: n=4). Over 85% are flavourings (n=2,008) which entered in the Register as individual listings under sensory additives (except 4 all the rest were covered by a generic authorisation under the Directive);

followed by silage additives under technological additives and amino acids/urea under nutritional additives (out of scope in the Directive, therefore excluded from the baseline). The baseline therefore counts a total of n=2,330 additives.

2.2 Intervention logic and changes from Directive 70/524/EEC to the Regulation

The intervention logic for the Feed Additives Regulation was not explicitly set out at the time of the introduction of the Regulation. The explanatory memorandum and documents accompanying the proposal for the Regulation were the basis for the reconstruction of the intervention logic, as presented below. The reconstructed intervention logic identified a number of needs, actions and expected results in relation to the following objectives:

1. Address the rise of antimicrobial resistance
2. Simplify the rules governing the authorisation of feed additives
3. Better protect humans, animals and the environment from unsafe feed additives
4. Foster innovation in livestock farming by taking into account scientific and technological progress
5. Protect consumer's interests

The intervention logic is presented graphically in Figure 1.1; full commentary is provided in Annex 1 to this report.

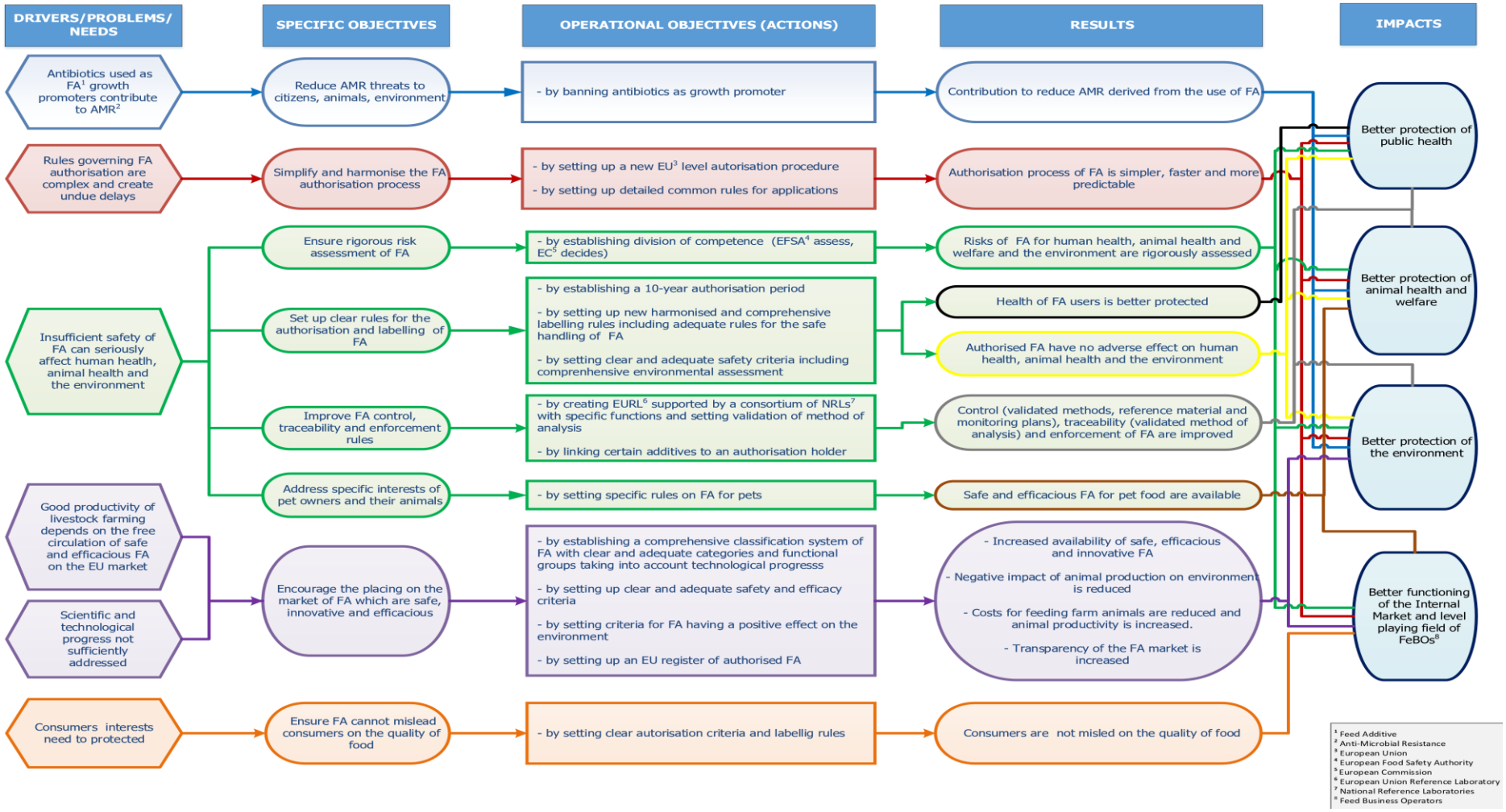
The key changes in the regulatory framework were as follows:

- ***General aspects:*** the types of feed additives are classified with more detail and clarity into categories and functional groups. There are 5 categories of additives: (1) technological additives, (2) sensory additives, (3) nutritional additives, (4) zootechnical additives and, (5) coccidiostats and histomonostats. For each category, there are different functional groups, defined, according to the function of the additive. The Regulation allows inclusion of new feed additives, such as silage agents (category 1), urea and amino acids (category 3), and digestibility enhancers (category 4); as well as, extrapolation of the assessment made in relation to the use of the additives in feed destined to the main animal species for authorisation of use to minor species (see Glossary). Authorisation of feed additives is granted to specific species (e.g. horses or pigs) or categories of animals (e.g. laying hens or chickens for fattening). Authorised new additives are brought into a single list (Register of feed additives) made publicly available.
- ***Definitions:*** The Regulation also revised the definition of additives to clarify that premixtures are not feed additives or preparations (see Glossary). While in the Directive, the distinction between premixtures and preparations was not clear, preparations are now characterised as feed additives composed by active substances and other components that facilitate the stability or administration of the active substance,(see Glossary). The Regulation also introduced the possibility to use additives in water for drinking that was not foreseen by the Directive.
- ***The authorisation process*** is made more specific and comprehensive, including post-marketing requirements for certain additives. This includes: the separation of risk assessment and risk management functions as required by the General Food Law; establishing more clear criteria for the classification and determination of the functions of feed additives and more comprehensive data requirements for applicants; linking the authorisation to the applicant (holder-specific authorisations) for substances belonging to the zootechnical category, coccidiostats and histomonostats (C&Hs), and additives produced from or containing genetically modified organisms (GMOs); laying down obligations for authorisation holders and specific methods of analysis (validated by the EU Reference Laboratory for Feed

Additives); requiring post-market monitoring, if after the assessment, it is concluded that there might be unforeseen effects from the use of additives; tightening time-limits for authorisation, including fast track re-authorisation to ensure the continuous supply of pre-existing feed additives and the evaluation of those additives in accordance with the new requirements; and, providing the possibility of revocation of authorisations if new scientific evidence emerges.

- ***Labelling:*** requirements are more comprehensive and standardised across all categories of feed additives, including directions for use, the identification number, batch reference number and date of manufacture, as well as additional requirements by category and/or for specific authorisations of feed additives. For example, the label may contain a provision indicating that gloves are necessary to manipulate the additive or may establish a maximum dose to prevent health problems to animals from over-dosage or to consumers of food of animal origin, if the additive or its residues accumulate in a way that may pose a risk to human health.

Figure 1.1 – Intervention logic for Regulation (EC) No 1831/2003



2.3 Wider regulatory framework

The feed additives Regulation is part of the wider EU legal framework governing food and feed safety, including:

- the **General Food Law**, which sets out the principles on which several provisions of the Feed Additives Regulation are based, including the separation of risk assessment and risk management (carried out by the Commission), the risk assessment carried out by EFSA, and the establishment of the FEEDAP Panel (see section 2.1.2);
- the **Feed Hygiene Regulation**[9], which aims to ensure that all feed business operators implement HACCP-based procedures in addition to the development of EU and national guides to good practices; requires the registration of all feed establishments with MS Competent Authorities; and, lays down specific traceability rules for feed additives manufacturers;
- the **Feed Marketing Regulation**[10] which provides additional definitions for the feed sector ('feed business operator', 'feed materials' and 'feed compound'); prohibits certain materials from use for animal nutrition (Annex III); and, lays down mandatory rules on labelling, as well as conditions for making voluntary claims;
- the **Official Controls Regulation**[11], which covers all controls of the feed and food chain, including feed additives, premixtures, compound feed and feed materials;
- the **Directive on undesirable substances in animal feed**[12], which lays down maximum permissible limits for substances present in/on products intended for animal feed (including feed additives) that may constitute a danger to human health, animal health or the environment or adversely affect livestock production (e.g. heavy metals, dioxins, mycotoxins etc.);
- the **Regulation on genetically modified food and feed**[13], which lays down rules for risk evaluation at EU level of genetically modified feed, authorisation, supervision and the relevant labelling requirements;
- the **Directive on medicated feed**[14], which governs the marketing of feed containing medicated premixes subject to medical prescription;

[9] Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene, OJ L 35, 8.02.2005, p.1

[10] Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC, OJ L 229, 1.09.2009, p.1

[11] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC. OJ L 95, 7.4.2017, p. 1–142.

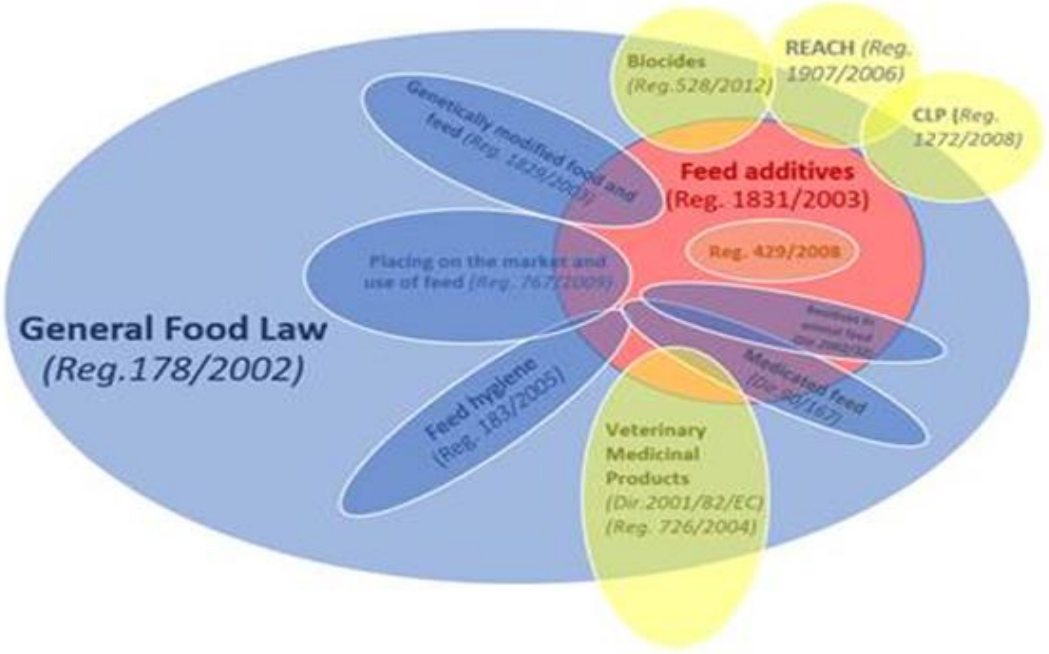
[12] Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed, OJ L 140, 30.5.2002, p. 10

[13] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268, 18.10.2003, p.1

[14] Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community, OJ L 92, 7.4.1990, p. 42. This will be replaced by Regulation (EU) No 2019/4 on medicated feed, that will apply from 28 January 2022.

- the **veterinary medicinal products (VMP) Directive**[15], which governs the marketing of veterinary medicinal products (VMPs) in the EU and expressly excludes from its scope feed additives and medicated feed;
- the **Biocides Regulation**[16], which includes rules on the establishment of an EU list of active substances that may be used in the formulation of biocidal products, their authorisation and labelling; and, foresees the prevalence of feed/feed additives legislation over legislation on biocidal products, unless used for purposes not covered by the scope of that legislation;
- the **REACH Regulation**[17], which lays down key principles of chemical safety and applies therefore to feed additives containing chemical substances (but not all provisions apply to feed additives, e.g. the provisions of Title IV on information in the supply chain do not cover feed mixtures);
- the **CLP Regulation**[18], which aims to harmonise the criteria for classification and the rules for labelling and packaging of chemical substances and mixtures; but, does not cover certain substances and mixtures in the finished state intended for the final user as e.g. feed additives (Article 1(5) (e) (iii) of CLP).

Figure 1.2 – Feed Additives Regulation and the wider legal framework for feed safety



Source: Agra CEAS, based on the EU legal framework.

[15] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, OJ L 311, 28.11.2001, p. 1. This Directive shall be replaced by Regulation (EU) 2019/6 on veterinary medicinal products, which will apply from 28 January 2022.

[16] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

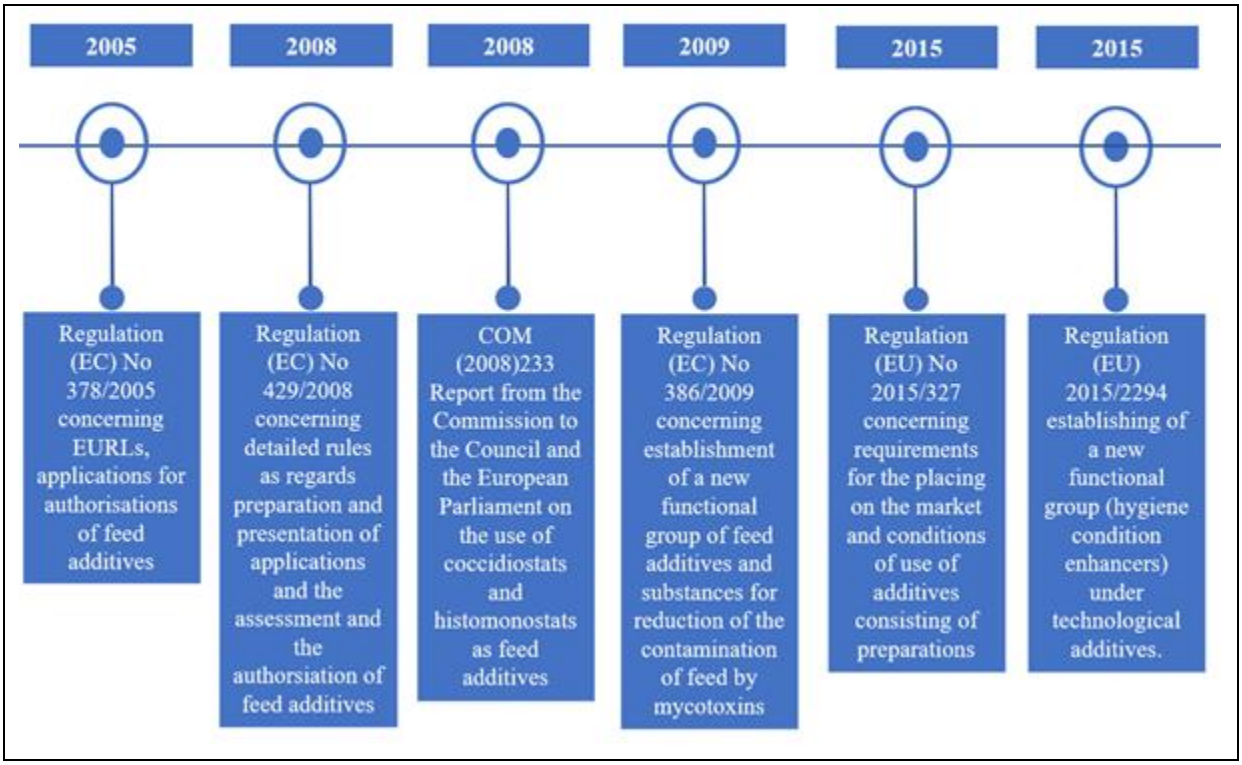
[17] Regulation (EC) No 1907/2006 of the European Parliament and the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. OJ L 396 30.12.2006, p. 1

[18] Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. OJ L 353 31.12.2008, p. 1

3. STATE OF PLAY

The Feed Additives Regulation has been amended several times since its adoption and additional relevant legislation has been introduced. Figure 2.1 gives an overview of the main developments since the Regulation's adoption in 2003. These include: (i) implementing rules on various aspects of the Regulation (setting the details for the authorisation procedure: Regulation (EC) No 429/2008; (ii) detailed duties and tasks of the EU Reference Laboratory: Regulation (EC) No 378/2005); (iii) establishing new functional groups of feed additives (Regulation (EC) No 386/2009 and Regulation (EU) No 2015/2294); (iv) examining whether coccidiostats and histomonostats can be phased out (European Commission, 2008); and (v) requirements for the placing on the market and conditions of use of additives including preparations. Furthermore, the Feed Marketing Regulation introduced new rules on the placing on the market of feed materials and compound feed.

Figure 2.1 – Overview of key developments since the introduction of Regulation (EC) No 1831/2003



Source: EU legal framework (graph elaborated by Agra CEAS).

In line with Article 7.6 of the Feed Additives Regulation, EFSA has released more than 20 separate guidance documents (administrative and scientific guidance) to date to assist applicants in the authorisation process. Some of those documents were revisions of existing guidance. Currently, one administrative guideline; nine scientific guidelines focusing on feed; and two guidelines on cross-cutting issues apply. EFSA has also organised webinars to assist applicants.

Finally, Regulation (EU) 2019/1381 on transparency and sustainability of the EU risk assessment in the food chain amends Articles 7 (application for authorisation) and 18 (confidentiality) of the Feed Additives Regulation. These amendments, which will become applicable on 27 March 2021, aim to address the challenges posed by confidentiality rules under the Feed Additives Regulation.

3.1 Implementation of the Regulation

3.1.1 AUTHORISATION OF FEED ADDITIVES

The revised authorisation procedure was one of the most significant changes introduced by the Feed Additives Regulation. It completely separated risk management (European Commission) from risk assessment, which was transferred to and centralised at EFSA. The centralised process to authorise a feed additive consists of several consecutive phases and involves the European Commission, the European Food Safety Authority (EFSA) and the EU Reference Laboratory for feed additives (EURL).

There are two types of authorisation concerning the holder:

- ***Holder-specific:*** for zootechnical additives, coccidiostats/histomonostats and additives containing or produced from GMOs, authorisations are issued to a holder.
- ***Non-holder-specific***, *so called* "generic additives": in the case of technological, sensory and nutritional additives authorisations are not issued to a specific holder.

Both types of authorisation are valid for 10 years throughout the EU and the European Economic Area (EEA) and are renewable for an additional 10-year period. More specifically, the centralised authorisation process of a feed additive consists of several consecutive phases and involves the European Commission, EFSA and the EURL-FA.

The Regulation (Article 4(1)) provides for the authorisation of new additives (e.g. a new enzyme, a new vitamin etc.) or of new uses (such as extending the use of an enzyme or a vitamin to other species e.g. from food producing animals to pets). It also provides for other types of authorisation, as follows:

- ***Re-evaluation of existing products*** (Article 10(2)): products already placed on the market under the former legislation may be notified to enter in the EU Register, if the application to the Commission is made within certain time limits. This provision does not apply to antibiotics being phased out (Article 11). EFSA is consulted in drawing up the list of such products. After the product is notified, an application for re-evaluation had to be submitted within 7 years after the entry into force of the Feed Additives Regulation or one year before the expiry date, for those additives that had a time-limit authorisation under the Directive.
- ***Modification of existing authorisations*** (Article 13): the Commission, after examining the opinion of EFSA (acting on its own initiative or following a request from a Member State or from the Commission) can take a decision to modify (or even suspend or revoke) an authorisation, if it no longer meets the conditions set out in the Regulation. Also, an authorisation holder may propose to change the terms of its authorisation, for instance, to introduce a small change in the composition of the additive.
- ***Renewal of authorisations*** (Article 14): authorisations granted under the Regulation may be renewed for a period of 10 years, provided that applications are sent to the Commission at the latest 1 year before the expiry date of the authorisation.
- ***Urgent authorisations*** (Article 15): under specific urgent procedures, additives can be authorised for a maximum period of 5 years in order to protect animal welfare. There have been two such cases, but no decision was taken as the Member States considered that the animal welfare was not compromised.

The conditions for authorisation are established under Article 5 of the Feed Additives Regulation, which defines a set of both negative ("the feed additive shall not") and positive ("the feed additive shall") criteria. Article 5(4) also establishes that antibiotics other than coccidiostats or histomonostats shall not be authorised as feed additives.

To measure the evolution in the number of approved feed additives, a comparison can be made between the ***baseline*** (First Register of 7 November 2005, without silage additives, amino acids and urea) and the ***current situation*** (additives authorised as of the end of December 2017[19]: this list (EU Register: Annex I) corresponds to the latest year for which complete data are available). The list reflecting the current situation does not include additives, which have been withdrawn, either because no applications were submitted for their re-authorisation, or because applicants could not provide sufficient information (in response to complementary information requested by EFSA) and consequently decided to withdraw their application.

According to the available data (Commission; EFSA), since the baseline and up to December 2017, the following observations can be made:

Number of applications submitted for authorisation[20] to the Commission:

applications for authorisation were made under Article 4(1) (new authorisations) and Article 10(2) (re-authorisations). In 2004-2017, there were two notable peaks, in 2010 and 2011 for all four categories of feed additives (not for C&Hs), due to the deadline for submitting applications for re-authorisations under Article 10(2). The timing of these peaks reflects the fact that many applications for re-authorisation, especially of technological additives, were submitted at the very end of 2010 and were processed in 2011.

- The largest number of applications for authorisation during this period (271) are for zootechnical additives (category 4). The majority of these are gut floral stabilisers and digestibility enhancers. This category also records the most stable pattern of annual applications of all five categories.
- The second largest number of applications (197) are for technological additives (category 1), of which the majority are silage additives. The number of applications peaked in 2010 due to the deadline for re-authorisation under Article 10.
- The third largest number of applications (174) are for nutritional additives (category 3). The fourth largest number of applications (112) are for sensory additives (category 2), of which the majority relate to flavouring compounds, with the same peak in 2010.
- In the case of C&Hs, there are no functional groups as for the other categories. In this case, 35 applications were made (counted together as one category).

Completeness of applications:

There are two ways to evaluate the completeness of applications: the DG SANTE database[21][22] for the rate of completion of the authorisation (authorisation granted/ application submitted) and, the EFSA database for the rate of completion of the evaluation (opinion issued/FAD applications submitted for evaluation to EFSA). The data available from these two sources are not directly comparable due to the different basis used for the calculation and the different outcomes: the authorisation granted, and the opinion issued. For completeness, the data from both sources are presented here.

According to the DG SANTE database, up to December 2017, 72% of applications had been processed and authorisations granted. Completion of the process was highest in the case of nutritional additives (92%), followed by zootechnical additives (83%),

[19] 2017 is the latest year for which complete data are available
[20] DG SANTE database - since implementation up to 31/12/2017. This refers to administrative applications; each administrative application may contain several additives or the same additive in different functional groups.
[21] DG SANTE database is an internal Commission's database managed by DG SANTE.
[22] Source: FAR - Reference 2: Register December 2017 (rev. 259) - since implementation up to 31/12/2017.

technological additives (62%), coccidiostats and histomonostats (54%), and sensory additives (42%). Of the remaining applications, the majority remain pending, some have been withdrawn and a few have been denied. The rate of completion was higher for Article 4(1) applications (80%) than for Article 10(2) applications (65%).

	RATE OF COMPLETION (%)		
CATEGORY	**ARTICLES 4(1) and 10(2)**	**ARTICLE 4(1)**	**ARTICLE 10(2)**
Technological Additives	62%	73%	59%
Sensory Additives	42%	61%	39%
Nutritional Additives	92%	85%	97%
Zootechnical Additives	83%	83%	83%
Coccidiostats and Histomonostats	54%	59%	50%
Total	**72%**	**80%**	**65%**

Source: DG SANTE data

According to the EFSA database, the rate of completion for the assessment of applications is higher than the above analysis suggests (80%). In total, out of 763[23] applications for Article 4(1) and 10(2) authorisations that were processed by EFSA during this period:

- New authorisations (Article 4(1)): 327 EFSA opinions were issued out of a total 355 applications, i.e. the rate of completion for the period is 92%.
- Reauthorisations (Article 10(2)): 286 EFSA opinions were issued out of a total 408 applications, i.e. the rate of completion is 70%.

	TOTAL APPLICATIONS	OPINIONS ISSUED	RATE OF COMPLETION (%)
ARTICLE 4(1)	355	327	92%
ARTICLE 10(2)	408	286	70%
ARTICLE 4(1) + 10(2)	763	613	80%

Source: EFSA data

The rate of completion was higher for Article 4(1) applications (92%) than for Article 10(2) applications (70%).

Number of additives authorised:

In terms of the number of additives authorised during the same period, it is noted that one application can cover several feed additives; it is therefore not possible to compare the number of applications with the number of additives authorised. Nonetheless, the

[23] It is noted that 148 of the total 969 FAD applications submitted to EFSA were under another legal base; of these, 71 were submitted under Article 29 of the General Food Law (GFL). These mainly represent cases where the EFSA opinion is inconclusive and the applicant, upon request of the Commission, decides to submit new information, for which the Commission asks EFSA for an opinion via Article 29 of the GFL. The significance of Article 29 dossiers is important as they reflect that applicants were unable to provide the necessary information to EFSA (there is no legal deadline of six months for delivery of the EFSA opinion for a request under Article 29 of the GFL , although EFSA is normally requested to issue an opinion within 6 months deadline).The applications withdrawn after the EFSA opinion is issued reflect also in almost all cases that applicants are unable to provide the information required by EFSA to perform the assessment.

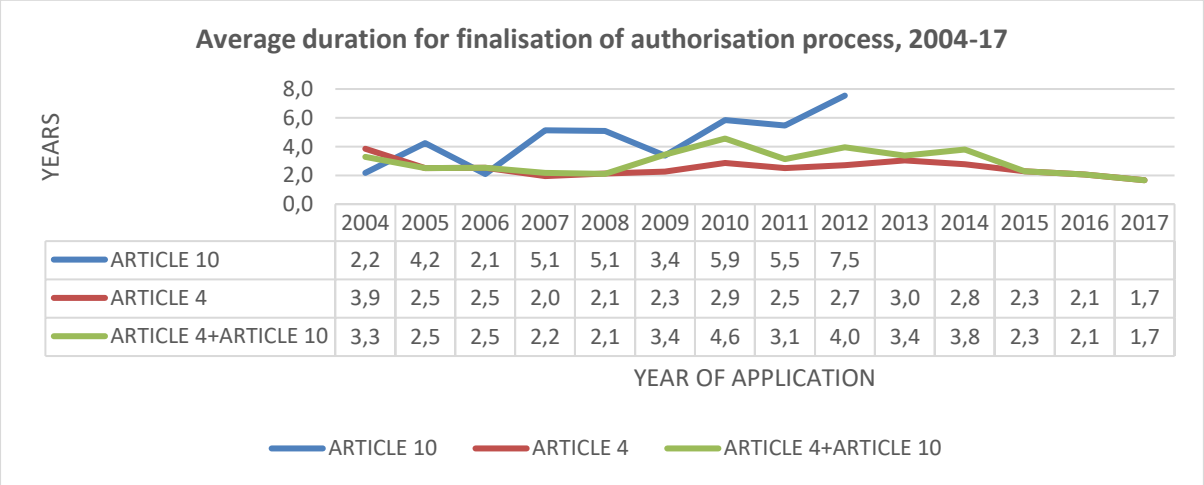
available data[24] indicate that in total, 775 feed additives were authorised, approximately a third of which (227) were flavouring compounds (category 2: sensory additives).

To accommodate these changes, the feed additives Register has been updated over 260 times.

Duration of the process:

According to the current rules, it should take about one year from acceptance of the applicant's dossier to the final decision for authorisation (publication in the Official Journal). In practice, the high number of applications still pending in some years adversely affects the average duration for authorisation, due to the backlog of applications being processed.

The average duration for finalisation of the authorisation process over the 2004-17 period was 3.3[25]years. This average period shows a fairly steady decline since the peak of 4.5 years for dossiers submitted in 2010, reflecting an accelerating pace in the processing of Article 4(1) applications. The average duration for finalising applications on Article 4(1) is 2.5 years with a peak in 2013 and a steady decline until the end of 2017. On the other hand, the pace of processing Article 10(2) applications has been slowing down, mainly due to the backlog of outstanding applications, and the average duration for finalising these applications is 4.5 years. The longest period for Article 10(2) applications is explained by the fact that a decision for authorisation may group several applications. For example, for vitamin D there were three applications. The decision for authorisation was adopted when the last opinion was issued. Similarly, for flavourings the decisions for authorisation were grouped to be adopted the same date. The delays did not pose a problem to the operators as the products could remain on the market until a decision for re-evaluation is taken.



	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
ARTICLE 10	2,2	4,2	2,1	5,1	5,1	3,4	5,9	5,5	7,5					
ARTICLE 4	3,9	2,5	2,5	2,0	2,1	2,3	2,9	2,5	2,7	3,0	2,8	2,3	2,1	1,7
ARTICLE 4+ARTICLE 10	3,3	2,5	2,5	2,2	2,1	3,4	4,6	3,1	4,0	3,4	3,8	2,3	2,1	1,7

For Article 4(1) and Article 10(2) applications, 4% of the applications are processed in one year and 35% within two years. In the case of Article 10(2), only 2% of applications are

[24] The calculation is made for all the additives authorised during the period 2004-2017. The reference is the date of adoption of the Regulation authorising the additives.

[25] The period is established by calculating the difference between the date of forwarding the application to EFSA and the date of adoption of the implementing Regulation. For Article 10 all the requests for re-evaluation were submitted by the applicant before the legal deadline of 8 November 2010, the majority of them were forwarded by the Commission to EFSA on 2010 and 2011.The reason by which the Commission forwarded the application beyond 2010 was the implementation of Article 10(2) that establishes a calendar listing the priorities for the evaluation. This provision was adopted as it was foreseen to receive many applications by the end of the legal deadline. Due to the limited resources, a prioritisation was necessary to cope with so many applications in a short period. Therefore, during the period 2004-2017, the applications for Article 10 were forwarded also in 2011 and 2012. Some applications were "frozen" for some time to be subsequently sent gradually to EFSA.

processed in one year and 17 % within two years; while for article 4(1), 7% of applications are processed in one year and 50% within two years.

Finally, the Regulation foresees the suspension or revocation of an authorisation in cases where one or more of the conditions for the authorisation no longer exist, because of new scientific evidence or following the use of safeguard measures (in line with Articles 53 and 54 of the GFL). To date, this provision has been applied in eight cases of substances authorised under the previous legislation (the former Directive on feed additives). Based on the underlying reasons provided in the implementing Regulations:

- In four of the eight cases, authorisation was denied following EFSA's opinion indicating potential adverse effects on animal health or on human health, when used as feed additives; in the remaining four cases, the authorisation was withdrawn because no applications for re-evaluation were submitted or the submitted applications did not cover the target animal species for which authorisation was sought.
- Two of the eight cases relate to a single substance, while each of the remaining six cases relate to two or more substances.

3.1.2 LABELLING

While the labelling provisions apply to any person placing a feed additive or pre-mixture on the market, it is incumbent on the Member State Competent Authorities to ensure compliance with these labelling requirements. Labelling rules were also previously laid down in the Directive, but requirements were standardised and made more detailed under the Regulation (as outlined in section 2.1). The establishment of more detailed labelling rules was meant to better protect workers, consumers, animals and the environment. Labelling provisions contain relevant information that can be used for example by feed business operators to ensure that maximum levels permitted are not exceed, so animals are safe but also consumers of animal products and the environment. This information is passed along the food chain and enable pet owners and farmers to follow the directions of use of the feed, to guarantee that the use of this feed does not pose any risk for the animals, consumers or the environment. The provisions included in the label of feed additives and premixtures for safe handling, inform workers on the risks derived from their use, so that workers can apply protective measures such as wearing glasses or gloves.

The Regulation also revised the definition of additives, to clarify that premixtures are not feed additives or preparations, and to specify the labelling rules applied to additives and premixtures.

The Feed Marketing Regulation lays down rules for labelling of feed materials and compound feed. 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). By contrast, according to the Feed Additives Regulation, for feed additives and premixtures the information must be contained on the label on the package or container; there is no possibility to pass the information by other means e.g. electronic means.

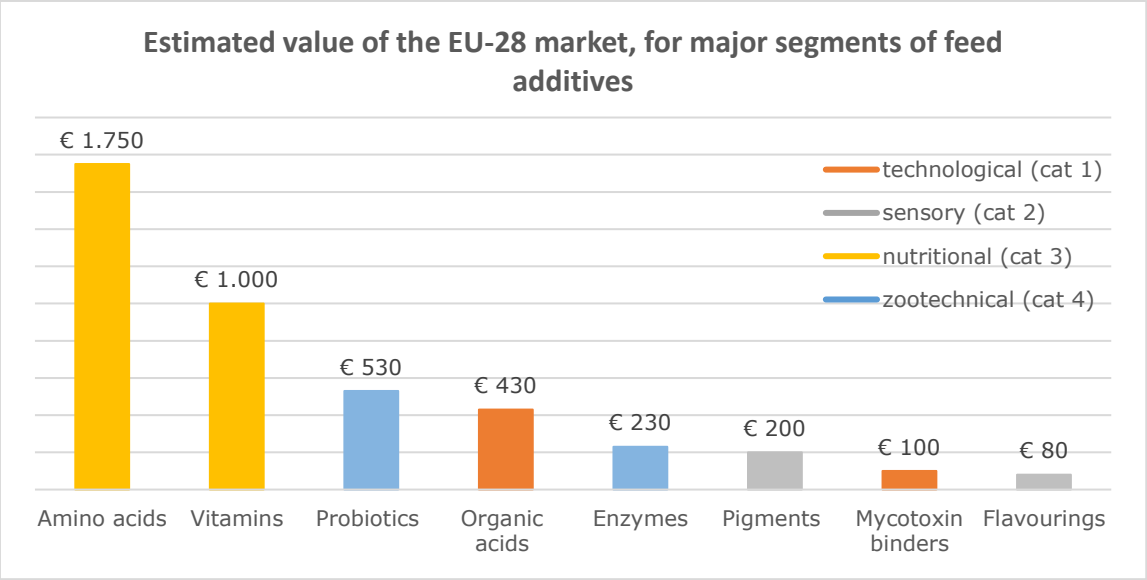
3.2 The market for feed additives

There are no data available on the feed additive market from Eurostat or national statistical services, as there is no specific industrial or trade classification for this sector. In view of this, various other sources were examined to analyse the characteristics and trends of the feed additives market.

Industry data indicate that the feed additives is a concentrated sector, with 94 companies currently accounting for an estimated 80% of the EU production value[26].

According to a late 2018 industry report[27]:

- The **global feed additives market** is valued at approximately $21.77 billion in 2015 and it is expected to reach $28.22 billion by 2022.
- The **EU-28 market** is estimated at around €7.8 billion, including coccidiostats and histomonostats; this represents approximately 35-40% of the global market. The EU-28 market is expected to grow to a value of €10.14 billion by 2022.
- The **largest two segments** are additives belonging to the nutritional category, in particular **amino acids** and **vitamins**. These are followed by zootechnical additives, notably **probiotics** and **enzymes**; and, technological additives, notably **organic acids** and **mycotoxin binders**. Smaller segments include sensory additives, notably **pigments** and **flavourings**.
- Furthermore, the industry indicates that in five commercially 'major' functional groups, the historic performance (2003-2018 period) and outlook (next five years) indicates market growth: amino acids; organic acids; vitamins; probiotics; and, enzymes.



(a) Data only cover the major groups of feed additives, for which estimates are available; excludes coccidiostats/histomonostats (no estimate available). The product groups follow the common business classification and have been re-classified, in consultation with the industry, to approximate the regulatory classification. For probiotics, organic acids, and pigments, the estimated value covers substances that can also be classified under other categories of additives.

Source: based on RM Associates Report for FEFANA (2018)

According to industry data[28, 29]:

[26] Source: FEFANA 2018.
[27] Report carried out for the organisation representing the EU feed additives industry (FEFANA) by RM Associates Ltd. The findings of the report, which have been made available for the present study, are based mainly on industry insights/interviews, cross-checked with data from various market research providers, and do not constitute a statistically representative data collection exercise. FEFANA notes that the data presented in this Report should be attributed to the author and are not validated by FEFANA.
[28] Latest data available from the associations representing the EU feed additives sector (FEFANA) and the feed industry (FEFAC). FEFAC and FEFANA jointly represent the premixtures sector.
[29] FEFAC: Feed & Food Statistical Yearbook, 2016; and, From Farm to Table statistics (July 2018).

- In 2015, speciality feed ingredients (the sector represented by FEFANA, i.e. feed additives) had a turnover of €5 billion, and represented 3.5% of the volume and 10% of the value of feed materials used by the food industry (feed cereals represent the major share, at 50% of the total value of feed materials used in feed).
- The current turnover of the EU-28 premixtures sector is estimated to be about €1.5 billion; this corresponds to about 1 million metric tonnes of products.
- The value of all feed used by EU livestock producers, including forages produced on the farm, was estimated at €94 billion in 2018, while purchases of commercial compound feed amounted to €49.3 billion in 2018. In 2018, 164.8 million tonnes of compound feed were produced by EU compounders, accounting for 80.1 % of all purchased feedingstuffs. This accounts for 37.3% of all inputs and 54.8% of the turnover in livestock production.
- In terms of pet food[30], an estimated 80 million EU households own at least one pet animal (at least 25% own one dog and at least 23% own one cat). This sector has an annual sales volume of 8.8 million tonnes and turnover estimated at €21 billion (2018); and is growing at an annual rate of 2.5%.

The organisation representing the EU feed additives sector has a membership of 94 companies, which account for an estimated 80% of the EU feed additives production value; of these, 60% are SMEs. SMEs tend to focus on specific (niche) segments of the market. In particular, SMEs are active mainly in five key functional groups (antioxidants; probiotics; pigments; flavourings; and, trace/micro minerals); and, only in one of these groups (flavourings), the market is dominated by SMEs.

Further indication of the business profile of manufacturers of feed additives and premixtures is provided by the profile of company respondents to the stakeholder survey. Nearly half (30) of the 63 manufacturers that responded to the survey produce both feed additives/premixtures and feed for food producing and/or non-food producing animals. The remaining 33 manufacturers are specialised in either of the two market segments. The largest number of manufacturers (43 out of 63) produce technological additives, followed by zootechnical additives (37), nutritional additives (20), sensory additives (18), while 3 manufacturers produce coccidiostats.

Although not all 63 manufacturers that responded to the survey indicated the relative importance of feed additives for their company, for a majority of those that did, feed additives are at the core of their business[31]. In particular, feed additives account for: more than 76% of their company's turnover for 16 of 37 respondents; more than 76% of their company's profits for 16 of 35 respondents; and, more than 76% of their company's expenditure on research and development (R&D) for 12 of 34 respondents. Conversely, for a large number of manufacturers, feed additives are a relatively small (5-10%), or even niche (<5%), segment of their business. In particular, feed additives account for: up to 10% of their company's turnover for 13 of 37 respondents; up to 10% of their company's profits for 12 of 35 respondents; and, up to 10% of their company's expenditure on R&D for 13 of 34 respondents.

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.

[30] Latest data available from the association representing the pet food industry (FEDIAF).
[31] Not all respondents answered these questions; hence the variation in the total number of respondents.

The market for feed depends on the market for livestock products. According to latest Eurostat data[32], EU-28 meat production amounted to 46.4 million tonnes in 2017, of which 7.8 million tonnes of beef (17%), 23.4 million tonnes of pig meat (51%), 0.8 million tonnes of sheep meat and goat meat (1.5%), and 14.4 million tonnes of poultry (31%). In addition, EU-28 milk production amounted to 164 million tonnes, while egg production amounted to 7.7 million. The EU-28 value of animal production reached €176 million in 2017, with beef veal and milk accounting for 53% of this total. According to FEFAC, although compound feed production in the EU has remained relatively stable since 1996, there is an increasing demand for feed by the pig and poultry sectors, as consumer demand has over the last 20 years shifted away from beef to these other types of meat.

[32] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Agricultural_production_-_animals

4. METHODOLOGY

This chapter summarises the methodology used in this evaluation.

4.1 Approach

The evaluation follows the four-phase structure set out in the better regulation guidelines:

- ***Structuring***, in which the evaluation was designed and evaluation tools were developed.
- ***Observing***, in which the evaluation tools were used to collect the data necessary to develop the evidence base for the evaluation.
- ***Analysing***, in which the evidence was triangulated and used to develop answers to the EQs.
- ***Judging***, in which evidence-based conclusions were developed for each EQ.

4.2 Structuring (evaluation design)

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

4.3 Data collection

Having set out the data to be collected and the corresponding methodologies, data were collected during this phase. The following interlocking methodologies were used, all in line with the better regulation guidelines. The outcome of these activities is summarised in the consultation synopsis report (Annex 3).

Desk research and literature review. All potentially 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 reduced further when screened for relevance to the indicators. As a result, only a few of these references could be closely linked to an indicator thereby being useful for the study. This is due to the specific nature of the subject matter and the indicators. Where relevant references are identified, they are quoted in the text.

Exploratory interviews. Interviews were held with the Commission (DG SANTE), EFSA, EURL, FEFANA, FEFAC, FEDIAF and AVC. They focused on identifying existing information/data that would be useful for the study and on developing the consultation strategy for collecting new information/data.

Other interviews and targeted research. Further research was conducted with several potential data sources to explore quantitative data availability, including with the Commission (DG SANTE) and private (market) data sources. As a result, it was concluded that the data of market research providers, which are only available on a paid basis, are not suitable for the analysis required in this study. In particular, the feed additives classification (business-defined segments rather than the categories/functional groups of the Regulation) and geographical scope (EU28 versus wider European region) do not match the requirements of the analysis, and the available data do not provide the historical perspective as the period covered tends to be recent years and to involve forward-looking forecasts. Furthermore, the methodology followed for the market research reports could not be independently verified.

Surveys. Two online surveys were conducted:

- A survey covering: (i) **EU-28 national Competent Authorities (MS CAs)**.
- A survey of **stakeholders** covering: (ii) feed additive, premixtures and feed industry organisations; (iii) feed additive, premixture and feed operators (feed operators – FeBOs); (iv) organisations representing end users, including farmers, the meat industry and the aquaculture sector; (v) organisations representing other interest groups including animal health and welfare experts, farm advisors, feed-food safety/science specialists. As part of this survey, specific questions were designed to collect detailed quantitative data relating to the effectiveness and efficiency part of the study was more narrowly targeted on groups (i) to (iii) [33]. The survey was disseminated with the support of key EU umbrella organisations, including FEFANA, FEFAC, FEDIAF, FEAP, AVC and Animal Heath Europe and by the European Commission. The information to facilitate the participation in the survey was published in the DG SANTE website. The Commission sent the survey to all the applicants for feed additives and organisations/associations related to the feed sector. In addition, 70 associations and NGOs representing consumers, farmers, environmental interests, trade unions interests, animal welfare interests and animal health interests were invited to participate, although the response from those groups was limited.

Main phase interviews were carried out with the following organisations: MS CAs; EFSA, EURL; and industry organisations (FEFANA, FEFAC, FEDIAF, AVC, Animal Heath Europe, Copa-Cogeca, AVEC, as well as consortia and individual company members of these organisations and FEAP). Key organisations were interviewed multiple times to gather the required information. These interviews went into more depth than the surveys, with topic guides tailored to each interviewee.

Case studies were aimed at understanding the application in practice of the Regulation, to identify and justify the factors that underpin the observed impacts, and to collect qualitative and quantitative data that cannot be collected from the other sources. The case studies were used in particular for the analysis of regulatory costs and non-quantitative impacts, for the analysis of the effectiveness and efficiency of the Regulation. Two thematic areas were covered: (i) the authorisation process; (ii) the labelling of feed additives. The case studies were based on a range of categories/functional groups of feed additives, to gain an overview across market segments. The evidence base was drawn from views, information and data provided through interviews with business stakeholders, as well as Competent Authorities in selected Member States, supplemented by relevant evidence collected through the stakeholder survey. Key conclusions from the case studies are incorporated within the Report, in particular the analysis of efficiency and effectiveness.

Other activities: In parallel, the Commission held an open public consultation (OPC) and a survey of Competent Authorities in a selected number of non-EU countries. The European Commission sent the OPC to the main stakeholders related to feed and to 70 associations and NGOs (indicated before). The OPC was publicly available in the EU survey portal and in the DG SANTE website.

4.4 Analysis

This evaluation phase involved:

1. Analysis of the evidence base generated from the various methodological tools
2. Combination and organisation of this evidence base by study issue and indicator

[33] It is noted that not all stakeholder survey respondents answered all questions. Hence the variation in some cases between the total number of responses provided.

3. Filtering and triangulation of the evidence base to draw findings for individual issues and indicators based on the weight of evidence in relation to the finding in question
4. Drafting of the findings against each indicator

Triangulation was performed consistently throughout the Report, where evidence was available. This included triangulation between: qualitative and quantitative evidence (to establish the extent to which views are supported by objective/factual evidence); and, sources of views (to establish the extent to which respondents to the consultation share the same views or have differing views, e.g. business stakeholders versus other stakeholders versus competent authorities, and reasons why). To this end, where possible, indicators combine qualitative and quantitative sources and judgment criteria combine quantitative and qualitative indicators/parameters.

Specific analytical tools from the Better Regulation Toolbox were used including the Standard Cost Model to analyse regulatory costs and Multi-Criteria Analysis to assess effectiveness, efficiency and coherence.

In particular, our approach to analysing the administrative and compliance costs stemming from the Regulation was based on the identification of relevant obligations and required actions, as defined in the standard cost model (SCM). This analysis covers: the costs of the authorisation process and of labelling for business operators; and, the costs for Member State Competent Authorities, EFSA, the EURL and the European Commission to fulfil their tasks under the Regulation. The costs include both the time required for the execution of the various obligations stemming from the Regulation (as determined by: staff time; staff category; unit costs) and the costs of materials and equipment. For the monetisation of the costs of staff time, in all cases:

- Earnings[34] are adjusted for overhead costs[35];
- The conversion of annual or monthly earnings to daily rates is based on 215 working days/year[36] and 8 hours/working day.

In addition, in the case of authorisation and labelling costs for business operators, indirect costs and losses were analysed, with the focus on reformulation costs and other costs/losses.

4.5 Conclusions and reporting

A concise summary of the triangulated evidence, structured by indicator, allowed the development of evidence-based conclusions through textual analysis for each EQ. The basis for each conclusion can be traced back through the overview of the evidence assembled (Annex 3).

4.6 Limitations

The significant challenges outlined below are exogenous to the evaluation methodology and were identified from the outset. These were addressed by expanding the data

[34] For earnings, the following sources were used:
- Business operators: EUROSTAT average annual earnings for industry (except construction), by economic activity and educational attainment (staff categories 1 to 4), average EU-28 (latest data: 2014)
- MS CAs: EUROSTAT average annual earnings for public administration, by economic activity and educational attainment (staff categories 1 to 4), per Member State (latest data: 2014)
- For the Commission, EURL and EFSA: 2019 rates of remuneration of EU officials, as published in OJ C 451, Volume 61, 14 December 2018. The same rates are assumed for all institutions (Commission, EFSA, EURL). AD rate is based on AD/AST, grade 10, step 1; AST rate is based on AST/SC, grade 4, step 1.

[35] According to Better Regulation toolbox #60: addition of 25% overhead on staff costs.

[36] Working days: https://ec.europa.eu/eurostat/documents/10186/7970019/Guideline-unitcosts.pdf

collection exercise and broadening the consultation to ensure that the study could gather an appropriate and objective evidence base; this is demonstrated by the comprehensive range 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.

In particular, several challenges needed to be overcome or mitigated in carrying out this evaluation as set out below:

- ***Categorisation of feed additives***. The commercial categorisation of feed additives does not cleanly match the categories set out in the Feed Additives Regulation. This problem 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.
- ***Availability and structure of data on the feed additives market***. There are no data on the EU feed additives market (turnover, added value, employment, trade) from official statistical sources (EUROSTAT), as there is no specific industrial or trade classification for this sector. No commercial data sources exactly matched the evaluation requirements. This 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 in order to produce the most reliable estimates.
- ***Temporal scope of the study/baseline***. The baseline for the study is based on the situation at the time of the entry into force of the Regulation; while comparison is also made to the situation under the former legislation. This poses difficulties because (i) there are only limited data for this extensive period; (ii) this period extends beyond institutional memory and the foundation of FEFANA, the industry organisation. Qualitative approaches were used to fill quantitative data gaps. The absence of an Impact Assessment prior to the Feed Additives Regulation necessitated the development of a baseline on the basis of other regulatory documents, data from the EU Registry and limited documents from academic/ scientific publications.
- ***Estimation of costs and benefits*** in a uniform manner to allow unit cost comparisons required considerable input from stakeholders, especially operators. This information is considered highly commercially sensitive and there was considerable unwillingness to make such data available; it is also very difficult for operators to isolate specific regulatory impacts on costs. To address this challenge: we applied the Standard Cost Model which allowed us to isolate key obligations arising from the Regulation and to then quantify these using a combination of staff time/grade required and cost per unit (EUROSTA data); and, we collected data from a large range of companies, in order to address gaps, improve the estimations and overcome confidentiality concerns.
- ***Stakeholder feedback***. Due to their active participation in the different consultations organised for the study, the views of competent authorities and of the feed industry are well reflected in this report. The views of the farming sector are represented by two EU organisations: COPA/COGECA (umbrella organisation representing all farm product sectors), and the poultry sector (AVEC); also, the views of the aquaculture sector are represented by national level stakeholders. However, other parties such as organisations representing pet owners, consumers as well as 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 and their views could therefore not be taken into account to inform the analysis.

Due to the mitigating measures taken, none of the identified challenges resulted in significant limitations in the analysis.

5. REPLIES TO EVALUATION QUESTIONS RELATED TO EFFECTIVENESS

5.1 Evaluation question 1: extent to which the Regulation met its objectives

EQ1: To what extent did the Regulation meet its objectives?

The core objectives of the Feed Additives Regulation are to ensure that feed additives placed on the market are efficacious, safe and ensure the protection of animal health and welfare, human health and the environment. These objectives are addressed through several provisions. A core requirement is the procedure set out for the authorisation of feed additives, with the safety and efficacy assessment performed by the European Food Safety Authority (EFSA), and the risk management, based on the EFSA opinion and other legitimate factors, which is delivered by the Commission. Other key requirements serving the same objectives include the labelling of feed additives; enforcement with validated method of analysis, establishment of infringements and penalties to be put in place by Member States; and, provisions contributing to the reduction of antimicrobial resistance (AMR) and post-market monitoring for certain additives.

EQ1 is addressed through six sub-questions testing the extent to which the above requirements meet the Regulation's core objectives. In doing this, comparison is made with the former legislation. Each sub-question analyses and triangulates the evidence gathered through the full range of methodological tools used (see Chapter 4). The evidence base presented includes references to survey results and the OPC (Annex 3).

5.1.1 ANALYSIS

EQ1.1: To what extent did the efficacy assessment of feed additives ensure that feed additives are effective? How do the achievements compare to Directive 70/524/EEC?

In line with the legal provisions[37], the requirement to assess efficacy is essential to ensure that substances placed on the market have proven efficacious for the intended purpose and to ensure the smooth functioning of the single market.

The assessment of efficacy by EFSA is a key requirement both for the authorisation of new feed additives (Article 4(1)) and for the reauthorisation (Article 10(2)) of pre-existing feed additives, which were placed on the market under the former Directive. As outlined in the background (Chapter 2), the authorisation process was made more specific and comprehensive in the current regulatory framework. The process now includes a requirement for an efficacy assessment, which is systematically applied as a prerequisite for authorisation in all cases[38].

EQ1.1 is addressed on the basis of four judgement criteria; findings for each of these are presented below.

[37] The Feed Additives Regulation and implementing rules (Regulation (EC) No 429/2008).

[38] The requirements are detailed for each category and type of feed additives in the EFSA FEEDAP Panel's Guidance on the assessment of the efficacy of feed additives. For additives used in food it is not necessary to demonstrate efficacy (e.g. flavourings), because they have the same function as in food, and they are considered efficacious.

Judgement criteria: "Feed additives on the EU market are considered efficacious"

Generally, the full range of parties (industry; the farming sector; Member State Competent Authorities) consulted through the surveys, interviews and the OPC believe that feed additives (including pet food additives) placed on the EU market are efficacious; very few respondents could not ascertain efficacy, lending credence to this point of view[39]. Nonetheless, citizens that responded to the OPC did not have a clear position on this with a significant proportion having not answered the question. According to both Member State Competent Authorities and industry and the farming sector, the evaluation of the efficacy of feed additives by EFSA and the high level of rigour applied by EFSA in this assessment ensures that feed additives placed on the market are efficacious.

In practice, however, there are many contextual factors, which influence the efficacy of a feed additive when this is applied in real conditions. With respect to zootechnical feed additives for food-producing animals, the feed additives industry has indicated that it has proven difficult in practice to demonstrate efficacy in every case. For example, trials with gut flora stabilizers to demonstrate improvements in productivity levels (feed conversion rates) have proven challenging.

Furthermore, manufacturers of feed additives/pre-mixtures and the organisations representing them have noted the commercial need to respond to buyers' requirements to demonstrate the efficacy of the products on offer in real conditions, for which tailor-made studies need to be conducted. Although the Regulation requires that the studies on animals must be performed in accordance with common farming practices in the EU, pre-existing studies conducted for commercial purposes may not be suitable for the efficacy assessment conducted by EFSA. There are also some additives for which "in vitro studies" can be conducted, which although of a lower cost, are not necessarily considered useful by applicants in a real market context (i.e. suitably adapted to buyer requirements or necessary for commercial purposes).

Against this context, the definition of measurable impacts on performance (so-called endpoints) for zootechnical additives in the legislation is considered too narrow to allow trials that can demonstrate that the feed additive results in a significant improvement for the required endpoints, e.g. productivity levels; and, too theoretical to indicate an improvement in real conditions. Furthermore, additional specific trials to demonstrate efficacy are typically required in real conditions, to address specific buyer requirements.

Judgement criteria: "Feed additive categories for which efficacy was not at all or partially evaluated are now fully evaluated"

The current legislation[40] lays down more detailed requirements for applicants to demonstrate efficacy for several important categories/ functional groups, which were already on the market at the time of introduction of the Regulation but were not sufficiently assessed under the former legislation[41]. This includes[42]:

- Certain important **technological** additives, which were not assessed under the former Directive because they were not regarded as feed additives. These were

[39] Annex 3: Consultation synopsis report, surveys of stakeholders and Member State competent authorities (sections 3.2.2.1 and 3.3.2.1), OPC (section 3.4.2.1) and interviews.
[40] The Feed Additives Regulation and implementing Regulation (EU) No 429/2008.
[41] Including Directive 70/524/EEC, and other Directives.
[42] The categories for which efficacy was not at all or partially evaluated under the former legislation are identified on the basis of the information available from the Feed additives Register (FAR). Source: FAR - Reference 1: list of Annex I of the Register December 2006 (rev. 7).

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 these cases, efficacy was only partially assessed: either it was not assessed at EU level (amino acids) or requirements were too general (zootechnical additives). Normally, the assessment of efficacy is not required for all amino acids but there are some cases where it is necessary to demonstrate it[43].

Approximate broad estimates[44] indicate that the value of the above categories in the current EU-28 market is important. The market for methionine and lysine (the two most important amino acids) is estimated to range between €0.8 and €1.2 billion. The market for enzymes is estimated to be approximately €230 million. Probiotics, a growing category of increasing use as gut flora stabilisers, has a market value of €530 million. Technological additives are also considered important: estimates of their market value only exist for some product groups, e.g. organic acids (€430 million) and mycotoxin binders (€80-100 million).

The importance of these categories/functional groups for the authorisation process is also indicated by the fact that, since the start of implementation of the Regulation up to end 2017, a total of 432 applications were made for the authorisation of feed additives within the above categories[45]. Of these applications, 132were for the authorisation of new feed additives or for new uses (Article 4(1)), and 300 for the reauthorisation of feed additives placed on the EU market under the Directive (Article 10(2)). The additives authorised by those applications were 339, the majority of them (more than 80%) under Article 10(2) applications i.e. additives already placed on the market at the time of the introduction of the Regulation. Although there were less applications for these pre-existing additives, they include few applications for flavourings that covered hundreds of additives.

The rate of completion of the assessment process for applications in the period 2004-17 is high[46]. In terms of the additives which were not evaluated for efficacy under the former Directive, 363 applications out of 417 applications for Article 4(1) and 10(2) authorisations were processed (i.e. opinion issued by EFSA), i.e. the rate of completion is 87%:

- New authorisations (Article 4(1)): 102 EFSA opinions were issued out of a total 116 applications, i.e. the rate of completion for the period is 88%.

[43] Evidence of efficacy should be provided for amino acid salts and analogues, new forms of compounds of trace elements, chemically well-defined substances having similar effect to vitamin and urea derivatives not authorised before as feed additives. This evidence can be provided by reference to literature or by *in vivo* studies. Source: EFSA Guidance document and Regulation (EC) No 429/2008.

[44] The absence of data on the sector for the same category classification as that followed in the Regulation means that it is not possible to estimate the value and volume of these categories with accuracy. The estimates provided here are based on industry data, following an industry classification (see section 3.2). Source: RM Associates Report (2018).

[45] Source: DG SANTE database since implementation up to 31/12/2017. The applications refer to each request for authorisation in each functional group. This does not match with the number of "Administrative applications" for which there can be several additives included in the application or, for the same additive, request for authorisation of this additive in different functional groups. Here, each additive is counted and if the same additive is requested in different functional groups the additive is counted for each functional group. E.g., an administrative application with three additives of which two are requested in one functional group and one in two functional groups is counted as four applications separately even though they can belong to one "Administrative application".

[46] These calculations are based on EFSA data and are not directly comparable to the data available in the previous source (the DG SANTE DATABASE). Source: calculated on the basis of FAD applications submitted for evaluation to EFSA. The number of EFSA applications (FAD-applications) is lower than the DG SANTE applications as this refers to the administrative application forwarded by the Commission to EFSA (one application may contain a request for several additives or additives in more than one functional group) or applications under Article 29 of the GFL that may also cover several additives or functional groups.

- Reauthorisations (Article 10(2)): 261 EFSA opinions were issued out of a total 301 applications, i.e. the rate of completion is 87%.

The rate of completion of the EFSA assessment process for these applications is higher than the rate of completion of all applications (87% compared to 80%[47]). In particular, it is higher for Article 10(2) applications (87% compared to 70%), but it is lower for Article 4(1) applications (88% compared to 92%).

Judgement criteria: "Feed additives for which efficacy/safety was not demonstrated under the Feed Additives Regulation (Article 10) were withdrawn from the market"

As it is not possible to distinguish between withdrawal due to non-demonstration of efficacy or for safety, the analysis below covers both cases.

Article 13 of the Regulation foresees the suspension or revocation of an authorisation in cases where one or more conditions of the authorisation no longer exist. This could be because of the emergence of new scientific evidence or following the use of safeguard measures (in line with Articles 53 and 54 of the GFL). To date, this provision has been applied in the context of the reauthorisation requirements of the Regulation (Article 10), in the cases of substances authorised under former legislation (Directive 70/524/EEC and other Directives)[48]. Consequently, an extensive number of feed additives authorised under former legislation for which efficacy/safety was not demonstrated by the applicant were withdrawn from the market. These included:

1. Feed additives covered by requests for total or partial withdrawal of applications submitted under Article 10. In such cases, applicants withdrew the application for a variety of reasons, including lack of sufficient information, cost of providing the information, and/or reputational damage (in case the EFSA opinion is negative)[49].
2. Feed additives notified under Article 10 for which no reauthorisation dossier was introduced at expiry date (an estimated 1,623 additives, mainly flavourings, silage additives and trace elements)[50] and 120 additives withdrawn or partially withdrawn during the authorisation process.

Judgement criteria: "New feed additives for which efficacy/safety is not demonstrated and the authorisation is denied or the application withdrawn (Article 4)"

[47] For the rate of completion of the EFSA assessment process of all applications see section 3.1.1.

[48] These substances were authorised by eight Commission Implementing Regulations adopted between 2012 and 2017.

[49] Applications were typically withdrawn because:
- EFSA requested the applicant to provide additional information, but the applicant withdraws the application before EFSA issue the opinion as it is not economically feasible to provide such data;
- The EFSA opinion is inconclusive, and the applicant is not interested to submit additional information but prefers to withdraw the application;
- The EFSA opinion is negative so the applicant withdraws the application (or else, the Commission must deny the authorisation).
- The applicant requested authorisation for the use of certain feed additives in water, but this is not possible, as there are certain categories for which the Regulation does not provides for the use in water e.g., flavourings.

[50] Withdrawal of these additives was implemented by: Regulation (EU) No 451/2012; Regulation (EU) No 230/2013; Regulation (EU) No 107/2014; and Regulation (EU) 2017/1490. In the case of Regulation (EU) 2017/1490, some additives were withdrawn (totally or partially) during or after the assessment, as the applicant withdrew the application for the reasons mentioned above (under point 1). The remaining Regulations relate to a denial of authorisation of specific feed additives (Regulation (EU) No 81/2012; Regulation (EU) No 796/2013; Regulation (EU) No 754/2014; and, Regulation (EU) No 2015/1399).

In the case of six applications for a new authorisation (Article 4) submitted during the period 2004-17, authorisation was not granted because efficacy/safety[51] was not demonstrated[52]. During the same period, there were 89 requests by applicants for withdrawal (total or partial) of applications submitted under Article 4[53] (compared to 205 requests for withdrawal (total or partial) of applications submitted under Article 10). It is noted that the number of applications submitted is not comparable with the number of requests for withdrawals, as one application may have more than one request for partial withdrawal.

The reasons for the withdrawal are similar as in the previous points, i.e. including lack of sufficient information, cost of providing additional information, and/or reputational damage (in case the EFSA opinion is negative).

EQ1.1 Answer:

Under the Regulation, efficacy is evaluated for several important categories/functional groups of feed additives which were not at all or not completely assessed under the former legislation because: (i) they were not considered as feed additives (e.g. silage additives); (ii) rules were not fully harmonised (e.g. amino acids); (iii) requirements were too general (zootechnical additives). The market relevance of these feed additives is indicated both by the total number of applications for new authorisations/reauthorisations (2004-17: 432) and their considerable market value (where estimates exist). In total, 339 additives authorised under the Regulation belong to categories that were not at all or not completely evaluated for efficacy under the former Directive. The majority of these (more than 80%) were pre-existing additives already placed on the market at the time of the introduction of the Regulation.

Furthermore, pre-existing feed additives for which efficacy/safety was not demonstrated under the Regulation were withdrawn from the EU market, including an estimated 1,623 additives notified under Article 10 for which no reauthorisation dossier was introduced at expiry date and 120 withdrawn during the authorisation process. Between 2004 and 2017, 89 applications for new authorisations and 205 applications for reauthorisation, were withdrawn (totally or partially) because efficacy/safety was not demonstrated (compared to a total 791 applications submitted for evaluation by EFSA under Articles 4(1) and 10(2)).

In the case of applications for the authorisation of new feed additives (Article 4(1)), when efficacy/safety was not demonstrated, the authorisation was either not granted (few cases), or the application was withdrawn (majority of the cases).

In conclusion, according to the available evidence, in comparison to the Directive the Regulation has achieved important improvements in the efficacy assessment, in ensuring that feed additives placed on the EU market are efficacious.

Although feed additives on the EU market are generally considered efficacious by the feed industry, the farming sector and Member State Competent Authorities, one shortcoming identified by manufacturers of feed additives/pre-mixtures is that the regulatory requirements to demonstrate efficacy do not always correspond to real conditions of use as defined by users. This is particularly highlighted for zootechnical additives, for which demonstrating efficacy in terms of the performance end-points

[51] It is not possible to distinguish between those cases where efficacy was not demonstrated and those where safety was not demonstrated.
[52] In two of these cases the application was submitted in the period 2004-2017 but the adoption of the Decision was taken after 2017.
[53] Source: calculations provided by DG SANTE on the basis of EFSA data.

defined in the Regulation has proven challenging and is not always considered appropriate for real market conditions and requirements as defined by users.

EQ 1.2: To what extent did the safety assessment of feed additives ensure safeguarding human and animal health and the environment? How do the achievements compare to Directive 70/524?

In line with the legal provisions[54], the requirement to assess safety is essential to ensure safety for animals, consumers of the food products obtained from animals that received the feed additive, users, and the environment.

EQ 1.2 is addressed on the basis of three judgement criteria; findings for each of which are presented below.

Judgement criteria: "Feed additive categories for which safety was not at all or partially evaluated are now fully evaluated"

The Feed Additives Regulation and Regulation (EU) No 429/2008 lay down more detailed requirements for applicants to demonstrate safety for several important categories/ functional groups, which were not sufficiently assessed under the former legislation (including Directive 70/524/EEC, and other Directives). This includes[55]:

- **Sensory** additives (certain colourants; nearly all flavouring compounds); and, **nutritional** additives (all vitamins, except A and D). Safety was **not assessed** for these additives, which were not specifically authorised but approved in a generic manner.
- Safety was only **partially assessed** in the case of: **amino acids** (an important category of nutritional additives); and, the most important and relevant **zootechnical** additives (enzymes, gut flora stabilisers). In the cases where assessment was partial, it was either not performed at EU level (amino acids) or requirements were too general (zootechnical additives). In the case of **coccidiostats and histomonostats**, antimicrobial resistance and Maximum Residue Levels were not fully addressed by the Directive; there were concerns over the source of the data provided and the independence of the risk assessment.

Approximate broad estimates[56], indicate that the value of the above categories in the current EU-28 market is important. The EU-28 vitamin market is estimated to be worth €1 billion (2015), with demand growing. The value of methionine and lysine (the two most important amino acids) is estimated by the same source to range between €0.8 and €1.2 billion. The value of enzymes is estimated to be approximately €230 million. Probiotics, a growing category of increasing use as gut flora stabilisers, are valued at €530 million. Sensory additives are also considered important as used widely by the feed industry: estimates of their value only exist for some product groups, e.g. pigments (€200 million) and flavourings (€80 million).

[54] Regulation (EC)No 1831/2003 and Regulation (EC) No 429/2008

[55] The categories for which safety was not at all or partially evaluated under the former legislation are identified on the basis of the information available from the Feed additives Register (FAR). Source: FAR - Reference 1: list of Annex I of the Register December 2006 (rev. 7)

[56] The absence of data on the sector for the same category classification as that followed in the Regulation means that it is not possible to estimate the value and volume of these categories with accuracy. The estimates provided here are based on industry data, following an industry classification (see section 3.2). Source: RM Associates Report (2018).

The importance of additives which were not evaluated for safety under the former legislation is also indicated by the fact that, since the start of implementation of the Regulation up to end 2017, a total of 458[57] applications were made for the authorisation of feed additives within the above categories[58]. Of these applications, 251 were for the authorisation of new feed additives or for new uses (Article 4(1)), and 207 for the reauthorisation of feed additives placed on the EU market under the Directive (Article 10(2)). Most of the applications relate to digestibility enhancers (112), gut flora stabilisers (112) followed by flavourings (79), amino acids (59), vitamins (53), coccidiostats/ histomonostats (35) and certain colourants (8).

EFSA has processed 441 applications[59], of which 208 correspond to Article 10(2) and 233 to Article 4(1). EFSA has issued 353 opinions, of which 151 were issued under Article 10(2) and 202 under Article 4(1).

According to DG SANTE data[60], for a total of 1,136 additives (including both new and pre-existing additives), safety was not at all or was only partially assessed under the former Directive, but is now fully (i.e. completely) assessed under the Regulation. Of these, 539 additives were authorised during the period 2004-2017 and the rest were under the process of authorisation during that period.

The rate of completion (i.e. EFSA opinion issued) of these applications is 80%, i.e. same as the rate of completion of all applications (80%)[61]. For Article 10(2) applications the rate of completion is higher than for all applications (72% compared to 70%) and for Article 4(1) applications it is lower (86% compared to 92%).

Judgement criteria: "Feed additives on the EU market are safe for humans (consumers; users/workers), animals, and the environment"

Generally, the full range of consulted parties (industry; farming sector; Member State Competent Authorities)[62] strongly believe that feed additives placed on the EU market are safe for animals, users and workers, the environment, and consumers. Nonetheless, citizens that responded to the OPC did not have a clear position on this with a significant proportion having not answered the question.

The achievement of these objectives is largely attributed to the safety assessment carried out by EFSA. The high level of the scientific evaluation performed by EFSA, as acknowledged in the latest independent external evaluation of EFSA[63], is considered to have played an important role in ensuring that feed additives are safe, particularly for substances and microorganisms that potentially pose a higher health risk or that exert complex/less well understood impacts (e.g. additives produced with genetically modified micro-organisms, for which there may be lack of presence of DNA in the final product).

[57] As indicated above, this does not correspond with administrative application. Each additive for each functional group is counted separately.
[58] Source: DG SANTE database - since implementation up to 31/12/2017.
[59] These calculations are based on data available in another source and are not directly comparable to the data available in the previous source (the FAR). Source: calculated on the basis of FAD applications submitted for evaluation to EFSA.
[60] Based on FAR (Reference 1: list of Annex I of the Register December 2006, rev. 7), Register December 2017 (rev. 259), and other sources.
[61] For the rate of completion of the EFSA assessment process of all applications see section 3.1.1.
[62] Annex 3: Consultation synopsis report, surveys of stakeholders and Member State competent authorities (sections 3.2.2.1 and 3.3.2.1), OPC (section 3.4.2.1) and interviews.
[63] The latest (third) external evaluation of EFSA over the period 2011-16 (Ramboll and Coffey, 2018) found EFSA's scientific system has successfully delivered high quality, fit for purpose scientific advice, that is responding to risk managers' needs.

No respondents consider feed additives placed on the EU markets to be unsafe. Nonetheless, a small number of respondents (manufacturers of feed additives/pre-mixtures; Member State Competent Authorities) noted that, ultimately, the safety of authorised feed additives for users/workers and for the environment depends on compliance with the conditions of use as set out in the authorisation decision (i.e. for users/workers respect of safety instructions; for the environment, respect of maximum doses)[64].

The Feed Additives Regulation establishes the conditions for authorisation and use of feed additives and premixtures. There are certain provisions in the authorisation that may refer to the conditions for the incorporation of feed additives in compound feed/feed materials, for example: maximum levels, direct incorporation into the feed or via a premixture, mandatory labelling on the compound feed of certain indications related to the additive.

The assessment by EFSA ensures that, if the additive is used along the feed chain in accordance with the conditions of authorisation and with the other requirements laid down in the Regulation, the additive will not have adverse effects on the environment. This preventive approach applies also for animal health and human health, as well as for the authorisation of regulated products in food. For some feed additives, the applicant has to perform a post-market monitoring (PMM) to identify unforeseen effects for human health, animal health or the environment. The PMM requirement is based on the EFSA assessment; EFSA decides on a case-by case basis whether a PMM plan is necessary or not.

The environmental assessment performed by EFSA takes into account the additives excreted by animals and their metabolites. Animals metabolise the additives and, depending on the metabolic path of the additive, the environmental impact may be different. Some additives are completely metabolised and animals do not release into the environment the additive or its metabolites, while others may be partially metabolised and may have a higher impact on the environment. The Feed Additives Regulation does require to perform environmental monitoring for the effects of additives on the environment through the additives excreted by animals as such, or as their metabolites.

While the Feed Additives Regulation establishes the conditions for authorisation and use of feed additives and premixtures, the control of the food chain, including the control of feed additives, premixtures, compound feed and feed materials, fall within the scope of the Official Controls Regulation. The scope of the Feed Additives Regulation does not regulate how compound feed or feed materials containing additives are placed on the market. Those aspects are regulated in the Feed Marketing Regulation and in the Feed Hygiene Regulation.

Data on RASFF notifications for the period 2004-2017[65], indicate that out of a total 517 notifications on feed, only 7 relate to feed additives and 5 on premixtures; the largest number of notifications on feed during the period relate to feed materials, followed by pet food. The reasons for the notifications on feed additives were mainly related to high levels of undesirable substances, 8 cases (5 dioxins, 2 arsenic, 1 botanical impurity), 1 case for contamination of salmonella, 2 cases for presence of prohibited substances (chloramphenicol) and 1 case for high content of selenium. In the case of premixtures, 2 notifications refer to a non-authorised premixture containing high levels of an authorised additive (selenium compound); the rest relate to presence of undesirable substances, microorganisms or prohibited substances.

[64] The conditions of use, as set out in each authorising Regulation, include *inter alia* labelling, directions for use, restrictions, characteristic of the additive to be respected.
[65] Source: RASFF database.

Judgement criteria: "Pet food additives are safe for pet animals"

Generally, the full range of consulted parties (industry; farming sector; Member State Competent Authorities) strongly believe that pet food additives placed on the EU market are safe for pet animals.

Safety is now fully (i.e. completely) assessed under the Regulation for a total 1,017 additives authorised for pet animals (specifically or for all animals including pets), which were not at all or were only partially assessed for safety under the former legislation. Of these, the largest category is flavouring compounds (974); the second largest category, by number, are nutritional additives (vitamins and amino acids: 34). This includes feed additives that were on the market at the time of introduction of the Regulation (although no data are available on their number).

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[66] introduced specific provisions on feed additives 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 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 were allocated in a specific Annex.
- 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 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 feed additives 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.

EFSA set up scientific guidelines for applicants regarding the assessment of additives intended for use in pet food, including clear and comprehensive data requirements[67]. 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[68].

[66] I.e. both the Feed Additives Regulation and implementing Regulation (EC) No 429/2008.
[67] https://www.efsa.europa.eu/en/applications/feedadditives/regulationsandguidance
[68] These are: Guidance on the identity, characterisation and conditions of use of feed additives; Guidance on the characterisation of microorganisms used as feed additives or as production organisms (if applicable); Guidance on the assessment of the safety of feed additives for the target species; Guidance on the assessment of the efficacy of feed additives; and, Guidance on studies concerning the safety of use of the additive for users/workers. There are also two guidance documents for the re-evaluation of feed additives (2008) or renewal of authorisation (2013), but these do not have any specific guidance for additives intended for pet food.

EQ1.2 Answer:

Under the Regulation, safety is evaluated for several important categories/functional groups of feed additives which were not at all or not completely assessed under the former legislation because: (i) they were not specifically authorised but approved in a generic manner (e.g. flavourings); (ii) they were not considered to be feed additives (e.g. silage additives); (iii) rules were not fully harmonised (e.g. amino acids); (iv) requirements were too general (zootechnical additives). The market relevance of these feed additives is indicated both by the total number of applications for new authorisations/re-authorisations (2004-17: 458) and their considerable market value (where estimates exist). In total, 1,136additives authorised under the Regulation belong to categories that were not at all or not completely evaluated for safety under the former Directive. Of these, 539 additives were authorised during the period 2004-2017 and the rest were under the process of authorisation during that period.

Furthermore, pre-existing feed additives for which efficacy/safety was not demonstrated under the Regulation were withdrawn from the EU market, including an estimated 1,623 additives notified under Article 10 for which no reauthorisation dossier was introduced at expiry date and 120 withdrawn or partially withdrawn during the authorisation process. Between 2004 and 2017, 89 applications for new authorisations and 205 applications for reauthorisation, have been withdrawn (totally or partially) as efficacy/safety is not demonstrated (compared to a total 791 applications submitted for evaluation by EFSA under Articles 4(1) and 10(2)).In the case of applications for the authorisation of new feed additives (Article 4(1)), when efficacy/safety was not demonstrated, the authorisation was either not granted (few cases), or the application was withdrawn (majority of the cases).

An additional indication of the high safety record of feed additives and premixtures placed on the EU market is the relatively limited number of RASSF notifications during the period 2004-17: out of a total 517 notifications on feed, 12were on feed additives/premixtures.

In conclusion, according to the available evidence, in comparison to the Directive the Regulation has achieved important improvements in the safety assessment, in ensuring that feed additives placed on the EU market are safe. The high safety standard of feed additives and premixtures placed on the EU market for pet animals (flavourings, vitamins and amino acids) is also demonstrated, with specific rules laid down in the Regulation for non-food producing animals, including for the assessment of their safety/efficacy by EFSA, for which specific guidance was set up by EFSA.

Consequently, feed additives on the EU market are unanimously considered to be safe by all consulted parties. The high level of the scientific evaluation performed by EFSA is considered to have played an important role in ensuring this objective. Ultimately, the safety of authorised feed additives depends on compliance along the feed chain with the conditions of authorisation and the use of feed additives and premixtures as set out in the Feed Additives Regulation. In this context, it is noted that the control of the feed chain falls within the scope of the Official Controls Regulation.

EQ 1.3: What elements of the authorisation procedure of feed additives are key drivers for its effectiveness and what elements hinder its effectiveness? Why?

As indicated in section 3.1, the EU authorisation procedure for feed additives consists of several consecutive phases and involves the European Commission, EFSA and the EURL, with time limits laid down in the Regulation for each phase as follows:

- Commission without delay inform the Member States and forward the application to EFSA;

- 15 days for EFSA to acknowledge receipt of the application dossier;
- 30 days for EFSA to carry out a completeness check[69] of the dossier and validate the application (with samples sent to the EURL), as foreseen in the EFSA guidance[70];
- 6 months for the risk assessment by EFSA, with extension possible should additional information be needed (so-called '*stop the clock'* procedure);
- 3 months for the European Commission to prepare a proposal for a decision to approve/reject the additive[71] (in exceptionally complex cases this delay can be extended).

This process applies both for the reauthorisation of new additives (Article 4) and for the reauthorisation of pre-existing substances and feed additives authorised under the Directive (Article 10) and for modification of an existing authorisation (Article 13).

According to these time limits, authorisation normally requires around one year without clock stoppages. This period is considered reasonable by the industry for placing products on the market. However, a longer period may be required if during the evaluation of the data EFSA request the applicant to provide additional information, in which case the assessment is put on hold ('*stop the clock'*). These requests arise frequently due to the complexity of the required assessment and incompleteness of information provided in original applications.

The discussions of the draft Decision at the Standing Committee may take longer than expected in certain complex cases (Article 9(1) of feed additives Regulation), for example, the opinion is favourable but there are issues on the proposed doses for certain animal categories, the functional group is not appropriate or the authorising decision deviates for efficacy from EFSA conclusions.

Thus, responding to EQ1.3 requires the identification of key elements of this procedure that may have a positive or negative impact on its implementation in practice. These include: the completeness of the information provided by applicants; delays occurring along the process, notably in the risk assessment phase and the decision-making phase; the process for renewal of authorisations (Article 14); the simplified procedure for extension of authorisation from food to feed; and, the procedure for extension of authorisation to minor species. The evidence base on these issues is drawn from EFSA, supplemented by feedback from applicants (including that provided in the context of the authorisation case study Annex 4).

Judgement criteria: "The information provided by applicants in their dossier to EFSA is fit to assess safety and efficacy"

EFSA requests to applicants for further information are an indicator of the extent to which the information provided in the original dossier is sufficient or appropriate; this is discussed under the next judgement criteria ("completeness of dossier"). The fitness of the information provided by applicants can be assessed by the extent to which it enables EFSA to assess the safety and efficacy of feed additives in an effective manner. This can be established by the type of information requested by EFSA and reasons why it is incomplete.

[69] After reception of the application dossier, the EFSA Applications Desk Unit (APDESK) checks the completeness of the application. The dossier is validated when it fulfils the legal requirements, as detailed in the EFSA guidance documents. EFSA endeavours to communicate to the applicant the outcome of the completeness check within 30 working days after the date of reception of the application.

[70] EFSA Administrative guidance to applicants on the preparation and presentation of applications for authorisation of additives for use in animal nutrition.

[71] The decision to authorise/reject an application is usually presented by the Commission and discussed with the Member States (PAFF) during the three-month period, but adoption takes longer (as the process includes translation into all EU languages, adoption by the College and publication in the Official Journal).

Systematic data on the type of questions asked by EFSA are not available for a long period. The more limited data available indicate that, out of a total 377 questions to applicants in 87 requests for data sent by EFSA in the first 7 months of 2019, the majority (244) related to the characterization of the additive; in particular for microorganisms since applicants are still adapting to the update of the corresponding EFSA guidance published in 2018. Of the remaining questions (133), 108 related to the safety assessment and 21 related to the efficacy assessment.

According to EFSA[72], the reasons for applicants not providing the complete dataset to address any of the aspects for the assessment of efficacy and safety tend to be similar. These include: understanding of the guidance and assessment process; interpretation of the requirements by the applicants e.g. on the studies to be conducted; and/or, interpretation of the results obtained in the studies. They may also be due to specific inherent challenges for assessing safety and efficacy as outlined below.

Fitness of information for safety assessment

For each of the different safety aspects, EFSA has developed a guidance document in which the requirements are established; the guidance documents detail when data are needed, the type of information required, and how the studies should be conducted and reported. The data requirements depend on the nature of the substance and on the use of the additive. For instance, for additives aimed to be used in feed for pets, the safety of the additive for consumers and the environment does not need to be addressed[73]. In the case of the safety studies, with the exception of the tolerance studies[74] in target species, the guidance documents normally refer to the relevant OECD Guidelines. According to both the EFSA and applicants[75], this generally facilitates safety studies and leads to a lower number of questions for issues like study design, conduct and reporting, compared to the efficacy section.

A more challenging assessment for applicants is the safety for users. This relates to the potential effects of an additive on the users' eyes, skin and respiratory system, and needs to be addressed in all cases. EFSA has indicated that in many instances, it is not possible to conclude on any of these aspects due to a lack of data. This tends to be due to the fact that:

- Depending on the characteristics of the additive, the regulator may decide to establish the use of protective measures by the users of the additive while handling it. The applicants tend to rely on the protective measures and do not provide further information.
- The studies should be conducted with the formulations of the additive that may be placed on the market. For non-holder-specific additives, this may represent a limitation: while the assessment is done at the active substance/agent level, the data provided may not permit to conclude on all the formulations that may be placed on the market. Thus, data on the active substance/agent may not reflect the properties of the final formulations in the market. However, it is noted that conditions of use

[72] Interview conducted with EFSA in the course of the study.
[73] In accordance with Commission Regulation (EC) No 429/2008, phase I of the environmental risk assessment is not performed for additives intended for non-food producing animals, due to the unlikelihood of a significant environmental effect, as no scientifically-based evidence for concern has been identified by EFSA.
[74] Tolerance studies are performed on the species or categories of animals for which the additive is intended for. These studies evaluate the short-term toxicity and establish the margin of safety in case the additive is consumed at higher doses than recommended.
[75] Interviews conducted with EFSA and applicants in the course of the study.

accompany the authorisation of the additives contained in preparations and these lay down provisions to protect workers when handling the preparation[76].

Fitness of information for efficacy assessment

EFSA indicated[77] that, when assessing efficacy, they consider that efficacy is demonstrated from the moment that the minimum number of studies with positive outcomes is documented. The studies should demonstrate the efficacy for each proposed use of the additive. The EFSA FEEDAP Guidance on the assessment of the efficacy)[78] details the type of studies required (*in vitro*, *in vivo*) and number of necessary studies (with positive outcomes)[79], as well as the end-points (i.e. the performance indicators, such as e.g. yield improvement, or improvement in quality of milk production) to be measured in the efficacy trials depending on the additive and the nature of the application (e.g. multiple animal species, single animal species/category). The guidance also establishes how the studies should be conducted and be reported (the latter also for literature papers). Nonetheless, it is acknowledged that the guidance does not consider all possible uses of the additives and leaves an open approach for the applicants to decide the approach for the studies to be submitted when a novel use is sought. This is the case for efficacy studies for which no standards are foreseen and, consequently, the operators must design their own studies.

In many cases, the information submitted by applicants in the dossiers does not allow a conclusion. This is usually due to the insufficient number of studies considered for the assessment with positive and significant effects on the relevant outcomes, and/or because the positive effects documented in studies submitted by applicants are in end-points that are not relevant (e.g. improvement in quality of milk production by measuring the dry matter in milk or the level of protein may not be relevant for non-milk producing species).

According to EFSA[80], reasons for incomplete/missing information provided by applicants include:

- Applicants who submit a dossier for the first time may not be very familiar with the requirements described in the EFSA guidance; also, when new guidance documents are released, it may take some time before applicants become familiar with any changes. This concurs with the views of applicants, who noted that familiarising themselves with changes to guidance documents was a challenge (although changes and updates were generally considered to be an improvement).
- Interpretation of guidance: it is the applicants' responsibility to design the strategy to follow in order to provide the necessary data (which includes type and number of studies and end-points to be addressed). In complex applications (e.g. additives covering different categories/functional groups), the approach to follow requires knowledge, scrutiny and consideration of all the requirements in the guidance and this may not be an easy task (as confirmed also by applicants). In a similar way, for novel uses no specific indications may be given, although this situation seldom arises.

[76] Only authorised technological additives can be used in preparations. The authorisation of these additives makes provisions to protect workers when handling the preparation. Firstly, additives can be used in those preparations in accordance with the conditions of authorisation. Secondly, applicants when placing on the market those preparations must ensure the physio chemical and biological compatibility of the preparation, as it is the case also for premixtures. Thirdly, when the preparation contains a technological additive that have a maximum dose. This has to be indicated on the packaging or container; also the other additives of the preparation for which no maximum dose is established should be also identified via any written medium or accompanying the preparation.

[77] Interview conducted with EFSA in the course of the study.

[78] EFSA FEEDAP Panel, 2018: Guidance on the assessment of the efficacy of feed additives.

[79] The number of studies is established to permit a statistical evaluation, for each species or for the related physiological species.

[80] Interview conducted with EFSA in the course of the study.

- At the level of the studies, several scientific limitations may be identified that do not allow to consider or draw conclusions from the study. This happens when the study does not comply with the guidance on the efficacy in terms of duration (e.g. in performance trials), end-points to be measured and/or when the animals are in poor health condition. Other limitations may include poor study design (e.g. not appropriate control), poor methodologies followed during the study (including also the statistical analysis), or poor reporting which does not allow assessment. To some extent, this is due to applicants using existing studies rather than designing new studies that increase the cost (as indicated by applicants during the authorisation case study, Annex 4). In addition, it is possible for applicants to use published studies or old studies, but in some cases, it is difficult to retrieve the data.

In some cases, despite the additional information submitted by applicants further to EFSA requests, conclusions may not be possible with the information provided in the dossier leading to a non-conclusive opinion.

A suggestion to improve the suitability of the authorisation procedure, put forward by some business stakeholders (and also one NCA), would be the acceptance of scientific evidence from literature or in vitro trials (rather than in vivo trials, or in combination with them) for easier and quicker authorisation of the use as feed additives of known substances that do not raise significant doubts in terms of safety and/or efficacy.

Judgement criteria: "Dossiers of applicants are complete"

As outlined in the introduction to EQ1.3, the completeness of dossiers submitted by applicants is examined by EFSA in two phases: firstly, when dossiers are submitted, they are checked at the administrative level (completeness check); and, secondly, once the application passes the completeness check (i.e. is validated), the detailed information is examined at a technical/scientific level during the risk assessment phase. The analysis below distinguishes between the two phases.

In relation to the completeness check performed by EFSA when applications are submitted, the available EFSA data suggest that:

- 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 check.
- There are no significant delays at the completeness phase of the process. 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[81].

By contrast, at the risk assessment phase, a significant number of applications are incomplete. Although these dossiers would have been validated as complete in relation to the requirements at submission phase, the analysis of the information/data provided by applicants indicates gaps and/or missing information and/or information that is not relevant for the safety or efficacy assessment. For example, data on the efficacy of an additive may extrapolate from another species; data on environmental impacts may have not been submitted or be incomplete and this needs to be investigated more fully. The available EFSA data indicate that a substantial majority of dossiers (78% of applications submitted under Article 4(1); and, 88% of applications submitted under Article 10(2)), are

[81] Source: calculations based on EFSA data.

pending due to missing/incomplete information during the assessment[82]. The reasons why dossiers are incomplete were outlined under the previous judgment criteria.

To address these gaps in the information provided by applicants, during the 2004-17 period, a total 764[83] finished dossiers (i.e. completed evaluations with an opinion issued by EFSA) were subjected to a request for complementary information, following which the clock stopped a total 1,320 times with a peak during 2010-12[84]. These figures include applications under both Article 4(1) and Article 10(2). On average, EFSA has made 1.73 requests for complementary information per finished dossier during 2004-17. Although separate data for Article 4(1) and Article 10(2) applications are not available, the peak in requests for complementary information in 2010-12 mainly reflects gaps in the large number of applications submitted on pre-existing additives/substances, and the fact that applicants were not yet familiar with the process and information requirements.

Judgement criteria: "EFSA opinions are issued within legal deadlines"

Adoption of the opinion

EFSA opinions are meant to be issued within a legal deadline, which is 6[85] months (i.e. 180 calendar days) from validation of the application. This legal deadline does not apply to Article 10 (2) applications but for the purpose of this evaluation the six month period will be used also in the analysis.

During the 2004-17 period, the share of EFSA's opinions adopted within legal deadlines was 20% of all opinions issued under Article 4(1) (i.e. 67 out of 327 opinions) and 12% of all opinions issued under Article 10(2) (i.e. 33 out of 286 opinions). 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. For the latter, the peak in 2010 and 2012 is due to the large number of applications for reauthorisation being processed and the fact that some applications covered multiple additives.

The average delay does not reflect the situation for a large number of applications. In the case of Article 4(1) applications, 40% of EFSA opinions were adopted within 9 months, 52% within 12 months and 73% within 18 months. In the case of Article 10(2) applications, 25% were adopted within 12 months and 41% within 18 months.

Publication of the opinion

Over 90% of the EFSA opinions on Article 4(1) applications issued within the 2004-2017 period (291 out of 323 opinions) were published within the appropriate deadline of 28 working days (i.e. 40 calendar days) from the date of adoption of the opinion by EFSA. In the case of Article 10(2) applications, 87% of the opinions (250 out of 286 opinions) were published within the above deadline. Currently EFSA aims at publishing within 28 working days from adoption[86].

[82] Source: calculations based on EFSA data.
[83] In this case the reference is not the FAD dossier but the EFSA question. This is not comparable with the EFSA completion rate indicated in previous paragraphs and in section 3.1.1.
[84] Source: calculations based on EFSA data.
[85] Opinions based on Article 29 of the GFL do not have a legal deadline, although this is normally established by EFSA and the Commission in 6 months. For Article 10(2) this deadline of 6 months does not apply either.
[86] It is noted that in 2016 EFSA migrated to a professional publisher (Wiley), and the new publication process has slightly increased the timeline from adoption to publication.

Judgement criteria: "Commission's decisions are issued within reasonable deadlines"

Considering the legal obligations of the Regulation and the legal administrative procedure for the adoption of the Commission acts, Commission's decisions are expected to be adopted within a reasonable deadline, which is 6 months (i.e. 180 calendar days) between publication of EFSA opinion and publication of the authorising Regulation[87]. Data on the delays actually incurred indicate that, on average, the time taken extends beyond the 180 days foreseen, by about 189 days (roughly 6 months) for Article 4(1) applications and 379 days (roughly 12 months) for Article 10(2) applications[88]. It is noted that the average delay does not reflect the situation for a large number of cases: for Article 4(1) applications, 37% of decisions are published in the OJ within 180 days from when EFSA opinions are issued and 78% within 4 months beyond the 180 days; for Article 10(2) applications, the 180 days deadline is met in 31% of authorisations and 46% of the cases within 4 months beyond the 180 days.

As discussed in the authorisation case study (Annex 4), these delays are often due to overload of the meeting agenda and/or complications in the legal translation of the scientific opinion. In the past, delays were also caused by requests for confidentiality of the data provided by the applicant, but this issue is now addressed, as EFSA can publish the opinion with the confidential parts hidden. Meeting agendas tend to be full and there is not enough time to address all the items during the meeting; if not addressed, the applicant can lose more time, because the Committee meets mostly every two months.

Delays are longer for Article 10(2), but this is to some extent due to reauthorisation of additives for which several applications are made (e.g. vitamins; flavourings), whereby several opinions are issued on a specific additive but authorising regulations are adopted when all the opinions on the specific additive are issued. In principle, the reauthorisation delays should not affect operators as the additives remain on the market as existing products.

Judgement criteria: "Applicants can ask questions and receive answers to complete their dossiers within reasonable deadlines"

Applicants may ask questions: 1) during the validation period and assessment period i.e. before EFSA issues its opinion; and 2) after EFSA issues its opinion.

Generally, according to applicants[89], there is extensive guidance provided by EFSA (latest in 2018 and 2019) and EFSA has improved its approach on 'application desk services' in recent years. At the pre-submission phase, applicants can only ask questions to the EFSA Helpdesk, while post-submission questions can be asked at the technical/scientific units. In both cases, applicants did not complain of any significant delays in receiving answers.

However, a key problem identified by applicants is the fact that there is no possibility at present to ask questions at a more technical level before dossier submission. This, in applicants' view, may contribute to some of the experienced delays. According to applicants, a major problem currently is that, in practice, there is a series of 'stop the clock' events throughout the procedure; in some cases, these events can be triggered by

[87] The time foreseen is 3 months, during which the draft proposal to authorise/reject an application is typically presented (after an internal administrative procedure within the Commission services) and discussed at PAFF (legal deadline). The adoption as such takes longer, as the process includes translation into all EU languages, adoption by the College and publication in the Official Journal. Hence, the period considered here is 6 months. The period 2004-2018 does not reflect the current situation as the PAFF meetings have been reduced from 10 meetings per year to 5 meetings per year and the internal administrative procedure for the presentation of the draft proposal has been extended.

[88] Source: calculations by DG SANTE, on the basis of the DG SANTE data base.

[89] Interviews conducted with applicants in the course of the study. See also Annex 4: authorisation case study.

requests for data, which were not requested from the outset; and/or, for data which were requested but there was lack of clarity in the original EFSA request. Due to this, for instance, one applicant indicated that for one dossier, the series of 'stop the clock' events took up to 4 years to complete in total.

According to applicants, the delays could be significantly reduced if EFSA could send all clock stop questions in one go. The possibility for a pre-submission meeting with applicants to clarify technical issues could also play a positive role in improving the timeline. This would allow clarifications on the specific data requirements that need to be prepared to support an application; e.g. to clarify the end points (performance indicators against which efficacy will be assessed) for new products when these are not yet established and that the intended technical approach will satisfy the EFSA requirements. An example was provided of an enzyme with an innovative mode of action and new type of benefits based on latest scientific developments, for which the EFSA assessment alone took 2.5 years.

Judgement criteria: "Commission acts within required deadlines on renewal of authorisation (Article 14) for renewals already granted"

The majority of requests for renewal were introduced in 2017, 2018 and 2019; many of them are currently being processed, and more additives are coming up for renewal in the next few years. The data available at DG SANTE include only applications for renewal that have been concluded to date and, as such, are only partly representative of the renewal procedure. Nonetheless, the available data indicate that in ten cases[90] the renewal of authorisation was granted with automatic extension due to the absence of a Commission decision within the 1-year period, as foreseen by Article 14.4.

It is noted that a large number of renewals are due to come up in future years (2020: 41, 2021: 33, 2022: 48, 2023: 32, 2024: 56); this raises some concern in the industry on the extent to which the workload involved could potentially result in bottlenecks in processing these requests.

Judgement criteria: "The simplified procedure for feed additives already authorised in food works well"

The procedure for additives authorised in food simplifies requirements for their authorisation in feed. Advantages include that efficacy does not need demonstrating; this is the case for example with flavourings, which include a large number of feed additives authorised in feed. Nonetheless, a high level of dissatisfaction was expressed by applicants[91] regarding the simplified procedure to extend authorisation for feed additives authorised in food. Notably, extrapolation of the safety and efficacy of feed additives from food use to feed use was not considered to be working well. For the extrapolation related to safety, a common problem highlighted by those operators was that the exposure of animals to the additive compared to the exposure of humans - which is established by EFSA on the basis of scientific methodology[92] - is normally higher for animals. Usually, the consumption level of the additive by humans is much lower than by animals, therefore, the extrapolation from humans to animals is not possible in the majority of the cases. This means that often a full safety study for all target species needs to be provided to support the use of a food additive in feed with an effective use level. While this approach is scientifically justified by the higher frequency of uptake of feed containing additives (major exposure) by animals compared to the uptake of foods containing similar additives in humans, operators believe that there is scope for fuller extrapolation.

[90] Source: calculations by DG SANTE, on the basis of the DG SANTE data base.
[91] Stakeholder feedback to survey (Annex 3, section 3.2.2.2) and interviews with stakeholders.
[92] Maximum acceptable feed concentrations (MAFC).

Judgement criteria: "The procedure to extend authorisation to minor species works well"

The procedure to extend authorisation to minor species involves the extrapolation of the results of studies carried on the safety and efficacy of feed additives from use in major species to use in minor species (including e.g. ruminants, rabbits, fish, pet animals)[93].

It is noted that, generally, there is lack of applicant interest in using the procedure[94]. Operators noted the lack of interest from applicants to broaden their product portfolios (particularly when the target market of minor species is limited and/or needs are not well understood), and/or lack of involvement of users further down the chain in the process to ensure that minor species of interest are covered by an application. For example, the pet food and aquaculture[95] industry indicated that there is not sufficient consultation of their members by applicants to ensure the use in minor species is sufficiently considered in applications. This requires substantial investment into data generation and, according to applicants, there is an issue over whether users are willing to contribute to the costs. There are also questions over the expected return on the investment (ROI), particularly for uses in species of low economic interest i.e. additives targeted to limited markets. Consequently, in most cases the extension to minor species (particularly of limited commercial prospects) is not sufficiently attractive for applicants.

As a result, according to operators, current initiatives to extend extrapolation across both minor and major species remain limited, although technically there is scope to extend the results of studies. For example, studies in any ruminant could be extrapolated to all ruminants, as they are physiologically similar species. Many feed additives could be extrapolated across all pets/non-food animals (e.g. live microorganisms and enzymes in cats and dogs). Thus, additive availability remains limited, mainly to those species that present some economic interest.

To some extent, the lack of interest is also due to the high requirements for safety and efficacy studies, which need trials that are costly to perform in certain minor species (e.g. fish other than salmonids) and/or conflict with ethical concerns (e.g. in the case of pet animals, tests on cats and dogs are not accepted as they may have a negative impact on the health of those animals). Another problem highlighted by some NCAs is that some minor species, e.g. pets and fish are physiologically different from other species, which makes is difficult to extrapolate to assess safety, when there is insufficient knowledge about different species' tolerance to the various substances. Also, the procedure is not adapted to minor 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 feed additives (e.g. zootechnical additives) available.

The high level of dissatisfaction expressed by operators regarding the procedure, which was not considered to be working well, reflects the compound effect of all these issues.

According to operators and the Commission, a simplification in species classification and requirements would allow more flexibility to extend additives already authorised in major species to minor species or where trials are costly and not easy to perform (for example a trial for chickens for fattening of 42 days can be extrapolated to all minor poultry species of the same physiological status- more or less same age). Since in such cases information

[93] Minor species' means food-producing animals other than bovines (dairy and meat animals, including calves), sheep (meat producing animals), pigs, poultry (including laying hens), turkeys and fish belonging to the Salmonidae (definition provided in Article 1 of the implementing Regulation (EC) No 429/2008).

[94] Stakeholder feedback to survey (Annex 3, section 3.2.2.2) and interviews with stakeholders (both applicants and users). See also NCA feedback to the survey (Annex 3, section 3.3.2.2).

[95] Fish species other than salmonids are covered by the definition 'minor species'.

will have been already submitted, the process should also move faster. Also, 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; e.g. extrapolating the authorisation of an additive used in pigs for fattening to sows for breeding and boars.

EQ1.3 Answer:

The authorisation procedure, from submission of the application dossiers by applicants to the final decision by the Commission, was analysed to identify key elements that drive and key elements that hinder its effectiveness.

In total, the average period taken for the authorisation procedure to complete (from forward application to EFSA to Commission decision) for both Article 4(1) and Article 10(2) applications is 3.3 years. For Article 4(1) applications it is roughly 2.5 years and for Article 10(2) applications 4.5 years.

The average delays indicated by companies to a 2019 internal survey by FEFANA generally match the average delays, as calculated above on the basis of EFSA/Commission data; however, companies highlight that delays are excessive in many cases both for new additives (Article 4) and for reauthorisations (Article 10).

In the case of the renewal of authorisations (Article 14), there is limited experience to date from the introduction of requests for renewals, which started since 2017 and are in most cases still ongoing. The industry has however expressed some concern on the potential bottlenecks that could be caused by the large number of requests for renewals that are expected to be submitted in future years.

Furthermore, applicants do not consider the process to extend the authorisation for use in feed of additives already authorised for use in food to be working well. This is largely attributed to the complexity of the extrapolation process. It is noted nonetheless, the simplification of requirements means that efficacy does not need demonstrating when these are already authorised in food, which has been advantageous for a large number of flavourings.

Similarly, applicants do not consider the procedure to extend authorisation to minor species to be working well in practice. This dissatisfaction reflects to some extent issues not linked to the procedure, in particular the lack of interest from applicants due to the relatively limited market prospects and expected ROI for species of lower economic interest. However, the lack of interest is compounded by the high requirements for safety and efficacy studies, which add to the costs and complexity of the authorisation procedure. The conclusions reached are presented below separately for each phase of the procedure (risk assessment; risk management).

A suggestion to improve the suitability of the authorisation procedure, put forward by some business stakeholders (and also one NCA), would be the acceptance of scientific evidence from literature or in vitro trials (rather than in vivo trials, or in combination with them) for easier and quicker authorisation of the use as feed additives of known substances that do not raise significant doubts in terms of safety and/or efficacy

Risk assessment (EFSA):

A substantial majority of dossiers submitted by applicants (78% of applications for new authorisations under Article 4(1); and, 88% of applications for reauthorisation under Article 10(2)), present important missing and/or incomplete information during the assessment. This triggered the clock stopping process 1,320 times in the 2004-17 period, with an average 1.73 requests of complementary information per finished dossier during this period. Consequently, a significant majority of EFSA opinions are not issued within

legal deadlines (i.e. within 6 months from valid application): on average, it takes 2.4 times longer for Article 4(1) applications and 4.6 times longer for Article 10(2) applications.

Systematic data on the type of questions asked by EFSA are not available. Overall, according to EFSA, reasons why applicants are not providing the complete data set to address certain aspects of efficacy and safety include: understanding of the guidance and assessment process; interpretation of the requirements by the applicants e.g. on the studies to be conducted; and/or, interpretation of the results obtained in the studies. These issues tend to be more common in the case of efficacy studies, due to the complexity involved. On the other hand, in the case of the safety assessment, the information provided by applicants tends to be suitable; this is facilitated by the EFSA guidance provided and its alignment to relevant OECD Guidelines. Nonetheless, a challenging aspect for applicants is demonstrating safety for users.

The delays in the authorisation procedure has been a major complaint amongst applicants. Key problems identified are: at the pre-submission phase, despite the updated (2018) EFSA guidance for the preparation of dossiers, the lack of possibility for applicants to ask questions at a technical level prior to dossier submission is considered a major hindrance to the effectiveness of the current procedure; and, in some cases EFSA's clock stop questions are sent to applicants in sequence rather than in one go, and this is to some extent attributed to lack of clarity in the original question. Apart from these issues, applicants are generally satisfied with asking questions after the submission of their dossiers and receiving answers to complete their dossiers within reasonable deadlines.

Risk management (decision making by Commission): The average delay for Commission decisions is 1.5 times longer than the reasonable deadline (180 days) for Article 4(1) applications and 2.1 times longer for Article 10(2) applications. Delays in many cases are considerably lower. It is noted that the average delay does not reflect the situation for a large number of cases: for Article 4(1) applications, in approximately 37% of cases, the authorisations are published in the OJ within 180 days from when EFSA opinions are issued and 78% of the cases within 4 months beyond the 180 days. For Article 10(2) the delay does not affect the operators as the additives remain on the market until a decision is taken. While the average delays incurred at this phase of procedure are not high when put in the context of the one year timeline foreseen for the completion of the procedure, they add to the deadlines incurred during the risk assessment phase of the process by EFSA.

EQ 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?

The role of the risk assessment process by EFSA is discussed under EQ1.3 and EQ1.5. EQ1.4 focusses on the role of other key provisions of the Regulation, including:

- Labelling requirements. These are meant to play a key role in facilitating traceability and B2B transactions, as well as informing those handling/using feed additives to ensure their safe use. As such, they contribute to ensuring the safety of feed additives for human health, animal health and the environment, and provide information to buyers, sellers and users of feed additives on the quality of feed additives placed on the market.
- Controls and penalties, including: control of imports; sanctions imposed by Member States; addressing fraud/noncompliance; conditions and restrictions imposed on the marketing of feed additives; and post-market monitoring plans. All these provisions are meant to play a role in enabling the effective control of the EU market.

- Other provisions include: the role of the EURL, in particular in defining suitable methods of analysis to enable the effective control of the market; and, provisions contributing to the reduction of antimicrobial resistance (AMR).

Judgement criteria: "Labelling requirements are fit for purpose"

A majority of manufacturers of feed additives/premixtures, and some Member State Competent Authorities[96], did not consider labelling requirements, as laid down in Article 16 of the Feed Additives Regulation, to be fit for purpose. The key problem identified by manufacturers (Annex 4: case study on labelling) is the extensive information required to be provided on the physical product label. The industry has highlighted that this is not aligned with the requirements in the Feed Marketing Regulation, which makes a distinction between a feed 'label' (the document attached to each pack) from 'labelling' (general documentation using any medium). This allows the information to be provided e.g. by electronic means. Hence, there is a strong perception amongst the feed additives industry that the Feed Additives Regulation and the Feed Marketing Regulation are not fully aligned with regard to the labelling provisions.

This requirement has implications in terms of operational complexity, in enabling the effective and efficient transmission of information along the feed chain for traceability purposes, as well as performing changes to labels when these are required (e.g. in the case of changes in the authorisation of a product). According to feed operators, traceability is in any case fully ensured by the systems and codes of practice already put in place by the industry, as this is a core responsibility of operators. The operational complexity of delivering the labelling in the form required by Article 16 has implications in terms of costs, which were explored during the case study on labelling and presented in EQ3. In particular, according to operators along the feed chain, the requirement to provide this information on the product's physical label creates an unnecessary burden that is disproportionate and does not add any benefits in terms of traceability.

Judgement criteria: "Member State controls and sanctions"

As indicated in EQ 1.2, the scope of the Regulation does not cover the control of compound feed or feed materials containing additives, i.e. whether the conditions of use/labelling of the additive have been respected when they are incorporated directly or via premixtures in those feeds. As also noted in EQ1.2, a preventive approach applies through the assessment by EFSA which ensures that, if the additive is used along the feed chain in accordance with the conditions of authorisation and with the other requirements laid down in the Regulation, the additive will not have adverse effects on animal health, human health or the environment; and, for some feed additives, the applicant has to perform a post-market monitoring (PMM) to identify unforeseen effects for human health, animal health or the environment.

The survey addressed to the Competent Authorities shows, in 16 MS, that all the establishments producing additives and premixtures received at least one inspection visit per year. This inspection covered all the aspects related to safety and placing on the market, including labelling, to ensure that the use of additives/premixtures complies with the safety requirements (for animals, consumers, workers and the environment) and with the directions for their use, and to prevent a misuse along the feed chain. The analysis performed by the competent authorities on the samples taken for additives and premixtures showed in general a high level of conformity; this analysis covers not only the characteristics of the additive but also the presence of undesirable substances (e.g.

[96] Annex 3: Consultation synopsis report (sections 3.2.2.3, 3.3.2.3) and interviews. See also feedback to the OPC, section 3.4.2.3.

dioxins) that may have a negative impact on the safety for humans, animals but also for the environment**.**

Sanctions in place applicable to infringements in the feed additives and premixtures sector are generally financial penalties (18 out of the 25 Member States that responded to the survey), with some countries also foreseeing other administrative penalties including withdrawal of approval/registration of the operator and imprisonment for the most serious non-compliances. Minimum sanctions ranged from €7 to €20,000 (median: €267); and, maximum sanctions ranged from €120 to €1.2 million (median: €25,000).

Data provided by authorities in 16 Member States indicate that, each year during the 2012-15 period[97], an average 3,182 controls were performed in 2,979 registered establishments producing feed additives/premixtures (total for the 16 MS), i.e. average control frequency is just over once per year per establishment. There are some differences between Member States, with 8 of the 16 Member States having a control frequency higher than once per year. During controls performed in 17 Member States 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).

Very few Member States provided any data on the number of penalties imposed and the number of cases where products have been withdrawn from the market in the case of infringements during the 2011-15 period. This is partly due to the different administrations involved for the collection of data on sanctions and penalties imposed (administrative and financial), and partly to the fact that there is no readily available breakdown for sanctions imposed specifically in the feed additives/premixtures sector. It is therefore not possible to conclude whether fraudulent/non-compliant feed additives are rapidly identified and withdrawn from market. However, with regard to the circulation on the EU market of imported products, the experience put forward by some operators suggests that some fraudulent products are present on the market; and, the feedback from Member State Competent Authorities indicates authorities face considerable challenges/difficulties to control imported products on the market.

Judgement criteria: "Imports of feed additives are adequately controlled"

Controls of imports take place at the EU borders and/or within the EU in manufacturing plants.

Data on RASFF notifications indicate that out of the relatively limited total number of notifications on feed additives and premixtures during the period 2004-2017 (12), 7 were on imports from non-EU countries. The largest number of notifications on feed imports from non-EU countries during the period relate to feed materials (non-EU: 108; EEA: 3) followed by pet food (non-EU: 59; EEA: 4).

Nonetheless, a significant share of stakeholders consider imports not to be adequately controlled, the majority of Member State Competent Authorities consider them only to be partially controlled[98]. The main reason provided for this, by both companies and Competent Authorities, is that the level of controls depends on Member States' requirements and priorities on control, as well as whether there is a pre-import notification

[97] This period was chosen as it is representative of the whole period and corresponds to a Multi Annual National Control Plan (MANCP). The Multi Annual National Control Plan (MANCP) contains general information on the structure and organisation of the systems of feed and food control and the results of such controls in the Member States. The MANCP is a legal requirement regarding Regulation (EC) No. 882/2004, therefore, Member States can more easily find the information for the completion of the survey.

[98] Annex 3: Consultation synopsis report (section 3.2.2.5 and 3.3.2.5) and interviews.

requirement in place[99]. A key related issue, raised both by stakeholders and Competent Authorities, is that the list of non-EU exporters is managed by each Member State, i.e. there is no EU list of non-EU country establishments from which feed additives can be imported; the lists intended in Article 23 of Regulation (EC) No 183/2005 on feed hygiene, are missing. It is also noted that the Commission overview report of audits carried out in Member States during the period 2006-11 (European Commission, 2012) indicated that official controls on imported feed were not satisfactorily complied with in an important number of Member States, where certain risks posed by imported products were not adequately taken into account.

Different conditions as well as varying controls amongst Member States on imports of feed additives from non-EU countries result in unfair competition both across Member States and between imports and EU producers. For example, some companies indicated that they have noticed on the market products imported as technical grade but sold as feed grade. When such cases are brought to the attention of the authorities it is not clear or certain whether action is taken. Generally, authorities seem slow to take action, when animal or consumer health is not directly at stake; but this is also due to limited resources, thereby the need to prioritise.

Authorities also highlighted that the import of feed additives can only be controlled to a certain limited extent, as controls are complex for a number of reasons:

- Imported products are tested for the level of concentration and undesirable substances; they are not tested to ensure they comply with the characterisation of the additives.
- It is not possible for Member States' competent authorities to check certain aspects of the authorisation of a product manufactured in a non-EU country, as they are not empowered to audit the production process (for example, to verify that the microorganisms used to produce the additive are as in the authorisation). The Commission is also not empowered to audit the production site in the non-EU country. It is the responsibility of the importer in the EU to ensure that the product complies with applicable EU rules before placing the product on the market.
- When chemicals are imported, it is not possible to know all final uses. For instance, copper (Cu) can be imported for food, feed or technical use by any company. The administration of these imports (the Customs administration) does not necessarily have the required expertise to support food or feed safety control of these imports. Controls would be facilitated if the Harmonized system of Customs would add CN codes for additives that are intended for food and feed use. Research on this particular subject is being carried out by the authorities in the Netherlands and the report is expected in May 2020.
- Finally, one Member State competent authority indicated that a general issue with imports (i.e. not just observed in this sector), is that importers self-declare the customs code of imported products (motivated also by the corresponding duty to be paid), which means that an imported product may escape controls by the appropriate authority..

Furthermore, in terms of feed additives and premixtures not authorised in the EU and intended for export[100], 19 Member States have taken action to prevent that these products end up on the EU market. These actions include: registration of operators handling such additives; monitoring their production, use (incorporation in premixtures) and exports,

[99] It has not been possible to establish the extent to which results of multi-annual national control plans (MANCPs) and annual reports of MS systematically include the control of imports of feed additives. No specific reference to this aspect of MANCP reports has been made by any of the respondents to the consultation, whether authorities or business stakeholders.

[100] So-called NAFA products. The exports of NAFA products, including the conditions that need to be fulfilled, are discussed under EQ2.2.

e.g. through obligation for operators to report movement and/or perform 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 Member States were generally considered effective and no problems were identified, except in the case of import controls (due to the issues outlined above). It is noted, however, that the approach varies considerably between Member States and that 6 NCAs indicated they have not taken any action to control these exports and their potential re-entry in the EU.

Judgement criteria: "Innovative feed additives can be placed on the market"

Article 6(3) of the Regulation foresees that, as a result of technological progress or scientific development, additional feed additive categories and functional groups may be established, in accordance with the procedure referred to in Article 22(2).

The available data suggest that innovation has taken place during the period under review. In total, nine new functional groups were incorporated in the Regulation or adopted after it came into force and until December 2017; of these, seven were included at the adoption of the Regulation. Beyond these nine groups, two further functional groups were added more recently, in 2019. Of the nine functional groups, three represented a clear innovation in relation to the former Directive.

Data provided by DG SANTE[101] indicate that the largest number of innovations in these new groups during the period 2004-17 are in the 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). This suggests that the Regulation has enabled innovation in new emerging segments of feed additives. Furthermore, some of the new additives play a key role in addressing current needs; for example, zootechnical additives contribute to improve sustainability and reduce negative impacts of livestock farming practices on the environment (see also EQ3.1).

Nonetheless, a majority of manufacturers of feed additives/premixtures believe that the Regulation does not fully allow innovative feed additives to be placed on the market. Key problems identified at present are: the cost of authorisation and time taken to complete authorisations; the time taken to create new groups; as well as, the absence of IP rights/protection in the case of non-holder specific authorisations. Several business stakeholders indicated that, in general, the length of the authorisation process and its lack of flexibility, as well as the difficulties and time needed for creating a new functional group, make it difficult to follow rapid developments in animal production techniques and/or to address emerging needs in specific/innovative sectors (e.g. aquaculture, animals reared for non-food uses, insects for biomass production, etc.). This means that only additives of commercially high value come to market, leading to a reduction in the range of additives available in certain categories. Several business stakeholders noted that technical progress and scientific developments in the field of animal nutrition have advanced rapidly in the last years, whereas the adaptation of authorisation criteria (Article 5) and functional groups has proceeded very slowly. For instance, in Article 5 the efficacy criteria relate to gains in productivity, but several innovative products (e.g. zootechnical additives: gut flora stabilisers) have positive effects – e.g. in terms of animal welfare, improved sustainability of livestock farming – without promoting productivity gains.

[101] Source: FAR - Reference 2: Register December 2017 (rev. 259) - since implementation up to 31/12/2017.

The feedback of the industry contrasts the views of a clear majority of Member State competent authorities, who deem the authorisation procedure, including the conditions of authorisation and re-authorisation, to be suitable to address scientific and technical developments. Some Member States noted, however, that flexibility to adapt to technological and scientific progress is provided as long as the substance is the same. For example, if there is a minor change of the microorganism, the substance will be regarded as a new substance; if there is a change in the function of the additive, there could be a lack of appropriate functional groups, which means it would need to be considered as a new substance.

Judgement criteria: "The EURL for feed additives can effectively carry out its tasks"[102]

The European Reference Laboratory (referred in the Regulation as Community Reference Laboratory) is established in Article 21 of the Feed Additives Regulation, with its duties and tasks defined in Annex II. In general, feed additives are authorised along with specific conditions of use such as legal limits. The enforcement of the conditions of use in the context of official controls requires suitable methods of analysis, which are proposed by the industry when applying for the authorisation. The main task of the EURL is the evaluation of the methods of analysis of feed additives and the preparation of the evaluation report that is submitted to the EFSA. The EURL is supported by a consortium of National Reference Laboratories (NRLs) to carry out the evaluation of the analytical methods and to establish whether the methods are fit for the intended purpose; this complex task is implemented by the EURL in cooperation with the network of NRLs, which allows a unique merging of expertise in analytical methodology at EU level[103].

During the 2004-17 period, the EURL issued 517 validation reports[104]. It also carried out 16 workshops (i.e. 1-2 workshops each year) to coordinate with NRLs, which is an essential task contributing *inter alia* to the validation reports.

A 2015 EURL review (Von Holst et al, 2016) had identified as a major challenge the evaluation of the analytical methods proposed by the applicants against their suitability for official controls[105], given the fact that the majority of the methods are single-laboratory validation methods.

The applicant may validate the method of analysis by two different procedures: via a ring test (involving several laboratories) in accordance with an internationally recognised protocol on collaboratory trials (ISO or IUPAC) or via in-house validation which requires that the performance characteristics of the method determined in the validation phase will be verified by an independent and accredited laboratory.

When the method is exclusively validated in a single laboratory, although supported by appropriate verification studies, the method's confidence level is lower compared to a method validated through ring trials which involves many laboratories. Methods validated by ring trials are Community methods or CEN and ISO standards. The Member States official control laboratories need to apply the method evaluated by the EURL, and subsequently, included in the corresponding Regulations authorising the feed additive. Priority for the methods to be used in official controls is given to 'Community' methods,

[102] The duties and tasks of the EURL are set out in Commission Regulation (EC) No 378/2005.
[103] The procedure followed for the evaluation of analytical methods is described in Von Holst et al (2016). Upon reception of a new feed additive dossier, the EURL nominates as rapporteur a national laboratory, experienced in the analytical field of concern, which will evaluate the information provided by the applicant and will draft the evaluation report to be finalised within three months ('evaluation report'). The 'validation report' is the validation of methods that were based on experiments.
[104] Source: EURL data.
[105] I.e. for controls focussing on verifying compliance with safety rules and detection of fraud issues.

with single laboratory methods used only when Community or other methods (CEN/ISO) are not available. This also applies to the EURL when evaluating analytical methods linked to the submission of request for authorisation. This means that the EURL evaluation report always recommends the corresponding Community method in its evaluation report, if such a method is available and proved to be applicable to the specific feed additive under investigation.

There is the trend that for feed additives that are considered important for official controls, Community or CEN/ISO methods are available, while for hundreds of authorised feed additives (each with its method of analysis and most often exclusively single laboratory validated and verified) only a small share (there are no data on their number) are regularly included in official control programmes. The 2015 EURL review had also identified as a challenge that existing 'Community' methods currently used to carry out the official control of feed additives in feed are in many cases based on obsolete methodologies, which raises the question of their suitability, particularly in the context of upcoming renewals of authorisations. According to the most recent feedback received from the EURL these issues are currently tackled by the Commission by working on a major revision of the compendium of Community methods.

Despite the challenges, the EURL did not identify any problems in fulfilling its tasks and the cooperation with national laboratories is working well. It was noted that within the current legal frame the EURL evaluation is generally finished once the EURL has issued our report. Regulation (EC) No 378/2005[106] foresees the option of additional work for the EURL triggered by the Authority or the Commission and reported via an amendment of the original report. However, it is not clear whether this option is confined to the time that EFSA has not finished yet its evaluation or is extended towards the period between EFSA's opinion and the final authorisation of the product. This needs to be clarified in the legislation.

Judgement criteria: "The Regulation contributes to reduce the likelihood of antimicrobial resistance (AMR)"

Recital 25 of the Feed Additives Regulation sets out the need to reduce the use of antimicrobial agents from classes, which are or may be used in human or veterinary medicine in order to minimise the risk of cross-resistance to therapeutic treatment. In accordance with this objective, the Regulation excluded two categories of substances, which were covered by the former Directive: growth promoters; and, antibiotics. In total:

- Before the entry into force of the Regulation 8 legal acts were adopted to ban 22 antibiotics used as growth promoters;
- When the Regulation entered into force the 4 remaining antibiotics used as growth promoters were banned.

Literature[107] notes that the Regulation's precautionary bans marked a significant victory for the EU and global fight against AMR; by adopting the bans, the EU also placed significant pressure on other countries to reform antibiotic use in livestock production.

[106] Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives. OJ L 59, 5.3.2005, p.8

[107] Kirchhelle, C. (2018)

Furthermore, during the 2004-17 period, 84 new additives were authorised[108], under the category "zootechnical additives": 60 of these are gut flora stabilisers; and, 24 are other zootechnical additives.

There are other additives that are reported as having antimicrobial activity, as is the case of some nutritional additives such as copper and zinc or some technological additives such as organic acids. Nevertheless, they are authorised for other purposes and the efficacy in relation to the antimicrobial activity is not evaluated.

Zootechnical additives favourably affect animal production, performance or animal welfare particularly by affecting the intestinal flora or digestibility. They contribute to affect positively the physiological condition of the animals thereby contributing to reduce the therapeutic use of antibiotics. EFSA and EMA in their 2017 RONAFA report identify as alternatives to antibiotics the use of certain substances as feed additives (e.g. zootechnical additives: probiotics and enzymes; nutritional additives: zinc and copper).

Nearly all of the public authorities responding to the OPC, as well as the one academic/research institute that responded, deemed that the ban on the use of antibiotics in feed introduced by the Feed Additives Regulation plays an important role in preventing AMR. At the same time, according to all types of stakeholders, including Member State Competent Authorities, the development of alternatives that reduce the need to use antimicrobial agents in animal husbandry needs to be promoted further.

Judgement criteria: "Post-market monitoring plans (PMM) enable to identify negative impacts and to take corrective actions"

In the implementation of the Feed Hygiene Regulation and Good Manufacturing Practices, several provisions are established in the framework of traceability of feed (including feed additives and premixtures). Feed business operators must keep a register of relevant data, comprising details of purchase, production and sales for effective tracing from receipt to delivery, including export to the final destination. EFSA suggests in its opinions to apply these rules as a general approach. To date EFSA required, after assessment, PMMs for, coccidiostats and histomonostats (C&Hs) and for one zootechnical additive[109]. A risk management measure is taken by the Commission to decide if the PMM proposed for EFSA is required as a condition for authorisation (see details of PMM procedure and requirements in the Glossary). The Commission has always included the PMM in the authorising Regulation when EFSA has proposed so in its opinion.

As already mentioned, the PMM is finished at the end of the authorisation period and few additives have reached the end of the 10 years of authorisation, so only few PMM have been assessed by EFSA. The situation will be different in the future when other additives come to the end of the period. It should be noted that for coccidiostats the Commission extended the PMM to monitor also the development of any AMR.

EQ1.4 Answer:

Beyond risk assessment, other provisions also play a role in meeting the objectives of the Regulation, as follows:

Labelling (Article 16): although labelling plays an important role in ensuring objectives, from a practical operational point of view the amount of information required to be

[108] Source: FAR - Reference 2: Register December 2017 (rev. 259) - since implementation up to 31/12/2017
[109] EFSA Journal (2007) 542, 2-15

included on the product's physical label is not considered to be fit for purpose or proportionate. The approach followed in the Feed Marketing Regulation is desired.

Controls and sanctions (Article 24):

Generally, data on **controls** performed (across 16 MS) indicate an average frequency of about once per year per establishment producing feed additives and premixtures (frequency can be higher in some MS and lower in others). The available data also indicate a high rate of conformity of samples and analyses.

Sanctions in place applicable to infringements in the feed additives and premixtures sector are generally financial penalties with some countries also foreseeing other administrative penalties including the withdrawal of approval/registration of the operator and jail time. This suggests that Member States have put in place adequate sanctions to address non-compliance, but given the wide variety in the types and level of sanctions applied it cannot be established whether these are proportionate or not. In addition, at the level of enforcement, the evidence provided by Member States is not sufficient to verify that sanctions are imposed in cases of infringements. This is due to the different administrations involved for the collection of such data and/or the lack of data on sanctions specifically imposed in the feed additives/premixtures sector (as the control of the feed chain, including feed additives and premixtures, falls within the scope of the Official Controls Regulation).

Controls on imports: despite the limited number of RASFF notifications on feed additives and premixtures during 2004-2017 (12, of which 7 on imports from non-EU countries), imports of feed additives are not considered to be adequately controlled within the EU market. This is attributed to diverse levels of implementation of import controls being carried out by Member States, and the absence of an EU list of establishments in non-EU countries authorised for exports to the EU. There are also technical factors (e.g. availability of specific CN for feed additives) and resource constraints that add to the complexity of import controls in practice.

Addition of new categories/groups: innovation has occurred during the period 2004-17, with the addition of three new functional groups that represented a clear innovation in relation to the former Directive. A total 79 applications and 35 authorisations fall in those three functional groups. The majority of these applications and authorisations belong to the 'other zootechnical additives' functional group, suggesting that the Regulation has enabled innovation in new emerging segments of feed additives that play a key role in addressing current needs. Nonetheless, most manufacturers of feed additives/premixtures believe that the Regulation does not fully allow innovative feed additives to be placed on the market, due to the high authorisation costs and time taken to get approval. Also, according to some manufacturers, the creation of new categories/functional groups can take too long.

EURL activities (Article 21): the available evidence indicates that the EURL for feed additives can effectively carry out its tasks, supported by the network of NRLs, despite the complexity and challenges. Key identified challenges are the fact that the majority of the analytical methods evaluated by the EURL are single-laboratory validation methods and in many cases based on obsolete methodologies.

Antimicrobials (*recital 25*): the Regulation has contributed to reduce the likelihood of antimicrobial resistance (AMR), with the ban on the use of antimicrobials as growth promoting agents. One post-market monitoring plan for coccidiostats established to date did not identify any negative impacts for human health, animal health or the environment. Furthermore, during the 2004-17 period, 84 new additives were authorised, mainly under the category "zootechnical additives", that provide alternative solutions to improve the physiological condition of the animals, thereby enhancing

performance (improving yields; reducing losses) and preventing the need for therapeutic use of antibiotics.

EQ 1.5: To what extent did the risk assessment allow sound decision-making?

The extent to which the EFSA risk assessment allowed sound decision-making by the Commission/PAFF is addressed on the basis of four judgement criteria; findings for each of these are presented below.

Judgement criteria: "EFSA opinions are not challenged for administrative reasons"

Article 19 of the Feed Additives Regulation ('administrative review') foresees that the EFSA assessment process and final decision 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.

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.

Judgement criteria: "Commission decisions are not challenged"

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).

Other previous Court cases related to previous legislation on feed additives, i.e. Directive 70/524/EEC.

Only two non-EU countries, the USA and India, have submitted comments to the WTO - under the SPS Agreement - as regards draft acts related to the Feed Additives Regulation. 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.

Judgement criteria: "EFSA has adequate information to give an informed opinion"

As discussed in EQ1.3, there are cases where information submitted by applicants is not considered adequate and, despite the additional information provided by applicants further to EFSA requests, it may not be possible for EFSA to reach conclusions with the information provided in the dossier leading to a non-conclusive opinion.

There are no readily available data on how many out of the total 969 EFSA opinions issued to date are non-conclusive. More generally, data on the number of favourable opinions, favourable opinions with limitations, non-conclusive and unfavourable opinions are not

systematically collected and processed by EFSA. These data are important for evaluating the assessment process.

However, an indication on the non-conclusive opinions can be retrieved from:

1. The number of dossier submissions received under Article 29 of the GFL, which relate to requests made by the Commission to complement the dossier after a non-conclusive opinion by EFSA[110]:71 out of a total of 969 EFSA applications, which represents 7% of the total applications, were based on Article 26 of the GFL.
2. The number of applications totally withdrawn after the EFSA opinion is issued: in total 84 applications. Almost all those applications were withdrawn because the EFSA opinion was inconclusive and the applicant did not want to submit complementary information under Article 29 of the GFL.

Taking into account those two indicators, it is estimated that around 15% of EFSA opinions are inconclusive.

Judgement criteria: "Elements other than risk related (social, economic) are sufficiently taken into account by the Commission"

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.

A majority of applicants[111] did not think that legitimate factors such as economic considerations are sufficiently taken into account by the Commission/PAFF. An indication, according to these respondents, is that it seems exceptional that the authorisation decision will go beyond the EFSA opinion; e.g. to authorise an additive despite a non-conclusive opinion, even if this is only on the efficacy of an additive. This problem is partly overcome by the Commission allowing applicants to submit additional information under Article 29 of the GFL (see previous judgement criteria). This process is considered as an important "rescue" mechanism by many applicants.

However, the Commission notes that according to the Regulation, when the decision for authorisation is not in accordance with the EFSA opinion, the Commission must provide an explanation of the reasons for the differences. In order to ensure a high level of safety, the Commission cannot deviate from the EFSA opinion when safety is concerned. For efficacy, in limited cases, it has been possible to consider certain studies and to grant an authorisation that may deviate from the EFSA opinion.

[110] When the opinion is non-conclusive, the Commission asks the applicant if they wish to submit complementary information to solve the concerns expressed in the EFSA opinion. If the applicant decides so, the Commission request EFSA for a new opinion based on Article 29 of the GFL.

[111] Annex 3: Consultation synopsis report (section 3.2.2.2) and interviews; this view was also expressed by some OPC respondents. This view was not shared by NCAs, who for the most part believe that legitimate factors are sufficiently taken into account by the Commission during authorisation (section 3.3.2.2).

Industry respondents (both applicants and users) also indicated that the wider economic benefits of authorisations for users and society need to be better considered in reaching a decision. This is especially important if the authorisation procedures result in high costs and unpredictability of outcome, which in turn discourage applicants and may cause a monopoly or oligopoly (i.e. a market dominated by only few manufacturers/suppliers) for certain feed additives. Also, OPC respondents noted that decisions should consider the economic impact resulting from the withdrawal of a feed additive, following an inconclusive EFSA opinion that may be due to insufficient efficacy data or scientific uncertainty.

Some respondents believe the European Commission and Member States, in their role of risk manager, need to consider the wider economic impact to reach more proportionate decisions. Although, according to most industry respondents, the EU Commission tries to give adequate transition periods, in some cases longer periods would be useful. This is particularly the case for users of feed additives i.e. premixtures and feed formulations. These operators typically need longer periods to adapt to changes in the feed additives contained in their products, in terms of stock management and product adaptations/ reformulations that typically take time.

EQ1.5 Answer:

The available evidence suggests that the EFSA risk assessment allowed sound decision-making by the Commission/PAFF, to a considerable extent. In particular:

- EFSA opinions have not been challenged under Article 19 of the Feed Additives Regulation for administrative reasons, except only in limited cases in the 2004-17 period; in all cases, the outcome justified the EFSA Opinion.
- Commission decisions have not been challenged, except only in limited cases in the 2004-17 period; in all cases, the outcome justified the decision taken by the Commission.

In a significant number of cases, estimated at around 15% of EFSA opinions, EFSA does not have adequate information to provide an informed opinion leading to non-conclusive opinions. It is noted that data on the number of favourable opinions, favourable opinions with limitations, non-conclusive and unfavourable opinions are not systematically collected by EFSA; this makes it difficult to monitor systematically the assessment process and to identify reasons for non-conclusive opinions

Legitimate factors other than risk (social, economic) are taken into account in the case of reauthorisations (Article 10), as indicated by the transitional periods provided by the Commission which are largely appreciated by the industry. However, these periods are not always considered sufficient, particularly for users of feed additives in pre-mixtures and feed formulations who require longer periods to adapt to changes.

There is not sufficient evidence to determine the extent to which legitimate factors are sufficiently taken into account by the Commission in the case of new authorisations (Article 4). According to the industry, an indication that they are not sufficiently taken into account is that the Commission rarely goes beyond the EFSA opinion to take into account other legitimate factors. The Commission noted that for those cases the deviations from the EFSA opinion need to be legally justified. For safety, the Commission cannot deviate but for efficacy it has been possible in few cases.

EQ 1.6: To what extent did coccidiostats and histomonostats produce the best results for poultry/rabbits farmers (health and welfare ensured, adaptation to farming practices, control)?

Ionophore coccidiostats[112] were first introduced in the 1970's (monensin) as an important breakthrough in the fight against coccidiosis in poultry. Before that, coccidiosis outbreaks were frequent and the disease was more difficult to treat and to prevent, because only non-ionophore coccidiostats were available. It is noted that no histomonostats are currently approved or used in the EU; therefore, the focus here is on coccidiostats.

Article 11 of the Feed Additives Regulation lays down that the Commission shall submit to the European Parliament and the Council a report on the use of coccidiostats and histomonostats as feed additives with a view to a decision on the phasing out of the use of these substances as feed additives by 31 December 2012. The report also has to address available alternatives and should be accompanied, where appropriate, by legislative proposals. The report[113] was adopted in 2008 and concluded that the regulatory framework established by the Feed Additives Regulation could be considered to work properly: '*The Commission believes that it is inappropriate to change the existing situation at the present time and that the current system is well placed to deal with the present situation, as it provides a high level of safety for consumers and adequately protects animal health and welfare and the environment, while providing a fair framework within which operators can do business. The European Commission will continue to monitor the development of new substances and techniques for the prevention of the diseases.'.* Those conclusions were supported by the EP and the Council.

Judgement criteria: "The use of coccidiostats and histomonostats as feed additives is important to ensure health and welfare of poultry; well adapted to current farming practices; and, effectively controlled"

The available evidence indicates that, since the adoption of the 2008 Commission report, no changes in the situation have occurred. Preventive measures for the control of coccidiosis in modern poultry production continue to be essential, given that no realistic alternatives are available and that the risk characteristics of the disease make it more appropriate to prevent than to treat. It is noted that coccidiostats are not used in human medicine, while antimicrobial resistance (AMR) is monitored and controlled though post-market monitoring (PMM) and farming practices.

There was consensus amongst the feed industry, the farming sector and Member State Competent Authorities[114] that the use of coccidiostats as feed additives is important to ensure the health and welfare of poultry; well adapted to current farming practices; and, effectively controlled. This view was supported by position papers[115] provided by respondents (including veterinary experts and the poultry industry), which maintain that preventive use of coccidiostats in poultry production remains necessary in modern animal

[112] Coccidiostats can be grouped into two major classes, namely polyether ionophore antibiotics and synthetic products (chemicals) not of an ionophoric nature. Ionophore coccidiostats are by far the most widely used coccidiostats.

[113] Report from the Commission to the Council and the European Parliament on the use of coccidiostats and histomonostats as feed additives submitted pursuant to Article 11 of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (COM/2008/0233 final)

[114] Annex 3: Consultation synopsis report, surveys of stakeholders and Member State competent authorities (sections 3.2.2.1 and 3.3.2.1), OPC (section 3.4.2.6) and interviews.

[115] These include four position papers, authored by: 1) the working group anticoccidials of the PVSG (Veterinary Poultry Specialists in the EU); 2) ELPHA-AVEC; 3) Zentralverband der Deutschen Geflügelwirtschaft e.V; and 4) the Association of Veterinary Consultants (AVC). The ELPHA-AVEC paper was cited by several of the consulted stakeholder organisations.

husbandry in the EU and is best applied via feed as feed additives. The position papers raise the continuous challenge of coccidiosis in poultry and recognise the contribution of coccidiostats as feed additives to maintain animal health and welfare, given also that effective alternatives for broilers and turkeys are only partly available.

The threat of coccidiosis continues to be present as an endemic disease in the EU. The parasite causing this disease (single-celled Eimeria) is universally present, occurs in all housing systems, and is very resistant. The use of coccidiostats as feed additives to control coccidiosis is considered essential by the EU conventional poultry industry, which accounts for 90%[116] of broiler production in the EU. Consequently, according to the poultry sector, EU farmers continue to make extensive use of ionophore coccidiostats combined with other chemicals acting against the parasite as feed additives in poultry feed, to prevent coccidiosis.

According to the feed additives industry and the farming sector, the use of coccidiostats as feed additives, rather than on-prescription antibiotics, presents important cost and efficiency advantages. The main reasons put forward for maintaining the classification of coccidiostats as feed additives are:

- Given that the parasite is ever-present, a visit to the veterinarian is not necessary to determine the parasite's presence. This would result in unnecessary action and an increase of costs to the supply chain. Furthermore, delayed prevention can weaken its efficacy, increasing the likelihood for spread of the disease.
- Classification as an antibiotic for medical use (i.e. as a veterinary medicinal product – VMP) would mean meeting the strict production requirements for antibiotics. This would lead to further unnecessary costs.

Coccidiostats as feed additives are not critical to the development of AMR in humans, as they are only used in animals and not in human medicine. Consequently, they are not rated by the WHO as important to human health. It is important to note that not all coccidiostats are antibiotics, therefore, subjected to a possible development of AMR; and, none of them is used in human treatments.

The available research on cross-resistance to antibiotics used in human medicine provides very limited evidence of potential impact. Research into the risks of the use of ionophore coccidiostats, conducted by the Norwegian Scientific Committee for Food Safety (VKM, 2015), indicates that using coccidiostats can lead to the development of resistance against the ionophore anti-coccidiosis agent and against the antibiotics bacitracine and vancomycine used in human healthcare. However, this research notes that results are based on a limited amount of data, and that alternative products tested for efficacy against coccidia have shown conflicting, non-consistent or non-convincing results.

As already indicated, two categories of substances are employed to control coccidiosis in poultry: ionophores (antibiotics) and synthetic agents (chemicals). The fact that their mode of action is different[117] provides the rational basis for the use of synthetic drugs and ionophores in rotation programmes, also in relation to the various periods of breeding, as a strategy to prevent parasitic resistance and to extend the useful life of coccidiostats.

Due to the very short rearing period of poultry, it is not realistic to treat the coccidiosis and the only effective method is to prevent it. The use of coccidiostats as additives is

[116] Source: European Parliament, 2019.

[117] Ionophores interfere with the passage of molecules across the cell membrane and, thereby, cause death of the parasite. They share a common mode of action and if parasitic resistance develops to one ionophore then it will also be apparent to the others. Synthetic drugs have an entirely different action and inhibit a variety of different biochemical pathways. If parasitic resistance develops then it will not be shared with an ionophore or synthetic drug of different type.

restricted to preventive use in the poultry sector with a low dosage, rather than the higher dosage required to fight the same parasite in the case of coccidiosis. With the more intensive treatment (higher dosage of coccidiostats and antibiotics) required to control the associated bacterial infection, the animal welfare and the related cost in terms of bird mortality and poor quality of products cannot be avoided. A factual valid alternative for prevention would be vaccination, but at present their effect in prevention is not always certain and cases of lack of protection leading to a disease is a realistic event.

The veterinary profession, represented by the EU organisation (FVE), argues against the use of coccidiostats as feed additives. FVE maintains that all coccidiostats/ anticoccidials and histomonostats should be used under veterinary prescription, following the examination of clinical signs and diagnosis based on the results of parasitic tests. According to the FVE, this would allow for a more controlled expert surveillance, as it would involve the veterinarian to diagnose and choose the best strategy for the use of coccidiostats. FVE argues that the need to have more control over the use of coccidiostats stems from the fact that some active substances are authorised in certain products as feed additives and in other instances as a VMP and therefore administered under veterinary prescription (e.g. Monensin); as literature indicates that cross-resistance to coccidiostats with the same mode of action from the same chemical class is common (Chapman et al, 2010), the wider spectrum of activity of a coccidiostat agent must be considered when examining resistance. This would extend the useful life of coccidiostats, to address the development of resistance to anticoccidial drugs (for therapeutic use) in the poultry sector[118]. The FVE is therefore of the opinion that in the longer term the aim should be to phase out the use of coccidiostats (whether preventive or medicinal); to this end, they also advise the inclusion of coccidiostats for monitoring purposes in the European Surveillance system for Veterinary Antimicrobial Consumption (ESVAC).

According to the industry, the farming sector and Member State Competent Authorities, the use of coccidiostats is effectively controlled through the PMM plans that form part of the conditions for the authorisation of coccidiostats (see Glossary and EQ1.4), requesting to verify the development of the coccidia resistance, an issue well known since at least 50 years. EFSA normally ask for the surveillance of resistance of the parasite to the additive. The Commission, in the authorising Regulation, extends this surveillance to a possible development of bacterial resistance.

The Commission's audits of official controls carried out by Member States in the feed sector (e.g. European Commission, 2012), as well as the results of Member State monitoring of coccidiostat residues in live animals and animal products (EFSA, 2019), indicate that the use of coccidiostats is effectively controlled, and that for many Member States the control of coccidiostats and histomonostats in feed is a priority.

Furthermore, by controlling coccidiosis and maintaining intestinal health in poultry, coccidiostats can help in subsequently decreasing the number of therapeutic antibiotic treatments which may be needed, and thus positively contribute to reduce the risk for AMR development. Recent studies in the UK, France and the Netherlands indicate that therapeutic antimicrobial use in poultry has fallen[119]. For example, the British Poultry Council surveillance report (BPC, 2019) on the UK strategy on antimicrobials highlight the poultry sector as a best case with a 71% reduction in the use of antibiotics during the 2012-2018 period whilst achieving an 11% increase in production; the report by the Dutch Veterinary Medicines Institute (SDa, 2019) indicates a 74% reduction in use of antibiotics

[118] Although, as outlined in previous paragraphs, strategies have been developed to extend the useful life of coccidiostats, e.g. the use of synthetic drugs and ionophores in rotation to prevent parasitic resistance.

[119] The EU antimicrobial resistance report by ECDC/EFSA/EMA (2017) also indicates declining trends in therapeutic antimicrobial use for all animal species, but does not separate per species.

in broilers between 2009 and 2017[120]; in France, the ANSES report on post-MA surveillance of veterinary medicinal products (ANSES, 2018) indicates a 43% reduction of poultry expenditure on antibiotics between 2012 and 2016.The above analysis pertains to the current situation. As also noted by some Member States, this situation needs to be periodically re-evaluated to take into account scientific advances in the development of effectives alternatives to coccidiostats as well as potential changes in farming practices.

EQ1.6 Answer:

The available evidence indicates that no changes in the situation have occurred since the adoption of the 2008 Commission report which concluded that the use of coccidiostats and histomonostats as feed additives could be considered to work properly.

Coccidiosis continues to pose challenges as an endemic disease in poultry farming in the EU. Hence, the preventive use of coccidiostats as feed additives is considered by the feed industry and the poultry sector as well adapted to current farming practices and presents important cost and efficiency advantages to ensure health and welfare of poultry. Preventive measures for the control of coccidiosis in modern poultry production continue to be essential, given that no realistic alternatives are available and that the risk characteristics of the disease make it more appropriate to prevent than to treat.

Coccidiostats are not used in human medicine and are not rated by the WHO as important to human health. According to the industry, the farming sector and Member State Competent Authorities, antimicrobial resistance (AMR) is monitored and controlled though post-market monitoring plans (PMM) that form part of the conditions for the authorisation of coccidiostats. The Commission's audits of official controls carried out by Member States in the feed sector and the results of Member State monitoring of coccidiostat residues in live animals and animal products also indicate that the use of coccidiostats is effectively controlled.

The EU organisation representing the veterinary profession maintains that all coccidiostats/ histomonostats should be used under veterinary prescription to allow for better surveillance (under the ESVAC system), to address the development of resistance to anticoccidial drugs for therapeutic use in the poultry sector. However, the development of coccidia and bacterial resistance is subject to post-market monitoring, while strategies have been developed to extend the useful life of coccidiostats. Furthermore, by preventing coccidiosis, given that the parasite is ever-present, coccidiostats are expected to have a positive impact in reducing dependence on antibiotics for therapeutic use; and, recent studies in the UK, France and the Netherlands indicate that therapeutic antimicrobial use in poultry has fallen.

These conclusions pertain to the current situation; this needs to be periodically re-evaluated to take into account scientific advances and potential changes in farming practices.

5.1.2 CONCLUSION

Ensuring that feed additives placed on the market are efficacious and safe for animals, humans and the environment are core objectives of the Feed Additives Regulation. In EQ1, the effectiveness of the Regulation in meeting these objectives is tested through the

[120] The report notes an increase in 2018, but this may be partly attributed to discrepancy in the data between the sources used; the SDa notes that it is monitoring further this increase. (SDa, 2019).

evidence and experience gained from the implementation of its core provisions, including the authorisation procedure and labelling requirements, as well as their enforcement.

Authorisation procedure: in comparison to the former legislation, the implementation of the procedure set out in the Regulation indicates important improvements in both the efficacy and safety assessment, thus positively contributing towards ensuring that feed additives placed on the EU market are efficacious and safe.

In particular, under the Regulation, both efficacy and safety are evaluated for several important categories/functional groups of feed additives which were not at all or not completely assessed under the former legislation because: (i) they were not considered as feed additives (e.g. silage additives); (ii) rules were not fully harmonised (e.g. amino acids); (iii) requirements were too general (zootechnical additives). The market relevance of these feed additives is indicated both by the total number of applications for new authorisations/re-authorisations during the 2004-17 period and their considerable market value (where estimates exist).

Furthermore, pre-existing feed additives for which efficacy/safety was not demonstrated under the Regulation were withdrawn from the EU market, including an estimated 1,623 additives notified under Article 10 for which no reauthorisation dossier was introduced at expiry date and 120 withdrawn during the authorisation process. Some 89 applications for new authorisations and 205 applications for reauthorisation were withdrawn (totally or partially) between 2004 and 2017, as efficacy/safety was not demonstrated (compared to a total 791 applications submitted for evaluation under Articles 4(1) and 10(2)).An additional indication of the high safety record of feed additives and premixtures placed on the EU market is the very limited number of RASSF notifications during the period 2004-17: out of a total 517 notifications on feed, 12 were on feed additives/premixtures. The high safety standard of feed additives and premixtures placed for pet animals (flavourings, vitamins and amino acids) is also demonstrated, with specific rules laid down in the Regulation for non-food producing animals, including for assessing their safety/efficacy, for which specific guidance was set up by EFSA.

Consequently:

- Feed additives authorised to be placed on the EU market are unanimously considered to be safe. The high level of the scientific evaluation performed by EFSA has played an important role in ensuring this objective. Nonetheless, ultimately, the safety of authorised feed additives depends on compliance with the conditions of their use along the feed chain, which is controlled under the Official Controls Regulation.
- Feed additives on the EU market are generally considered efficacious. However, one shortcoming identified by manufacturers of feed additives/premixtures is that the regulatory requirements are not always considered fully relevant in real conditions. This is particularly highlighted for zootechnical additives, for which demonstrating efficacy in terms of the performance end-points defined in the Regulation has proven challenging and is not always considered appropriate for real market conditions and requirements as defined by users.

The authorisation procedure, from submission of the application dossiers by applicants to final decision by the Commission, was also analysed to identify whether certain elements drive or conversely hinder its effectiveness. This analysis identified significant delays in the completion of the procedure, beyond the reasonable deadline of one year. In total, based on Commission data, the average time taken for the procedure to complete (from validation of application by EFSA to Commission decision) is roughly 2.5 years for Article 4(1) applications (authorisation of new feed additives) and 4.5 years for Article 10(2) applications (reauthorisation of pre-existing feed additives/substances). In view of this, there is some concern on the potential bottlenecks which could arise from the large number of requests for the renewal of authorisations (Article 14) that are expected to be submitted

in future years. These delays were found to be mainly due to the high incidence of missing and/or incomplete information/data during the assessment, for a substantial majority of applications (78% of applications under Article 4(1); and, 88% of applications under Article 10(2)). This has triggered the clock stopping process 1,320 times in the 2004-17 period, with an average 1.73 requests of complementary information per finished dossier. Consequently, a significant majority of EFSA opinions are not issued within legal deadlines (i.e. within 6 months from valid application): on average, it takes 2.4 times longer for Article 4(1) applications and 4.6 times longer for Article 10(2) applications.

The reasons why applicants are not providing complete information/data include: understanding of the guidance and assessment process; interpretation of the requirements by the applicants, e.g. on the studies to be conducted; and/or, interpretation of the results obtained in the studies. These issues tend to prevail more in the case of efficacy studies, due to the complexity involved. On the other hand, in the case of the safety assessment, the information/data provided by applicants tends to be fit to assess safety, facilitated by the EFSA guidance provided and its alignment to relevant OECD Guidelines; with the exception of demonstrating safety for users, which remains challenging for applicants, particularly for non-holder-specific additives. A suggestion to improve the suitability of the authorisation procedure, put forward by some business stakeholders (and also one NCA), would be the acceptance of scientific evidence from literature or in vitro trials (rather than in vivo trials, or in combination with them) for easier and quicker authorisation of the use as feed additives of known substances that do not raise significant doubts in terms of safety and/or efficacy.

EFSA risk assessment has allowed sound decision-making by the Commission, to a considerable extent, as neither EFSA opinions nor Commission decisions have been successfully challenged in the 2004-17 period. Nonetheless, in some cases, due to the missing information/data, EFSA does not have adequate information to provide an informed opinion, leading to non-conclusive opinions (an estimated 15% of EFSA opinions). According to the industry, an indication that legitimate factors are not sufficiently taken into account is that hardly any cases were identified of additives being authorised when EFSA opinions are non-conclusive. On the other hand, the Commission cannot deviate from the EFSA opinion unless there is scientific evidence that justifies such deviation, which is not the case for those non-conclusive opinions where the main problem is the lack of appropriate data. However, this issue is partly addressed by the additional information submitted by applicants on request of the Commission under Article 29 of the GFL. This allows the Commission to request a new evaluation based on solid scientific grounds.

In conclusion, although the authorisation procedure has improved significantly in comparison to the Directive, its effectiveness is partly undermined by length and complexity. It is noted that data on the number of favourable opinions, favourable opinions with limitations, non-conclusive and unfavourable opinions are not systematically collected by EFSA; this makes it difficult to monitor systematically the assessment process.

Other key provisions of the Regulation also play a positive role in meeting the core objectives of the Regulation. However, their effectiveness is also partly undermined by complexity:

- **Labelling (Article 16)**: although labelling plays an important role in ensuring objectives, 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 or proportionate, with important cost implications for operators.
- **Controls and sanctions (Article 24)**: data on controls performed by Member States indicate an average frequency of about once per year per establishment producing feed additives and premixtures; and, a high rate of conformity of samples and analyses. In addition, Member States have put in place sanctions to address

non-compliance. However, at the level of enforcement, the evidence provided by Member States is not sufficient to verify that sanctions are imposed in cases of infringements. It is noted that the control of compliance along the feed chain with the conditions of authorisation of feed additives falls within the scope of the Official Controls Regulation. There is also some evidence that controls on imports are not adequate, despite the limited number of RASFF notifications on feed additives/premixtures between 2004 and 2017 (12, of which 7 on imports from non-EU countries). In particular, diverse levels of implementation of controls on imported products, the absence of an EU list of non-EU establishments authorised for exports to the EU, as well as constrained resources and complexity of import controls in practice, all contribute to question whether imports of feed additives are adequately controlled.

Finally, the following provisions are found to have effectively contributed to reduce the likelihood of **antimicrobial resistance (AMR)**: the ban on the use of antimicrobials as growth promoting agents; maintaining coccidiostats as a feed additive for the prevention of the continuing widespread risk of coccidiosis in poultry; and, the authorisation during the 2004-17 period of 84 new (zootechnical) additives, thereby enhancing performance (improving yields; reducing losses; reducing stress) and reducing the need for therapeutic use of antibiotics.

Coccidiosis continues to pose challenges as an endemic disease in poultry farming in the EU. Hence, the preventive use of coccidiostats as feed additives is considered by the feed industry and the poultry sector as well adapted to current farming practices and presents important cost and efficiency advantages to ensure health and welfare of poultry. Preventive measures for the control of coccidiosis in modern poultry production continue to be essential, given that no realistic alternatives are available and that the risk characteristics of the disease make it more appropriate to prevent than to treat.

5.2 Evaluation question 2: contribution of the Regulation towards a competitive and innovative EU feed additives industry

EQ2: How did the Regulation contribute to develop a competitive and innovative EU feed additives industry?

The global feed additives market is a highly competitive and relatively concentrated sector (see section 3.2). The Regulation aimed to support competitiveness and foster innovation in the EU feed additives industry through a series of actions, which sought to make the authorisation process streamlined, clear, and transparent for operators. This particularly targeted emerging and new categories of additives and uses (e.g. zootechnical additives, amino acids, and silage agents), to enable the development of new products taking into account scientific and technological progress.

EQ2 is addressed through three sub-questions testing the extent to which the competitiveness and innovation of EU producers is affected by regulatory requirements in the EU, also in comparison with requirements in non-EU countries, versus other factors.

5.2.1 ANALYSIS

EQ2.1: How does the authorisation procedure for feed additives affect the competitiveness between EU and non-EU feed business operators?

The authorisation procedure affects the sector's competitiveness to the extent that it aims to enable the development of innovative products responding to market needs. The following provisions of the Regulation aim to improve innovation prospects:

- The Register of feed additives lists all additives authorised in the EU and provides access to the Regulations authorising feed additives.
- A comprehensive classification system for additives according to their intended use, including clear criteria for the classification and determination of the functions of feed additives and data requirements for the preparation of the application and the compilation of scientific dossiers, are established.
- For innovative additives (e.g. zootechnical additives), the holder of the authorisation benefits from marketing exclusivity for the whole period of authorisation (holder-specific authorisations).
- Certain new categories of additive (amino acids, silage agents and urea and derivatives) are established; the use of additives in water for drinking is allowed.
- Certain new functional groups (reduction of contamination of feed by mycotoxins, hygiene condition enhancers, 'other technological additives') are established.
- A procedure for establishing criteria for new types of additives in the future, as required by scientific or technological developments, is laid down.
- Guidelines for applicants, including detailed data requirements to demonstrate the safety and efficacy.
- Authorisations are periodically reviewed (every 10 years). The aim is to ensure timely reassessment of the safety of feed additives as scientific knowledge on their effects and impacts evolve and to promote the development of feed additives with better safety/efficacy profiles. This allows applicants to consider if it is necessary to invest in the renewal of an additive that has been replaced on the market by other safer and/or more efficacious additives.

These provisions aim to promote innovation and encourage the EU feed additives industry to fund research to develop new products, by improving the prospects for future profits from sales of new products.

The extent to which the Feed Additives Regulation contributed to the EU industry's relative competitiveness is addressed on the basis of four judgement criteria; findings for each of these are presented below.

Judgement criteria: "The Regulation has encouraged the development of new and innovative feed additives to cover new needs of the livestock sector, including feed additives to replace growth promoters"

The Regulation has encouraged the development of new and innovative feed additives to cover new needs of the livestock sector, with a total 176 additives approved during the 2004-17 period across the 9 new functional groups in 3 categories[121]. This includes 115 silage additives, 28 amino acids and 1 urea derivative, all of which were out of the scope of the former Directive; 5 substances for the reduction of contamination by mycotoxins, 1 hygiene condition enhancer; and, 24 zootechnical additives (functional group 'other zootechnical additives'). Although some of these additives were already emerging in animal nutrition at the time of the Directive, e.g. amino acids[122] which can lower plant-based protein requirements in feed while improving performance[123], and the use of feed additives on silage as a means to preserve quality, these were not covered by the Directive. Under the Regulation, the authorisation of these additives requires to demonstrate efficacy, which has encouraged applicants to develop new forms of additives that are more innovative and efficient. In the case of the 'other' zootechnical additives, the functional group includes diverse products (excluding microorganisms that were already covered by the previous Directive).

[121] Source: data provided by DG SANTE, on the basis of FAR (Reference 1: list of Annex I of the Register December 2006, rev. 7) and Register December 2017 (rev. 259).
[122] E.g. AWT, 2000; D'Mello, J. P. F. (ed.), 2003
[123] E.g. Karau, A. 2014

Although it is not possible to determine the total value and volume of these additives, approximate estimates on the value of some categories indicate their economic importance. The current EU-28 market for all amino acids is valued at €1.75 billion, of which lysine and methionine account for the major share. Amino acids are described by the feed additive industry as of major and growing commercial importance, unlike the other types of additives which are of lower economic value. In particular, silage additives are valued at less than €200 million[124]; and, mycotoxin binders at less than €100 million.

Nonetheless, according to business stakeholders the shortcomings identified - notably the length and cost of the authorisation process and the difficulties and time needed for creating a new functional group as well as the current criteria for authorisation (Article 5) (as discussed under EQ1.4) - make it difficult to follow rapid developments in animal production techniques and/or to address emerging needs in specific/innovative sectors.

Judgement criteria: "Identification of major factors affecting competitiveness of the EU feed additives industry vs non-EU operators"

According to the industry[125], both non-regulatory factors (labour, overheads and material/input costs) and regulatory factors were identified to exert a negative impact on the competitiveness of EU versus non-EU operators. Amongst the non-regulatory factors, lower labour costs in important non-EU country producing countries (including China and Brazil) are identified as a major factor affecting competitiveness.

Aside from the importance of non-regulatory factors, in particular labour costs, regulatory aspects are identified as a major factor affecting competitiveness. It should be noted that any form of regulatory requirements implies some costs; the question is to determine the extent to which regulatory requirements are proportionate. In particular:

- **Authorisation costs**: the majority of applicants for an authorisation indicated that the regulatory costs of authorisation have a negative impact[126]. The main elements of the authorisation process which are identified as constraining competitiveness are: a) costs, particularly the costs of efficacy studies which are considered disproportionate to real market needs (this issue is discussed under EQ3.1); and, b) time required from application to approval, including the unpredictability of the process.
- **Labelling costs**: the majority of operators (producers of feed additives/ premixtures and compound feed manufacturers) indicated that labelling costs have a negative impact, although for many operators there is no impact[127]. The main elements of the labelling requirements which are identified as impacting costs, thereby constraining competitiveness (as further discussed under EQ3.1), are: a) the amount of information required on the physical product label; and, b) the need for regular review of the information on the label, particularly for premixtures, which is triggered by regulatory changes (e.g. in the approval status of the feed additives contained in the pre-mixtures). The latter affects not only premixtures placed on the EU market, but also exports (to the extent that non-EU countries require the exact formula of the premixture to be registered in their country), thereby impacting profitability.
- **Other regulatory requirements**: the EU is generally considered to have high standards, which generally implies a high cost. These range from requirements in

[124] Estimate based on RM Associates Report for FEFANA (2018).
[125] Industry feedback to stakeholder survey and interviews with the industry.
[126] Annex 3, section 3.2.2.4. This view was confirmed by the interviews, including those conducted during the case study on authorisation (Annex 4).
[127] Annex 3, section 3.2.2.4. This view was confirmed during interviews, including those conducted during the case study on labelling (Annex 4).

other EU legislation of relevance to feed additives (e.g. feed hygiene requirements) to environmental and social standards, which are generally considered higher in the EU when compared to some important non-EU producing countries. While this is a general perception amongst operators, there is no specific evidence to substantiate it. In the case of feed hygiene requirements, although the majority of operators (feed additives/premixtures producers and compound feed manufacturers) indicated a negative impact, the industry-developed standard FAMI-QS[128] encompasses the regulatory hygiene requirements and has contributed to establish a level playing field amongst EU and non-EU operators[129].

According to operators, the regulatory requirements equally apply to non-EU and EU producers. In practice, Member State controls are meant to ensure an equal application of labelling requirements on both EU and imported products. In addition, products placed in non-EU markets have to comply with the regulatory requirements applying in those markets.

Judgement criteria: "Impact of the Regulation on relative competitiveness of the feed additives industry (EU vs non-EU operators)"

Focusing on the authorisation process, which is identified as the most important regulatory factor affecting relative competitiveness between EU and non-EU operators, it is noted that all feed additive producers, whether EU or non-EU, face the same requirements for placing their products on the EU market.

When comparing the relative competitiveness of EU vs non-EU producers in global markets, EU producers placing their products in non-EU markets have to comply with the regulatory approval requirements in force in those markets. The following main factors affect EU producers' relative competitiveness globally:

- On the **positive** side, EU approval of novel feed additives tends to be highly regarded, in some cases even allowing direct product approval/registration in non-EU markets. This can ensure a positive impact on global sales for EU producers. This point is further discussed under EQ2.3.
- On the **negative** side, according to the EU industry, regulatory costs for authorisation in non-EU markets tend to be lower, than in the EU, and the procedure tends to be quicker. Both these factors result in a competitive advantage for non-EU producers in non-EU markets: they enable them to move quicker to bring to market innovations and ensure faster a return on their investment (ROI), when compared to the time and costs needed for EU producers to place similar products on the EU market.

The costs of the EU authorisation process for applicants are presented under EQ3.1. The costs of efficacy studies, in particular for zootechnical additives, are a key element that differentiates the requirements that EU applicants face for placing their products on the EU market compared to non-EU producers placing their products in non-EU markets. Similarly, EU requirements for modifying an authorisation, to address a process change

[128] FAMI-QS is the worldwide Quality and Feed Safety Management System for the sector of Specialty Feed Ingredients. https://www.fami-qs.org/home.html. The benefits of recognised feed certification schemes (such as FAMI-QS) in significantly reduce official controls for business operators who are members of the schemes have been outlined in a Commission report on the basis of findings in four Member States (European Commission, 2017b).

[129] The benefits of the interaction of official feed controls and private assurance schemes are described in an overview report by the Commission services; nonetheless, interactions are not uniformly well established across all Member States (European Commission, 2017a).

for a product that remains of the same (or, even, improved) quality as that originally authorised, are significantly more demanding than in non-EU countries.

EU operators have specified that beyond the costs, there are wider implications of the delays in the EU authorisation process for the competitiveness of EU operators. The EU process can take up to three years to be concluded from application to approval, while the time required for product registration in important non-EU markets is on average one year (as outlined under EQ2.3, based on feedback received from six non-EU countries). The time of not being able to market a new product is an opportunity cost both in terms of recovering the cost on the investment, and in terms of ensuring protection of the innovation. This type of burden creates a competitive disadvantage, since it does not allow EU operators to rapidly adopt scientific and technological advances to bring products to the market, via vis non-EU competitors that can move faster to place similar products in non-EU markets.

The impact of EU labelling requirements on competitiveness is identified to be of much lesser importance, except in the case of premixtures. For operators using the same standard approach to labelling and composition of premixtures for both the EU and non–EU markets, frequent changes in premixture labels due to changes in the authorisation status of the feed additives these contain mean that the product may need to be re-registered in non-EU markets (to the extent that destination countries require the exact formula of the premixture to be registered). According to manufacturers, this affects largely the profitability for exporting premixtures or blended specialty products.

Judgement criteria: "Significance of feed additives in the economic activity of EU feed additive operators"

The membership of FEFANA, the EU organisation representing the feed additives sector, gives an indication on the current structure of the industry, in which both multinationals and SMEs operate, with 60 % of members being SMEs[130].

There is wide variation in the share of feed additives in the overall company turnover, profits[131], and research and development (R&D) spending. According to industry data, large and medium size companies seem to be less specialized in feed additives than smaller companies: feed additives 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[132]. 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, compared to 8% for the medium-size businesses.

Feed additives are a low volume high value sector; according to industry data (2015), feed additives represent 3.5% of the feed market volume but 10% of its value[133]. According to the industry, in some market segments, e.g. in the production of holder-specific zootechnical additives, only a few market players are present (in the EU and globally). This relatively competitive high-value sector justifies a significant effort in R&D to maintain know-how and create innovation. The companies consulted in the context of the case studies (Annex 4) indicated that the share of R&D budget focused on feed additives closely

[130] Source: FEFANA (see section 3.2).
[131] Due to confidentiality reasons, no systematic data are available on profits.
[132] 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.
[133] Source: latest data available from FEFANA/FEFAC (see section 3.2).

follows the share of feed additives in overall turnover, reaching in some cases 95% for companies with activities dedicated to this product sector.

EQ2.1 Answer:

The Regulation has encouraged the development of new and innovative feed additives to cover new needs of the livestock sector (e.g. silage additives and amino acids to improve performance and sustainability in the use of feed resources, zootechnical additives to replace growth promoters). The high standard of the EU rules for feed additives, particularly the authorisation procedure followed for their approval, is recognised worldwide.

Feed additives are a significant economic activity for EU operators (in terms of turnover, profits, R&D spending), although the profile of companies active in this sector and the product range tend to be diverse. This is a relatively concentrated, low volume high value sector: 94 companies that are members of the EU association FEFANA (mainly from the EU and EEA, and few companies that are globally present) account for an estimated 80% of the EU feed additives production value. Of these member companies, 60% are SMEs. In some market segments, e.g. in the production of holder-specific zootechnical additives, only a few market players are present (in the EU and globally).

Although the Regulation should not affect the relative competitiveness of EU vs non-EU companies in the EU market, as all companies need to comply with the same rules, the authorisation process affects the relative competitiveness of EU vs non-EU operators in global markets. Regulatory costs for the approval of feed additives in non-EU markets tend to be lower than in the EU and the procedure tends to be quicker. This - in addition to lower labour costs in important non-EU country producing countries (including China and Brazil) - results in a competitive advantage for non-EU producers. It enables them to move quicker to be the first to bring to market innovations and to ensure a quicker return on their investment (ROI).

The impact of EU labelling requirements on competitiveness is identified to be of much lesser importance, except in the case of premixtures, to the extent that operators use the same standard approach for the labelling and composition of premixtures for both the EU and non–EU markets.

EQ2.2 What factors support or hinder competitiveness?

Apart from the impact of the authorisation procedure on competitiveness (EQ2.1), other specific factors that may support or hinder the competitiveness of EU producers of feed additives and premixtures were investigated as follows.

Judgement criteria: "Feed additives not authorised in the EU are produced for exports"

A large number of respondents to the stakeholder and NCA surveys[134] were aware of feed additives and premixtures not authorised for placing on the EU market, which are produced in the EU only for export to non-EU countries in accordance with the requirements laid

[134] Annex 3: Consultation synopsis report, sections 3.2.2.5 and 3.3.2.5; and interviews.

down in Article 12 of the GFL[135] ,so-called NAFA[136] products. Feed can only 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 feed concerned could not be placed on the market in the EU. This includes 14 operators who indicated that they export to non-EU countries feed additives not authorised for placing in the EU, or premixtures/compound feed and feed materials containing such additives.

NAFA exports include substances not authorised in the EU as feed additives or authorised in the EU as feed additives only for specific animal species and/or under specific conditions of use (e.g. dose rate). It may also involve cases where an EU authorisation has not yet been obtained, because the authorisation procedure takes typically longer in the EU than in non-EU countries (e.g. zootechnical additives). Examples of such NAFA products include: mycotoxin binders; enzymes; preservatives; antioxidants; probiotics; and, several live microorganism strains. Also, according to several industry respondents, a large proportion of premixtures and feed exported to non-EU countries contains NAFA products. Furthermore, there is some export at small pilot scale for the purposes of R&D and trials on animals (for which an authorisation is requested if performed in the EU).

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-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 disproportionate in view of their small scale of business.

Information collected from industry and from national authorities tend to indicate that there are diverse national approaches on this issue, which leads to significant competitive disadvantages amongst companies based in the different Member States. The industry indicated that completing the documentation required to enable the export to non-EU countries of NAFA products is a common problem with variable levels of complexity/difficulty across the EU; and that the bureaucracy involved and lack of clarity on the requirements are detrimental to EU trade. Based on evidence provided by some operators and competent authorities, approaches between Member States vary significantly: for example, one Member State has particularly difficult procedures in place effectively restricting exports of NAFA products, while another Member State has provided a clearly set out procedure established in a relevant protocol..

A majority of business stakeholders perceive that the rules applicable to the export of feed additives are currently properly addressed by not forming part of the Feed Additives Regulation, although a significant share of business stakeholders have the opposite view. For those against, the Feed Additives Regulation should not interfere with placing on the market feed additives outside the EU, to allow fair competition in global markets. For those

[135] According to Article 12 of the GFL, food and feed exported for placing on the market of a non-EU country should 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 in force in the importing country. In other circumstances, food and feed can only 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. Where the provisions of a bilateral agreement concluded between the EU or one of the Member States and a non-EU country are applicable, food and feed exported to that non-EU country should comply with these provisions.

[136] NAFA: 'non-authorised' feed additives (for placing on the EU market).

in favour, there is currently no level playing field on this, due to the different approaches followed by Member States on exports of NAFA products.

Judgement criteria: "Trend in R&D invested to develop new feed additives"

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 feed additives sector. It is therefore not possible to establish with certainty whether R&D investment to develop new feed additives 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 feed additives 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.

The number of patent applications is another indicator of innovation propensity. It indicates both that the outcome of R&D leads to innovative products and that interest in the EU market justifies the time and money spent by applicants to register a patent for these products in the EU. According to the European Patent Organisation (EPO) database, a total 310 patents are currently registered in the feed additives sector in the EU. The owners of these patents are both from EU and non-EU companies, but the global profile of many multinational companies active in the sector should be taken into consideration (as discussed under EQ2.1).

Since the Feed Additives Regulation was in place the number of applications for patent registration submitted to EPO nearly 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 vs non-EU applicants has remained the same over the two periods with 44% applicants from the EU and 56% from non-EU. This suggests that the Regulation has had some positive effect on innovation both for EU and non-EU companies.

Judgement criteria: "Extent to which the authorisation procedure more specifically affects SMEs"

The presence of SMEs in the feed additives/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 feed additives on the EU market; of these, 11 are SMEs (of which, 3 are part of a larger company) and 14 are large companies.

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.

According to the industry, SMEs are active in the sector of holder-specific feed additives, 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.

EQ2.2 Answer:

Other factors that affect EU competitiveness include the export potential, innovation propensity and extent to which the authorisation process specifically affects SMEs.

Feed additives not authorised in the EU and premixtures/feed containing them (so-called NAFA products) are an important business segment for EU companies, especially SMEs, as they are still produced for exports. This opportunity is to some extent hampered by differential rules and approaches on NAFA exports between Member States.

Although the number of patent applications (EPO data) has doubled since the Regulation came into force, compared to the preceding period, the share of EU vs non-EU applications has remained stable. This suggests that the Regulation has had some positive effect on innovation both for EU and non-EU operators.

The presence of SMEs in the feed additives/premixtures sector is important and some SME applicants are actively involved in the authorisation process for holder-specific feed additives (e.g. zootechnical additives), but they apply strategies to reduce costs (e.g. focussing on fewer categories of animals or species). At the same time, 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.

EQ2.3 Which non–EU countries recognise the EU authorisation procedure to allow companies to directly enter their market and why?

Recognition of EU standards and procedures by non-EU countries is an important achievement. It drives export competitiveness and allows leading innovative EU-based companies, of any size, to become pioneers in their field in world markets.

EQ2.3 is addressed based on three judgement criteria, findings of which are presented below. The evidence presented here is based on the results of a dedicated EU survey addressed to eight non-EU countries that are major producers of feed additives, as well as industry feedback. Six countries responded to the EU survey**: Argentina, Canada, Chile, China, Japan, and the USA**. These six countries account for an estimated 40% of the world feed additives market[137], which is similar to the EU-28 share of the world market[138]. The extent to which these countries recognise the EU authorisation procedure is therefore a significant indicator of the contribution of the Regulation to support the competitiveness of EU companies.

[137] Estimates based on data available on a broader regional basis at: https://www.futuremarketinsights.com/reports/animal-feed-additives-market
[138] Based on the estimates provided by RM Associates Report, 2018 (see section 3.2).

Judgement criteria: "Extent to which the EU authorisation process is recognized in non-EU countries"

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:

- The Chilean legislation on animal feed takes the EU legislation as a reference point: *inter alia*, the Feed Additives Regulation (list of additives); Directive 96/25/EC (list of raw materials); and, Directive 2002/32/EC (undesirable substances).
- Canada has always accepted data based on the EU application package as part of a Canadian submission application. Furthermore, Canada is currently in the process of reviewing its legislation. In this context, it has recently carried out a comparison on the basis of the EFSA guidance documents, which indicates that the scientific assessment requirements in the EU and Canada are very much aligned. Once completed, and if there is a positive outcome, Canada will be in a position to accept EFSA conclusions with the submission of a summary dossier.

Although the approach followed in all six countries differs from the EU system, in the remaining four countries (Argentina, China, Japan and 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 of feed additives authorised in the EU are being used as a reference for the technical assessment of these substances by the authorities in China. The main differences between the approaches followed in the EU and in the six countries are outlined under the next judgement criteria.

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.

Judgement criteria: "Major differences in the authorisation procedure in non-EU countries compared with the EU"

The main differences between the authorisation procedure in the EU and the approach followed in non-EU countries are identified based on the replies received by six countries that responded to the non-EU country survey. Key differences can be summarised as follows:

- **Definition and classification**: feed additives are not always defined as a distinct category; and, tend to be classified less precisely than in the EU. Where this occurs, depending on type of feed additive, they may be covered by several pieces of legislation. For example, in the case of one of the six non-EU countries, the definition *'food additives'* covers use both in humans and animals; in the case of another non-EU country, *'single ingredient feed'* includes what in the EU would be considered as feed additives and feed materials. However, in the former case additives used in animal feed are not classified based on their function in the feed (except in a few cases, e.g. colourants); while in the latter case, there is a positive list of all approved ingredients which are somewhat classified per purpose.
- **Authorisation process**: all countries have a process in place for the approval of feed additives, 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 vary significantly per country. One of the six countries appears to be the most aligned to the EU, in that all requirements for safety and efficacy assessment need to be met; followed by three countries, which impose in most cases similar requirements as in the EU. The remaining two countries generally apply requirements based on the product's

process monograph[139]; 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, (except in one country) hold meetings before formally submitting the application, mainly for clarification purposes.

- **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 can the procedure take up to several years.
- **Renewal of authorisation**: the authorisation is granted on an indefinite basis in three countries. In two of these countries, there is no mandatory requirement as such, 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.

It is noted that differences in approaches between countries were already identified by the industry in work conducted in 2013 (IFIF, 2013). In 2017, the International Feed Industry Federation (IFIF) together with regulatory authorities and feed ingredient associations from the EU, Canada, and the USA launched the International Cooperation for Convergence of Technical Requirements for the Assessment of Feed Ingredients (ICCF). This initiative aims to develop and establish common guidance that covers technical requirements for the assessment of feed ingredients, including new uses of existing feed ingredients; the first two guidance documents were produced in March 2019[140].

Judgement criteria: "Extent to which the EU authorisation system is attractive to non-EU operators"

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.

[139] Process monographs cover the characterisation, safety and efficacy of a single substance, and are generally based on survey of specialist research literature.

[140] The first two guidance documents cover 'Stability Testing of Feed Ingredients' and 'Sub-chronic Oral Toxicity Testing in Laboratory Animals'.

EQ2.3 Answer:

Based on feedback received from six non-EU countries, the process followed for the approval of products in their market tend to differ from the EU authorisation process. Nonetheless, some countries (e.g. Chile, Canada; to some extent China) recognise some elements of the EU feed additives authorisation process, thus making it easier for a feed additive to be approved in those countries if it has already been authorised in the EU.

Several major differences are identified in the process followed for the approval of feed additives in non-EU countries compared with the EU authorisation procedure, stating from definitions/classification of these substances. Feed additives are not always defined as a distinct category; and, tend to be classified less precisely than in the EU. Although all countries have processes in place for the approval of feed additives which includes a scientific risk assessment, when compared to the EU authorisation process, the components of the process in non-EU countries tends to have generally less demanding requirements, which vary significantly per country. This is reflected in timelines for the completion of the procedure, which tend to be shorter than in the EU, lasting from a few months to about a year; only in one country can the procedure take up to several years. The duration of the authorisation is indefinite in three countries, but in two of these countries, the authorisation may be re-evaluated based on the applicant's request or new information becoming available.

On the other hand, although the extent to which the EU authorisation system is attractive to non-EU operators cannot be comprehensively established, the available data indicate that during the 2004-17 period applications for authorisation have been received from at least seven non-EU countries. Furthermore, it is noted that companies involved in the feed additives industry are often global, multinational entities and some of them also have EU interests/subsidiaries.

5.2.2 CONCLUSION

Feed additives are a significant economic activity for EU business operating in this sector (in terms of turnover, profits, R&D spending). The profile of companies active in this sector and the product range tend to be diverse. This is a relatively concentrated, low volume high value sector: 94 companies that are members of the EU association FEFANA (mainly from the EU and EEA, and a few companies that are globally present) account for an estimated 80% of EU feed additives production value. Of these member companies, 60% are SMEs. In some market segments, e.g. in the production of some holder-specific zootechnical additives, only a few market players are present (in the EU and globally).

The Regulation has encouraged the development of new and innovative feed additives to cover new needs of the livestock sector (e.g. silage additives and amino acids to improve performance and sustainability in the use of feed resources, zootechnical additives to replace growth promoters, substances to reduce the contamination of feed by mycotoxins, hygiene condition enhancers or physiological condition enhancers). This is indicated by the number of patent applications (EPO data), which has doubled since the Regulation came into force, compared to the preceding period (although the share of EU vs non-EU applications has remained stable). This suggests that the Regulation has had some positive effect on innovation both for EU and non-EU operators.

The high standard of the EU rules for feed additives, particularly the authorisation procedure followed for their approval, is recognised worldwide. Although the process followed for the approval of products in key non-EU countries tends to differ from the EU authorisation process (based on feedback received from six non-EU countries), some countries (e.g. Chile, Canada; to some extent China) recognise substantial elements of

the technical dossier of the EU feed additives authorisation process: this makes it easier for a feed additive to be approved in those countries if it has already been authorised in the EU.

Although the Regulation should not adversely affect the relative competitiveness of EU vs non-EU companies in the EU market, as all companies need to comply with the same rules, the authorisation process affects the relative competitiveness of EU vs non-EU operators in global markets. Regulatory costs for the approval of feed additives in non-EU markets tend to be lower than in the EU and the procedure tends to be quicker. This - in addition to lower labour costs in important non-EU country producing countries (including e.g. China and Brazil) - results in a competitive advantage for non-EU producers. It enables them to move quicker to be the first to bring to market innovations, as well as to ensure a quicker return on their investment (ROI).

Another factor adversely affecting the EU industry in global markets is the absence of a common approach for exports of feed additives not authorised in the EU and premixtures/feed containing them (so-called NAFA products). Although no data exist on the actual volume/value of exports of NAFA products, these are an important business segment for EU companies (especially SMEs), and this opportunity is to some extent hampered by differential rules and approaches on NAFA exports between Member States.

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; some SME applicants are also actively involved in the authorisation process for holder-specific feed additives (e.g. zootechnical additives).

The impact of EU labelling requirements on competitiveness is identified to be of much lesser importance, except in the case of premixtures, to the extent that operators use the same standard approach for the labelling and composition of premixtures for both the EU and non–EU markets.

It can therefore be concluded that, on balance, the Regulation has positively contributed to develop a competitive and innovative EU feed additives industry. However, some shortcomings were identified in the way the Regulation affects the relative competitiveness of EU producers in global markets.

6. REPLIES TO EVALUATION QUESTIONS RELATED TO EFFICIENCY

EQ3 addresses the balance between the costs and benefits of the Regulation. This includes the estimation of compliance and administrative costs linked to the main requirements of the Regulation (authorisation, labelling) for applicants, feed business operators (FeBOs) and the EU institutions (Commission, EURL, EFSA), and assessing the cost-effectiveness of the authorisation process.

The assessment of efficiency has been particularly challenging in this evaluation, given that no specific cost impact analysis was carried out when the Regulation was drafted and data, even on current costs, are difficult to gather. When it comes to authorisation costs, the collection of data 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. When it comes to costs for public authorities to perform verification checks, and labelling costs for operators along the supply chain, these costs are often not analysed by specific activity and are merged with other legislative provisions. These challenges were identified from an early stage of the study and were addressed by a wide consultation and data collection as described in the methodology (section 4), to gather a representative and usable evidence base.

6.1 Evaluation question 3: costs and benefits of the Regulation

EQ3: To what extent are the costs of the implementation of the Regulation justified given the benefits achieved?

6.1.1 ANALYSIS

EQ3.1 What are the compliance costs and administrative costs linked to the requirements of the Regulation (labelling, monitoring, etc.)?

Adherence to the Regulation's requirements and obligations entails costs for operators, Member State Competent Authorities, as well as EFSA, the EURL and the Commission. These costs are presented separately below. As it has not been possible in all cases to provide data for the full 2004-17 period, the period covered by the costs has been adjusted to the best available data.

Judgement criteria: "Costs for feed business operators (FeBOs) including authorisation, labelling, monitoring"

The direct costs for operators to fulfil their legal and administrative obligations and responsibilities stemming from the Regulation mainly relate to:

a) applications for authorisation of a new additive (Article 4);
b) applications for reauthorisation of pre-existing additives/substances (Article 10)
c) applications for renewal of an authorisation granted under the Regulation (Article 14);
d) costs for operators along the feed chain, from feed additives and premixtures to compound feed and pet food, to meet the labelling requirements (Article 16).

The direct costs of these obligations have been estimated as an average over the last three years (2016-18), on the basis of detailed information provided by operators[141] for the following activities:

	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

(a) The staff time provided by operators was monetised using EUROSTAT data[142]
(b) Costs were provided by operators in €
(a) 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).

The costs involved vary considerably between operators. To some extent this reflects the type of feed additive in which the operator specialises; e.g., additives such as those in the zootechnical category tend to be new substances or substances with new uses, and this involves a large number of high-cost safety and efficacy studies. To allow for these differences, operators were asked to provide data on the costs involved both in the stakeholder online survey and in the case studies: in the survey, data were collected on an average basis across all types of feed additives (per authorisation application; per labelling change). In the case studies, the focus has been on specific additives.

Costs of authorisations:

The average cost per **authorisation** application was estimated at €1.1 million, across all applicants that provided complete data to the survey (*n=31*) and all types of feed additives 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 bulk of this cost is spent on safety and efficacy studies (37% and 32%, respectively), followed by internal staff costs (22%). The activities involved for the preparation and submission of an authorisation dossier tend to require senior staff: cat 1 staff account for 64% on average of the internal staff time required per application, followed by cat 2 staff (23%). No significant differences in average costs indicated by companies of different size (SMEs vs large companies) were identified, as the cost determinants are largely independent of company size. It was noted, however, that the high costs of authorisation for certain additives require significant investment, and access to finance generally tends to be a problem for smaller companies that are not part of a larger entity.

This **average cost masks differences by type of additive, which depend on the type and number of studies required**. For instance, the average cost per application for the authorisation of a zootechnical additive (holder-specific enzyme) was estimated at €2.6 million, across six applicants (*n=6*). The average cost of authorisation of coccidiostats was estimated at €3.4 million per application, across 2 coccidiostats. Also, data provided

[141] Data provided by operators during the survey (Annex 3: section 3.2.2.4) and interviews. Due to the need to respect confidentiality, data collected from the survey and interviews were analysed and presented jointly, in the authorisation and labelling case studies. Details can be found in the case studies (Annex 4: Authorisation; Labelling).
[142] EUROSTAT average annual earnings for industry (except construction), by economic activity and educational attainment (staff categories 1 to 4); average EU-28 (latest data: 2014), adjusted for overhead costs (addition of 25%) in accordance with the Better Regulation toolbox #60.

by one company on an average basis, across holder-specific zootechnical additives versus non-holder specific nutritional additives, indicate average costs of around €2.4 million for the authorisation of a zootechnical additive versus €2.1 million for the authorisation of a nutritional additive.

Operators indicated that additional indirect costs and losses are generated by delays in the deadlines foreseen by the Regulation for the authorisation process, including the requests for supplementary data by EFSA ('stop the clock' procedure) and the final Commission decision regarding the authorisation. Nearly all applicants complained of the 'unpredictability' of the authorisation process, in terms of: 1) unexpected requests for supplementary data by EFSA and undue delays in these requests; 2) delays in the final Committee (PAFF) procedure for a decision; and, 3) other delays (e.g. mandate to EFSA; validation of dossier). These delays also exert negative impacts further down the feed chain as reported by users. It was not possible to estimate in monetary terms these indirect costs and losses.

Costs of renewal of authorisations:

The average cost per **renewal of authorisation** application was estimated at €216,000, across all applicants that provided complete data to the survey (*n=18*) and across all feed additives for which a renewal dossier was submitted in 2016-18[143]. This represents, **on average, about 20% of the authorisation costs**. The bulk of this is spent on safety and efficacy studies (33% and 55%, respectively), followed by internal staff costs (9%). The activities involved for the preparation and submission of a renewal dossier also tend to require senior staff, but less senior than for an authorisation: cat 2 staff account for 66% on average of the internal staff time required per application, followed by cat 1 staff (28%).

Labelling costs (Article 16):

The costs considered in this case are those **linked to label changes that are triggered by regulatory changes** (i.e. changes in authorisation under the Feed Additives Regulation requiring adaptations to labels)[144]. The total costs involved to perform labelling changes vary considerably between operators. Although the staff time required per label change tends to vary less and appears relatively low at around 20 hours on average, this substantially increases when multiplied by: i) the number of languages; ii) frequency of changes; and, iii) the number of product references.

Generally, feed additives tend to carry labels in all EU languages, while premixtures (which contain several additives) tend to carry labels in few languages (typically 3-4). Nonetheless, the highest cost is to perform changes on the labels of premixtures: the higher the number of additives contained in any premixture, the more likely it is for any changes in the authorisation of the individual additives to trigger changes in the information required to be provided on the premixture label, hence the higher the frequency of labelling changes required. Furthermore, according to most operators (22 out of 30 respondents to the survey; and, all operators interviewed), changes to the authorisation of the feed additive (e.g. the scope of the species covered or conditions of use) are the first reason why they change labels (other reasons being requests of Member State authorities and market-driven factors).

Thus, the costs of changes on the label of single **feed additives** due to regulatory changes are relatively minor, given the relatively low frequency of changes and number of product

[143] Annex 4: authorisation case study
[144] Annex 4: labelling case study

references. Data collected from nine manufacturers of feed additives (*n=9*) indicate minimal/negligible costs.

The costs are higher for manufacturers of **premixtures**. Costs of labelling changes estimated on the basis of data provided by four manufacturers of premixtures (*n=4*) range from €80,000 to approximately €223,000 per plant per year, as an average over the changes performed in the past 3 years. Staff costs (design of labels; and, when required, product reformulation) and, to a lesser extent, external services (translation and printing services); disposal costs tend to be relatively minor/negligible in most cases.

The indicated costs in the case of premixtures labelling can be considered to represent an over-estimate of the actual costs of labelling changes due to regulatory requirements as such. However, it is not possible to separate the costs of changes triggered by regulatory changes from those triggered by other factors (namely, Member State interpretation of regulatory requirements and market-driven factors); mainly because, to save costs, operators try to perform simultaneously labelling changes triggered by different reasons.

Although the costs are due to changes performed mainly in response to regulatory requirements, operators provided examples indicating that some gold-plating of requirements by Member State authorities (NCAs) takes place. Examples provided include: some NCAs require all information to be available in all languages, while other NCAs provide some flexibility for some of the information to be available in the main EU languages; some NCAs require larger font size although this is not specified in the legislation; some NCAs insist on listing a representative company in their country, whereas already a European operator is indicated on the label; some NCAs accept listing a "minimum" content on the label while others insist on listing a fixed value. Also, some costs, e.g. for the translation and design of labels are triggered by a regulatory requirement that is compounded by market-driven factors such as customer requirements or operator strategies to target multiple markets.

On the other hand, NCAs identified some more technical issues pertaining to more general aspects of the Regulation (and other applicable legislation) which may create differential understanding and interpretation of labelling requirements by authorities across the EU. Examples provided include: use of additives in drinking water (the use of additives/premixtures is not authorised via drinking water, but complementary feed can be used in drinking water); the approach to claims on the label with regard to the effects of an additive (extent to which these are restricted to the specific function for which the additive is authorised, as stated in the authorising Regulation); extent to which quantity of carriers is to be declared on the label (not explicitly required by Article 6 of the Feed Additives Regulation) versus the extent to which carriers are to be included in the list of feed materials used in compound feed (Article 17 of the Feed Marketing Regulation).

The costs can be more significant for **pet food manufacturers**, due to the large number of product references[145] potentially affected by a regulatory change. Typically, the withdrawal of a declared additive or the imposition of a new content limit that requires declaration means that the product formulation and label must change to reflect this, which can affect many hundreds of items of packaging. Companies specified that they generally try to reduce complexity in recipes, by relying on a smaller number of key ingredients, including feed additives. The extent of the costs will depend on the case: if the regulatory change affects a major critical additive used across a large number of product references, e.g. a nutritional additive such as a vitamin, a change could affect thousands of packaging units with over €1 million in relabelling costs, in addition to reformulation costs (estimated

[145] This reflects the wider product range of pet food manufacturers, in terms of: number of products/formulations, multiplied by number of packaging per product/formulation (different sizes and types of packaging for the same product/formulation), multiplied by number of label versions/packaging (source: Annex 4, labelling case study).

by one company at €30,000). According to data provided by two companies on another case of a feed additive widely used in the pet food industry which was recently withdrawn from the market, reformulation costs are expected to reach in excess of €3-4 million; in addition, there are important re-labelling costs and at least 10% of the production volume is expected to be destroyed at an expected cost of €15,000 - €20,000 (excluding loss of product value).

The indicated costs in the case of pet food labelling are not representative averages across a period; they correspond to the specific cases of major regulatory changes and therefore can be considered to represent the top range of costs of labelling changes due to regulatory requirements. They may also represent an over-estimate of the actual costs of labelling changes in that pet food has standard, more sophisticated, packaging and a large number of product references. In the case of food producing animals the feed is prepared upon request and labelled at that moment; this increases flexibility to accommodate changes and is therefore expected to imply lower costs for manufacturers of compound feed for food-producing animals, in comparison to pet food manufacturers.

Other key factors in reducing the costs of labelling changes are:

- **Transitional measures for existing products:** these should reduce the administrative costs for labelling. All the additives reauthorised under Article 10(2) have transitional measures to adapt to the labelling requirements. However, as highlighted during the labelling case study, the periods are not considered sufficient in many cases by the premixtures and feed industries (including pet food); as users of feed additives, these stages of the feed chain typically need more time to adapt to changes from an operational point of view (inventory management; reformulation, if required).
- **The level of automation in labelling systems:** the costs for companies that have in place automated systems were estimated at up to €114,000 per plant per year. Automated systems result in lower costs per year, once the initial cost of the investment in such systems is written off (this applies to all stages of the feed supply chain, not just pet food). Company size does not affect the costs of labelling, as the aforementioned factors i) to iii) are independent of company size. Disposal costs/losses tend to be low and not systematic.

On the other hand, the main impact of the Regulation's labelling provisions for the feed additives industry is in terms of the amount of information and the form in which it is required on the label versus the need for some of this information to be on the physical product label. According to both feed additives/premixtures operators and operators using premixtures in compound feed, most of the information that users need to have is transmitted via other relevant documents, notably, the product specification sheets used by the industry in B2B transactions, ahead of the product's purchase to ensure that the product conforms to the technical specifications required by the buyer. To this end, a number of Codes of good labelling practices have been developed by the industry (endorsed by producers and users of feed additives).

Judgement criteria: "Costs for MS CAs"

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

a) participation to the meetings of the Standing Committee in Brussels;
b) control activities carried out for inspections and verification checks; and,
c) other legal and administrative obligations.

The staff time devoted to these activities has been estimated by the national Competent Authorities[146], as an average over the last three years (2016-18). It is noted that the estimates provided vary considerably between Member States. To some extent, this reflects the size of the MS (large versus small MS) and importance of the feed additives sector in each MS, as well as specificities in the structure of the national authorities in the different MS (e.g. decentralised structure in Spain and Italy). It is also partly due to differences in the way the estimates were calculated by authorities. In particular, it has proven difficult for authorities to estimate the staff time spent on control activities related specifically to the enforcement of the Regulation versus other legislation; as well as to differentiate between controls in all feed establishments versus controls in establishments producing feed additives/premixtures only. As a consequence, several MS could not provide estimates of time spent on legal/administrative obligations and controls (task b and c above), including in two of the case study MS (France and Germany). To allow for the differences in the estimates provided by MS, the staff time has been calculated as an average across those MS that provided complete data.

On this basis, over the 2016-18 period, the tasks of MS CAs have involved on average (across 14 MS) approximately 500 working days per MS per year. Of this total, roughly two-thirds (344 days: 69%) was spent on control activities; the remaining one-third was divided between fulfilment of legal/administrative obligations (92 days per MS per year) and the preparation/attendance of the meetings of the Standing Committee in Brussels (60 days per MS per year).

On average, across the 14 MS, cat 3 and cat 2 staff account for the bulk of the time spent on enforcement of the Regulation (34% and 32%, respectively), followed by cat 1 staff (26%); cat 4 staff account for 9% of total staff time[147]. The use of cat 4 staff is proportionately more prominent in the attendance of Standing Committee meetings (task a) and for the execution of the administrative/legal obligations (task b). On the other hand, the use of cat 2 and 3 staff is proportionately more prominent in the implementation of the control activities (task c). Nonetheless, these averages mask considerable variations in the distribution of staff time by category across MS.

The annual cost of these inputs has been estimated using EUROSTAT data[148] at €103,000 on average per Member State across the 14 Member States. The actual range of costs varies very significantly between MS, from €21,000 in Estonia to €265,000 in Ireland. The range of costs reflects not only the considerable variation in the number of days estimated by the MS CAs to be devoted to the implementation and enforcement of the Regulation, but also differences in the breakdown of staff categories employed on these tasks and important differences in annual earnings between MS.

Judgement criteria: "Costs for the Commission"

The costs cover the following activities for the Commission staff dedicated to the procedure of authorisation and other obligations under the Feed Additives Regulation during the period 2004-2017. The main tasks can be summarised as follows:

a) Administrative procedure:
- Verification of the compliance of the applications: 791[149] applications.

[146] Data provided by NCAs during the survey. Due to the need to respect confidentiality, data collected from the survey were analysed jointly (for all Member States that provided data), as presented here.
[147] Total number of days of all staff categories in this calculation is 469 days. This is slightly less than the previous total number of staff days for all tasks (496 days) due to small data gaps in the individual average calculations across the available data series per MS.
[148] 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.
[149] Administrative applications for Article 4(1) and Article 10(2).

- Mandates to EFSA: 1066 (DG SANTE data base):
  - for new applications/renewal/modification of authorisations;
  - requests to EFSA for evaluation of supplementary information (Article 29 of GFL); this action entails previous request to applicants for new data following an inconclusive EFSA opinion.
- Evaluation of EFSA opinions: 613 opinions (opinions finished-EFSA data for Article 4(1) and 10(2)).

b) Adoption of legal decisions: this entails drafting Regulations, drafting decisions on confidentiality and consultations with other DGs and the Legal Service:
   - Regulations for the obligations derived from the Feed Additives Regulation: 444
   - Confidentiality decisions: 515

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

d) Standing Committee in Animal Nutrition: 235 days

Over the 2004-17 period, these tasks have involved a total of 15,426 working days of AD[150] staff (or 1,102 working days/year) and 4,000 working days of AST staff (or 250 working days per year). These inputs have involved, on average, 4.6 FTE[151]s of AD staff and 1.1 FTE of AST/SC1 staff per year over the period. Average yearly costs over the 2004-17 period are estimated at €756,000[152], of which the cost of AD staff is 90% and the cost of AST staff 10%.

Considering the application as the first part of the procedure that triggers the majority of the Commission's actions, with different outcomes depending on the EFSA assessment, 58,6 applications were processed per year on average during the 2004-2017 period, at an estimated €13,000 in staff costs per application.

The number of working days spent on the main legal and administrative obligations of the Commission has been relatively stable year-on-year since the main phase of the implementation period (2012-17) 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).

On the other hand, the Commission's participation in meetings of the Standing Committee has involved, on average, 46 working days/year of AD staff time. During the period 2014-17, this has fallen in line with a reduction in the number of meetings conducted per year.

Judgement criteria: "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 having different expertise: animal nutrition/animal physiology/production, toxicology,

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

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

[152] Monetised on the basis of 2019 rates of remuneration of EU officials, OJ C 451, Volume 61, 14 December 2018, 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, EURL).**

pharmacokinetics/pharmacodynamics/metabolism studies, microbiology, antimicrobial resistance and environmental risk assessment.

The FEEDAP Panel meets frequently to discuss and adopt the opinions in the Plenary. The FEEDAP Panel has set up several working groups composed of scientific experts that carry out preparatory works for the Plenary. Those working groups also meet frequently.

The costs related to the EFSA tasks involve:

a) the cost of the FEEDAP Panel/WG meetings; and,
b) staff time to fulfil the legal and administrative obligations related to the risk assessment of feed additives.

Over the 2014-18 period[153], the cost of the FEEDAP Panel/WG meetings has fallen by 40%, from €861,000 in 2014 to €515,000 in 2018. 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 reimbursables). This task has involved 5,690 expert days over the five-year period, or on average 1,138 working days/year. 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[154] and reflects efforts to streamline costs by:

- using digital tools to work (i.e. tele-meetings, web-conferences) which is more cost-effective and time efficient; and,
- centralising some aspects of the work. E.g., the costs covering experts' flights were transferred to a different, common budget line dedicated only to flights for all EFSA[155].

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 feed additives 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. Although the required internal staff time has increased substantially, there has also been an increase in the number of AST/FG[156] staff 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 same as in 2014/15)[157].

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. increase in quality and harmonization of outputs
ii. shorter timelines
iii. improved control of the entire process

[153] Due to major system changes, EFSA were not able to provide data for the period 2004-13.
[154] EFSA's overall budget had a downward trend during the last five years (until recent announcement in relation to the changes introduced by the review of GFL and the announced increased in EFSA budget).
[155] The flight cost is still borne by EFSA, but it is showing under a different budget line; but centralising this aspect aims to ensure lower administrative costs.
[156] AST: Assistant performing administrative tasks, both admin and scientific tasks .
[157] It is not possible to have a separate breakdown of time spent by internal AD and AST staff.

iv. increased number of adopted outputs per year

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. Total staff costs over the 2014-18 period are estimated at €1.1 million per year[158]. Average annual costs for EFSA over this period are therefore estimated at €1.9 million.

Considering the EFSA applications (FAD applications) as the first part of the procedure that triggers the majority of the actions performed by EFSA, 69.2[159] applications per year were processed on average during the 2004-2017 period, at an estimated cost of €27,500 per application, of which €16,000 are internal staff costs.

Judgement criteria: "Costs for the EURL"

The costs in terms of staff time related to the EURL tasks involve:

a) participation in the meetings of the Standing Committee in Brussels;
b) legal and administrative obligations: these include the preparation of validation reports, and keeping samples; and,
c) the annual coordination meeting with National Reference Laboratories (NRLs).

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 these tasks has been relatively stable year-on-year throughout the period. Average annual costs over the 2004-17 period are estimated at €684,000[160], of which the cost of AD staff is 90.5% and the cost of AST staff 9.5%.

During this period, the bulk of the AD staff time (94%) was spent on the preparation of validation reports and keeping samples, which are the main legal and administrative obligations of the EURL: 13,226 working days, or 945 working days/year on average. Additionally, all of the AST staff time (3,500 working days) was spent on these obligations.

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.

Considering the validation report as the main output that triggers the majority of the actions performed by the EURL, which is also related to the applications and to the maintenance of samples derived for each application, 37 validation 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.

Judgement criteria: "Benefits"

According to a substantial majority of stakeholders and all Competent Authorities[161], the Feed Additives Regulation provides important benefits for farmers, per owners, animal welfare, human health, consumers and the environment, as well as for feed additive and

[158] Monetised on the basis of 2019 rates of remuneration of EU officials, OJ C 451, Volume 61, 14 December 2018. Details of the methodology on the calculation of costs in section 4.4.
[159] A total of 969 applications for Articles 4(1), 10(2) 13, 14 and 15 of the Feed additives Regulation and 71 applications for Article 29 of the GFL.
[160] *idem*
[161] Annex 3: Consultation synopsis report, surveys of stakeholders and Member State competent authorities (sections 3.2.2.4 and 3.3.2.4), OPC (section 3.4.2.4) and interviews.

compound feed producers. It is noted that although feed additives exert a broad range of impacts – including on animal welfare, health and safety, food safety, the environment – they tend to be viewed by the wider public as being too 'distant' or just one of many factors affecting these societal concerns. This is reflected in the very limited response received from consumer organisations and civil society NGOs, despite efforts to extend the consultation for this study (OPC, stakeholder survey and interviews) to these organisations. The benefits outlined below are based mainly on feedback received from each relevant group of stakeholders, unless otherwise indicated.

Benefits for FeBOs (applicants and others along the feed chain):

The benefits of the most important provisions of the Feed Additives Regulation (authorisation, labelling, and the ban on antibiotics/growth promoters) are acknowledged by operators along the feed chain[162]:

- Labelling provisions contribute to ensuring traceability as feed additives move along the supply chain for their use in pre-mixtures, complementary feed, and compound feed both for food producing animals and for pet animals. They also ensure the transmission of appropriate information to end-users: farmers, farm advisors, veterinarians.
- The authorisation procedure (including reauthorisation of additives approved under the previous Directive and renewal of authorisations granted under the Regulation) enables manufacturers of feed additives to place their products on the EU market for a period of 10 years. The independent scientific scrutiny placed on the safety and efficacy assessment by EFSA ensures the availability of high-quality feed additives for the EU feed supply chain as well as end users. It also ensures the recognition of the high quality of EU feed products amongst non-EU countries; this is identified as an important strength improving the competitiveness of EU products in world markets (see EQ2.3).
- Moreover, the ban of antibiotics/growth promoters under the Regulation has led to the development of innovative approaches, such as enzymes, probiotics[163], organic acids[164]. According to the industry, this market is continuously developing and some of the applications are still in their infancy.

The benefit to feed additive manufacturers, in terms of the EU-28 feed additives market value, is estimated at €7.8 billion in 2016 and projected to reach €10.1 billion in 2022[165]. This accounts for approximately 40% of the world feed additives market value. Key growth categories include important zootechnical additives (e.g. enzymes: €0.23 billion) and nutritional additives (e.g. vitamins: €1 billion; amino acids: €1.75 billion), as well as additives which may perform diverse functions falling under several categories of the Regulation (e.g. probiotics: €0.53 billion; organic acids: €0.43 billion) (all figures relate to the EU-28 market, see section 3.2).

However, there is some concern amongst the industry that the benefits of authorisation are not fully achieved in terms of encouraging innovation in the development of new

[162] Annex 4 (case studies), based on stakeholder feedback to survey and interviews with stakeholders along the feed chain.

[163] This industry-defined term refers to live microorganisms, including bacteria and yeasts, which can confer a health benefit for the host when administered in appropriate and regular quantities. This category is not defined as such in the Regulation. Some bacteria and yeasts fall under zootechnical feed additives, and to a lesser extent under the sub-category of the technological feed additives (1.k) silage additives.

[164] This industry-defined term refers to organic acid substances such as formic acid, fumaric acid, lactic acid and propionic acid with diverse functions. These may fall under the sub-category of the technological feed additives (a) preservatives, (j) acidity regulators and (k) silage additives, but also under zootechnical feed additives.

[165] Source: value of turnover in the EU-28 market, as estimated by RM Associates Report (2018) based on a range of market research sources. All values are approximate estimates; estimates of sub-categories are provided as a range. Details in section 3.2.

products (e.g. zootechnical additives), due to the high costs involved. This issue is further discussed under the judgement criteria "*benefits justify costs*".

Benefits for farmers: according to operators along the supply chain, including the consulted farmer and aquaculture organisations, the availability of safe and efficacious feed additives and feed contributes to the competitiveness of EU livestock and aquaculture producers, by lowering costs and improving yields/performance. Costs are lowered by reducing the required volume of feed materials/compound feed and other inputs including recourse to medicines.

In particular, the use of feed additives enables the provision of more balanced diets to animals, improves animal health and welfare, and ensures optimal performance by decreasing the rearing time, lowering feed costs and preventing exposure to potential losses caused by animal diseases. For example: the addition of amino acids in feed helps to achieve higher yields using far less feed, thus saving on feed costs. More generally, the use of feed additives contributes to improving the physiological condition of animals, which results in a lower use of therapeutic antibiotics and other medicines, and reduced costs and losses for farmers, as well as improving animal welfare. For example: the addition of vitamins in feed prevents vitamin deficiency, particularly in intensive production systems which are most susceptible to vitamin deficiencies that can cause severe limitations in production performance; the use of coccidiostats as a prevention measure in poultry farming plays a crucial role in preventing the potential costs that would arise in the case of spread of coccidiosis (yield costs/losses, veterinary costs, antibiotic treatments, etc.). Furthermore, feed additives are useful in enabling farmers address environmental restrictions such as the control of the emission of nitrates and phosphates on the environment.

There is, however, some concern over the availability of both mainstream and innovative feed additives, due to the authorisation costs and delays involved. Of particular concern is the availability of feed additives for use in minor species (e.g. turkeys, guinea fowls, ducks, and geese among others) as well as in the aquaculture sector, due to the high costs involved to conduct studies in these sectors. For instance, in the context of the reauthorisation of some technological additives (preservatives; some organic acids), minor species are not targeted whereas these products were formerly authorised for all species.

Benefits for animal health and animal welfare: according to operators along the supply chain, including the consulted farmer and aquaculture organisations and the pet food industry, the availability of safe and efficacious feed additives contributes to improving the physiological condition and welfare both of food-producing animals, animals reared for non-food or recreational purposes (e.g. fur animals, horses), and pet animals. Some feed additive operators and the pet food industry have noted however, that animal welfare is not currently the focus of the scientific assessment, as the required studies are mainly targeted to performance criteria. Some citizens consider that feed additives should not be used to compensate poor animal welfare conditions[166].

Benefits for pet owners: according to operators along the feed supply chain, including feed additive producers and the pet food industry, the use of safe and efficacious feed additives in pet food improves the availability of safe and nutritious foods for pets. Labelling provisions in feed additives and premixtures allow pet food manufacturers to properly label pet food and allow pet owners to understand the nutritional composition of pet food and to make informed choices when buying food for their pets.

Benefits for consumers / human health: according to operators along the feed supply chain and the consulted farmer organisations, the use of safe and efficacious feed additives

[166] Source: Consultation synopsis report (Annex 3)

in animal feed improves the availability of safe, high quality and nutritious foods of animal origin. The safety for consumers is considered by EFSA in the assessment, in terms of assessing the safety of the products on humans and the impact for human health of additive residues in animal food products. Also, the use of feed additives contributes to improving the physiological condition of animals, which results in a lower use of therapeutic antibiotics in animals and contributes to address the risks of AMR (in addition to the ban on antibiotics/growth promoters, which was introduced by the Regulation). Furthermore, the risk assessment process includes toxicological studies on safety for users, which ensure that all feed additives are safe for users. No negative impacts on consumers/human health were identified by any of the consulted stakeholders.

Benefits for the environment:

Livestock farming exerts various effects on the environment:

- Greenhouse emissions[167]: agricultural activities in the EU-28 generated 470.6 million tonnes of CO_2 equivalent in 2012, corresponding to about 10 % of total greenhouse gas. Livestock farming accounts for around 5% of total greenhouse gas emissions in the EU, mainly through enteric fermentation (3.24%) and manure management (1.73%). Ruminants are important contributors to the emissions of methane, a greenhouse gas with a warming potential 28 higher than CO_2[168], Manure management, which produces by decomposition, methane and nitrous oxide emissions (with a warming potential 265 higher than CO_2), is the third larger contributor to greenhouse gas emissions in agriculture.
- Excretions of animals contain important quantities of phosphorus and nitrogen. These substances are present in the manure and may pose important risks of leaching of soil[169] and eutrophication of waters[170]. This is especially the case in intensive farming systems as the quantities of manure produced exceed the capacity of soils to use them as natural fertilisers for the cultivation of plants and crops[171].
- Available environmental studies and Life Cycle Assessments (LCAs) [172] have shown that feed production is a significant contributor to the environmental footprint of animal products[173], therefore, an important element to take into account when considering mitigation options. Reducing feed consumption and waste are key elements in that respect.
- Manure accounts for around 1.73% methane emissions by agriculture in most countries[174] and is a source emission of nitrous oxide and ammonia. Those pollutants affect climate change, ocean acidification, stratospheric ozone depletion, biodiversity loss, water eutrophication, groundwater pollution and toxic, ground-level ozone pollution.

The use of feed additives can contribute to mitigate these environmental effects:

- Feed additives can be used **to improve the digestibility of the feed itself or its ingredients**. For instance, improving the digestibility of feed ingredients containing high levels of undigestible nutrients (e.g. fibres) can increase the quantities of

[167] EUROSTAT
[168] IPCC Fifth Assessment Report, 2014
[169] Leaching is the loss of water-soluble plant nutrients from the soil due to rain and irrigation.
[170] Eutrophication is when a body of water (e.g. sea, river, lake) becomes overly enriched with minerals and nutrients which induce excessive growth of algae.
[171] FAO, 2019.
[172] The European Commission developed a horizontal methodology, called Product Environmental Footprint (PEF), to measure and communicate the lifecycle environmental performance of products in a harmonized way.
[173] In an LCA study of the Australian poultry supply chain, feed production was identified as the most important area of environmental impact in the chicken meat supply chain (46-63% of greenhouse gas and energy). Source: Wiedemann et al., 2012
[174] Source: Chadwick et al., 2011

energy, amino acids and minerals brought by the feed. Consequently, the quantities of feed needed by the animals to cover their physiological needs can be reduced, thereby reducing the animals' footprint on the environment. Animals performance (growth rate or milk/egg production) as well as the quality of animal products may also be improved. Increasing forage digestibility by ruminants can also help reduce methane emissions.

- The use of feed additives can **also contribute to reduce the phosphorous and nitrogen excretion by the animals,** therefore reducing risks of soil leaching and water eutrophication. An example is phytase which reduces phosphorus excretion.
- Silage additives, antioxidants and preservatives can **contribute to preserve feed and avoid feed losses.**
- As the **level of emissions from manure** depends on the storage duration, temperature and manure composition, feed additives can help reduce ammonia and methane emissions by modifying the physico-chemical characteristics of manure.
- Some feed additives such **as amino acids can have combined effects**: when feeds are deficient in essential amino acids, the organism can not use the other amino acids present in the protein and this ends up with more nitrogen compounds excreted in manure. Nitrogen compounds from manure and urine are oxidized/reduced and nitrous oxide (N_2 O) is released into the atmosphere. Consequently, amino acids mitigate the global warming effects and contribute also to a better utilization of farmland.

According to all groups of stakeholders, the use of certain feed additives can reduce the carbon footprint, water pollution (nitrates and phosphates) and methane emission of livestock farming. For example, zootechnical additives can play a key role in improving sustainability and reducing negative impacts of livestock farming practices on the environment[175]. The environment is less polluted, as the amount of pollutants is lowered by the use of feed additives, and/or by the reduction in the required amount of compound feed. For example: enzymes can significantly reduce the use of feed and simultaneously reduce the excretion of molecules (phytate-bound phosphorus), which have a negative impact on the environment; amino acids lower plant-based protein requirements in feed, which helps conserve crop resources and frees up arable land for other uses.

The scientific risk assessment performed by EFSA includes consideration of toxicological studies on environmental impact, which ensure that all feed additives are safe for the environment. The authorisation of feed additives includes restrictions to ensure that there are no adverse effects for the environment e.g. in terms of the maximum dose permitted, or, for certain categories of additives (nutritional, zootechnical and coccidiostats & histomonostats), a post-market monitoring (PMM) plan to identify unforeseen effects resulting from the use of feed additives. The PMM has been requested by EFSA for coccidiostats & histomonostats and one additive belonging to the category zootechnical additives. PMM plans are addressed under EQ 1.2.

As discussed under EQ1.2 and EQ1.4, the use and control of those additives in compound feed/feed materials is regulated in other pieces of legislation: Feed Marketing Regulation, Feed Hygiene Regulation and Official Controls Regulation. The post-market monitoring, that includes also 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 Member States cover all the aspects related to safety and placing on the market, including labelling, to ensure that additives/premixtures comply with the safety requirements (for animals, consumers,

[175] The positive role that certain feed additives can play is supported by literature (e.g. Lewis et al, 2015; Klop G., 2016; Lemos and Tacon, 2016).

workers and the environment) and with the directions for their use, and to prevent a misuse along the feed chain.

As a conclusion, the effects on the environment are considered to be adequately assessed by EFSA and the level of compliance for additives and premixtures is high and provides relevant information to ensure a proper use by operators along the feed chain.

It is noted that no negative impacts on the environment were identified by any of the consulted stakeholders (whether competent authorities or the feed additives/premixtures industry or users of feed additives/premixtures).

Judgement criteria: "Benefits justify costs"

In analysing the cost:benefit balance, a distinction needs to be made between, on the one hand applicants and other operators along the feed chain (FeBOs), and, on the other, the wider society.

According to a majority within the feed chain, i.e. feed additive/premixtures and compound feed/pet food producers, although the benefits of the Feed Additives Regulation are appreciated, they do not fully justify the costs, in particular the costs associated with the authorisation procedure and, to a lesser extent the labelling provisions of the Regulation[176]. The analysis performed during the case studies for each of these provisions, as also reported in other sections of the Report (EQ1 to EQ3, and EQ9), provide further evidence on the cost:benefit balance, as summarised below.

Authorisation: costs versus benefits for FeBOs

The evidence presented in the preceding judgement criteria indicates that the most important costs stemming from the Regulation for operators as those borne by applicants i.e. related to the applications for new authorisations:

COSTS *(a) (b)*
Authorisation (average cost per application)
€1.1 million (across all types of feed additives) *(n=31)*
€2.6 million (zootechnical additive: holder-specific enzyme) *(n=6)*
€3.4 million (coccidiostats) (*n=1; 2 coccidiostats*)
Renewal of authorisation (average cost per application)
€0.2 million (across all types of feed additives) *(n=18)*
Labelling (average annual cost per plant for performing label changes)
Feed additives: minimal/negligible *(n=9)*
Premixtures: €80,000 to €223,000 per plant *(n=4) (c)*
Pet food: depends on the case, i.e. whether a critical feed additive (e.g. a vitamin) and number of products affected by the change. *(n=3) (d)*

a) 'n' indicates number of companies that provided data
b) Costs relate to the three most recent years (2016-18 period)
c) The indicated costs can be considered to represent an over-estimate of the actual costs of labelling changes due to regulatory requirements as such. It is not possible to separate the costs of changes triggered by regulatory changes from those triggered by other factors (namely, Member State interpretation of regulatory requirements and market-driven factors), as operators try to perform simultaneously labelling changes.
d) The indicated costs are not representative averages across a period and can be considered to represent the top range of costs of labelling changes.

[176] Data collection on this was targeted only to those operators that could provide informed answers, i.e. those that have filed applications for an authorisation, reauthorisation and/or renewal ('applicants') and those that are responsible for complying with labelling obligations along the feed chain.

Source: FCEC based on data collected from the industry

Although authorisation costs are an important upfront investment - in addition to R&D costs that also need to be borne in advance - companies proceed to an application when they expect a satisfactory return on their investment (ROI). The large number of additives authorised in the 2004-17 period (including 339 additives for which efficacy was not previously assessed and 1,136 additives for which safety was not previously assessed[177]), and the important market value of these additives (EQ1 and EQ2) indicate the ROI on additives whose authorisation was made possible by the Regulation is positive. However, the 'unpredictability' of the authorisation process and delays incurred can erode the initial expectations on the ROI.

The ROI depends on the product's market significance, i.e. expected sales over the 10-year authorisation period. Zootechnical additives tend to be 'flagship' products of high value and, in some cases, significant potential market outreach (i.e. targeting a large market e.g. enzymes). The ROI in such cases is high for companies specialising in specific products: when a product accounts for 60% of a company's sales, authorisation costs ranging around 2-5% of the product's total cost[178] are feasible to bear and to recover over the 10-year period, despite the high level of upfront investment. Companies indicated generally that it takes more or less 1-3 years to recover the cost of authorisation through sales, depending on the type of product. Fermented products such as enzymes are situated towards the longer end of this time range. For other feed additives (with a smaller market), authorisation costs account for a higher share of total costs and a less attractive cost:benefit balance.

In the case of non-holder specific authorisations, there is a cost-benefit imbalance for applicants in that the companies that bear the costs (or most of the costs) do not necessarily reap the benefits (or most of the benefits), as the benefits are typically shared with the wider industry (both feed additive manufacturers and feed additive users), thus causing a '*free-rider'* effect. The industry illustrated the case of the withdrawn application for authorization of the antioxidant TBHQ[179], due to the issue of non-protection of non-holder-specific additives versus the high costs of the application[180].

Further down the feed chain, for users of feed additives in premixtures and feed, to the extent that the high authorisation costs and 'unpredictability' of the process may discourage applicants and adversely affect the availability of additives on the EU market, users may also be negatively affected.

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[181]. For these reasons, SMEs - particularly the smaller companies - either tend to specialise in a few feed additives 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

[177] Source: EQ1.1 and EQ1.2. The number of additives quoted here cannot be added, as there is some overlap between certain categories/functional groups that were not previously assessed for efficacy and those not previously assessed for safety. The range in the number of feed additives not previously assessed for safety (1,136 to 1,277) is due to the use of two different datasets for this calculation.
[178] Based on estimates provided by two companies (Annex 4: authorisation case study).
[179] This case concerns the application for authorisation of the antioxidant tertiary-butylhydroquinone (TBHQ) as a technological feed additive in the EU.
[180] See Annex 4, authorisation case study.
[181] See Annex 4, authorisation case study.

SMEs rely on the non-holder-specific authorisations, their drawbacks as a disincentive to apply for such authorisation may penalise more SMEs.

Labelling: costs versus benefits for FeBOs

According to the industry along the feed chain[182], although labelling costs are relatively lower than authorisation costs, the benefits of traceability are already conferred through the use of other means by which this information is provided in B2B transactions (product specification sheets), in line also with industry standards and codes of practice. This enables, for example, the efficient recall of products along the chain in case any issues arise with any feed additive contained in premixtures/feed. Thus, the Regulation's requirement to provide this information on the product's physical label creates an unnecessary burden that is considered to be disproportionate and which does not add any benefits or have any added value in terms of traceability.

Overview: costs versus benefits for the wider society

According to the wider range of stakeholders consulted on this study, notably Competent Authorities and the industry along the feed chain including farmer organisations[183], benefits tend to justify costs given the important benefits of feed additives for farmers, per owners, animal welfare, human health, consumers and the environment.

EQ3.1 Answer:

The requirements of the Feed Additives Regulation entail compliance costs and administrative costs for feed business operators (FeBOs: applicants and others) and for the EU institutions (Commission, EFSA, EURL).

The most important costs stemming from the Regulation for applicants are related to the applications for new authorisation (Article 4), estimated at an average €1.1 million/ application (2016-18 average). The costs for a renewal of an authorisation represent on average about 20% of the initial authorisation costs. This average cost masks considerable variation by type of additive, which depends on the type and number of studies required; e.g. for enzymes, the average cost was estimated at €2.6 million/application. Additional indirect costs and losses for operators along the feed chain are generated by delays in the deadlines foreseen, including requests for supplementary data by EFSA ('stop the clock' procedure) and the final Commission decision, and 'unpredictability' in the final outcome; these indirect costs and losses were not possible to estimate.

The costs of labelling changes are relatively low in comparison to authorisation costs, although they tend to be more important for premixtures and pet food. Indicatively, in the case of premixtures, costs of labelling changes performed pursuant to changes in regulatory requirements range from €80,000 to €114,000 per year per plant (with automated labelling systems). Although mainly triggered by labelling changes due to regulatory requirements, these costs can be considered to represent an over-estimate of the actual costs of the Regulation, as they are compounded by requirements stemming from Member State authorities and operators' own production and marketing strategies. The costs can be more extensive for pet food labelling in the case of widely used feed additives (e.g. a vitamin), due to the large number of product references potentially affected by a regulatory change.

[182] I.e. feed additive /premixture manufacturers as well as compound feed and pet food producers.
[183] Annex 3: Consultation synopsis report, surveys of stakeholders and Member State competent authorities (sections 3.2.2.4 and 3.3.2.4), OPC (section 3.4.2.4) and interviews.

At the level of Member State Competent Authorities, the cost of the activities related to the implementation and enforcement of the Regulation is estimated at €103,000 on average per year per Member State, for approximately 500 working days of staff time per MS (across 14 MS that provided complete data: *n=14 MS*). The staff time and categories devoted to MS CA tasks vary considerably between MS. The main task accounting for most of the staff time is the controls carried out to ensure operators' compliance to the Regulation's requirements.

At the level of the EU institutions, the main legal and administrative obligations for the implementation of the Regulation have involved the following costs:

- The bulk of the Commission staff time involved over the 2004-17 period was spent on tasks related to the authorisation of feed additives. Most of this staff time (79%) involved AD staff, hence the cost of AD staff accounts for 90% of the total staff costs over the period (€756,000 on average per year, or €13,000 per application).
- The staff time required to fulfil these tasks increased slightly since the early years of implementation but has remained relatively stable since 2012.
- Costs over the 2014-18 period for EFSA are estimated at €1.9 million on average per year (€27,500 per application), of which €1.1 million in internal staff costs (€16,000 per application) and €762,000 in FEEDAP Panel/WG meetings. Although the internal workload of EFSA indicates an increase in staff time required for the risk assessment of feed additives, there are efforts to reduce costs and increase productivity by using more internal staff to replace external expertise, shifting towards more AST/FG staff and centralising some operations. These efforts have led to a notable fall in the costs of FEEDAP Panel/WG meetings over the last five years.
- Staff costs over the 2004-17 period for the EURL are estimated at €684,000 on average per year (€18,500 per validation report). The bulk of the EURL staff time related to the preparation of validation reports and keeping samples. Most of this staff time (79%) involved AD staff, hence the cost of AD staff accounts for 90% of the total costs over the period. The staff time required to fulfil these tasks has remained relatively stable throughout this period.

Although authorisation costs are important for operators, benefits tend to justify costs. This is evidenced by the large number of additives authorised during the 2004-17 period and their market value. Generally, authorisation costs ranging around 2-5% of the product's total cost are feasible to bear and to recover over the 10-year authorisation period, despite the high level of upfront investment. 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 are not significantly different between SMEs and large companies as the underlying factors determining costs tend to be independent of company size. However, the impact is different, as the high costs of authorisation for certain additives require significant investment and access to finance tends to be a problem for smaller companies that are not part of a large company. Specialisation to specific additives/animal species and/or reliance on generic, non-holder-specific authorisations allow SMEs to reduce costs.

More generally, given the important benefits of feed additives for farmers, per owners, animal welfare, human health, consumers and the environment, the wider view is that benefits tend to justify costs. The availability of safe and efficacious feed additives

contributes to: mitigate the adverse environmental and climate impacts of livestock and feed production; and, improve the physiological status and welfare of animals. However, unlike the effects on the environment which are considered to be adequately assessed by EFSA, animal welfare is not currently the focus of the scientific assessment (as the required studies mainly address performance criteria).

EQ3.2 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)?

To ensure the efficiency of the authorisation process, whether for new authorisations, reauthorisation of pre-existing additives/substances and/or renewal of authorisations, the Feed Additives Regulation and implementing Regulation (EC) 429/2008 lay down rules and procedures to be adhered to by applicants, EFSA and the Commission. These cover *inter alia* the timeline of the different steps of the process.

Judgement criteria: "The procedures for placing new feed additives on the market (Art 4) and for renewing an authorisation (Art 14) are considered efficient"

A small majority of applicants that have filed applications for new authorisations, reauthorisation and renewal of authorisations (under Articles 4, 10 and 14) do not consider the current implementation of the procedures and timelines laid down in these provisions to be efficient[184]. The main issues raised relate to the timeliness of the process and adherence to the deadlines as set out in the Regulation. These issues, which have already been identified as a key aspect undermining the effectiveness of the process (EQ1.3), are discussed below.

Judgement criteria: "Deadlines foreseen by the Regulation in the authorisation process are reasonable. The deadlines applied in practice do not significantly deviate from the legal deadlines"

As already indicated in EQ1.3, according to the legislation, the period required from receiving the application for authorisation to the date of publication of the authorisation includes: 30 days for dossier completeness check and acceptance date by EFSA; 6 months for adoption of the EFSA opinion; and, 6 months for the publication of the decision for authorisation in the Official Journal. According to these time limits, authorisation normally requires around 1 year without clock stoppages. This period is considered reasonable by the industry for placing products on the market.

In practice, data provided by DG SANTE on the basis of their internal database indicates that delays for authorisation of an additive are typically longer than the timeline considered as reasonable in accordance with the deadlines foreseen in the legislation (1 year). 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) i.e. **3.3 times higher** than the reasonable deadlines of 1 year.

The length of the assessment process has an important impact on the whole authorisation period. EFSA opinions are meant to be issued within a legal deadline, which is 6 months (i.e. 180 calendar days) from validation of the application. During the 2004-17 period, the

[184] Annex 3, section 3.2.2.4, as further elaborated during interviews. Also, authorisation case study (Annex 4).

share of EFSA's opinions adopted within legal deadlines was 20% for opinions issued under Article 4(1) and 12 % for opinions issued under Article 10(2).

According to all consulted parties (including EFSA and the Commission), these delays are due to two main reasons:

1. During the assessment EFSA request complementary information from the applicant and stops the clock; and,
2. After publication of the EFSA opinion, the opinion can be non-conclusive (estimated 15%), so the applicant is requested to provide complementary information. When the complementary information is submitted by the applicant, the Commission has to request a new opinion to EFSA.

As not all applicants have experienced delays, they are rather divided on whether the different deadlines foreseen by the Regulation are reasonable[185]. These issues and the underlying reasons for the delays – including, notably, that data provided by applicants for the assessment of efficacy and safety for users/environment tend to be incomplete/not fit - have been addressed in more detail in the effectiveness EQs (EQ1.1 to EQ1.4).

Judgement criteria: "The procedure to modify an authorisation when the authorisation holder changes do not imply undue burden"

During the 2004-17 period 444 Regulations were adopted in relation with the obligations laid down by the Feed Additives Regulation, of which 397 Regulations were adopted for the authorisation or modification of authorisation of feed additives; of these, 281 Regulations are linked to an authorisation holder (holder-specific). During the 2004-17 period, 28 Regulations have been adopted to modify the holder of authorisation. This represents 10% of all the adopted Regulations on additives linked to an authorisation holder. Although this procedure involves a modification only to indicate the new authorisation holder, not the submission of a new dossier[186], it nonetheless involves a process requiring the adoption of an Implementing Regulation, which implies undue burden for applicants, the Commission and the Member State competent authorities. This can be done following a less burdensome administrative procedure.

Judgement criteria: "Majority of stakeholders consider the procedure for authorisation does not need to be modified significantly"

In line with the views expressed on the efficiency of the current implementation and timelines of the authorisation procedure, according to a small majority of applicants the procedure for authorisation needs to be modified significantly[187]. The main driver for a modification would be to address the issues that cause the current delays. This includes certain issues that contribute to submissions of incomplete dossiers by applicants, such as in terms of addressing data needs for the efficacy assessment. For example, improving the performance end-points to assess efficacy, as particularly highlighted for zootechnical additives (EQ1.1) could (at least partly) address the delays caused by the clock-stopping process. Revisiting the 10-year authorisation period and requirements for renewal of applications could (at least partly) address the potential bottlenecks in the system, which are expected in the future when the 10-year authorisation period expires for important groups of additives. These improvements, according to business stakeholders, can improve the process and reduce the burden. These issues are discussed under EQ9.

[185] Annex 3, section 3.2.2.4, as further elaborated during interviews.
[186] Unlike the case of a modification of the authorisation e.g. to extend to a new species, for which effectively the submission of a more complete dossier by applicants is required.
[187] Annex 3, section 3.2.2.4, as further elaborated during interviews. Also, authorisation case study (Annex 4).

EQ3.2 Answer

To ensure the efficiency of the authorisation process, the Feed Additives Regulation and implementing Regulation (EC) 429/2008 lay down rules and procedures to be adhered by applicants, EFSA and the Commission, including the timeline of the process.

Most applicants that have filed applications for new authorisations, reauthorisation and renewal of authorisations (under Articles 4, 10 and 14 of the Regulation) do not consider the current implementation of the procedures laid down in these provisions to be efficient. The main issues raised relate to the timeliness of the process and adherence to the deadlines as set out in the Regulation.

Based on DG SANTE data, it can be concluded that the deadlines applied in practice for the authorisation procedure deviate significantly from the legal deadlines. The reasons for the deviation relate mainly to EFSA requests for complementary information, with a series of clock-stopping events in some cases. These requests are mainly triggered by incomplete and/or not fit information provided by applicants for certain aspects of the assessment (notably, of efficacy and safety for users). The obligation to change the authorisation when the holder of the authorisation changes is burdensome for applicants, the Commission and the competent authorities.

Consequently, the authorisation procedure is not considered sufficiently cost-effective, efficient or flexible. According to a small majority of applicants, the procedure needs to be modified significantly. The main driver for a modification would be to address the issues that cause the current delays, including those issues that contribute to submissions of incomplete dossiers by applicants (see EQ 1.3 for more detailed information).

6.1.2 CONCLUSION

The requirements of the Feed Additives Regulation entail compliance costs and administrative costs for feed business operators (FeBOs: applicants and others) and for the EU institutions (Commission, EFSA, EURL)[188]. The most important costs stemming from the Regulation for applicants are related to the applications for new authorisation (Article 4(1)), estimated at an average of €1.1 million/application. Additional indirect costs and losses for operators along the feed chain (applicants and users of feed additives/premixtures) are generated by delays in the deadlines foreseen, including requests for supplementary data by EFSA ('stop the clock' procedure) and the final Commission decision, and 'unpredictability' in the outcome; these costs were not possible to estimate.

The costs of labelling changes are relatively low in comparison to authorisation costs. Although costs tend to be more important for premixtures (indicatively, costs of labelling changes due to the changes caused by the Regulation range from €80,000 to €114,000 per year per plant), these costs can be considered to represent an over-estimate of the actual costs of the Regulation, as they are compounded by requirements stemming from Member State authorities and operators' own production and marketing strategies. Examples of additional labelling requirements include: providing all information in all languages; using larger font size; listing a representative company in each country. The costs can be more extensive for pet food labelling in the case of widely used feed additives

[188] The calculation of average costs for each of these organisations (applicants; MS CAs; Commission; EFSA; EURL) is based on data availability over different time periods, details in the main text of EQ3.1.

(e.g. a vitamin), due to the large number of product references potentially affected by a regulatory change.

On the other hand, the main impact of the Regulation's labelling provisions for the feed additives industry is in terms of the amount of information and the form in which it is required on the label versus the need for some of this information to be on the physical product label, as stipulated by Article 16 of the Regulation. According to both feed additives/premixtures operators and operators using premixtures in compound feed, most of the information that users need to have is transmitted via other relevant documents, notably, the product specification sheets used by the industry in B2B transactions.

At the level of Member State Competent Authorities, the average annual cost of the activities related to the implementation and enforcement of the Regulation is estimated at €103,000 per Member State, for approximately 500 working days of staff time per MS (across 14 MS that provided complete data: n=14 MS). The main task accounting for most of the staff time are the controls carried out to ensure operators' compliance to the Regulation's requirements.

At the level of the EU institutions, the average annual cost to perform the main legal and administrative obligations related to the implementation of the Regulation were estimated at: the Commission, mainly for the authorisation of feed additives (€756,000 in staff costs, i.e. €13,000 per application); EFSA (€1.9 million, of which €1.1 million in internal staff costs and €762,000 in FEEDAP Panel/WG meetings, i.e. €27,500 per application, of which €15,900 are internal staff costs); and, the EURL mainly on validation reports and keeping samples (€684,000 in staff costs, i.e. €18,500 per validation report). Cost-cutting efforts have been made in all cases.

Although authorisation costs (in particular) are important for operators, benefits tend to justify costs. This is evidenced by the large number of additives authorised during the 2004-17 period and their market value. 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. 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.

Nonetheless, most applicants that have filed applications (under Articles 4, 10 and 14 of the Regulation) do not consider the current implementation of the procedures laid down in these provisions to be efficient. The main issues raised relate to the timeliness of the process and adherence to the deadlines as set out in the Regulation. Based on DG SANTE data, it can be concluded that the deadlines applied in practice for the authorisation procedure deviate significantly from the legal deadlines.

The main reasons for the deviation relate to EFSA requests for complementary information, with a series of clock-stopping events in some cases. These requests are mainly triggered by incomplete, insufficient and/or inappropriate information provided by applicants for certain aspects of the assessment, particularly in complex cases. The challenges for applicants notably relate to the assessment of: efficacy, e.g. the studies should demonstrate the efficacy for each proposed use of the additive, but the approach to be taken is not always detailed in the EFSA Guidance, such as in the case of novel uses; and, safety for users, e.g. data provided by applicants in the case of the active substance/agent may not reflect the properties of the final formulations of the additive as placed on the market. Although there are also some delays in the Commission management process, these are not as significant, with approximately 37% of authorisations under Article 4(1) published in the OJ within 180 days from when EFSA opinions are issued and 78% within 4 months beyond the 180 days.

The obligation to change the authorisation when the holder of the authorisation changes is burdensome for applicants, the Commission and the competent authorities.

Consequently, the authorisation procedure is not considered to be sufficiently cost-effective, efficient or flexible. According to a small majority of applicants, the procedure needs to be modified significantly. The main driver for a modification would be to address the issues that cause the current delays, including those issues that contribute to submissions of incomplete dossiers by applicants as outlined above.

The costs of authorisation/labelling and the Regulation's overall cost:benefit balance are not significantly different between SMEs and large companies, as the underlying factors determining costs tend to be independent of company size.

The availability of safe and efficacious feed additives contributes to: mitigate the adverse environmental and climate impacts of livestock and feed production; and, improve the physiological status and welfare of animals. However, unlike the effects on the environment which are considered to be adequately assessed by EFSA, animal welfare is not currently the focus of the scientific assessment (as the required studies mainly address performance criteria).

In conclusion, given the important benefits of feed additives for farmers, per owners, animal welfare, human health, consumers and the environment, the wider view is that benefits tend to justify costs. Nonetheless: the cost:benefit balance of non-holder-specific authorisation is an issue for applicants; and, the cost-effectiveness of the authorisation procedure in particular, and to some extent of the labelling provisions, was not considered to be sufficient and can be improved.

7. REPLIES TO EVALUATION QUESTIONS RELATED TO COHERENCE

Coherence is addressed through three evaluation questions. These essentially aim at identifying any coherence issue across the EU legal framework applicable to feed additives that may have impacted negatively on the objectives of the Feed Additives Regulation. The analysis presented below is based on: (1) information gathered during the consultations of Member States' competent authorities, industry and other stakeholders [189], (2) the experience acquired in the implementation of the Regulation by the Commission; and, (3) the review of the minutes of SCOFCAH / PAFF meetings.

The evaluation questions look into the coherence of the Feed Additives Regulation with other EU feed related legislation (EQ4), between EU feed legislation and EU food law and chemical legislation (E5) and, finally, between the very same provisions of the Feed Additives Regulation (EQ6). A brief description of other relevant legislation can be found in section 2.3.

7.1 Evaluation question 4: extent to which the provisions of the Feed Additives Regulation are coherent with other EU feed related legislation

7.1.1 ANALYSIS

EQ4: To what extent are the provisions of the Feed Additives Regulation coherent with the other feed related legislation (feed hygiene, marketing of feed, residues in feed, genetically modified food and feed and medicated feed)190 allowing for clear and consistent rules for use of additives in feed? What are the consequences of incoherencies, if any?

Judgement *criteria: "Lack of contradiction between the Feed Additives Regulation and the general provisions of the EU legislation on the marketing of feed''*

EU legislation on the marketing of feed provides additional definitions for the feed sector, amongst which 'feed business operator', 'feed material' and 'feed compound'. It prohibits the use of certain materials for animal nutrition and lays down mandatory rules on labelling as well as conditions to make voluntary claims.

Views expressed by consulted parties point to the existence of a few major inconsistencies.

Several Member State competent authorities and manufacturers of feed additives 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 feed additives 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 feed

[189] Including surveys of stakeholders and Member State competent authorities (Annex 3: Consultation synopsis report, sections 3.2.2.6 and 3.3.2.6) and interviews.

[190] This refers in particular to: Regulation (EC) No 183/2005 (the Feed Hygiene Regulation); Regulation (EC) No 767/2009 (the Feed Marketing Regulation); Regulation (EC) No 1829/2003 (the Regulation on genetically modified food and feed); the Directive on undesirable substances in animal feed (Directive 2002/32/EC); and, EU legislation on medicated feed (Directive 90/167/EEC, to be replaced by Regulation (EU) No 2019/4), and on veterinary medicinal products (Directive 2001/82/EC, to be replaced by Regulation (EU) 2019/6).

additives has been laid down by the Commission[191], there are certain substances that are currently listed in both the EU Register for feed additives and in the EU Catalogue for feed materials[192] (e.g. sodium citrates, cellulose powder, ammonium dihydrogen orthophosphate, algae and certain botanical extracts). This leads to uncertainty as to the actual legal status of a substance. It may also undermine a level playing field between FeBOs as some operators may opt for the classification of a substance as a feed material rather than as a feed additive, which involves a higher regulatory burden. Those operators that choose the wrong status for the classification of the product may be forced by Member State competent authorities to change their approach; otherwise, they can be prosecuted, and penalties may be imposed.

Member States and FeBOs confront the situation referred to above regularly and, in some instances, request a clarification at EU level. 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 that out of 224 items that have appeared in the agenda of those committees, the largest number (49) concerned the interaction between the Feed Additives Regulation and the Feed Marketing Regulation and notably the classification of a given substance as a feed additive or a feed material. Essential fatty acids, sulphur and bile acids / salts for aquaculture are examples of substances whose classification has been discussed during SCOFCAH/PAFF meetings. Accordingly, at EU level, specific provisions have been adopted during the application of the Feed Additives 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[193]. Nonetheless, based on the findings of the study, legal uncertainty seems still to persist in this area.

Further to this, according to industry stakeholders, there are a number of ingredients that are currently classified as feed materials and which would be better classified as feed additives as they can be more precisely defined (additives must be standardised and they must perform specific function) and this would ensure tighter control (e.g. ammonium acetate, ammonium lactate). Likewise, there are certain authorised feed additives that would be better classified as feed materials as they are widely used in feed and which, according to the feed industry, do not pose high safety risks (e.g. products used in high dosage such as urea, monoammonium phosphate, diammonium phosphate, ammonium sulphate). However, no scientific evidence or relevant literature to support this position was identified.

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.

Judgement criteria: "Lack of contradiction between the Feed Additives Regulation and the labelling provisions of the EU legislation on the marketing of feed''

Views expressed by consulted parties point to the existence of one major inconsistency.

[191] Commission Recommendation establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products (2011/25/EU).
[192] Commission Regulation (EU) No 68/2013 of 16 January 2013 on the Catalogue of feed materials, OJ L 29, 30.1.2013, p. 1
[193] Commission Regulation (EU) No 892/2010 of 8 October 2010 on the status of certain products with regard to feed additives within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council, OJ L 266, 9.10.2010, p. 6

Several national competent authorities and manufacturers of feed additives and feed materials identified an overall lack of alignment of labelling requirements under the two frameworks (notably, article 16 of the Feed Additives Regulation as opposed to Articles 11-23 of the Feed Marketing Regulation)[194]:

- The Feed Additives Regulation only allows provision of information on the packaging of feed additives, while the Feed Marketing Regulation foresees also the use of modern communication (e.g. internet-based) tools for the labelling of feed materials and compound feed; [195]
- EU legislation on the marketing of feed provides for a legal basis for the development of Community Codes of good labelling practice,[196] while a similar provision is not laid down for feed additives.

The greater flexibility in the practical application of the labelling provisions laid down in the Feed Marketing Regulation has allowed the industry to use more up to date (e.g. internet-based) technologies that, whilst allowing more cost-effective approaches for the transmission of information along the supply chain, are consistent with the rules. It has also allowed integrating the regulatory provisions for the labelling of feed materials and compound feed in Community guides of good practices[197], as well as in the industry developed quality standard FAMI-QS that is widely used throughout the feed chain (this standard integrates regulatory provisions laid down in feed legislation, including on hygiene, traceability and labelling).

On the other hand, in the case of the rules laid down in the Feed Additives Regulation, operators have faced more difficulties to apply what are perceived to be, technically and operationally, obsolete requirements for labelling. This has resulted in some costs/burden in the labelling of feed additives, premixtures and pet food, as discussed under EQ3.1.

Judgement criteria: "Lack of contradiction between the Feed Additives Regulation and the EU legislation on feed hygiene''

The primary objective of the EU feed hygiene legislation is to provide a high level of consumer protection, by ensuring that feed safety is guaranteed at all stages, from primary production of feed up to the feeding of food-producing animals. To this end, the rules require all FeBOs (except primary producers) to implement procedures based on Hazard Analysis and Critical Control Points (HACCP) principles; and, encourage the development of EU and national guides of good practices in this area[198]. The Regulation also requires the registration of all feed establishments with national competent authorities, whilst establishments handling sensitive substances, including certain feed additives, pre-mixtures and compound feed need approval.[199] Specific traceability

[194] See, for instance, *Proposals on New Concepts for Labelling*, FEFANA, Labelling Workshop, Brussels, October 18, 2016.
[195] In particular, Article 16 par. 1 of the Feed Additives Regulation as opposed to Article 11, par. 3, of the Feed Marketing Regulation.
[196] See Article 25 of the Feed Marketing Regulation.
[197] Community guides of good practices have been drafted on the basis of the principles and objectives laid down in the feed hygiene Regulation. Four guides have been endorsed by PAFF: FEFAC guide (compound feed and pre-mixtures for food producing animals); FEDIAF guide (pet food); EFISC guide (feed materials: oilseeds, oils, starch and biodiesel); and, the guide for handling cereals, oilseeds and protein crops. In addition, PAFF has reviewed the guide FAMI-QS for feed additives and premixtures; and, further guides exist at national level in nine Member States. The list of EU and national guides to good practices in the feed sector is available at the DG SANTE website: https://ec.europa.eu/food/safety/animal-feed/feed-hygiene/guides-good-practice_en
[198] The guides are indicated under previous judgment criteria on "labelling of feed materials and compound feed''.
[199] The full list of approved feed establishment is available at the DG SANTE website: https://ec.europa.eu/food/safety/animal-feed/feed-hygiene/approved-establishments_en

requirements also apply to feed additives manufacturers (e.g. nature and quantity of feed additives produced/supplied, date of manufacture, batch number etc.)[200].

Views expressed by national competent authorities and industry point to one inconsistency (in relation to imports) and one difference in approach (in relation to exports) between the Feed Additives Regulation and the EU legislation on feed hygiene.

In particular, the inconsistency pointed out by both national competent authorities and industry stakeholders lies with imports of feed, including feed additives, 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 Member States[201]. 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 feed additives 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 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 feed additives and premixtures not authorised to be placed on the EU market (NAFA products), the Feed Additives Regulation has no provisions laid down for export (see also EQ2.2). However, this is not an inconsistency between the legal frameworks on feed additives and on feed hygiene, but a difference in approach which is essentially due to a gap in the Feed Additives Regulation. Consequently, this issue is discussed under EQ5.1.

Judgement criteria: "Lack of contradiction between the Feed Additives Regulation and EU legislation on GMOs''

The marketing of genetically modified feed is currently regulated under the general framework that the EU has designed for genetically modified organisms (GMOs). The legislation lays down provisions for the performance of the risk evaluation at EU level concerning food and feed, whether destined to food-producing animals or to animals that are not intended for food production, containing, consisting of or produced from GMOs. It also defines the authorisation procedure as well as supervision provisions and labelling requirements[202]; this is complemented by rules on the traceability of GMOs and feed and food produced from them[203].

[200] As per Annex II of the Feed Hygiene Regulation.

[201] 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.

[202] As laid down in Chapter III of the Regulation on genetically modified food and feed.

[203] Regulation (EC) No 1830/2003 of the European Parliament and the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

Information collected during the study did not identify inconsistencies between the Feed Additives Regulation and EU GMO legislation on food and feed.

Judgement criteria: "Lack of contradiction between the Feed Additives Regulation and EU legislation on medicated feed and veterinary medicinal products (VMPs)

As noted in section 2.3, new EU Regulations on VMPs and medicated feed have been adopted in 2019, replacing the previous Directives; the new legal framework will apply from 28 January 2022.

In accordance with the legislation previously in force[204], a VMP is any substance or combination of substances with properties for treating or preventing animal diseases or which may be used in or administered to animals to either restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis. Medicated feed[205] is the second most important route for administering veterinary medicines to animals and sometimes the most effective way in which breeders can treat their livestock.

The VMP Directive expressly excludes from its scope medicated feed and feed additives. For situations where doubts exist about the specific nature and classification of a certain substance, the guidelines issued by the European Commission in 2011[206] clarify that such a substance should be regarded and treated as a VMP in case all its characteristics point out to such a conclusion, in line with the principle of prevalence of VMP legislation over feed legislation. However, feed additives represent an exception to this rule.[207]

Views expressed by national competent authorities and industry did not point to any major inconsistency or contradiction between the Feed Additives Regulation and EU legislation on medicated feed and VMPs.

However, some respondents from the feed additives industry 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 feed additives with nutritional functions that help maintain animals in good health.

A specific consistency issue is the decision taken in June 2017 by the EU Standing Committee for Medicinal Products for Veterinary Use (CVMP) to phase out the use of zinc oxide in VMPs by 2022 for reasons of safety to the environment. The EU-wide ban on the use of zinc oxide in VMPs was based on a final opinion adopted by consensus, which recommended the refusal of the granting of marketing authorisations and the withdrawal of the existing marketing authorisations for VMPs containing zinc oxide. The Committee concluded that the animal health benefits of zinc oxide used for medicinal purposes do not outweigh the risks for the environment. This issue merits therefore further examination to the extent that it bears relevance to the authorised use of zinc oxide as a feed additive. The use as feed additive is restricted to satisfy the nutritional requirements (category: 'nutritional additives') as zinc is an essential trace element for animals. The increasing authorisation of chelated forms (zinc bounded to an organic substance such as an amino

[204] Article 1(2) of the VMP Directive, which currently governs the marketing of VMPs in the EU. A new definition of VMP is now laid down in Article 4 (1) of the new VMP Regulation.
[205] Currently, this is subject to the provisions of the Directive on medicated feed.
[206] Commission Recommendation 2011/25/EU establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products, January 2011.
[207] Point 3.2 of the Commission Recommendation of 14 January 2011 cited above.

acid) reduce the impact on the environment as they are better assimilated by the animals and zinc excretion is reduced.

Judgement criteria: "Lack of contradiction between the Feed Additives Regulation and EU legislation on undesirable substances in feed''

In accordance with the current EU legislation[208] and from the standpoint of animal nutrition, 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 health, animal health or the environment or adversely affect livestock production. In concrete terms, the list of undesirable substances currently includes certain inorganic contaminants (e.g. heavy metals), mycotoxins, plant toxins, organochlorine compounds and dioxins and PCBs that may be found in feed (including feed additives); and, 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. Furthermore, contaminated feed cannot be mixed for dilution purposes with products destined to animal nutrition of the same or of different nature[209].

Overall, the information collected during the study did not point to any major inconsistency or contradiction between the Feed Additives Regulation and EU legislation on undesirable substances.

Judgement criteria: "Difference in interpretations by MS CAs of the Feed Additives Regulation and of other EU feed legislation''

The interaction between the Feed Additives Regulation and other feed-related legislation has given rise occasionally to divergent interpretations at Member State level.

In particular, the analysis of the issues discussed at SCOFCAH/PAFF level during the period covered by the study shows that out of 224 items that have appeared in the agenda of those committees 61 concerned, among others, issues stemming from diverging national interpretations. As discussed in previous judgment criteria (*''Lack of contradiction between the Feed Additives Regulation and the general provisions of the EU legislation on the marketing of feed*''); amongst those, the largest number (49) concerned the classification of a given substance as a feed additive or a feed material.

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 Member States persist. This is mostly due to the lack of fully harmonised EU rules in commonly acknowledged complex areas (e.g. export of non-authorised feed additives 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).

Judgement criteria: "Impact of lack of coherence in EU feed legislation"

Over time, the interaction between the Feed Additives Regulation and other feed-related legislation analysed in the context of EQ4 has given rise occasionally to a certain degree of legal uncertainty.

In particular, the analysis of the issues discussed at SCOFCAH/PAFF level during the period covered by the study shows that 58 out of 224 items that have appeared in the agenda of those committees could be partly attributed to the lack of legal clarity. As discussed under

[208] Undesirable substances and maximum limits are listed in Annex I of the Directive on undesirable substances in animal feed.
[209] Article 5 of the Directive on undesirable substances in animal feed.

previous judgment criteria, the largest number (49) of those concerned the classification of a substance as a feed additive as opposed to a feed material, an issue also frequently identified by industry stakeholders.

7.1.2 CONCLUSION

Overall, during the period covered by the study the Feed Additives Regulation has proven to be coherent with other EU feed-related legislation to a satisfactory extent.

Few major inconsistencies were nevertheless identified, in particular, in relation to the interaction between the Regulation and EU legislation on feed materials and compound feed (the Feed Marketing Regulation and the Catalogue of feed materials). The most frequently identified concerns the alleged lack of sufficiently clear legal criteria at EU level allowing classifying a substance as a feed additive or a feed material. Another relates to labelling rules for feed additives, which, as currently designed, do not allow business operators to implement practical solutions in the same way labelling rules for feed materials and compound feed do, leading to some additional costs for those operators.

Furthermore, the Feed Additives Regulation has proven to be consistent only in part with the Feed Hygiene Regulation. In this context, the main inconsistency identified during the study results from different national approaches implemented by Member States with regard to EU imports of feed / feed additives from non-EU countries, owing to complexity and the lack of fully harmonised rules in this area. According to industry stakeholders, this situation has led to a degree of legal uncertainty that does not contribute to the creation of a level-playing field for all business operators of the feed sector.

Conversely, evidence collected during the study did not point out to any major inconsistencies between the Feed Additives Regulation and EU legislation on GMO feed, undesirable substances and medicated feed and VMP.

7.2 Evaluation question 5: extent to which the provisions of the Feed Additives Regulation are consistent with other related legislation on food and chemicals

EQ5: To what extent are the provisions of the Feed Additives 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 incoherences, if any?

As indicated in section 2.3, on the top of EU feed-related legislation, a wider legal framework exists at EU level that is relevant for the regulation of feed additives. This encompasses, in the first place, the General Food Law (GFL), which lays down the fundamental rules for the governance of both the food and feed chain in the EU. As feed additives may be also of chemical nature, certain EU legislation on chemicals applies to them, notably the CLP' Regulation, and some of the provisions of the REACH' Regulation. Finally, EU legislation of biocidal products, notably the Biocides Regulation is relevant in this context too insofar as it establishes the criteria to determine whether certain substances are subject to EU requirements for biocidal products or to other product-specific legislation, including the Feed Additives Regulation.

EQ5 is addressed through two sub-questions, which aim to identify potential loopholes or grey zones (EQ5.1) and overlaps or inconsistencies (EQ5.2).

7.2.1 ANALYSIS

EQ5.1: Are there loopholes or grey zones to be addressed? How does this impact competitiveness?

EQ5.2: Are there overlaps or inconsistencies, which hinder the effective and efficient application of the Feed Additives Regulation?

Judgement criteria: "Lack of contradiction / inconsistency between the Feed Additives Regulation and the GFL"

Adopted prior to the Feed Additives Regulation, the GFL laid down the basic principles of the "farm to table" approach, aiming to provide a coherent regulatory framework across the feed and food supply chain. Most notably, the following GFL rules have been carried through in the Feed Additives Regulation: definitions (feed, feed business operator, placing on the market, traceability); a common, centralised approach for authorisation and placing on the market of feed additives; the formal separation of the risk assessment and risk management functions; the establishment of EFSA and of FEEDAP; the consideration of legitimate factors (societal, economic or environmental aspects) and the precautionary principle (human health, animal health and environmental issues) in the final management decision by the Commission; subjecting imports from non-EU countries to the same/equivalent requirements for placing feed additives on the EU market as for EU products; and, emergency measures when there is a risk that Member State measures alone cannot address.

The information collected during the study pointed to the existence of one loophole in the interaction between the GFL and the Feed Additives Regulation.

Notably, while the export to non-EU countries of feed additives and premixtures not authorised to be placed on the EU market (so-called NAFA products) is allowed under the conditions set out in Article 12 of the GFL, the Feed Additives Regulation has no provisions laid down for export (see also EQ2.2). This gap or loophole has resulted over time in the adoption of different national approaches at Member State level, with exports allowed in some cases and in others not. Further to that, results of the survey of Member State Competent Authorities indicate that over one third of them have no market knowledge as to whether such additives are currently being manufactured in the EU and, as a result, have taken no action to prevent them from being placed on the EU market. According to business stakeholders, this situation creates a lack of level-playing field across the EU, particularly as exports of products not authorised in the EU account for an important share of the turnover of feed additive manufacturers (including SMEs).

No other major contradictions or inconsistencies were identified. The interaction between these two legal frameworks has been discussed and clarified by the European Commission on a number of occasions (15) at the level of SCOFCAH/PAFF meetings.

Judgement criteria: "Lack of contradiction / inconsistency between the Feed Additives Regulation and REACH"

The REACH legislation lays down key principles in the area of chemical safety and applies therefore to feed additives containing chemical substances (e.g. entries 28-30 of Annex XVII to REACH), although not all provisions of this legislation apply to feed additives[210].

[210] In particular, the provisions of Title IV of the REACH Regulation (which concern 'Information in the supply chain') do not cover feed mixtures (including use as an additive in feed) in the finished state intended for the final user (Art. 2(6)(d)(iii)).

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 Feed Additives 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 Feed Additives Regulation. No specific overlap or inconsistency was raised and discussed at the level of SCOFCAH/PAFF meetings during the period covered by the study.

Judgement criteria: "Lack of contradiction / inconsistency between the Feed Additives Regulation and the CLP"

Pursuing the same main aims as REACH, the CLP Regulation aims to harmonise the criteria for classification and the rules for labelling and packaging of chemical substances and mixtures. As in the case of REACH, not all provisions of the CLP Regulation apply to feed additives/premixtures[211].

The information collected during the study singled out one loophole in the interaction between the CLP Regulation and the Feed Additives Regulation.

Various industry stakeholders consider that currently Annex VI of the CLP Regulation, which contains a list of harmonised classification and labelling for certain hazardous substances, does not cover the whole range of substances that can be defined as feed additives.

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 feed additives, this has occasionally resulted in redundant, different or even conflicting provisions[212].

Though no specific overlap or inconsistency was raised at the level of SCOFCAH / PAFF meetings, one issue identified by some Member States and industry stakeholders from the different stages of the feed chain is the potential misleadingness for the user of certain mandatory warning symbols required under the CLP Regulation that must appear on the labelling of feed additives (e.g. a pictogram alerting on the hazardous effects on the environment that portrays a dead fish when the product is intended for aquaculture feed).

Judgement criteria: "Lack of contradiction / inconsistency between the Feed Additives Regulation and the biocides Regulation"

EU rules for biocidal products include the establishment of an EU list of active substances that may be used in the formulation of biocides, their authorisation and labelling. It is noted that, in line with the 2011 Commission guidelines[213], the rules foresee the prevalence of feed/feed additives legislation over legislation on biocidal products, unless the feed/feed additives are intended to be used for purposes not covered by the scope of that legislation[214].

[211] In particular, the CLP Regulation does not cover certain substances and mixtures when they are in the finished state intended for the final user as e.g. feed additives (Article 1(5) (e) (iii) of CLP) fulfilling the conditions for exemption.

[212] COPA-COGECA, FEFAC, EMFEMA, FEFANA common principles for labelling feed additives through the supply chain, 2014.

[213] Commission Recommendation 2011/25/EU establishing guidelines for the distinction between feed materials, feed additives, biocidal products and veterinary medicinal products, January 2011.

[214] In accordance with Article 2 (2) (d) of the biocides Regulation, it does not apply to biocidal products or treated articles that fall under the scope of other specific EU legal acts, including, *inter alia*, the Feed Additives Regulation. Similarly, the Regulation does not apply to biocidal products when used as processing aids within

Information collected during the study pointed out to the existence of only one major grey zone between the Feed Additives Regulation and the Biocides Regulation. Notably, several Member States indicated that legal certainty is needed at EU level in order to establish whether certain substances intended for use in drinking water, such as organic acids, are to be classified as feed additives or biocides, taking into account the specific function they may perform as water disinfectants, preservatives specifically designed to be administered to animals in water or both of the above. During the 2004-17 period, this issue was raised several times (35), directly or indirectly, at the level of SCOFCAH / PAFF meetings and it is not yet clarified. Also, in the OPC, nearly 40% of respondents indicated that the use of additives in drinking water needs to be clarified, in particular it should be made clear which additives can be used in drinking water and which cannot[215].

The distinction between feed additives and biocides has regulatory implications. While feed additives are subject to a centralised EU authorisation procedure, active substances qualifying as biocides must be approved at EU level and formulated products containing them be authorised either at Member State or at EU level before they can be placed on the market. A substance that qualifies as a biocide as well as a feed additive to be administered in water may in principle comply with both authorisation regimes. Use of feed additives is generally not authorised via drinking water, unless specifically applied and authorised for this mode of administration.

No specific adverse impacts of this issue were identified by industry stakeholders, such as cases in which the applications for feed additives had to be partially withdrawn. No specific overlap or inconsistency was raised and discussed at the level of SCOFCAH/PAFF meetings during the period covered by the study.

Judgement criteria: "Difference in interpretations between the Feed Additives Regulation and other EU legislation on food and chemicals made by MS CAs"

Information collected during the study did not point out to any specific inconsistencies affecting the application of the Feed Additives Regulation as a result of different national interpretations of other EU food and chemical legislation. In line with that, no item of this kind was discussed at the level of SCOFCAH / PAFF meetings during the period covered by the study.

Judgement criteria: "Impact of lack of coherence in legislation"

Information collected during study - notably the analysis of the items discussed at SCOFCAH / PAFF level during the period covered by the study - did not point out to any case where contradictions, overlaps or gaps between the Feed Additives Regulation and EU food and chemical legislation led to situations of legal uncertainty or generating an unnecessary regulatory burden.

the meaning provided for by EU feed legislation (Article 2 (5) (b)). However, when a biocidal product falls within the scope of one of the legal acts referred to above (feed additives; feed) and is intended to be used for purposes not covered by these acts, the biocides Regulation may apply to that biocidal product.

[215] Annex 3: Consultation synopsis Report, section 3.4.2.5.

EQ 5 Answer:

Few loopholes and grey zones are identified in the interaction between EU food and chemical legislation and the Feed Additives Regulation, as follows. No specific adverse impacts of these issues were identified by industry stakeholders.

Food and chemical legislation interacting with the Feed Additives Regulation	Loophole / Grey zone
General Food Law (GFL)	❖ Lack of harmonised provisions on exports of feed additives, to implement the general provisions of Article 12 of the GFL
CLP Regulation	❖ Partial applicability of the harmonised classification and labelling for certain hazardous substances to feed additives ❖ Certain warning symbols required by CLP Regulation for the final user of feed additives could be potentially misleading ❖ Occasional lack of consistency between labelling requirements laid down by CLP Regulation and those established by feed additives' authorisations.
REACH	*None identified*
Biocides	❖ Lack of clear criteria to determine if certain substances for use in drinking water are feed additives or biocides

7.2.2 CONCLUSIONS

Overall, during the period covered by the study the Feed Additives Regulation has proven to be coherent with other EU food and chemical legislation to a large extent.

Information collected during the study did not point to any overlap or inconsistency with regard to the interaction between the Feed Additives Regulation and the General Food Law. Nonetheless, one gap within the Feed Additives Regulation was identified in relation to the lack of harmonised provisions on exports of feed additives, which constitutes a loophole in terms of allowing the harmonised implementation of the general provisions on exports laid down in Article 12 of the GFL.

Conversely, some inconsistencies were identified with regard to the relation between the Feed Additives Regulation and the CLP Regulation. These are, in particular, the occasional lack of consistency between labelling requirements set by CLP Regulation and those laid down by feed additives authorisations and the potential misleadingness of certain warning symbols required under CLP Regulation when considered in relation to feed additives.

Also, in the case of EU legislation on biocidal products, only one grey zone has been identified. This concerns the legal status of certain substances to be used in drinking water as feed additives versus biocides, which is a long-standing issue at EU level.

7.3 Evaluation question 6: extent to which the provisions of the Regulation are internally coherent

***EQ6: To what extent are the provisions within the feed additives legislation internally coherent? What are the consequences of incoherences, if any*?**

Various factors may have affected negatively the overall coherence of the different provisions of the Feed Additives Regulation, including the presence of contradictory requirements or measures, legal gaps, issues leading to legal uncertainty and diverging interpretations and enforcement approaches by Member States.

7.3.1 ANALYSIS

Judgement criteria: "Lack of internal inconsistency in the Regulation"

Information collected through the study did not point to any specific contradictory definitions, measures and/or requirements within the Feed Additives Regulation.

Judgement criteria: "Low number of gaps identified in the provisions of the Regulation"

Information collected during the study indicates that the number of gaps identified in the provisions of Feed Additives Regulation is limited.

The most important gaps signalled by consulted parties (notably, Member States and manufactures of feed additives and compound feed) are the lack of harmonised rules for imports for feed additives, on the one hand, and for the export of non-authorised feed additives outside the EU, on the other. These issues have been discussed under EQ1.4 and EQ4 (import controls) and EQ2.2, EQ4 and EQ5 (exports of NAFA products).

In addition, there are a few definitions that would be missing from the current legal framework and whose adoption would increase legal certainty. According to Member States' competent authorities, a specific definition of 'preparations' and more precise definitions of 'silage additives' and 'processing aids', amongst others, are desirable. From an industry perspective, a harmonised definition for recommended maximum levels (RMLs) for feed additives is necessary. RMLs are limits for use of feed additives that provide for a certain flexibility as opposed to maximum limits. They have been recently set for some feed additives subject to reauthorisation. The Feed Marketing Regulation lays down the obligation to indicate on the label of the product containing a feed additive if the respective RML has been exceeded. A single definition of this concept would ensure a harmonised implementation across the EU.

Judgement criteria: "Low number of legal complaints"

There are no legal complaints against the Feed Additives Regulation since its implementation to date[216].

The only complaint submitted to the Ombudsman did not concern the legislation as such, but rather the Commission's administrative handling in the case of the authorisation of formaldehyde as a feed additive (Complaint 0268/2017/MH). In this case, the complainant considered that the Commission had lacked objectivity, not sufficiently taken into account scientific evidence and not adequately motivated its decision to refuse the authorisation of that substance. Notwithstanding that, the Ombudsman found that the Commission had acted on objective grounds, taking into account all the relevant factors, in particular, the scientific opinion issued by EFSA, and provided a satisfactory justification to its refusal of the authorisation**.**

Judgement criteria: "Few cases in which feed additives not authorised in the EU and intended for export find their way into the EU market"

There are no precise data on the number of cases in which feed additives 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 feed additives with EU origin detected by Member States is limited during the period

[216] Note: this is different from some complaints received in relation to alleged breaches of EU legislation by companies or alleged non-compliance of some MS legislation with EU rules.

covered by the study. Overall, the type of national measures aimed at controlling FeBOs carrying out such export activities significantly vary across Member States, 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 feed additives; 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. The challenges associated with the performance of controls on imports and exports have been discussed more generally under EQ1.4 (with reference to import controls) and EQ2.2 (exports of NAFA products).

Judgement criteria "Few cases not covered by current list of functions and functional groups"

There have been only few cases of feed additives not covered by the current list of functions and functional groups in the Regulation. This included: four cases of request for authorisation of feed additives for which there was no functional group; and, one case (microtracers) for which Member State Competent Authorities considered it necessary to clarify the status, with some Member States considering those products as additives but no functional group to allocate them. Microtracers are products composed of particles (e.g. iron) and are used to trace a substance with a reliable and accurate method of analysis to ensure that ingredients are present/not present at the formulated and desired levels within the feed. The Regulation does not provide clearly for the possibility to create such a functional group; consideration of these products as feed additives would ensure a stricter control for their use in feed.

Judgement criteria: "Few cases in which feed additives had to be withdrawn from market, because rules on use in water are not applicable to all additives"

The use in water is not possible for technological additives, colourants belonging to the functional group of substances that add and restore colour to feed, and flavourings. Against this background, over the period covered by the study there were 789 flavourings withdrawn for the use in water for drinking as the use in water was not permitted for flavourings.

Judgement criteria: "Low number of regulations had to be published because the authorisation holder had changed"

The number of Regulations published due to a change in the authorisation holder is low: during the 2004-17 period, 28 Regulations were published for this reason. This represents only 10% of all the Regulations adopted for feed additives linked to an authorisation holder (holder-specific authorisations). As also indicated under EQ3.2, although the procedure is relatively less complex than modifications such as change in the scope of an additive, which involve submission of a new dossier, they are considered burdensome for applicants, the Commission and the Member State competent authorities.

Judgement criteria: "Difference in interpretations of provisions laid down in the Feed Additives Regulation made by MS CAs"

Overall, the information collected during the study point out that the provisions of the Feed Additives Regulation have given rise on several occasions to diverging interpretations between Member States.

Discussions at the level of SCOFCAH / PAFF meetings confirm that, out of 224 items concerning the Feed Additives 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. This is the case, for instance, of the legal status of microtracers (see above) and of a set of issues regarding use of feed additives in water.

Judgement criteria: "Lack of significant divergences between the penalties set out at MS level for non-compliance''

As discussed under EQ1.4, sanctions applied by Member States to infringements in the feed additives and premixtures sector (in application of Article 24 of the Feed Additives 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: "Failure to update the legislation on renewal of authorisation is not perceived as a major problem''

Feed additives may be subject to renewal after the expiry of their 10-year authorisation period. In the next five years the authorisation of various feed additives will come to an end (2020: 41, 2021: 33, 2022: 48, 2023: 32, 2024: 56). This includes for example organic acids (the current value of which is estimated at €430,000).

Against this background, views over the need to update EU legislation on the renewal of the 10-year authorisation for feed additives slightly varies across consulted parties. Overall, feed additives 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, Member States and EFSA). A few Member States also share this view. From an industry perspective, for certain feed additives (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 creates uncertainty and unpredictability for the feed chain on the availability of feed additives, 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: "Impact of lack of coherence in legislation''

Over time, the application of the Feed Additives Regulation has given risen occasionally to a certain degree of legal uncertainty.

In particular, the analysis of the issues discussed at SCOFCAH/PAFF level during the period covered by the study shows that out of 224 items that have appeared in the agenda of those committees 39 could be attributed, among others, to the lack of legal clarity. Of those, the largest number (15) concerned rules on export of non-authorised feed additives outside the EU, followed by issues regarding the use of feed additives in water. As previously mentioned, these are issues that have not been yet fully addressed at EU level. Conversely, no cases where contradictions, overlaps or gaps in legislation at EU level have led to situations resulting in an unnecessary regulatory burden were identified.

7.3.2 CONCLUSION

Overall, during the period covered by the study the provisions of the Feed Additives Regulation have proven to be internally coherent to a satisfactory extent. In particular, evidence collected during the study did not point out to any legal complaint filed against the Regulation or to any unjustified regulatory burden for the operators of the sector ensuing from its provisions.

Notwithstanding that, during the application of the Regulation internal coherence between its provisions has been negatively impacted by different factors to a varying degree. These include, amongst others: the lack of certain specific definitions, as in the case of preparations of additives despite the existence of EU provisions regulating some aspects (e.g. labelling); the lack of clarity of some of the current definitions (e.g. silage additives, processing aids) laid down in the Feed Additives Regulation; the lack of certain provisions regulating specific aspects (e.g. specific rules for imports and for the export of non-authorised feed additives outside the EU); and the relatively high number of issues raised at EU level on interpretation of the Regulation and the importance of those that still have to be fully addressed (e.g. use of feed additives in water, legal status of microtracers).

The definition of preparations is not established but the modification of the Feed Additives Regulation has regulated their characteristics, requirements and conditions for placing on the market.

Further to that, feed additive manufacturers, in particular, perceive the failure to update EU rules for the renewal of feed additives authorisations as a major problem as they consider that there is a need to reduce the administrative and regulatory burden on all parties involved in the authorisation process besides ensuring that authorisations are increasingly risk-based.

8. REPLIES TO EVALUATION QUESTIONS RELATED TO RELEVANCE

Due to the issues covered by the relevance theme, in several instances, answers to evaluation questions 7 and 9 overlap with answers to evaluation questions 1 and 2 dealing with effectiveness. To avoid repetitions, readers are referred to the relevant sections of Chapter 5 wherever appropriate.

8.1 Evaluation question 7: extent to which the Regulation is addressing needs

EQ7: 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?

The needs identified at the time of the drafting of the Feed Additives Regulation include:

- reduction of AMR threats to citizens, animals and the environment;
- simplification of the feed additive authorisation process in comparison to the previous process under the directive;
- ensuring the safety of feed additives for human health, animal health and the environment;
- ensuring rigorous risk assessment of feed additives;
- ensuring the traceability of feed additives;
- need of clear rules for authorisation and labelling;
- addressing specific interests of pet owners and pet animals;
- facilitating the placing on the market of feed additives that are safe, innovative and efficacious.

The linkages between the identified needs and the objectives of the Feed Additives Regulation are explained at Annex 1 (intervention logic).

The assessment under evaluation question 7 also considered:

- the need of ensuring that feed additives cannot mislead consumers on the quality of food;
- new needs / objectives which emerged since the drafting of the Regulation.

Business stakeholders and Member State Competent Authorities (NCAs) were consulted[217] to assess: i) whether they consider the original needs are still relevant; and, ii) whether they consider new needs have emerged.

8.1.1 ANALYSIS

Judgment criteria: "Relevance of the reduction of AMR threats to citizens, animals and the environment".

The linkage between this need and the objectives of the Regulation is explained in Annex 1 (intervention logic).

The seriousness of threats from AMR is well acknowledged in the EU and worldwide, as confirmed by the reviewed literature, and in particular by Kahn (2016), EMA and EFSA

[217] Annex 3: Consultation synopsis report, surveys of stakeholders and Member State competent authorities (sections 3.2.2.5 and 3.3.2.5), OPC (section 3.4.2.5) and interviews.

(2017) and WHO (2017). The situation is closely monitored, with updated information on consumption of antimicrobial agents and occurrence of AMR in bacteria from humans and food-producing animals reported by ECDC/EFSA/EMA (latest in 2017; update due in 2020). It is noted that although addressing AMR is a global fight (WHO), a recent Commission survey of non-EU countries found that a significant number of responding countries (40 out of 77 countries that responded to the survey) permit the use of antimicrobial growth promoters in animals, a matter which has received attention from the WHO, OIE, the FAO as well as the EU (European Commission, 2018b).

As discussed in EQ1.4, the ban on the use of antibiotics in feed introduced by the Feed Additives Regulation has played an important role in preventing AMR. There is wide consensus, across all the categories of business stakeholders and a clear majority of NCAs, about the continuing relevance of the need to reduce AMR threats in the current context.

Furthermore, as discussed in EQ1.6, the use of coccidiostats/histomonostats continues to be relevant in that it is adapted to current poultry farming practices while no realistic alternatives are available at present. It is important to note that the use of these substances does not contribute to the development of AMR in humans (as they are only used in animals and not in human medicine; and, not all coccidiostats are antibiotics) while, by controlling coccidiosis and maintaining intestinal health in poultry, coccidiostats are expected to contribute to prevent the need for therapeutic antibiotic treatments. At the same time, according to both private stakeholders and NCAs, there is scope to promote further the development of alternatives that reduce the need to use antimicrobial agents in animal husbandry. EFSA and EMA in their 2017 RONAFA[218] report identify as such an alternative the use of certain substances as feed additives (e.g. zootechnical additives: probiotics and enzymes; and, nutritional additives: zinc and copper[219]).

Judgment criteria: "Relevance of the simplification of the feed additive authorisation process in comparison to the previous process under the directive".

The linkage between this need and the objectives of the Regulation is explained at Annex 1 (intervention logic).

Unsurprisingly there is a wide consensus amongst NCAs and industry representatives that the authorisation process of feed additives should be simple, fast and predictable. Business stakeholders, in particular manufacturers of feed additives, premixtures and pet food, specialist consultants assisting them with their applications, as well as the associations representing them (FEFANA, FEDIAF and AVC) consider that the authorisation procedure should be further simplified. They pointed to the current complexity of the process, the time taken for completion of the dossiers and the unpredictability of the authorisation process (these issues were reported under EQ1 and EQ3). The cost and complexity of the authorisation procedure, particularly for new feed additives for which functional groups or performance criteria (end-points) may not be readily available, are also the main obstacles to innovation highlighted by some NCAs[220].

Judgment criteria: "Relevance of ensuring the safety of feed additives for human health, animal health and the environment".

The linkage between this need and the objectives of the Regulation is explained at Annex 1 (intervention logic).

[218] EMA and EFSA, 2017.
[219] Even though they are authorised as nutritional additives, i.e. their antimicrobial effect has not been formally evaluated.
[220] Annex 3: Consultation synopsis report, section 3.3.2.3.

The full range of consulted parties (industry; other stakeholders; NCAs) deem that the need of ensuring the safety of feed additives for human health, animal health and the environment is still relevant. No NCA deemed such need "irrelevant", and extremely few consulted business stakeholders expressed that view. All interviewed business associations underlined the critical importance of a purely scientific approach to the assessment of the safety of feed additives for human health, animal health and the environment.

Judgment criteria: "Relevance of the rigorous risk assessment of feed additives".

Ensuring a rigorous risk assessment of feed additives is a specific objective of the Feed Additives Regulation (see Annex 1, intervention logic).

An extremely wide consensus about the current relevance of a rigorous risk assessment of feed additives emerged among all the categories of consulted stakeholders, including NCAs.

Judgment criteria: "Relevance of ensuring the traceability of feed additives".

Recital 20 of the Feed Additives Regulation refers to the need to use "a product tracing framework similar to that which already exists in other sectors and in line with the traceability requirements laid down in food law".

Most of the consulted parties (industry; other stakeholders; NCAs) deem that the need of ensuring the traceability of feed additives is still relevant. Consensus on the matter is quasi-unanimous among NCAs, and extremely wide among business stakeholders. 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 feed additives.

Judgment criteria: "Relevance of clear rules for authorisation and labelling".

Establishing clear rules for authorisation and labelling of feed additives is a specific objective of the Feed Additives Regulation (see Annex 1, intervention logic).

All the consulted parties (industry; other stakeholders; NCAs) agree about the current relevance of clear rules for authorisation and labelling of feed additives. A quasi-unanimous consensus on the matter emerged among NCAs and business stakeholders.

Judgment criteria: "Relevance of addressing specific interests of pet owners and pet animals".

The Feed Additives Regulation (recital 4) recognises the need to better address the specific issues facing pet animals and their owners through dedicated measures (see Annex 1, intervention logic).

Even if the majority of the consulted parties (industry; other stakeholders; NCAs) agree that this specific need is still relevant, two notable elements emerged: i) an important share of the consulted business stakeholders were not able to express a judgment as this is not their area of expertise; ii) an important share of NCAs deems that the need of addressing specific interests of pet owners and their animals is only "moderately relevant" at present, even though few NCAs made specific considerations to explain their judgment. In particular, one NCA indicated that: i) only few additives are specifically authorised for use in pet food; and, ii) the use of many of the technological additives authorised for pet food is often not necessary: especially colorants and flavourings are mainly used to make pet food more appetising and/or appealing to pet owners by conferring to it organoleptic properties that are missing in the main ingredients.

On the other hand, amongst the majority that considered this specific need relevant, some concerns were expressed on the extent to which this is currently fully addressed. In particular, the main aspect identified by several consulted parties (across all categories) as not sufficiently addressed by the current authorisation process, is enabling authorisations for feed additives intended for a limited market, such as the specific ones for use in pet food, which lack substantial commercial support. In other words, the current authorisation process is perceived as too burdensome and costly to promote the development of feed additives specifically intended for pet food, in the light of the limited size of the related market segments, and hence of the expected returns.

Judgment criteria: "Relevance of facilitating the placing on the market of feed additives that are safe, innovative and efficacious".

The Feed Additives Regulation aims at facilitating the placing on the market of feed additives that are safe, innovative and efficacious through a combination of measures: i) a comprehensive classification system of feed additives with clear and adequate categories and functional groups, taking into account scientific and technological progress; ii) clear and adequate safety and efficacy criteria; iii) a set of criteria to identify feed additives having a positive effect on the environment; iv) an EU register of authorised feed additives.

An extremely wide consensus about the current relevance of facilitating the placing on the market of feed additives that are safe, innovative and efficacious emerged among all the categories of consulted stakeholders via interviews, as well as among NCAs. Industry respondents largely underlined that further efforts are needed to promote the development of truly innovative feed additives (especially by SMEs), their authorisation and their availability on the market. Ensuring innovation and new product development (especially by SMEs) is considered important to address evolving societal needs, such as 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.

Judgment criteria: "Relevance of ensuring that feed additives cannot mislead consumers on the quality of food".

Ensuring that feed additives cannot mislead consumers as to the quality or characteristics of food that they purchase implies ensuring that only safe and efficacious additives are used in feed. Addressing this need requires a predictable, trustworthy and transparent regulatory system from the authorisation to the final user (livestock farmer or pet food owner), based on clear authorisation criteria and labelling rules for feed additives. This system should prevent the use of feed additives that could pose a risk for the consumers of animal products, and should also ensure that they are not misled on the quality of the food of animal origin they consume (e.g. when a feed additive gives a non-characteristic flavour to such food).

Partially diverging judgments on the relevance of this specific need emerged between NCAs and business stakeholders. The need is deemed to be "fully relevant" or "highly relevant" by the majority of NCAs. As for business stakeholders, over a third of business stakeholders did not express a judgment; while the majority of the remaining two thirds of respondents deemed this need to be "fully relevant" or "highly relevant" and few respondents considering it less relevant. The most frequent points made by the (few) business stakeholders that explained their unfavourable judgments were that: i) they saw an indirect (at best), weak or non-existent link between feed additives and the characteristics of food of animal origin; and, that ii) in any case consumers usually do not have any specific knowledge/understanding about the feed additives used in the production of food of animal origin.

Judgment criteria: "New needs / objectives which emerged since the drafting of the Regulation".

Surveyed stakeholders and CAs were given the possibility to define any new needs/objectives that, in their views, emerged since the drafting of the Feed Additives Regulation. The identified needs were classified into categories (and where relevant, sub-categories). A quantitative assessment (based on a 'fulfilment rating': 1=fully; 3=to a moderate extent; 5=not at all) of the extent to which the identified additional needs/objectives are met by the Regulation was also performed. It should be noted that: i) some of the needs identified as "new" by the consulted stakeholders were actually already identified as needs/objectives in the Regulation at the time of its original drafting; and, ii) several of the "new" needs identified can be considered as requests for change to specific aspects of the Regulation, rather than as overarching needs *per se*. It is noted, that no further needs were identified from respondents to the other consultation tools (i.e. any needs identified belong to the categories presented here). The "new" needs most frequently identified by stakeholders, in decreasing order of prevalence, are reported in the consultation synopsis Report (Annex 3, section 3.2.2.5).

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 resources and sustainable farming/food production; need to consider animal welfare aspects; need to promote innovation (in terms of speeding up the introduction of innovative feed additives and/or feed additive production processes). Since most survey respondents are directly linked with the feed additives 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 feed additives; organisations/consultancies that complete/assist clients with applications for authorisation of feed additives. 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[221]. By contrast, no clearly prevailing "new" needs could be identified among those highlighted by organisations/consultancies that complete/assist clients with applications for authorisation of feed additives.

As explained, only some of the "new" needs identified by stakeholders were not considered in the original Feed Additives Regulation: in the first place, the need to consider sustainability aspects in the development, approval and use of feed additives. By contrast, some of the "new" issues in the authorisation process were already considered (at least in part) in the Feed Additives Regulation; the same can be said for environmental and animal welfare aspects, as well as for the development of new feed additives 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 Feed Additives Regulation, than to taking into account needs that were not considered at the time of drafting. Based on the views expressed by some consulted business stakeholders and NCAs, it appears that those flagging environmental and animal welfare aspects as "new needs" did so because they deemed that those needs are not sufficiently addressed by the Regulation. According to them, EU legislation on feed additives should put even greater emphasis on aspects related to environmental conservation (including in the manufacturing of feed additives) and animal welfare[222]. It can be argued that some of those business stakeholders and NCAs may have failed to consider the significant environmental benefits stemming from the use of feed additives

[221] See Annex 3: Consultation synopsis report, section 3.2.2.5.

[222] In that respect, one consultancy assisting with applications for authorisation of feed additives welcomed the recent introduction of the functional group "Physiological conditions stabilisers", which covers certain functions related to animal welfare.

identified under EQ 3.1. As for potential environmental impacts from feed additives production (in terms of depletion of scarce natural resources, energy consumption, emissions, etc.[223]), these can be deemed as falling outside the scope of the Regulation: the environmental impacts and the overall sustainability of manufacturing activities are indeed addressed by other pieces of EU legislation. It should finally be noted that some consulted business stakeholders and NCAs consider environmental and animal welfare aspects as broadly related to the concept of "sustainability", which is indeed a "genuinely new need".

Focusing on the "genuinely new needs" most frequently identified during the consultations, the main one, which was mostly mentioned by business stakeholders[224], is to better take into account the role that feed additives can play in promoting a modern and sustainable livestock farming. These stakeholders highlighted the beneficial effects that feed additives have by: i) reducing the quantity of feed needed by the animals, thereby enabling the saving of natural resources; ii) reducing greenhouse gas emissions from animals through a positive action on their metabolism (these effects are discussed in detail under EQ 3.1). It is important to consider that "sustainability" was not included as such in the objectives of the Regulation: this concept has gradually become an EU policy priority only afterwards, and is currently the core element of the European Green Deal roadmap[225] and of the Farm to Fork strategy for sustainable food[226]. The feed additives, premixtures and feed industry generally observed that with its strong focus on safety aspects, the Feed Additives Regulation could only provide limited support in addressing new needs, including sustainability-related ones. Suggestions were put forward aimed at improving the relevance of the Feed Additives Regulation with respect to sustainability aspects. Important improvements suggested by the industry are the need to expand efficacy end-points beyond those purely focusing on gains in productivity. It was observed that many feed additives, e.g. zootechnical ones, are not aimed at achieving productivity gains, but at improving the sustainability of animal farming; however, the only way to get an authorisation for those feed additives is to demonstrate efficacy in terms of a gain in productivity. It was also suggested by some in the industry that to better consider innovation in feed additives that address sustainability aspects, a shift towards holder-specific authorisations would be needed; however, this view is not uniformly shared across the industry.

As for the extent to which the Feed Additives Regulation currently meets the identified "new" needs, the 'fulfilment rating' is – as would be expected – generally low. The lowest 'fulfilment rating' (close to "not at all") emerged for the need of ensuring more effective economic protection to producers, also to promote investments in the development of truly innovative feed additives. Most of the business stakeholders that flagged the issue would welcome a shift towards holder-specific authorisations that, as already indicated, is not a view shared by all in the industry.

8.1.2 CONCLUSION

The needs identified at the time of the drafting of the Feed Additives Regulation include: i) reduction of AMR threats to citizens, animals and the environment; ii) simplification of the feed additive authorisation process in comparison to the previous process under the directive; iii) ensuring the safety of feed additives for human health, animal health and the environment; iv) ensuring rigorous risk assessment of feed additives; v) ensuring the traceability of feed additives; vi) need of clear rules for authorisation and labelling; vii) addressing specific interests of pet owners and pet animals; viii) facilitating the placing on

[223] See FAO (2019).
[224] Only 1 consulted NCA highlighted sustainability in the use of resources among the "genuinely new needs".
[225] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en
[226] https://ec.europa.eu/food/farm2fork_en

the market of feed additives that are safe, innovative and efficacious. The linkages between the identified needs and the objectives of the Feed Additives Regulation are explained at Annex 1 (intervention logic).

The assessment under evaluation question 7 also considered: ix) the need of ensuring that feed additives cannot mislead consumers on the quality of food; x) new needs / objectives which emerged since the drafting of the Regulation.

A quasi-unanimous consensus among all the consulted parties (feed additives industry; organisations/consultancies assisting with applications for authorisation of feed additives; manufacturers of compound feed; users of compound feed/pet food; as well as Member State competent authorities) emerged on the current relevance of most of the needs and specific objectives of the Feed Additives Regulation considered in the assessment, i.e.: ensuring the safety of feed additives for human health, animal health and the environment (overarching need); rigorous risk assessment of feed additives, ensuring the traceability of feed additives, clear rules for authorisation and labelling (specific objectives); facilitating the placing on the market of feed additives that are safe, innovative and efficacious.

A wide (albeit non-unanimous) consensus emerged among the consulted parties (private stakeholders and NCAs) on the current relevance of the need of reducing AMR threats to citizens, animals and the environment, and of simplifying the feed additive authorisation process.

The need for further improvements of the relevance of the Feed Additives Regulation in terms of simplification of the authorisation process and of promoting the availability of truly innovative feed additives was found to be widely felt among the consulted parties, and especially among business stakeholders.

The views of the consulted parties (private stakeholders and NCAs) were more mixed in assessing the current relevance of addressing specific interests of pet owners and their animals, and of ensuring that feed additives cannot mislead consumers on the quality of food (it should be noted that the lowest awareness levels among the consulted parties emerged in relation to the relevance of these two needs). However, the majority of the consulted business stakeholders and NCAs deems that also these two needs are still relevant.

It can hence be concluded that **all the needs/objectives identified at the time of the drafting of the Feed Additives Regulation are still relevant, even if to a different extent**.

As for new needs/objectives that have emerged since the original drafting of the Feed Additives Regulation, very few of those identified by the consulted parties (private stakeholders and NCAs) can be defined as "entirely/genuinely new needs" not considered by the Regulation. **Improved sustainability of animal farming through the use of innovative feed additives** emerged as the **"genuinely new need" most frequently highlighted** by the consulted parties, and **especially by business stakeholders**. In their views, the suitability of the Feed Additives Regulation in meeting this specific need could be improved through a revised approach to efficacy assessment, and through a shift towards holder-specific authorisations (this view is however not uniformly shared across the industry), to promote investments in the development of innovative feed additives. It is important to note that "sustainability" was not included as such in the objectives of the Regulation: this concept has gradually become an EU policy priority only afterwards, and

is currently the core element of the European Green Deal roadmap[227] and of the Farm to Fork strategy for sustainable food[228].

Several business stakeholders and some NCAs also highlighted needs related to environmental and animal welfare aspects as "new" ones, even though those needs are actually considered by the Regulation. Based on the views expressed by some of those stakeholders/NCAs, it is likely that needs related to environmental and animal welfare aspects were flagged as "new" because the concerned subjects deem that they are not sufficiently addressed by the Regulation. According to some business stakeholders and NCAs, EU legislation on feed additives should put even greater emphasis on aspects related to environmental conservation and animal welfare[229]. However, it can be argued that those stakeholders and NCAs failed to consider the significant environmental benefits stemming from the use of feed additives, as identified under EQ 3.1. It should also be noted that some business stakeholders and NCAs consider environmental and animal welfare aspects as broadly related to the concept of "sustainability", and hence to this "genuinely new need".

8.2 Evaluation question 9: extent to which the Regulation allows adaptation to technical and scientific progress

EQ9: To what extent has the Regulation provided for the possibility and/or flexibility for adaptation to technical and scientific progress, to minimise unnecessary administrative burden or to adapt to new issues or necessities since the adoption of the Regulation?

The Feed Additives Regulation aimed at addressing a number of shortcomings in the previous regulatory framework (capacity to take into account technological progress and the evolution of scientific knowledge; complexity of the framework and the resulting administrative burden; see Annex 1, intervention logic).

Furthermore, since new developments – i.e. changes in business practice, in the general economic and trade environment, and in the wider legal framework - may interfere with the attainment of the objectives of the Feed Additives Regulation, some **capacity to adapt to new issues or necessities** may be needed, mainly in the form of amendments to the Regulation itself.

EQ9 is addressed through five sub-questions. Each sub-question analyses the information gathered during the study, including findings from previous EQs. Stakeholder consultation[230] allowed assessing to what extent the Feed Additives Regulation provided for the possibility and/or flexibility to overcome these constraints, i.e. to adapt to technical and scientific progress, to minimise unnecessary administrative burden or to adapt to new issues or necessities that emerged since its adoption.

[227] https://ec.europa.eu/info/strategy/priorities-2019-2024/european-green-deal_en
[228] https://ec.europa.eu/food/farm2fork_en
[229] In that respect, one consultancy assisting with applications for authorisation of feed additives welcomed the recent introduction of the functional group "Physiological conditions stabilisers", which covers certain functions related to animal welfare.
[230] Annex 3: Consultation synopsis report. The five sub-questions of EQ9 draw on feedback to a cross section of the issues covered by the surveys of stakeholders and NCAs (as indicated in each sub-question), as well as the OPC and interviews.

8.2.1 ANALYSIS

EQ9.1: Are the definitions, procedures and criteria in the Feed Additives Regulation still clear and relevant in the light of scientific and technical developments, in the light of present needs of livestock production and pets?

The analysis draws on findings outlined in previous EQs (under effectiveness and coherence), including feedback to the stakeholder consultation[231].

Judgment criteria: "A majority of stakeholders perceive the definitions to be in line with current state of scientific and technical progress".

The different views of the parties consulted as well as the issues identified have already been presented under the coherence section (EQ4 to EQ6).

Judgment criteria: "A majority of stakeholders perceive the authorisation procedure to be suitable to address scientific and technical developments for pets and livestock production".

The issue has been assessed in the framework of EQ 1.4 (placement of innovative feed additives on the market) and EQ 2.1 (encouraging the development of new feed additives): please refer to the related answers.

Judgment criteria: "A majority of stakeholders perceive the criteria for authorisation of feed additives as still relevant in the light of scientific and technical developments".

The issue has been assessed in the framework of EQ 1.4 (placement of innovative feed additives on the market) and EQ 2.1 (encouraging the development of new feed additives): please refer to the related answers. The specific shortcoming identified by business stakeholders concerns excessive emphasis in Article 5 on efficacy criteria related to gains in productivity: for example, several innovative products (e.g. zootechnical additives: gut flora stabilisers) have positive effects in terms of animal welfare and improved sustainability of livestock farming without promoting productivity gains. Nonetheless, the available evidence (EQ1.4) suggests that innovation in those groups takes places, e.g. the largest number of innovations in new groups during the period 2004-17 are in the zootechnical additives category and functional group 'other zootechnical additives'.

EQ 9.1 Answer:

Based on evidence presented in previous EQs, it can be concluded that: the definitions are not always entirely clear, with shortcomings identified by the range of consulted parties (see coherence EQs 4 to 6); and, although according to business stakeholders the authorisation procedures and criteria are not deemed to be fully relevant in the light of scientific/technical developments and present needs of livestock production and pets, the available evidence suggests that innovation in new types of feed additives (e.g. zootechnical category) takes place (as discussed in EQ1.4 and EQ2.1).

[231] Annex 3: Consultation synopsis report, sections 3.2.2.5, 3.3.2.5, 3.4.2.5; and interviews.

EQ9.2: What conclusions may be drawn from the experience so far concerning the reauthorisation process?

The process for the reauthorisation of additives authorised under former legislation on feed additives, as defined under Article 10(2) of the Feed Additives Regulation, is outlined in section 3.1.1.

The experience gained from the reauthorisation process draws on the analysis conducted in previous EQs (EQ1 and EQ3), including feedback to the stakeholder consultation[232].

Judgment criteria: "A majority of stakeholders consider that the reauthorisation (Article 10 2) process has helped adapt future renewal of authorisations to new requirements".

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[233]: those changes in requirements also applied to reauthorisation dossiers as they were progressively entering into the assessment process.

Judgment criteria: "A majority of stakeholders perceive that the reauthorisation process has provided applicants with enough flexibility to adapt to technological and scientific progress".

The views of the consulted parties are divided on whether the reauthorisation process has provided applicants with enough flexibility to adapt to technological and scientific progress. Whereas only one of the consulted NCAs expressed a negative judgment on the matter, the views among the consulted business stakeholders were definitely mixed, with a slight prevalence of negative judgments. Some manufacturers indicated limited flexibility by EFSA about the methods to be used by applicants for the required studies, or in terms of accepted endpoints, or in terms of the need to perform again efficacy studies for products that had already been positively assessed for efficacy under former legislation on feed additives.

Judgment criteria: "A majority of stakeholders/MS perceive that the reauthorisation process has helped place on the market safer additives for farm animals".

The assessment revealed diverging views between NCAs and business stakeholders on whether the reauthorisation process has helped place on the market safer additives for farm animals Whereas none of the consulted NCAs expressed a negative judgment in that respect, a majority of consulted business stakeholders judged the reauthorisation process unfavourably. Some business associations and companies argued that most of the products that were successfully reauthorised were those for which operators had sufficient resources to apply for reauthorisation; other products for which operators did not have

[232] Annex 3: Consultation synopsis report, sections 3.2.2.2 and 3.3.2.2.
[233] EFSA, *Guidance for the preparation of dossiers for zootechnical additives*, EFSA Journal 2012;10(1):2536; EFSA, *Guidance on the assessment of the efficacy of feed additives*, EFSA Journal 2018;16(5):5274.

sufficient resources to start the process, disappeared from the market, but certainly not for safety reasons. Those stakeholders deem that reauthorisation should have concerned only those products for which there was an identified safety risk for users, animals, the environment or consumers of food products of animal origin.

Judgment criteria: "A majority of stakeholders perceive that the reauthorisation process has helped place on the market safer additives for pet animals"

Diverging views between NCAs and business stakeholders emerged also on whether the reauthorisation process has helped place on the market safer additives for pet animals. None of the consulted NCAs expressed a negative judgment in that respect; by contrast, a clear majority of negative judgments prevailed among business stakeholders. Some business associations and companies presented the same arguments made for farm animals, i.e. that the reauthorisation of products has more to do with the resources available to individual operators rather than the safety of products: for many products no application for reauthorisation was made due to lack of resources rather than due to safety issues One of the consultancies assisting applicants indicated that EFSA has been reluctant to accept a long history of safe use, although this is foreseen in Regulation (EC) No 429/2008, and that the established safety requirements for common additives used in pet food, e.g. flavours and colorants, are disproportionately demanding.

Judgment criteria: "A majority of stakeholders perceive that the burden of the new safety requirements for reauthorisation was proportionate to the benefits".

Diverging views between NCAs and business stakeholders emerged also on whether the burden of the new safety requirements for reauthorisation was proportionate to the benefits. A generally positive judgment emerged among NCAs; by contrast, a generally negative judgment emerged among business stakeholders. Besides disputing the actual extent of benefits in terms of increased safety of feed additives stemming from reauthorisation (as previously observed), a number of companies argued that especially in the case of non-holder-specific authorisations, the burden (particularly in terms of investments to carry out the needed studies) is excessive compared to the expected returns.

Judgment criteria: "A majority of stakeholders perceive that the burden of the new requirements for the reauthorisation as regards the efficacy assessment was proportionate to the benefits".

Similarly to what was observed for most of the judgment criteria under EQ 9.2, diverging views between NCAs and business stakeholders emerged also on whether the burden of the new requirements for the reauthorisation as regards the efficacy assessment was proportionate to the benefits. A generally positive judgment emerged among NCAs also on this aspect, albeit with a significant share of consulted NCAs expressing a neutral judgment. As also observed in the case of the safety requirements, negative judgments clearly prevailed among business stakeholders: an important majority of them deems that the new requirements for the reauthorisation as regards the efficacy assessment were not proportionate to the benefits. According to both business associations and companies, the disproportion mainly derives from a combination of: i) substantial costs needed for efficacy trials, often also for additives marketed since decades and already assessed for efficacy under former legislation on feed additives (for which new data tend to be requested); ii) the cost of additional efficacy tests required by customers for reauthorised products (some customers are not satisfied with regulatory tests only); and, iii) limited expected returns especially for non-holder-specific authorisations.

EQ 9.2 Answer:

Diverging views between NCAs and business stakeholders emerged for five out of six criteria considered for the assessment of the relevance of the reauthorisation process, respectively focusing on: the flexibility provided to applicants; its contribution to placing on the market safer feed additives for, respectively, farm animals and pet animals; the proportionality to benefits of the burdens from, respectively, new safety requirements and new requirements for the efficacy assessment.

For all these five criteria, whereas NCAs expressed generally positive judgments, a relative majority of business stakeholders (especially manufacturers of feed additives/premixtures) expressed negative judgments, which were substantiated by the identification of both general and specific issues. The strongest criticism by business stakeholders derived from a perceived disproportion between the substantial burden to comply with safety and efficacy requirements, and the limited benefits, in terms of both returns for operators and added value in terms of ensuring presence of safe and effective products on the market.

The only exception to a rather wide dissatisfaction by business stakeholders emerged for the first criterion considered in the assessment: both NCAs and business stakeholders deem that the reauthorisation process has generally helped adapt future renewal of authorisations to new requirements (even though a significant minority of business stakeholders disagrees with such a judgment).

It can hence be concluded that the reauthorisation process has generally met the needs and expectations of the NCAs, whereas it generally failed to meet those of business stakeholders, and of manufacturers of feed additives/premixtures in particular.

EQ9.3: Is the provision for a '10-year authorisation period' considered to be still adequate?

Recital 21 of the Feed Additives Regulation states that "*in order to allow technological progress and scientific development to be taken into account, it is necessary to revise the authorisations of feed additives regularly. Time-limited authorisations should allow this review*". This is provided through the 10-year authorisation period, renewable for a further 10 years, as outlined in section 3.1.1. Stakeholder consultation[234] allowed to assess to what extent the 10-year authorisation period is adequate to promote innovation, necessary to ensure safety of feed additives, and adequate for holder-specific and non-holder-specific additives.

Judgment criteria: "A majority of stakeholders perceive that the 10-year authorisation period is adequate to promote innovation".

The consulted parties had different views on the adequacy of the 10-year authorisation period for promoting innovation. The consulted NCAs generally deem that the 10-year authorisation period is adequate to promote innovation. However, the views of business stakeholders on the matter are divided. Several business associations and producers deem that 10 years are too short a period to justify the substantial costs for developing an innovative product and having it authorised, also considering the risk that the product may not be reauthorised after the 10-year period has expired. According to several business stakeholders, the entry into force of Regulation (EU) No 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain further complicates the

[234] See Annex 3: Consultation synopsis report, sections 3.2.2.2 and 3.3.2.2.

matter, since in their views it would weaken protection of intellectual property for innovative operators. Some NCAs and several business stakeholders suggested to establish authorisation periods of different duration according to the functional group, or to establish a longer period (possibly for renewed authorisations only).

Judgment criteria: "A majority of stakeholders perceive that the 10-year authorisation period is necessary to ensure safety".

Diverging views between NCAs and business stakeholders emerged with respect to the necessity of a 10-year authorisation period to ensure safety. A majority of consulted NCAs expressed a positive judgment in that respect, even though the views of a significant minority of NCAs were neutral or negative. By contrast, negative judgments clearly prevailed among business stakeholders, despite an important share of neutral judgments. Some NCAs observed that for a number of feed additives with a long history of safe use, the authorisation period could be extended (up to 20 years), and that it would be sensible to establish authorisation periods of different duration according to the functional group. Other NCAs argued that significant safety-related developments may occur over a 10-year period: as a consequence, they do not perceive such duration as excessive. The key arguments made by business associations and companies concern the lack of longer authorisation periods for feed additives with a long history of safe use, and that safety should be ensured through other, more effective means (rigorous pre-market evaluation carried out by EFSA and supported by Member States, plus continuous post-market monitoring of safety aspects).

Judgment criteria: "A majority of stakeholders perceive that the provision for a 10-year authorisation period is still adequate for holder-specific additives".

The assessment revealed diverging views between NCAs and business stakeholders also on this specific aspect A majority of consulted NCAs expressed a positive judgment in that respect, even though a significant minority of NCAs were neutral or negative. As for business stakeholders, besides an important share of neutral judgments, negative judgments generally prevailed. Some NCAs observed that longer authorisation periods might be established, but based on the safety profile of individual additives, rather than on the holder-specific/non-holder-specific status of authorisations (e.g. 20 year-periods for lower risk additives). Some business stakeholders that elaborated on the matter argued that a 10-year authorisation period could still be adequate for holder-specific additives only if intellectual property protection is enhanced by applying holder-specific authorisations to all feed additives, which should be made permanent (no expiry of exclusivity).

Judgment criteria: "A majority of stakeholders perceive that the provision for a 10-year authorisation period is still adequate for non-holder-specific additives".

Diverging views between NCAs and business stakeholders emerged also on whether the provision for a 10-year authorisation period is still adequate for non-holder-specific additives. A majority of consulted NCAs had a positive view, even though significant minority of NCAs were neutral or negative; in fact, the highest share of negative views by NCAs was on the adequacy of the 10-year authorisation period for non-holder-specific additives. As for business stakeholders, negative judgments concerning the 10-year authorisation period clearly prevailed. Several companies, including producers of feed additives, premixtures and feed, commented that renewal of the authorisation after a 10-year period for non-holder-specific additives whose approval was based on dossiers submitted by consortia might become a challenge, since members in the consortia may have changed in the meantime.

EQ 9.3 Answer:

Article 10(8) of the Feed Additives Regulation establishes that the authorisation granted in accordance with the procedure laid down in the Regulation itself shall be valid throughout the EU for 10 years.

Diverging views between NCAs and business stakeholders emerged for all four criteria considered for the assessment of the relevance of the provision for a 10-year authorisation period, in terms of: the objective to promote innovation; the need to ensure safety; adequacy for holder-specific and non-holder-specific additives. For three of these four criteria, whereas NCAs expressed generally positive judgments, a relative majority of business stakeholders expressed negative judgments. The only exception was with respect to the adequacy of the 10-year authorisation period in terms of promoting innovation: in this case, business stakeholders' views are more equally shared, and a relative majority of them expressed a neutral judgment.

The most widely shared consideration emerged with respect to safety aspects: some NCAs and several business associations and companies argued that the duration of authorisation period should be tailored to the safety profile of functional groups/individual products, rather than being set to 10 years for all of them.

With respect to the promotion of innovation, several business associations and producers observed that 10 years are too short a period to justify substantial innovation costs, also considering that reauthorisation cannot be taken for granted, and taking into account the issues for protection of intellectual property that would derive from the entry into force of Regulation (EU) No 2019/1381.

It can hence be concluded that the provision for a 10-year authorisation period is generally perceived as adequate – under all the aspects considered – by NCAs; by contrast, a rather wide dissatisfaction about the adequacy of the provision emerged among business stakeholders.

EQ9.4: 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 feed additives, etc.)?

The consultation[235] of private stakeholders and NCAs allowed to assess whether and to what extent new issues/developments that may have emerged since the adoption of the Feed Additives Regulation are not properly addressed by the Regulation itself. The assessment focused on identifying any new issues/developments that may create new needs in relation to: i) updating the method of analysis for the renewal of authorisations; ii) role of EU Reference Laboratories[236]; iii) export of non-authorised feed additives.

Judgment criteria: "A majority of stakeholders perceive that updating the method of analysis is necessary for the renewal of authorisation".

As explained in a 2016 review of the EURL[237], the use of standardised methods of analysis is important to ensure harmonised control of compliance with the relevant EU legislation and thus to enforce regulatory requirements. However, according to the review, the

[235] Annex 3: Consultation synopsis report, sections 3.2.2.2 and 3.3.2.2.
[236] The EURL was also consulted on this aspect.
[237] von Holst et al (2016).

existing official methods[238] currently used to carry out the control of feed additives are in many cases based on obsolete methodologies. Moreover, most of those methods just allow the measurement of a single analyte, while current trends go towards multi-analyte methods and/or standards that still leave some freedom to laboratories of choosing between different types of instrumentation. To close the gap between the existing analytical methods and the demands from Member States' official laboratories with respect to modern analytical methods, the Commission has issued different mandates addressed to the European Committee for Standardisation (CEN). In line with the Commission's approach, the EURL contributes to foster the use and availability of analytical methodologies validated according to international guidelines through:

- the recommendation to applicants to provide standard methods for official controls in their dossiers; this may include the request to applicants to use standards to check whether their methods work well for the specific feed additives under assessment;
- the active contribution of the EURL to the standardisation process of analytical methods (by acting as project leader for some of the items included in corresponding Commission mandates to CEN).

When consulted for the study, the EURL confirmed the relevance of updating the methods of analysis, and noted that this task is not difficult to accomplish from the point of view of technical and scientific progress. However, it also observed that Member States' official laboratories require updated methods even though they know that these methods will rarely be used by applicants in practice, and this is a difficult problem to address.

Strongly diverging views between NCAs and business stakeholders emerged on whether updating the method of analysis is necessary for the renewal of authorisations. Nearly all the consulted NCAs perceived this to be necessary, even with some nuances and a diverging position. In particular, two NCAs observed that updated analytical methods would allow better controls; on the other hand, one NCA noted the significant costs of updating methods, therefore standardisation of analytical methods should be pursued rather than a continuous adaptation to new analytical techniques.

By contrast, a clear relative majority of business stakeholders see no necessity of systematically updating the method of analysis for the renewal of authorisations. The main issues raised are: if the most up-to-date method implies higher analytical costs with limited benefits in terms of accuracy/reliability, there is no point in systematically asking applicants to use that method; on the contrary, if a new analytical method with lower operational costs and higher/equivalent accuracy/reliability becomes available, applicants for renewal of authorisations should be allowed to use it. Several business stakeholders also argued that if the method has not changed since the last application, and was assessed to be suitable for use by the EURL at that time, there should not be a requirement to update the method; analytical methods must be "fit for purpose", not necessarily state of the art.

Judgment criteria: "A majority of stakeholders perceive that the role of the EURL is still properly addressed in the Regulation".

The role of the EURL, as addressed in the Feed Additives Regulation, was one of the few relevance criteria where full alignment between the positions of NCAs and business stakeholders emerged from the consultation. A clear majority of both NCAs and business stakeholders perceive that the role of the EURL is still properly addressed in the Feed Additives Regulation. Several business stakeholders commented that the role of the EURL

[238] As identified by Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed.

should not be extended; the EURL should continue to focus on evaluating analytical methods provided by applicants, with a view to identifying adequate analytical tools for NCAs to perform the required controls. Nonetheless, one NCA see scope for the EURL to have an extended role, to include enhanced support to National Reference Laboratories (NRL) for the development of analytical methods and/or carrying out analysis, as well as support to NCAs on an 'as needed' basis.

Judgment criteria: "A majority of stakeholders perceive that the rules applicable to the export of feed additives are not properly addressed in the Regulation".

The different views of the parties consulted as well as the issues identified have already been presented under EQ2.2 and EQ4.

EQ 9.4 Answer:

Strongly diverging and clearly polarised views emerged during the consultation on whether updating the method of analysis is necessary for the renewal of authorisation. NCAs tend to consider it necessary, as these are important in the context of controls) , whereas a majority of business stakeholders deems that analytical methods should be updated only where they cease to be "fit for purpose", and/or where the most up-to-date methods combine accuracy/reliability with cost-efficiency.

Similarly, views diverge between business stakeholders on the approach for rules applicable to the export of feed additives (an issue discussed under EQ2.2 and EQ4).

By contrast, a clear majority of both NCAs and business stakeholders perceive that the role of the EURL is still properly addressed in the Feed Additives Regulation.

EQ9.5: Are there any provisions, which create unnecessary administrative burden?

Stakeholder consultation[239] allowed assessing whether there are any provisions in the Feed Additives Regulation that create unnecessary administrative burden. Besides the identification of the concerned provisions, the assessment also investigated: i) any additional issues that that may prevent the Feed Additives Regulation from meeting current needs; and, ii) any issues in the Feed Additives Regulation that have created new needs or problems in the feed additives sector.

Judgment criteria: "A majority of stakeholders perceive that administrative burden can be reduced".

A relative majority of NCAs and a clear majority of business stakeholders perceive that the administrative burden deriving from the Feed Additives Regulation can be reduced.

Several business stakeholders generally commented that in the absence of specific concerns in terms of safety and/or efficacy, the administrative burden imposed on applicants (especially in the case of renewal of authorisations) could be reduced. The consulted business associations representing the interests of manufacturers of feed additives and feed suggested that the administrative burden could be reduced by tailoring the duration of authorisation periods to the safety profile of functional groups/individual products (instead of setting the duration to 10 years for all of them). Operators identified examples of additives for which the 10-year authorisation period would not be relevant in

[239] Annex 3: Consultation synopsis report, sections 3.2.2.4 and 3.3.2.4.

additives that are authorised for use in food (technological, flavourings, nutritional) and that have a long-established history of safe use in animal nutrition. According to operators, the renewal obligation for those additives creates unnecessary burden for all the parties involved (Commission/PAFF; EFSA; NCAs; and, the industry). In the operators' view, there should hence be a more flexible approach when the risk profile of the products is low and not changing; unless there is a scientific basis raising concern on the use of these additives, renewal may not be required or could be streamlined/fast tracked.

Additional opportunities for burden reduction were identified by operators with respect to labelling provisions.

These, and some other identified opportunities for burden reduction, are also discussed under EQ3.2.

Judgment criteria: "Other issues that may prevent the Regulation from meeting current needs"

No significant additional issues (i.e. issues not identified under the previous judgment criteria) emerged from the consultation. Several business stakeholders highlighted their potential concerns in terms of protection of data/intellectual property that may arise from the implementation of Regulation (EU) No 2019/1381 on the transparency and sustainability of the EU risk assessment: in their views, these rules could have negative implications in terms of discouraging the development of innovative feed additives.

EQ 9.5 Answer:

A clear majority of business stakeholders and NCAs perceive that the administrative burden deriving from the Feed Additives Regulation can be reduced. This view is particularly widespread among business stakeholders: some of them identified specific areas for burden reduction (e.g. tailoring the duration of authorisation periods to the safety profile of functional groups/individual products; not requiring or streamlining/fast tracking the renewal of authorisations for feed additives with a low risk profile; providing information through other media than physical labels, such as electronically readable labels). These, and some other identified opportunities for burden reduction, are also discussed under EQ3.2.

8.2.2 CONCLUSION

The consultation of private stakeholders and NCAs allowed assessing to what extent the Feed Additives Regulation allowed the possibility and/or flexibility to adapt to technical and scientific progress, to minimise unnecessary administrative burden, and to adapt to new issues or needs that emerged since its adoption. The analysis of these issues draws also on evidence presented in previous EQs, particularly on effectiveness, efficiency and coherence.

In general, the views of NCAs and business stakeholders were aligned only with respect to few specific aspects. Both groups perceive that: i) the reauthorisation process has generally helped adapt future renewal of authorisations to new requirements (even though this view is not shared by a significant minority of business stakeholders); ii) the role of the EURL is still properly addressed in the Feed Additives Regulation; and, iii) the administrative burden deriving from the Feed Additives Regulation can be reduced. For most of the other aspects considered, views diverged between the two groups, with the consulted NCAs expressing mainly positive judgments, whereas more or less strong criticism came from the consulted business stakeholders.

In the views of business stakeholders, several limitations hamper the Feed Additives 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 Feed Additives 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 consulted NCAs. Also, the available evidence suggests that innovation in new types of feed additives (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 Feed Additives 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 feed additives 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.

With respect to the capacity of the Feed Additives Regulation to adapt to new issues or necessities emerged since its adoption, the main shortcoming identified by business stakeholders is the necessity of updating the method of analysis for the renewal of authorisations. In their views, analytical methods should be updated only where they cease to be "fit for purpose", and/or where the most up-to-date methods combine accuracy/reliability with cost-efficiency. By contrast, NCAs were in favour of updating analytical methods (which are important in the context of controls). Business stakeholders were also rather divided on whether the export of feed additives (whether authorised or not for placing on the EU market) is currently properly addressed by not forming part of the Feed Additives Regulation.

On the other hand, both NCAs and business stakeholders perceive that the role of the EURL is still properly addressed in the Feed Additives Regulation. In the views of business stakeholders, the role of the EURL should not be extended; the EURL should continue to focus on evaluating analytical methods provided by applicants, with a view to identifying adequate analytical tools for NCAs to perform the required controls.

9. REPLIES TO EVALUATION QUESTIONS RELATED TO EU ADDED VALUE

9.1 Evaluation question 10: EU added value

EQ10: 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?

EU added value is addressed through three judgement criteria. These aim at understanding whether a harmonised procedure at the EU level is perceived as achieving better results than a national level authorisation process; understanding whether harmonisation is perceived as being more advantageous than non-harmonisation; and, understanding whether an EU level approach is still warranted. These judgement criteria were assessed based on the results of the various consultations carried out for this study[240].

9.1.1 ANALYSIS

Judgement criteria: "A majority of stakeholders perceive that the harmonised authorisation procedure at EU level achieves better results than a national level authorisation procedure"

There was a wide consensus amongst all consulted parties (citizens, Member State competent authorities, industry and other private stakeholders) that there is an added value in having a harmonised EU authorisation procedure, i.e. that it achieves better results than a national level authorisation procedure.

The smooth operation of the EU's Single Market was the key stakeholder consideration in this opinion with two Member State competent authorities also drawing attention to the intra-EU trade in feed additives, which is facilitated by a central approach.

Another reason provided for favouring an EU-level system included that this is more economic in that there is no need to replicate the large scientific involvement in the authorisation process. A central system also prevents applicants from "authorization tourism" where they make applications to what they perceive as the least rigorous Member State (assuming that such an authorisation would be accepted in other Member States, e.g. that there would be mutual recognition). Two NCAs raised the possibility of small changes being advantageous; one to introduce some flexibility for Member States to authorise niche products available only on their domestic market and the other to involve national institutes or Member States in the procedure to share the administrative burden.

Judgement criteria: "A majority of stakeholders perceive that harmonisation of labelling rules at EU level is more advantageous than non-harmonised rules"

All of the consulted Member State competent authorities and the majority of stakeholders agreed that harmonisation of labelling rules at the EU level is more advantageous than having different rules in different Member States.

As noted above, the smooth operation of the EU's Single Market is central to this opinion both in terms of reducing complexity and cost and in facilitating intra-EU trade.

[240] Including surveys of stakeholders and Member State competent authorities (Annex 3: Consultation synopsis report, sections 3.2.2.7 and 3.3.2.7) and interviews.

Judgement criteria: "A majority of stakeholders perceive that EU level intervention is still warranted"

All of the consulted Member State competent authorities and the majority of stakeholders were of the opinion that EU level intervention in the area of feed additives needs to continue.

One Member State competent authority expressed a wish to see a simplified approvals procedure to ensure that the feed additives necessary for animal production can be authorised (or not) in a more timely manner. A stakeholder made a related point in that if the authorisation process because too stringent and/or too complex, there is a risk that operators will look to commercialise feed products outside the EU.

9.1.2 CONCLUSIONS

It is clear that there is widespread and strong agreement that the centralised, EU-level approach to authorisation is appropriate; the harmonisation of labelling rules at the EU level is widely seen as being more advantageous than having non-harmonised rules. The main advantage of this approach is to facilitate the smooth operation of the EU's Single Market. For this reason, there is a strong body of opinion in favour of maintaining this EU level intervention.

10. OVERALL CONCLUSIONS

Ensuring that feed additives placed on the market are efficacious and safe for animals, humans and the environment are core objectives of the Feed Additives Regulation. The Regulation's **effectiveness in meeting the core objectives** (*EQ1*) was assessed by analysing the evidence and experiences with implementing and enforcing the Regulation during 2004-2017, including the procedure for authorising feed additives and rules on labelling.

The analysis concludes that the Regulation is more effective than the former legislation. Nonetheless, certain shortcomings were also identified.

Compared with the former legislation, the **authorisation procedure** set out in the Regulation **significantly improves both the efficacy and safety assessment** helping meet the core objectives to a greater degree. In particular, under the Regulation:

- Both efficacy and safety are evaluated for several important categories/functional groups of feed additives which were not at all or not completely assessed under the former legislation (e.g. silage additives, amino acids and zootechnical additives). The market relevance of these feed additives is indicated both by the total number of applications for new authorisations and reauthorisations (under Articles 4(1) and 10(2), respectively) and their considerable market value.
- Pre-existing feed additives for which efficacy/safety was not demonstrated were withdrawn from the EU market. This included an estimated 1,623 additives notified under Article 10(2) for which no reauthorisation dossier was introduced upon the expiry date, and 120 additives withdrawn during the authorisation process.
- Some 89 applications for new authorisations and 205 applications for reauthorisation were withdrawn, totally or partially in 2004-2017 as efficacy/safety was not demonstrated (compared to a total of 791 applications submitted for evaluation under Articles 4(1) and 10(2)).
- An additional indication of the high safety record of feed additives and premixtures placed on the EU market is the very limited number of RASSF notifications in 2004-2017: out of a total 517 notifications on feed, only 12 were on feed additives/premixtures.
- The high safety standard of feed additives and premixtures placed on the market for pets is also demonstrated, thanks to specific rules laid down in the Regulation for non-food producing animals, including for assessing their safety/efficacy, for which specific guidance was set up by EFSA.

Despite the above achievements, the **effectiveness** of the authorisation procedure **is partly undermined by length and complexity**:

- The analysis of the entire procedure, from submission of application dossiers by applicants to final decision by the Commission, identified significant delays beyond the legal deadline of 1 year. In total, based on EFSA/Commission data, the average time taken to complete the procedure (from validation of application by EFSA to Commission decision) is roughly 2.5 years for Article 4(1) and 4.5 years for Article 10(2) applications. In view of these delays, there is some concern about the potential bottlenecks which could arise from the large number of requests for the renewal of authorisations (Article 14) that are expected to be submitted in future years.
- It is noted that the delays in the entire process are considerably shorter for new authorisations (Article 4(1)) than for reauthorisations (Article 10(2)). For the latter, the delay does not affect operators as the additives remain on the market until a decision is taken.
- These delays were found to be mainly due to the high incidence of missing and/or incomplete information/data during the assessment for a substantial majority of applications (78% of applications under Article 4(1) and 88% of applications under

Article 10(2)). This triggered the clock-stopping process 1,320 times in 2004-2017, with an average of 1.73 requests for complementary information per finished dossier. Consequently, a significant majority of EFSA opinions are not issued within legal deadlines (i.e. within 6 months from valid application). On average, it takes 2.4 times longer for Article 4(1) and 4.6 times longer for Article 10(2) applications.

- Systematic data on the type of questions asked by EFSA are not available. Overall, according to EFSA, reasons why applicants fail to provide complete information/ data include: (i) lack of sufficient understanding of the guidance and assessment process; (ii) misinterpretation of the requirements, e.g. on the studies to be conducted; and/or (iii) misinterpretation of the results obtained in the studies. These issues tend to be more common in efficacy studies due to the complexity involved. On the other hand, for the safety assessment, the information/data provided by applicants tends to be sufficient for assessing safety, thanks to the EFSA guidance and its alignment with relevant OECD guidelines. Demonstrating safety for users is an exception. This remains challenging for applicants, particularly for non-holder-specific additives.

The **EFSA risk assessment has allowed sound decision-making by the Commission**, evidenced by the fact that neither EFSA opinions nor Commission decisions have been successfully challenged in 2004-2017. However, some **shortcomings** were identified:

- In some cases, due to missing information/data, EFSA cannot provide an informed opinion, leading to non-conclusive opinions (an estimated 15% of EFSA opinions). According to the industry, legitimate factors are not sufficiently taken into account as hardly any cases of additives being authorised following non-conclusive EFSA opinions were identified. However, where the main problem is the lack of appropriate data, the Commission cannot deviate from the EFSA opinion unless there is scientific evidence that justifies such deviation. This issue is partly addressed by the additional information submitted by applicants on request of the Commission under Article 29 of the General Food Law.
- According to manufacturers of feed additives/premixtures, a shortcoming that contributes to the complexity and length of the procedure, and the non-conclusive outcome in some cases, is that regulatory requirements are not always fully relevant to demonstrate efficacy in real conditions. This is particularly highlighted for zootechnical additives, for which demonstrating efficacy in terms of the end-points defined in the Regulation has proven challenging and is not always appropriate in terms of buyer requirements for placing them on the market.
- Data on the number of favourable opinions, favourable opinions with limitations, non-conclusive and unfavourable opinions are not systematically collected by EFSA, making it difficult to systematically monitor the assessment process.

Other key provisions of the Regulation also play a **positive role in meeting the core objectives**. However, their effectiveness is also **partly undermined by complexity**:

- **Labelling (Article 16)**: although labelling plays an important role in ensuring objectives are met, 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 or proportionate.
- **Controls and sanctions (Article 24)**: data on controls performed by Member States indicate an average frequency of about once per year per establishment producing feed additives and premixtures, and a high rate of conformity of samples and analyses. In addition, Member States have put in place sanctions for non-compliance. However, the evidence provided by Member States on enforcement is not sufficient to check that sanctions are imposed in cases of infringements. It is noted that the control of compliance along the feed chain with the conditions of authorisation of feed additives falls within the scope of the Official Controls Regulation. There is also some evidence that controls on imports are not adequate,

despite the limited number of RASFF notifications on feed additives/premixtures between 2004 and 2017 (12, of which 7 were on imports from non-EU countries). In particular, diverse levels of implementation of controls on imported products, the absence of an EU list of non-EU establishments authorised for exports to the EU, as well as constrained resources and complexity of import controls in practice, all contribute to question whether imports of feed additives are adequately controlled.

The **Regulation has effectively contributed to reduce the likelihood of antimicrobial resistance (AMR)** with: the ban on the use of antimicrobials as growth promoting agents; maintaining coccidiostats as a feed additive for the prevention of the continuing widespread risk of coccidiosis in poultry; and, the authorisation during the 2004-17 period of 84 new zootechnical additives, thereby enhancing performance (improving yields; reducing losses) and reducing the need for therapeutic use of antibiotics.

The Regulation has also positively contributed to develop a **competitive and innovative EU feed additives industry** (*EQ2*). In particular:

- The Regulation has encouraged the development of innovative feed additives to cover new needs of the livestock sector (e.g. silage additives and amino acids to improve performance and sustainability in the use of feed resources, zootechnical additives to replace growth promoters, substances to reduce the contamination of feed by mycotoxins, hygiene condition enhancers or physiological condition enhancers). This is indicated by the number of patent applications (EPO data), which has doubled since the Regulation came into force, compared to the preceding period (although the share of EU vs non-EU applications remained stable).
- The high standard of the EU rules for feed additives, particularly the authorisation procedure followed for their approval, is recognised worldwide. Although the process followed for the approval of products in key non-EU countries tends to differ from the EU authorisation process, some countries (e.g. Chile, Canada; to some extent China) recognise some elements of the EU feed additives authorisation process: this makes it easier for a feed additive to be approved in those countries if it has already been authorised in the EU.

However, some **shortcomings** were identified as regards the way the Regulation affects the relative competitiveness of EU producers in global markets. In particular:

- Regulatory costs for the approval of feed additives in non-EU markets tend to be lower than in the EU and the procedure tends to be quicker. This - in addition to lower labour costs in important non-EU country producing countries (including China and Brazil) - results in a competitive advantage for non-EU producers in global markets. It enables them to move quicker to be the first to bring innovations to the global market, as well as to ensure a quicker return on their investment (ROI).
- The EU industry is also adversely affected in global markets by the absence of a common approach for exports of feed additives not authorised in the EU and premixtures/feed containing them (so-called NAFA products). Although no data exist on the actual volume/value of exports of NAFA products, these are an important business segment for EU companies (especially SMEs), and this opportunity is to some extent hampered by differential rules and approaches between Member States on NAFA exports.

The analysis of the Regulation's **efficiency** demonstrates that benefits tend to justify costs, when considering the broader benefits of feed additives for farmers, per owners, animal welfare, human health, consumers and the environment (*EQ3*). Nonetheless, the cost:benefit balance of non-holder-specific authorisations is an issue for applicants; and,

the cost-effectiveness of the authorisation procedure in particular, and to a lesser extent of the labelling provisions, was not considered to be sufficient and could be improved.

The requirements of the Regulation entail compliance costs and administrative costs for feed business operators (FeBOs: applicants and others) and for the EU institutions (Commission, EFSA, EURL)[241]:

- The most important costs stemming from the Regulation for applicants are related to the applications for new authorisation (Article 4(1)), estimated at an average of €1.1 million per application, although costs widely vary depending on the type of feed additives. Additional indirect costs and losses for operators along the feed chain (applicants and users of feed additives/premixtures) are generated by delays in the deadlines foreseen, including requests for supplementary data by EFSA ('stop the clock' procedure) and the final Commission decision, and 'unpredictability' in the outcome; these costs were not possible to estimate.
- The costs of labelling changes are relatively low in comparison to authorisation costs, although, they tend to be more important for: premixtures (indicatively, costs of labelling changes due *inter alia* to the changes caused by the Regulation range from €80,000 to €114,000 per plant per year); and, pet food in the case of widely used feed additives (e.g. a vitamin). On the other hand, the main impact of the Regulation's labelling provisions for the feed additives industry is in terms of the amount of information and the form in which it is required on the label versus the need for some of this information to be on the physical product label, as stipulated by Article 16 of the Regulation. It is noted, in this context, that these costs can be considered to represent an over-estimate of the actual costs of the Regulation, as they are compounded by requirements stemming from Member State authorities and operators' own production and marketing strategies.
- At the level of Member State Competent Authorities, the average annual cost of the activities related to the implementation and enforcement of the Regulation is estimated at €103,000 per Member State (across 14 MS that provided complete data: n=14 MS). The main task accounting for most of the staff time is the controls carried out to ensure operators' compliance with the Regulation's requirements.
- At the level of the EU institutions, the average annual cost to perform the main legal and administrative obligations related to the implementation of the Regulation were estimated at: the Commission, mainly for the authorisation of feed additives (€756,000 in staff costs, which represents €13,000 per application); EFSA (€1.9 million, of which €1.1 million in internal staff costs and €762,000 in FEEDAP Panel/WG meetings; this represents €27,500 per application, of which €15,900 are staff costs); and, the EURL, mainly on validation reports and keeping samples (€684,000 in staff costs; this represents €18,500 per validation report). It should be recognised that cost-cutting efforts have been made in all the institutions.

Although authorisation costs are important for operators, benefits tend to justify costs. This is evidenced by the large number of additives authorised during the 2004-17 period and their market value. However, there are some shortcomings:

- 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. Most applicants that have filed applications (under Articles 4, 10 and 14 of the Regulation) do not consider the current implementation of the procedures laid down in these provisions to be cost-effective, mainly due to the significant delays incurred in practice for the authorisation procedure to complete (for the reasons outlined earlier, under the effectiveness of the procedure).

[241] The calculation of average costs for each of these organisations (applicants; MS CAs; Commission; EFSA; EURL) is based on data availability over different time periods, details in the main text of EQ3.1.

Consequently, according to these applicants, the procedure needs to be modified significantly.
- 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 are not significantly different between SMEs and large companies, as the underlying factors determining costs tend to be independent of company size. However, access to finance the investment required for an authorisation application tends to be a problem for smaller companies that are not part of a larger entity. Non-holder specific authorisations are therefore 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. SME applicants are also actively involved in the authorisation process for holder-specific feed additives (e.g. zootechnical additives).

The availability of safe and efficacious feed additives has also contributed to mitigate the adverse environmental and climate impacts of livestock and feed production and to improve the physiological status and welfare of animals. However, unlike the effects on the environment which are considered to be adequately assessed by EFSA, animal welfare is not currently the focus of the scientific assessment (as the required studies mainly address performance criteria)

The analysis of the Regulation's **coherence** demonstrates this is generally satisfactory. Nonetheless, certain shortcomings were also identified. In particular:

- The Regulation has proved to be **coherent with the wider EU legal framework** that is relevant for feed additives to a satisfactory extent. Areas where consistency can be improved are identified as follows:
  - In the case of feed-related legislation (*EQ4*), areas for improvement include: the updating of labelling requirements for feed additives in line with current rules for feed materials and feed compound set out in the Feed Marketing Regulation; the establishment of clearer criteria to distinguish between feed additives and feed materials; and, the development of harmonised rules for imports of feed additives from non-EU countries.
  - A better interaction could be pursued with other legislation (*EQ5*). In particular, the provisions set out in Article 12 of the GFL on exports to non-EU countries are not followed up within the Feed Additives Regulation, resulting in the lack of a harmonised approach across the EU on exports of feed additives and premixtures. Also, interaction could be improved with certain EU chemical legislation that applies to feed additives. This includes: the need to clarify whether premixtures fall under the scope of CLP Regulation and the development of clearer criteria to determine whether certain substances used in drinking water are feed additives or biocides for the purpose of EU legislation.
- The Regulation has proven to be **internally coherent** (*EQ6*). Areas for improvement are identified as follows: the development of specific definitions for certain key terms (e.g. preparations, silage additives, etc.); and, simplifying and making more risk-based the current EU rules for the renewal of feed additives authorisations.

The **relevance** of the Regulation was assessed in terms of: i) addressing the needs/objectives identified at the time of the Regulation's drafting, and capacity of the Regulation to tackle any new needs/objectives emerged since then (*EQ7*); and, ii) extent to which the Regulation provided for the possibility and/or flexibility to adapt to technical and scientific progress, to minimise unnecessary administrative burden or to adapt to new issues or necessities emerged since its adoption (*EQ9*). The analysis demonstrates the **Regulation's continuing high relevance**. Nonetheless, certain shortcomings were also identified. In particular:

- All the **original needs/objectives are still relevant**, to varying extents. Areas for improvement include: simplification of the authorisation process; and, promoting the availability of truly innovative feed additives. Very few **new needs/objectives have emerged** since the Regulation was drafted. Improving the **sustainability of animal farming** through innovative feed additives is a need most frequently highlighted by all groups of consulted stakeholders; in their views, the Regulation could better address this need through a **revised approach to efficacy assessment**.
- Several limitations[242] were identified by business stakeholders, which, in their opinion, hamper the Regulation's possibility and/or flexibility to **adapt to technical and scientific progress** (although these were generally not shared by Member State Competent Authorities). Also, according to business stakeholders and most Competent Authorities, **the administrative burden deriving from the Regulation could be reduced**. For instance, according to business stakeholders, the burden of the new safety-related and efficacy-related requirements for renewals is not proportionate to the benefits.
- As for the capacity of the Regulation to **adapt to new issues or necessities emerging since its adoption**, the role of the EURL is considered to be still properly addressed in the Regulation. On the other hand, Competent Authorities were in favour of updating analytical methods for the renewal of authorisations, unlike business stakeholders; and, business stakeholders were divided on whether the export of feed additives (whether authorised or not for placing on the EU market) is currently properly addressed by not forming part of the Regulation.

Finally, in terms of the **EU added value,** there is widespread and strong agreement that the centralised, EU-level approach to authorisation is appropriate and the harmonisation of labelling rules at the EU level is widely seen as being more advantageous than having non-harmonised rules (*EQ10*). The main advantage of this approach is to facilitate the smooth operation of the EU's single market. For this reason, there is a strong body of opinion in favour of maintaining this EU level intervention.

[242] Limitations would mainly derive from: i) lack of clarity/precision in some of the definitions provided by the Regulation, plus missing definitions for some key concepts (an issue highlighted under EQ4 to EQ6); ii) the difficulties and the long time needed for creating new functional groups to respond to emerging needs; iii) slow adaptation of authorisation criteria vis-à-vis rapid evolution of technical progress and scientific developments in the field of animal nutrition; and, iv) lack of flexibility in the reauthorisation process.