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

Annex 3: Consultation Synopsis Report

[Written by Food Chain Evaluation Consortium - FCEC]
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TEMPLATE XX – Evaluation Final Report

This document provides indicative **structure for the Evaluation Final Report** (language). As such it provides **overview of content** that should be covered by the report.

The final report will be published on Europa.

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

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ANNEX 3: CONSULTATION SYNOPSIS REPORT

As part of the "Study supporting the REFIT Evaluation of the Regulation (EC) No 1831/2003", the opinions of stakeholders, competent authorities, as well as other interest groups and third countries were collected. A wide range of consultation activities was employed to reach out to this diverse group. This report provides an overview of the consultation activities, the organisations reached out to, and an overview of the main outcomes. The outcome of the consultation carried out in the context of the case studies is included in the analysis of the case studies (Annex 4).

3.1 Consultation strategy

The European Commission (EC) developed a consultation strategy, which was fine-tuned by the FCEC over the course of the study. Stakeholders were mapped to identify all relevant groups and to identify suitable consultation activities to reach out to these groups. The objective of the consultation was to collect information, data, knowledge and opinions. Many participants of the consultation shared their experiences with the implementation of the Regulation, as well as the wider legal framework of relevance to the study, and provided additional supporting evidence. Information was collected on all five evaluation criteria of the study: effectiveness, efficiency, relevance, coherence, and EU added value.

After a few initial exploratory interviews in June-October 2018, the consultation activities took place between December 2018 and October 2019.

The key elements of the consultation included:

- An **Open Public Consultation (OPC)**. All types of stakeholders, including research organisations/experts, citizens, consumers, civil society and organisations representing them were invited to voice their views on the topics of this study. The OPC ran between December 2018 and April 2019.
- **Targeted consultation** with relevant stakeholders to gather specific inputs and to explore certain issues in more depth. The targeted consultation included two targeted surveys, conducted between July and September 2019. The surveys targeted stakeholders and Competent Authorities of the EU28 Member States:
    1. A **survey of national (MS) competent authorities (CAs)** in the EU-28 in the area of feed additives. The survey was open to competent authorities from EEA countries.
    2. A **survey of stakeholders**. The survey targeted the following groups of stakeholders (including specific questions for feed operators):
        a. **Feed additive/premixtures and feed industry organisations** (i.e. those represented by the following EU umbrella organisations: FEFANA; FEFAC; FEDIAF; Animal Health Europe; AVC; EMFEMA).
        b. **Feed additive/premixtures and feed operators**, including consultants working on their behalf (for the preparation of authorisation dossiers).
        c. **End users**: organisations representing farmers, the meat industry and the aquaculture sector.
        d. **Organisations representing other groups** (animal health and animal welfare experts, farm advisors, feed-food safety/science specialists)[1].

[1] Research organisations/experts, citizens, consumers, civil society and organisations representing them including NGOs were consulted through the open public consultation (OPC).

Stakeholders (from all groups a-d above), as well as the Competent Authorities in four Member States (selected in the context of thematic case studies) were invited to interviews which were held in September to November 2019, as a follow-up to the survey and in order to complement the data collection.

Many of the stakeholders of the feed additives supply chain (including manufacturers, traders, users) are represented by umbrella associations. The associations presented in the following Table engaged actively in the consultation process.

	Key stakeholders that contributed to the consultation *(a)*
FEFANA	EU Association of Specialty Feed Ingredients and their Mixtures. FEFANA membership comprises manufacturers and traders of feed additives, functional feed ingredients, premixes and other mixtures of specialty ingredients for animal feed. The FEFANA membership comprises only companies (94 in total), which account for an estimated 80% of the EU feed additives production value. Of these member companies, 60% are SMEs. FEFANA and FEFAC jointly represent the premixtures sector.
Animal Health Europe	The association represents manufacturers of animal medicines, vaccines and other animal health products in Europe, including coccidiostats and histomonostats. The association's membership, which includes both animal health companies (13 companies) and 15 national associations in 17 EU Member States (as well as Norway and Switzerland), covers 90% of the European market for animal health products.
FEFAC	The association represents manufacturers of feed materials and compound feed, as well as premixtures. FEFAC membership consists of 23 national associations in 23 EU Member States as full members, and an increasing number of observer/associate members from non-EU countries. FEFAC and FEFANA jointly represent the premixtures sector.
FEDIAF	The association represents pet food manufacturers. FEDIAF's membership consists of both national pet food industry associations (14 associations covering 16 Member States, as well as Norway and Switzerland) and direct company members (5 companies).
EMFEMA	The association represents EU-located producers of macro minerals, trace element compounds and specific minerals for use in animal nutrition, as well as EU producers of on-farm mineral mixes as an associate member. The association's core membership is comprised of more than 30 companies manufacturing minerals for animal nutrition.
AVC	The association represents veterinary consultants across the EU. Most of these consultants provide consultancy on regulatory affairs, including on animal nutrition issues.
Copa-Cogeca	Copa-Cogeca are the united voice of farmers and agri-cooperatives in the EU. Copa represents over 23 million farmers and their families, and Cogeca represents the interests of 22,000 agricultural cooperatives. Copa-Cogeca have cover 60 organisations from the EU-28 Member States and 6 partner organisations from EEA countries/Turkey.
AVEC	AVEC represents the EU poultry sector. The association's membership includes national organisations that represent the poultry industry and trade in 17 EU Member States, covering 95% of the EU poultry meat production.

(a) This is not a comprehensive list of all stakeholders; others are mentioned in this Synopsis.

Despite efforts to consult the wider range of stakeholder groups likely to be affected by the Regulation, consumers, animal welfare organisations and environmental organisations did not contribute to the consultation. When contacted directly, these organisations explained that although the Regulation was of interest to them, they did not have the capacity to participate in all consultations due to the broad spectrum of policy areas they were following.

Interviews in the course of the study were also held with the EU institutions involved, i.e. the European Commission (DG SANTE), the European Food Safety Authority (EFSA) and the European Union Reference Laboratory for feed additives (EURL).

The following sections provide information on all consultation activities. Each section provides an overview of the nature and number of the respondents. The sections also summarise the main outcomes of each of the activities.

Prior to the study, in 2017, the Commission carried out a consultation to the Roadmap for the evaluation of the feed additives Regulation[2], the outcome of which is provided below. This feedback was taken into account in the early stages of the study, notably the refinement of the consultation strategy and the development of indicators for the data collection, enabling the examination of the issues raised by respondents to the Roadmap. Thus, the feedback to the Roadmap has been superseded by the more detailed feedback to the extensive consultation carried out during the study (surveys; interviews; OPC) of the same organisations that responded to the Roadmap.

3.1.1 Roadmap: summary of feedback

The Commission's Roadmap consultation, which was carried out prior to the study, run from 28 August 2017 - 25 September 2017. The number of responses was low (13 contributions were received) but represented a wide variety of interests:

- 6 business associations (5 European associations and one association from a Member State) representing the feed sector, the animal health sector and the farmers;
- 2 companies producing feed additives and/or premixtures;
- 1 research organisation;
- 1 consultancy on feed additives;
- 1 competent authority for health (CA);
- 1 European NGO working in cooperation that have a project on antimicrobial resistance;
- 1 citizen.

DEFINITIONS: 4 respondents (1 CA, 2 companies and 1 business association) recognised the necessity to clarify certain definitions, notably to better distinguish feed materials from feed additives. One of the respondents indicated that the definition of premixtures was not clear enough. One of the industry respondents claimed that the long period required for having an additive authorised facilitates the incorrect classification of many additives as feed materials.
IMPLEMENTATION AND ENFORCEMENT: 4 respondents (1 CA, 2 companies and 1 business association) addressed this issue; the main concern is the different interpretation of the provisions of the Regulation by MS that created unfair competition amongst operators from different MS. The competent authority considered that specific rules on modalities and frequency of controls should be laid down in the Regulation. One industry respondent indicated that traceability requirements should be established in the Feed Additives Regulation and not in the General Food Law.
LEVEL PLAYING FIELD: the two farmers' organisations stressed the importance of ensuring a level playing field.
AUTHORISATION: this was one of the aspects more commented, in total 6 respondents (1 CA, 1 citizen, 2 companies, 2 business associations). They showed concerns about the long period to get an authorisation and about the renewal process. They consider that the duration of the authorisation may be extended on a risk assessment basis and the history of safe use of the additive. One business association was concerned by the procedure of

[2] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1483-Evaluation-of-the-feed-additives-Regulation

modification of the authorisation that was too demanding. The citizen indicated that for the renewal, new studies should be used. The competent authority insisted on the need to have special rules on the rules of FA in water for aquaculture.

ASSESSMENT: 5 respondents (1 consultancy, 1 citizen, 1 company and 2 business association). In general, the assessment process is not predictable for the operators (EFSA guidance more demanding than the Regulation with changing requirements when new guidance documents are adopted). The CA indicated that the efficacy must be evaluated with more attention to prevent non-efficacious additives to be placed on the market. On the other hand, 1 company considered that the efficacy must be evaluated by the market, and 2 business organisations that efficacy assessment needs to be revised, although they do not provide any indication. The citizen asked if during the feed trials antibiotics are used as this may conduct to incorrect results.

INNOVATION: 7 respondents (farmer, citizen, consultancy and business organization) raised the necessity to improve the Regulation in order to facilitate innovation to allow the availability of additives at affordable prices, the increase of animal performance and the sustainability of livestock farming. The research institute insisted that legislation should not restrict the development of additives needed in organic farming (use of insect-based food additives and algae).

FACILITATE THE EXTENSION OF USE TO MINOR SPECIES: 5 respondents (farmers, business association, and a research organisation) considered that the Feed Additives Regulation does not address properly the extension to those species. Fish and insects were mentioned as relevant species to consider.

LABELLING: the necessity to revise the labelling rules was raised by 5 respondents (farmers, business associations, and companies). The lack of coherence between the CLP Regulation and the Feed Additives Regulation was pointed out by one company.

ANIMAL WELFARE/ HEALTH: 5 respondents (2 farmers associations, 2 business organisations and 1 citizen). Farmers stressed the importance of animal welfare and animal health in livestock production. The business associations asked for a specific category to support animal welfare in healthy animals**.** For the citizen, the Feed Additives Regulation should also focus on animal welfare, but he did not consider appropriate to authorise those type of additives but to decrease the usage of additives. According to him, those animal welfare additives might be used to cover an inappropriate environment and a low animal welfare practices.

ANTIMICROBIAL RESISTANCE: The NGO stressed the importance to develop new alternatives to the use of antibiotics and the competent authority indicated that coccidiostats and histomonostats should not be governed by the Regulation but by specific rules to ensure animal health and reduce antimicrobial resistance.

REGISTER: the competent authority claimed that the Register of Feed Additives should be updated continuously.

PUBLIC PARTICIPATION: the citizen indicated that people should be more involved in the revision of the EU legislation on feed additives by promoting the use of social media.

3.2 Survey of stakeholders

3.2.1 PARTICIPANTS

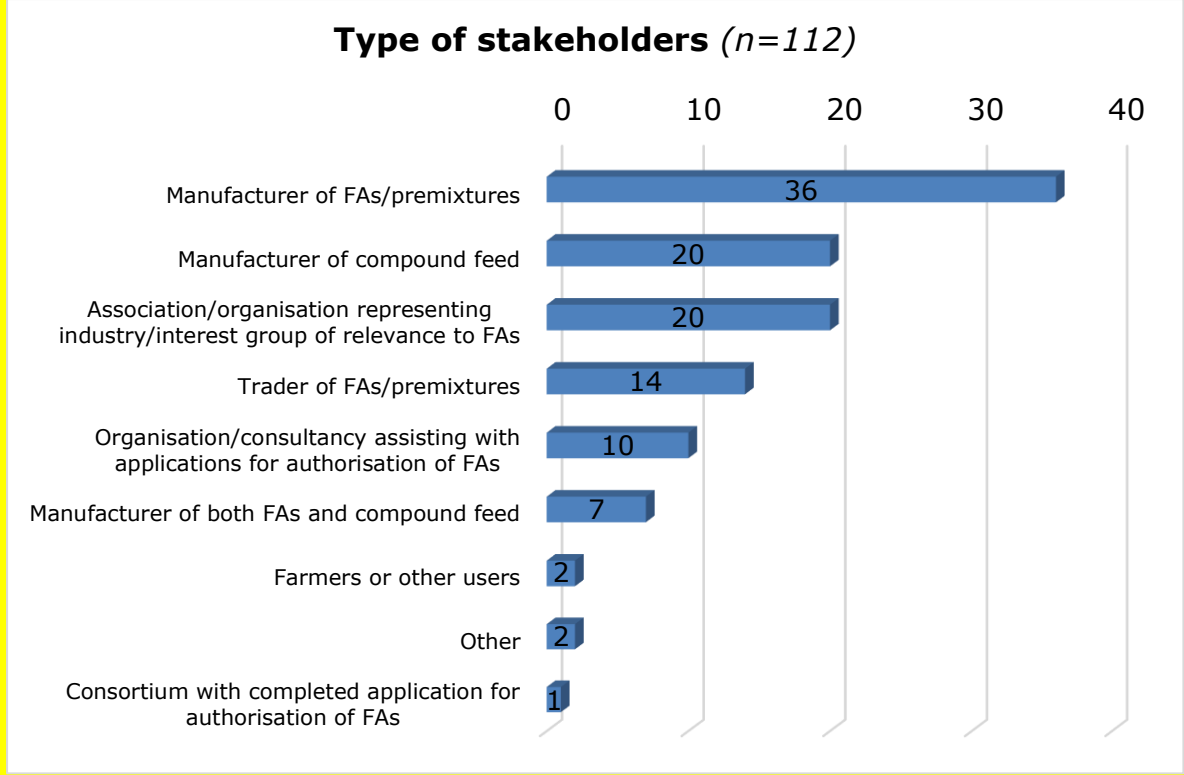
A stakeholder survey consisting of 65 open and closed questions was widely disseminated to all stakeholders affected directly or indirectly by Regulation (EC) 1831/2003. The objective of the survey was to collect data and opinions on the implementation of the Regulation from the main stakeholder groups targeted by the data collection. The survey included: general questions for all groups of stakeholders; and, specific questions for some groups, in particular applicants (authorisation) and feed operators (labelling) to collect quantitative data on the costs and benefits of the Regulation.

EU umbrella organisations were requested to make the survey available to their members, in order to obtain replies both from national level associations and from individual operators. Most of the relevant EU associations' membership is a mix of corporate members and national associations, while the feed additives association FEFANA consists only of corporate members. Responses to the survey therefore came from both national associations and individual members.

In total, **112 replies** were received from the targeted range of stakeholders (this includes only valid, completed replies). **Amongst these, 63 manufacturers of feed additives/premixtures and/or compound feed responded to the survey.**

Manufacturers of feed additives and premixtures account for the largest number of replies (36 out of 112), followed by: manufacturers of compound feed and pet food (20); associations/organisations representing an industry segment or interest group of relevance to feed additives, including the main EU stakeholder organisations active in this sector (FEFANA; FEFAC; AH Europe; FEDIAF) as well as users (farmers and cooperatives: Copa-Cogeca; the poultry sector: AVEC; the lecithin industry: ELMA) as well as some national associations (20); traders of feed additives and/or pre-mixtures, i.e. importers/ exporters/ distributors (14); organisations/consultancies which complete/assist clients with applications for authorisation of feed additives (including the association representing them at EU level: AVC) (10); manufacturers of both feed additives and compound feed (7); farmers or other users of compound feed (2); and, consortia which have completed an application for authorisation of feed additives (1). Two (2) replies came from other types of stakeholders (a veterinarian; and a technical expert). Despite efforts to disseminate the survey to wider stakeholder groups, consumers and animal welfare organisations did not contribute to this survey.

It is noted that, **as not all stakeholder survey respondents answered all questions, there are variations in some cases in the total number of responses provided per question.**



There is a good representation of EU Member States in the replies received:

- **All EU28 Member States are represented by the total sample of respondents**. Overall, less respondents tend to be based in smaller Member States with the lowest number (5) in Malta, and more respondents tend to be based in larger Member States with the highest number (31) in France, followed by 27 in Germany, 26 in Italy, 24 in Spain, 22 in the UK and 19 in Poland. Nonetheless, a large number of respondents are also based in the Netherlands (26), Belgium (25), Austria (18) and Ireland (16).
- Many respondents, particularly manufacturers of feed additives and/or compound feed and traders, as well as associations/organisations representing the industry or an interest group of relevance to feed additives, are based in several Member States. The eight EU associations that responded to the consultation have a wide representation across the EU-28.

As certain topics of the survey were targeted to specific groups of respondents, and not all respondents targeted by these questions provided an answer, the number of responses received to the various questions varies and is in most cases less than 112. For certain questions, many respondents did not answer as they '*did not know*' the topic; this is the case for example with questions on specific additives such as coccidiostats and histomonostats, pet food additives and additives for minor uses. Confidentiality issues were another common reason why respondents did not provide answers to certain questions, in particular on the costs of the Regulation. Finally, in some cases, a large number of respondents did not provide a definite answer (i.e., '*neither agreed not disagreed'* with the statement questions); this may suggest that they do not have a strong opinion or that their opinion is conflicted, and/or more granular, than could be expressed in relation to the question as it was formulated.

Nearly half (30) of the 63 manufacturers that responded to the survey produce feed additives and/or feed both for food producing and 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 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. 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.

Out of the 42 of the 63 manufacturers that responded to this question, 24 have placed one or more feed additives with a non-holder-specific (generic) authorisation on the EU market, while 18 have not placed any non-holder-specific feed additives. Of those that have placed non-holder-specific additives on the EU market, these account for at least 76% of turnover for 11 companies and more than 50% of turnover for 4 companies.

The sample of responses suggests that the manufacturing and trading operations (import, export, as well as distribution within the EU) of feed additives and/or premixtures tends to be conducted as a separate business, with only 3 manufacturers indicating they are involved in trading (although this question was answered only by 37 respondents, out of the 63 manufacturers and 14 traders that responded to the survey).

Amongst manufacturers and traders, almost equal numbers of responses come from larger companies (30; including 10 SME companies that are part of a larger company that is not an SME), and SMEs (28, including 9 medium, 16 small and 3 micro-enterprises).

In total, 3 additional documents were provided by stakeholders to further support the information they provided. The documents were: a position paper by Copa-Cogeca on the Commission's proposal for the Regulation on the transparency and sustainability of the EU risk assessment process (November 2018); a joint position paper by AVEC-ELPHA on the use of coccidiostats and histomonostats as feed additives (September 2019); and, a position paper by a private company (manufacturer of coccidiostats) (February 2019). The two position papers on coccidiostats were also provided by respondents to the OPC (see section 3.4.2.6).

3.2.2 OUTCOME

The synopsis of survey results can be found in the following sections. The feedback provided in the open questions has been taken into account and synthesised when addressing the relevant judgement criteria and evaluation questions in the main Report.

In summary:

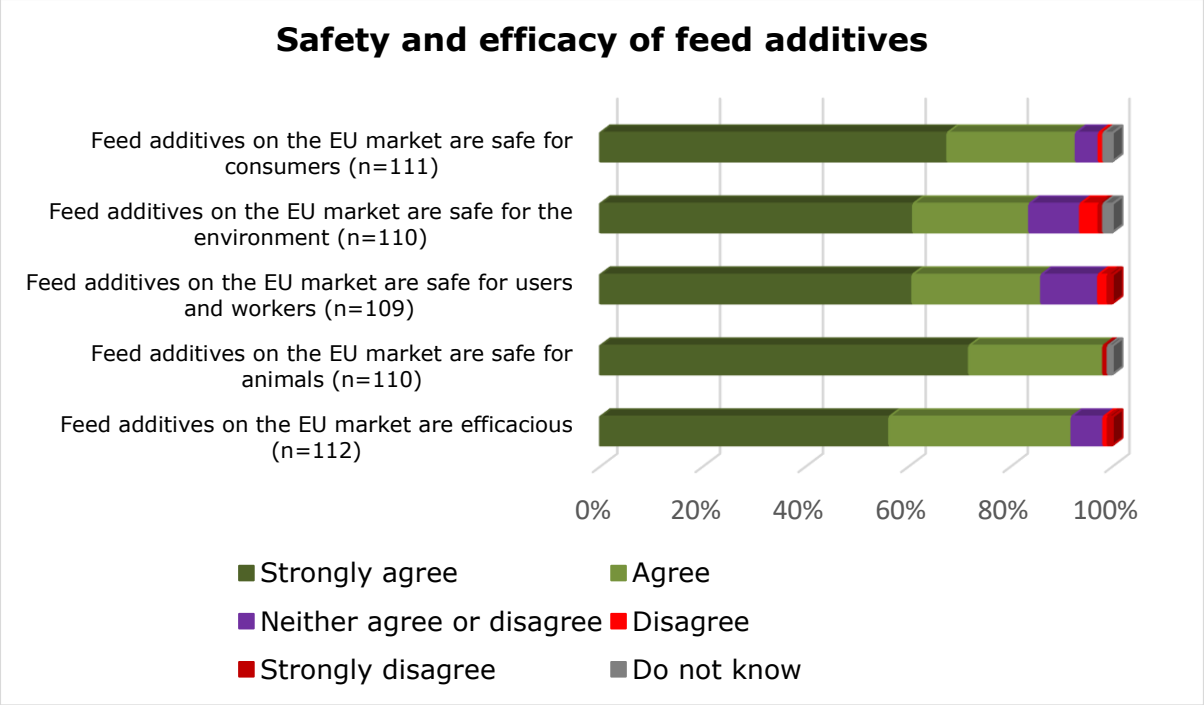
- Stakeholders generally believe feed additives are safe and efficacious. In particular, 103 out of 112 respondents believe feed additives are efficacious; only 2 respondents (manufacturers of feed additives/premixtures) do not believe so. It should be noted, nonetheless, that over 90% of responses came from the feed additives/premixtures and feed sector.
- The authorisation procedure is seen, by applicants, as more or less working well, though views on the 10-year authorisation period and on the re-evaluation procedure are more varied and a high level of dissatisfaction is noted for the procedures to extend authorisation for feed additives authorised in food and for minor species. A majority of those respondents that can apply for the authorisation of a feed additive have applied during the 2004-17 period. For 3/4 of those

applicants, the authorisation was granted, while for the remaining quarter the process is ongoing. Only 1 respondent indicated that their application for authorisation was rejected.

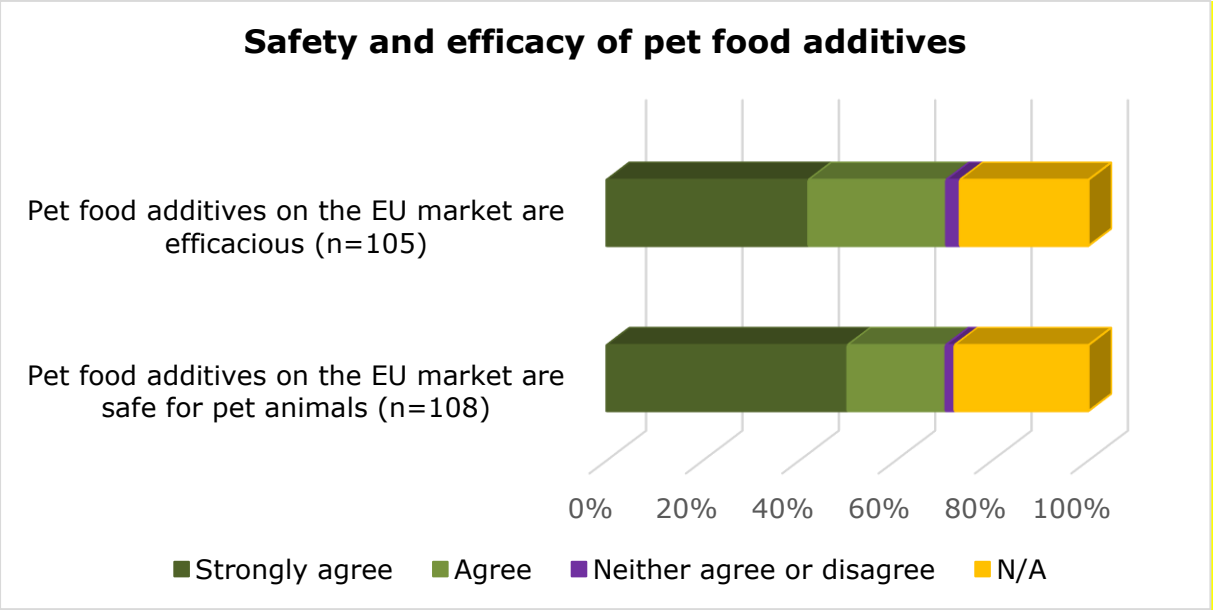
- Stakeholders appear rather divided on whether labelling requirements are fit for purpose, with a majority of manufacturers of feed additives and premixtures considering them not fit.
- Regarding scientific and technical progress, the Regulation is not considered sufficiently suitable by respondents, particularly by manufacturers of feed additives and premixtures, as well as organisations/consultancies assisting them.
- For a majority of all types of respondents, the Regulation provides benefits for farmers, pet owners, animal welfare, human health, consumers and the environment, as well as for feed additive and compound feed producers. However, it is noted that consumers and animal welfare organisations did not contribute to the survey, despite the efforts to involve them.
- On the other hand, applicants in particular expressed some concerns over the efficiency of current implementation of the procedures laid down in Articles 4, 10 and 13, and consider there is scope for reduction of administrative burden.
- Most needs identified during the drafting of the Regulation are considered to have a high level of relevance, though some new needs are also identified.
- In terms of coherence with other EU legislation, contradictions/inconsistencies are identified mostly with Regulations EC No 767/2009 on feed marketing and EU No 68/2013 on feed materials (both in general and as regards the labelling provisions contained in the Regulations). Beyond definitions not being apt to the current state of scientific and technical progress for a slight majority of respondents, missing functional groups are the most common issue identified within Regulation (EC) 1831/2003 itself (although by less than a quarter of respondents).
- For over 90% of respondents, harmonisation of the feed additive rules at EU level achieves better results than action at national level; hence, EU level intervention in the area of feed additives needs to continue.

3.2.2.1 Safety and efficacy of feed additives

A substantial majority of respondents agree that **feed additives** on the EU market are efficacious (103 out of 112 respondents), safe for animals (108 out of 110), safe for users and workers (92 out of 109), safe for the environment (92 out of 110), and safe for consumers (103 out of 111).

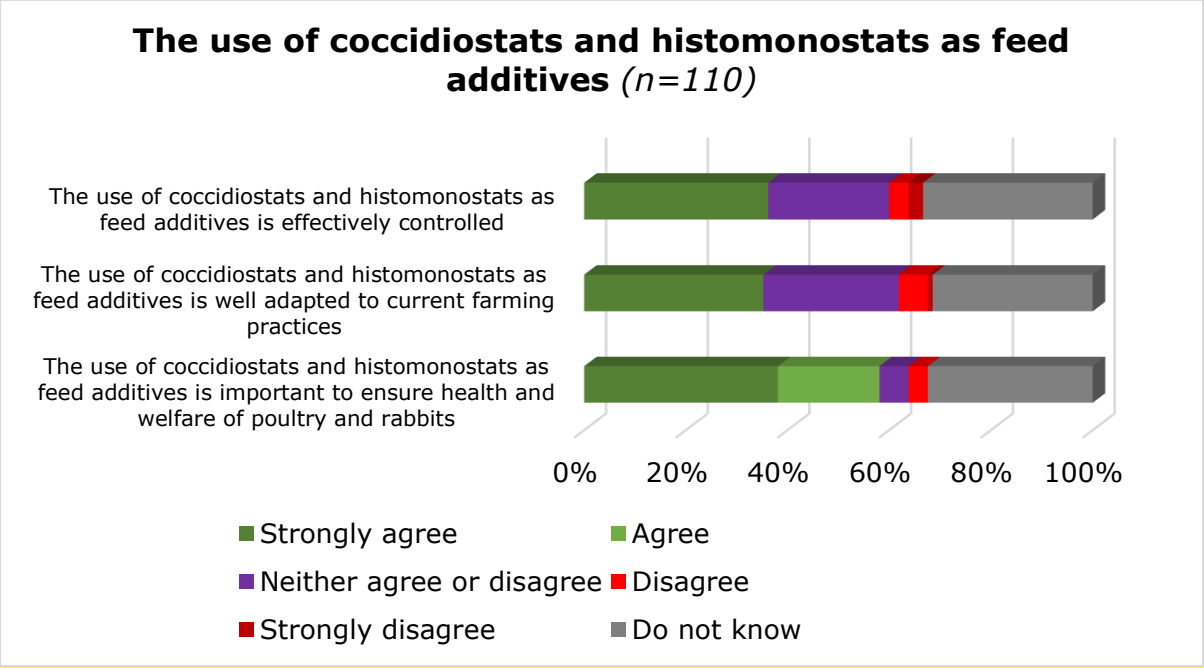


With regard specifically to **pet food additives** on the EU market, nearly all respondents agree that they are efficacious and safe for pet animals (74 and 76, respectively, out of 78 respondents; excluding, respectively 28 and 30 respondents that did not provide an answer as pet food is not relevant for their organisation). It is noted that no organisation representing the interests of pet owners as such, or animal welfare NGO, provided feedback to the survey, despite the efforts to involve them in the consultation.



A substantial majority of respondents also consider important the use of **coccidiostats and histomonostats** as feed additives to ensure health and welfare of poultry and rabbits (61 out of 71), well adapted to current farming practices (65 out of 72), and effectively controlled (63 out of 70) (in all cases, excluding a significant number of respondents that could not answer as they did not know). From the end user point of view, the organisations representing farmers and the poultry sector indicated that the use of coccidiostats and histomonostats as feed additives is well adapted to current farming practices, favourable for animal health and welfare, but also as a prevention measure in controlling the potential

spread of coccidiosis; this effectively leads to economic benefit for farmers, by preventing the potential costs arising in terms of veterinary costs and antibiotic treatments.



3.2.2.2 Authorisation, re-evaluation and renewal procedures

A majority of those respondents that can apply for the authorisation of a feed additive in the EU, whether holder-specific or non-holder-specific, have applied before the end of 2018 (38 out of 67 respondents). In particular, 23 of the 36 manufacturers of feed additives and premixtures have applied, as well as all 6 manufacturers of both compound feed and feed additives, 5 of the 9 organisations/consultancies assisting with authorisation applications, 3 traders and 1 consortium. On the other hand, 29 respondents indicated they have not applied for an authorisation.

Of those that have applied (38), the authorisation was granted for 30 respondents, and the process is ongoing for 7 respondents. Only 1 respondent indicated that their application for authorisation was rejected.

Regarding the authorisation and re-evaluation procedures, questions were addressed only to those stakeholders that have applied for an authorisation (38), whether holder-specific or non-holder-specific, and are therefore familiar with the process, to ensure that only informed feedback is provided on this topic.

According to a substantial majority of those stakeholders that applied for authorisation (Article 4), applicants have sufficient time to complete their dossiers when requested by EFSA and the Commission (34 respondents). On the other hand, according to a majority of applicants the simplified procedure for feed additives already authorised in food does not work well (23; 9 did not know); also, the procedure to extend authorisation to minor species does not works well (18; 9 did not know). The large number of '*do not know*' responses is noted in both cases. Finally, a majority of applicants (24) did not think that elements other than risk and efficacy (e.g. social, economic) are sufficiently taken into account by the Commission during authorisation (e.g. transitional periods to adapt to changes); although according to 10 respondents these elements are sufficiently taken into account and 4 could not provide a definite answer.

Regarding authorisation delays and the 10-year authorisation period, although all respondents were asked questions, a large number did not know or could not provide a

definite answer (i.e. neither agreed nor disagreed). Given their large number, *'do not know'* answers have been excluded from the totals indicated below.

According to a majority of those stakeholders that could provide an answer, Commission decisions regarding feed additive authorisation under Article 4 are issued within reasonable deadlines, i.e. 6 months from publication of EFSA opinion to publication of the Regulation, most of the time (41 out of 71 respondents) or sometimes (21). On the other hand, respondents were divided on the delays involved with Commission decisions regarding feed additive authorisation under Article 10(2), which are rarely issued within reasonable deadlines according to 37 out of 75 respondents, while according to 21 respondents the deadlines are reasonable sometimes and for 15 most of the time.

Respondents are also divided on the adequacy of the 10-year authorisation period to promote innovation, which is considered adequate by 29 and not adequate by 27 out of 99 respondents (43 neither agree not disagree). It is considered particularly inadequate for non-holder-specific additives (39 respondents; compared to 20 that consider it adequate). Similarly, the 10-year authorisation period is considered necessary to ensure safety by 24 and not necessary by 37 respondents out of 100 respondents (39 neither agree not disagree).

Updating the method of analysis is not considered necessary for the renewal of authorisation by a majority of respondents (51 out of 101), while considered necessary by 26 respondents. On the other hand, the role of the EU-RL is adequately defined in the Regulation according to the majority of respondents (61 out of 92).

For a majority of respondents (51 out of 71), non-holder-specific authorisations for nutritional additives, technological additives and sensory additives should not be replaced by authorisations linked to a specific holder; while for 20 respondents they should.

Of those that have applied for re-valuation under Article 10.2 (41 respondents), a majority agree that the re-evaluation process has helped adapt the future renewal of authorisations to new requirements (25) and has provided applicants with enough flexibility to adapt to technological and scientific progress (23). On the other hand, respondents are more divided on whether the re-evaluation process has helped additives safer for animals (whether food producing or no-food producing animals) to be placed on the market. Overall, a majority of respondents do not consider the burden of new safety and efficacy assessment required for re-evaluation to have been proportionate to the benefits (19 and 20 respondents, respectively); only 4 and 5 respondents, respectively, consider the burden to have been proportionate.

3.2.2.3 Labelling and placing on the market

A majority of respondents (53 out of 111) consider labelling requirements to be fit for purpose, although, a large number of respondents (45), particularly manufacturers of feed additives and premixtures (19 out of 36), do not consider them to be.

3.2.2.4 Costs versus benefits

Costs

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.

- **Authorisation costs**

This section of the survey was open only to applicants for an authorisation, i.e. manufacturers of feed additives, manufacturers of both compound feed and feed additives, as well as consortia and consultants assisting applicants with the preparation of their dossiers. The aim was to collect data from stakeholders that have incurred authorisation

costs. Of the total 112 respondents to the stakeholder survey, 38 respondents indicated that they have applied for a new authorisation (Article 4); of these, 32 were manufacturers (including 3 traders), 5 consultants and 1 consortium. For 12 of the 32 manufacturers, feed additives contribute more than 76% of their company's turnover and profits, and for another 4 of them feed additives contribute between 26-75%; while for 11 of them, the contribution of feed additives to turnover and profit is up to 10%.

Respondents on authorisation costs:	Number of respondents
Total number of respondents to the survey	112
Total number of respondents that have applied for authorisation *(a)*	38
of which:	
• manufacturers of FAs/premixtures/compound feed	32
• consultants	5
• consortia	1
Applicants: **manufacturers of FAs/premixtures/compound feed**, per contribution of feed additives to turnover/profits (%):	
• ≤ 10%	11
• 26-50%	3
• 51-75%	1
• >76%	12
• not indicated	5
Total	*32*

(a) A subset of those respondents provided data on staff time, external costs and costs of studies.

Only a subset of these 38 respondents provided data on the costs of the authorisation, i.e. on staff time, external costs and costs of studies. The range of responses on the average number of (safety; efficacy) studies required and average costs per study, and on this basis **average cost of studies per application**, **varies considerably between applicants**. Similarly, the average costs (staff time; external costs) for preparing and submitting the administrative dossier varies considerably between applicants. Interviews with some applicants in the context of the authorisation case study investigated in more depth the authorisation costs both on an average and on a case by case basis.

The majority (34 out of 38 applicants) indicated that the regulatory costs of authorisation have a negative impact on competitiveness; for 20 of them, the negative impact is strong. This view was confirmed by the interviews conducted during the case study on authorisation. The main elements of the authorisation process which are identified as impacting competitiveness are: costs, in particular the costs of efficacy studies which are considered disproportionate to real market needs; and, b) time required from application to approval, including the unpredictability of the process.

- **Renewal of authorisation costs**

In total, 24 respondents have applied for a renewal of an authorisation. Only a subset of those provided complete data on costs. As in the case of authorisation costs, the range of responses on renewal costs vary considerably per applicant. The interviews conducted investigated in more depth the reasons for the variation.

Respondents on renewal of authorisation costs:	Number of respondents
Total number of respondents to the survey	112
Total number of applicants for renewal of an authorisation *(a)*	24
of which:	
• manufacturers of FAs, or of FAs/compound feed	19
• consultants	5

(a) A sub-set of those respondents provided data on staff time, external costs and costs of studies.

- **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 a large number of operators there is no impact. In particular, 45 out of 80 respondents to this question indicated a negative impact; on the other hand, for 32 operators there is no impact. This view was confirmed during interviews, including those conducted during the case study on labelling. The main elements of the labelling requirements which are identified as impacting costs 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).

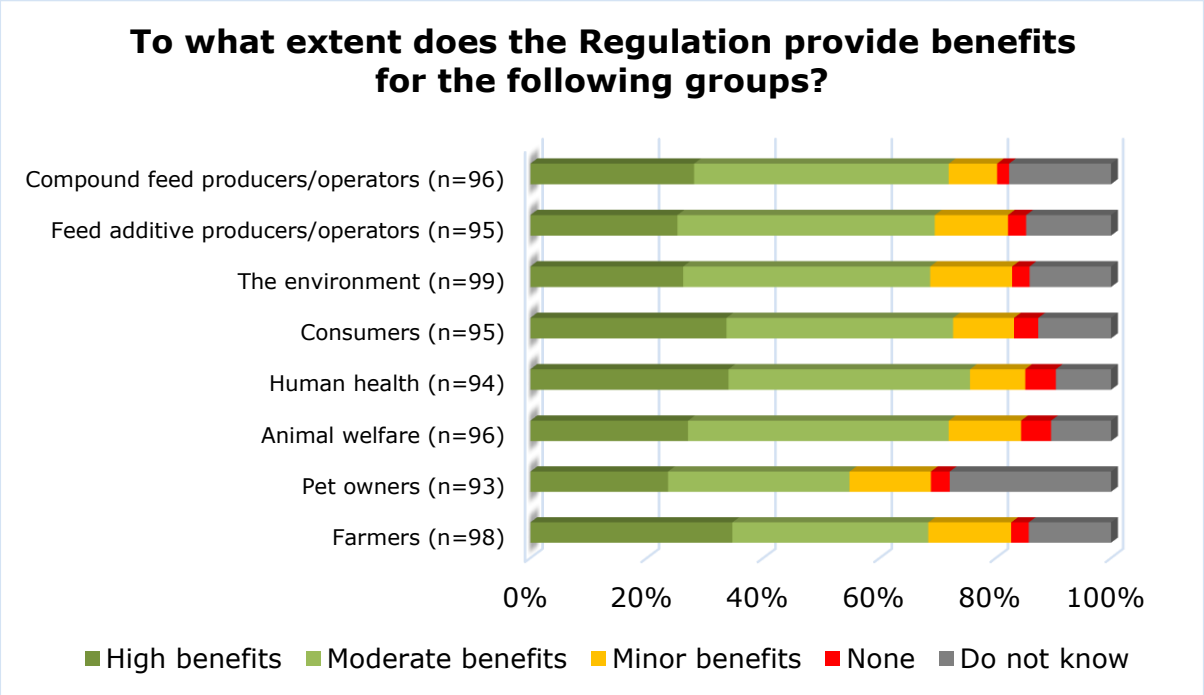
Of the total 112 respondents to the stakeholder survey, the questions on labelling changes and costs were answered only by 27 respondents. The data provided range considerably between respondents; the reasons for this variation were investigated in the context of the labelling case study.

- **Other costs: costs of disposal**

Only 3 respondents (of the total 112) indicated they have faced disposal costs for unsold products due to changes in legislation; only 2 of these respondents provided an estimate of the costs of disposal.

Benefits

The questions on the benefits of the Regulation were addressed to all types of stakeholder. According to substantial majority of respondents, the Regulation provides benefits for farmers, pet owners, animal welfare, human health, consumers and the environment, as well as for feed additive and compound feed producers.



Furthermore, according to most respondents (35 out of 55; excluding 29 '*do not know*' and 27 '*neither agree or disagree*' responses), innovative feed additives can be placed on the EU market.

Costs versus benefits

Respondents are rather divided on the **relationship between costs and benefits** of certain provisions of the Regulation (in particular Articles 4, 10 and 14), with a slight majority (of those respondents that provided a definite answer) considering current implementation of the procedures laid down in these provisions not to be efficient. It is noted that these questions were addressed only to respondents that have filed applications under Articles 4, 10 and 14 and therefore could provide informed answers.

In particular:

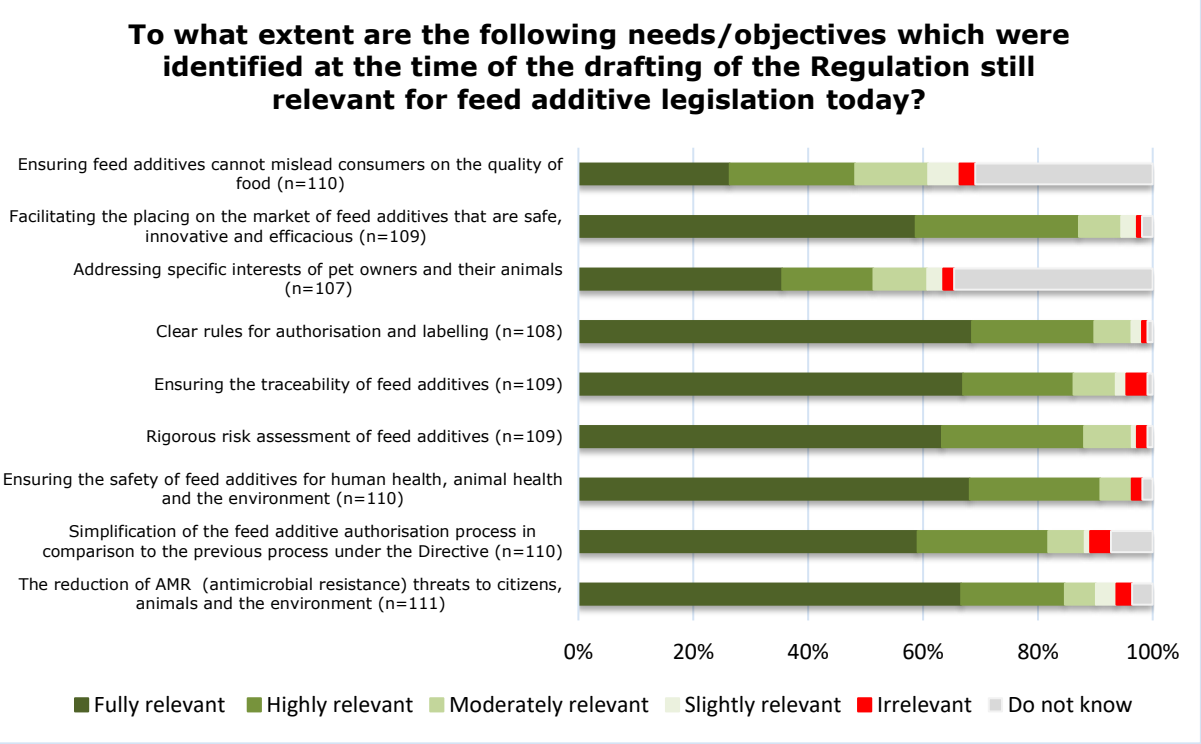
- The procedure for placing new feed additives on the market (Article 4) is considered not efficient by 16 out of 37 respondents, while 10 consider it efficient (11 respondents did not have a view and 3 respondents did not answer). Consequently, according to 14 respondents, this procedure needs to be modified significantly.
- The procedure for renewing an authorisation (Article 14) is considered not efficient by 12 out of 36 respondents, while 9 consider it efficient (15 respondents did not have a view and 4 respondents did not answer).
- The different deadlines foreseen by the Regulation (authorisation, re-evaluation, renewal, modification, suspension and revocation, i.e. Articles 4, 10 and 13) are considered not reasonable by 12 out of 37 respondents, while 10 consider them reasonable (11 respondents did not have a view and 3 respondents did not answer).

Furthermore, according to a majority of respondents (37 out of the 38 applicants), the **administrative burden** (e.g. for obligations relating to change of authorisation holder, modification of authorisation for non-holder-specific additives) can be reduced.

3.2.2.5 Suitability of the Regulation

A majority of respondents consider that the **needs/objectives** identified at the time of the drafting of the Regulation to be still highly to fully relevant for feed additive legislation today.

In particular, the reduction of antimicrobial resistance (AMR) threats to citizens, animals and the environment is still considered relevant by 94 out of 111 respondents. The simplification of the feed additive authorisation process in comparison to the previous process under the Directive, as well as ensuring the safety of feed additives for human health, animal health and the environment are still considered relevant by 90 out of 101 respondents. Providing a rigorous risk assessment of feed additives and ensuring the traceability of feed additives are still considered relevant by 96 and 94, respectively, out of 109 respondents. Most of the remaining respondents consider each of the above needs/objectives to be moderately relevant, and only very few respondents consider them slightly relevant or irrelevant.



At the same time, a majority of respondents (75 out of 112) identify new needs/objectives for the EU feed additive legislation, which emerged since the Regulation was adopted. An analysis of the identified needs was performed to classify them by broad theme and the extent to which stakeholders considered these needs to be fulfilled.

"New needs" identified by the consulted stakeholders and extent to which they are met by the Regulation

Need	Number of cases	Fulfilment rating *(1= fully; 3= to a moderate extent; 5= not at all)*
Issues related to authorisation *(issues vary, main sub categories identified below)*	**41**	**3.56**
- Efficiency of the authorisation process	25	3.60
- Factors taken into account during authorisation	7	3.71
- Fast track authorisation procedures for certain FAs	4	3.00
Environment *(environmental impact of FA use and the reduction of emissions should be taken into account)*	**39**	**3.05**
Sustainability *(the sustainable use of resources, and sustainable farming/food production)*	**34**	**3.18**
Animal welfare	**35**	**3.11**
Innovation *(generally the ability to quickly introduce innovative products or technologies)*	**31**	**3.77**
Clarifications and definitions in the Regulation *(issues varied, but in general they related to the categorisation of FAs in the Regulation – 13 cases)*	**16**	**3.69**
Availability of feed additives *(i.e. the need to make certain specific FAs available to address certain identified problems)*	**12**	**3.33**
Administrative burden *(generally the level of administrative constraints and harmonisation)*	**12**	**3.75**
Labelling *(generally the clarity of labelling)*	**8**	**3.00**

Need	Number of cases	Fulfilment rating *(1= fully; 3= to a moderate extent; 5= not at all)*
Economic protection *(generally that FAs should only be holder-specific)*	**7**	**4.29**
Grey areas *(generally the border between FAs and other products)*	**5**	**3.33**
Anti-microbial resistance (AMR)	**3**	**2.67**

Source: Survey results

Regarding **scientific and technical progress**, results indicate that the Regulation is not considered sufficiently suitable by respondents. Amongst respondents, manufacturers of feed additives and premixtures, as well as organisations/consultancies assisting them with authorisation applications, are those particularly discontent with the suitability of the Regulation to address scientific and technical progress.

In particular, respondents are divided on whether the definitions in the Regulation are in line with the current state of scientific and technical progress, with a slight majority (44 out of 108) finding them not to be (compared to 39 that consider them to be). Similarly, a majority (45 out of 107) consider the authorisation procedure to be not suitable to address scientific and technical developments for pets and livestock production, due to the delays incurred (compared to 34 that consider it suitable); and, in the light of scientific and technological developments, the criteria used for authorisation of feed additives are not considered still relevant by 28 out of 44 respondents (compared to 13 that consider them still relevant).

Regarding **trade**:

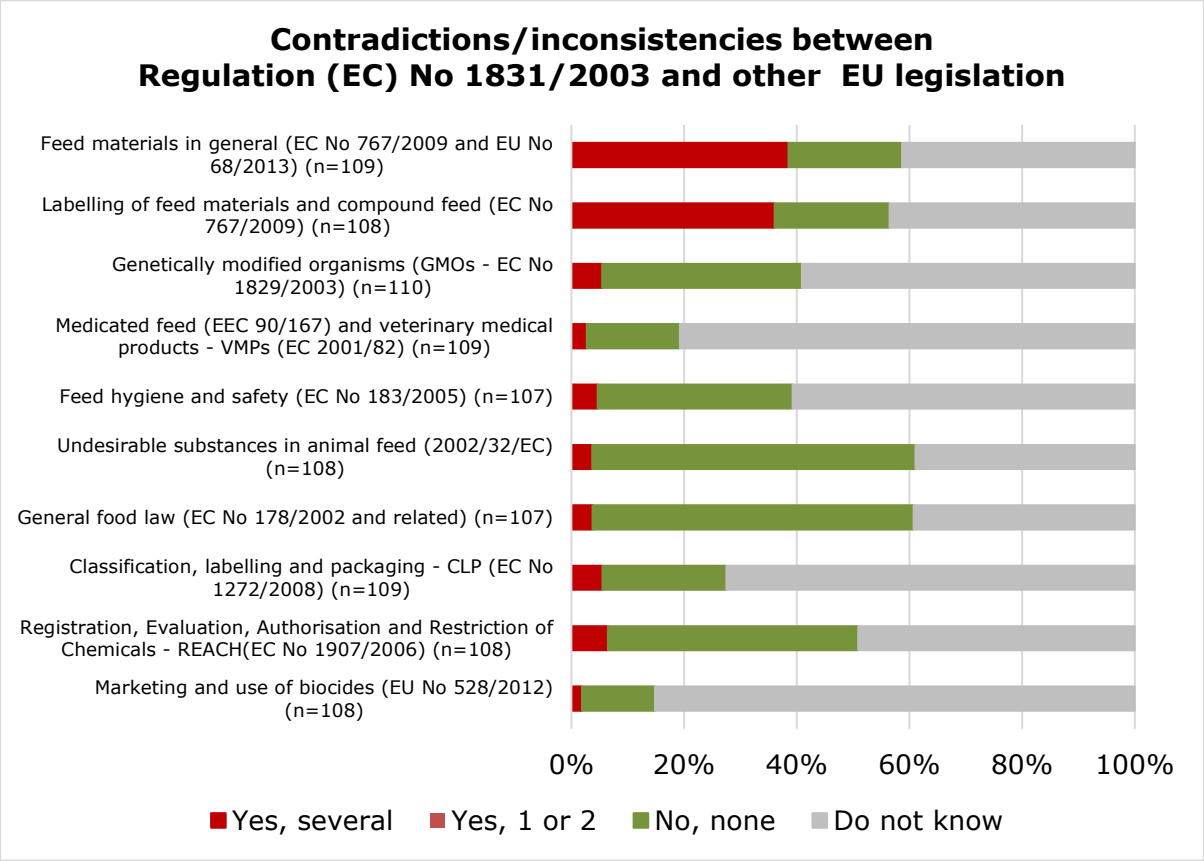
- **Exports:** a majority of respondents (35 out of 65; excluding 19 '*do not know*' responses) consider the rules applicable to the export of feed additives to be properly addressed in the Regulation; while 20 consider them not to be properly addressed. About a third of respondents (27 of 98), including manufacturers, traders, and associations/organisations in the sector, were aware of 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.
- **Imports**: a majority of respondents (40 out of 62; excluding 17 '*do not know*' responses) consider imports of feed additives into the EU to be adequately controlled; while 14 consider them not to be adequately controlled.

In terms of whether there is **scope for updates to the Regulation**, according to a substantial majority of respondents (75) no functional groups are missing from the Regulation at present (e.g. additives which cannot be placed on the market as they do not fall inside the Regulation's functional groups). Nonetheless, 26 respondents identify missing functional groups. On the other hand, according to a substantial majority of respondents (61 out of 71; excluding 36 '*do not know*' responses) there is a need to update the requirements for the renewal of authorisations.

3.2.2.6 Coherence

A large number of respondents could not provide answers on the coherence of the Regulation with other EU legislation; for this reason, the '*do not know*' responses have been excluded from the totals indicated below. This may possibly suggest that they do not encounter any conflicts between the Regulation and other legislation in the course of their work. Amongst those respondents that could provide an answer, generally, more respondents tended to identify (several) contradictions/inconsistencies than those that did not. The largest number of respondents identified contradictions/inconsistencies with the EU legislation on feed marketing (Regulation (EC) No 767/2009), particularly as regards labelling provisions for feed materials and compound feed (42 and 39 respondents,

respectively, out of 64). The key inconsistency identified by respondents is that the labelling provisions of the Feed Additives Regulation require all information to be available on the physical product label, while Regulation (EC) No 767/2009 also allows the use of other means (e.g. through other media such as electronically readable labels) that reduce the costs of the information provision.



3.2.2.7 EU added value

For a substantial majority of respondents, harmonisation of the feed additive rules at EU level achieves better results than action at national level. This is the case both with the centralised EU-level authorisation procedure and harmonised labelling rules (according to 101 and 105, respectively, out of 110 respondents). Hence, EU level intervention in the area of feed additives needs to continue, according to 71 out of 79 respondents (excluding 31 *'do not know'* responses).

3.3 Survey of MS CAs

3.3.1 PARTICIPANTS

The survey consisted of 47 open and closed questions and was made available to all national Competent Authorities (NCAs) from all 28 Member States. The objective of the survey was to collect data and opinions on the implementation of Regulation (EC) 1831/2003.

In total, **27 replies** were received from:

- 25 EU Member States (all MS except Hungary, Romania and the UK);
- Norway and Switzerland.

The analysis below focuses on EU Member State NCAs only.

Finally, 3 additional documents were provided by 3 Member States to further support the information they provided. These are:

- A letter by one MS NCA regarding PAFF committee discussions to update implementing Commission Regulation (EC) No 429/2008. The letter provides initial NCA feedback to proposals on methods for detection and identification of genetically modified strain in feed additive material.
- A legal act in one MS, detailing the necessary complementary measures at national level for the application of the Feed Additives Regulation, including operator obligations and competent authority controls.
- A national protocol in place in one MS on the authorisation of manufacturing for export feed products not authorized for placing on the EU market.

3.3.2 OUTCOME

The synopsis of survey results can be found in the following sections. The feedback provided in the open questions has been taken into account and synthesised when addressing the relevant judgement criteria and evaluation questions in the main Report.

In summary:

- NCAs generally believe feed additives are safe and efficacious.
- The authorisation procedure and the re-evaluation procedure are seen as working better than the Directive but some issues and scope for improvements are identified; views on the 10-year authorisation period are more varied.
- Most NCAs consider current implementation of the Regulation to be efficient, although, according to 10 NCAs, there is scope to reduce administrative burden.
- Most needs identified during the drafting of the Regulation are considered to have a high level of relevance, though some new needs are also identified.
- Few (1 or 2) contradictions between the Regulation and other legislation are perceived by respondents to currently exist. Most common are respondent perceptions on contradictions with the feed legislation (Regulations EC No 767/2009, EU No 68/2013 and EC 183/2005). Absent definitions are the most common issue identified within Regulation (EC) 1831/2003 itself.
- Just under 1/3 of NCAs thought there are differences between Member States in the interpretation of the Regulation; and over 40% thought there are differences between Member States in the interpretation of other legislation particularly other feed legislation, which creates issues of coherence for feed additives placed on the EU market.

- Action has been taken by 19 Member States to avoid additives and premixtures not authorised in the EU which are intended for export ending up on the EU market; while 6 Member States have not taken any action.
- All NCAs agreed that harmonisation of the feed additive rules at EU level achieves better results than action at national level; hence, EU level intervention in the area of feed additives needs to continue.

3.3.2.1 Safety and efficacy of feed additives

Overall, nearly all Member States agree that feed additives on the EU market are efficacious and safe for animals, for users and workers, for the environment and for consumers. As regards safety for users and workers and safety for the environment, 6 NCAs and 3 NCAs, respectively, did not provide a definite answer (i.e. neither agreed nor disagreed that they are safe):

- In terms of safety for users and workers, several NCAs commented that as long as rules are properly enforced feed additives should be safe; but, according to two NCAs, it is not always possible for the NCA to enforce. In particular, the Competent Authority responsible for controlling the production and use of feed (Veterinary Inspection) may not have the appropriate knowledge and competence to enforce the warnings placed in the additive's authorisation regulation regarding the principles of safe use and personal protection.
- In terms of safety for the environment, two NCAs commented that the impact on the environment has been less examined by EFSA for older applications/approvals but has increased in interest in recent years. Some NCAs commented that there are challenges in the assessment of the impact on the environment in certain cases: e.g. one NCA reported challenges for assessing the impact on the marine environment, such as in the case of the authorisation of increased maximum content of vitamin D in salmon feed; several NCAs indicated there are challenges in the case of additives produced with genetically modified micro-organisms.

As regards specifically pet food additives on the EU market, nearly all respondents agree that they are efficacious and safe for pet animals (3 NCAs neither agreed nor disagreed that they are efficacious). Two of these NCAs commented that it is not so clear what efficacy means and what is being measured in the case of pet animals; adding that the efficacy of many additives used in pet food is extrapolated from their use in food.

Nearly all NCAs consider important the use of coccidiostats and histomonostats as feed additives to ensure health and welfare of poultry and rabbits (24 NCAs; no NCA disagreed), well adapted to current farming practices (20; 1 NCA disagreed), and effectively controlled (19; 2 NCAs disagreed); the remaining few NCAs did not provide a definite answer (i.e. neither agreed nor disagreed with the above statements). Key comments provided by those NCAs that disagreed or did not provide a definite answer are that the use of coccidiostats is adapted to current farming practices, in particular large scale commercial poultry farming, but the situation needs to be periodically re-evaluated to take into account scientific advances (e.g. vaccination) and potential changes in farming practices.

3.3.2.2 Authorisation, re-evaluation and renewal procedures

Overall, Member States appear to be satisfied with the current **procedure to authorise feed additives (Article 4)**. Both the simplified procedure for feed additives already authorised in food and the procedure to extend authorisation to minor species work well, according to most NCAs (15 and 17 NCAs, respectively). Most NCAs (16) believe that elements other than safety and efficacy (e.g. social, economic, environmental) are sufficiently taken into account by the Commission during authorisation (e.g. transitional periods to adapt to changes). It is noted that, for each of the above aspects, only 1 to 3 NCAs were not satisfied, although several NCAs (5-7) did not provide a definite answer.

Key comments provided by those NCAs that disagreed or did not provide a definite answer on the above aspects of the authorisation procedure are:

- In most cases the simplified procedure for feed additives already authorised in food works well. However, there are cases where differences between food and feed (typical composition, moisture content, etc.), or differences between human and animal physiology, render the presumption of efficacy somewhat less likely.
- The procedure to extend authorisation to minor species generally work well. However, applicants may not use it, either because they are not interested, or because they are not aware of the potential interest to use it in other species. Another problem 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. Finally, 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.
- Consideration of elements other than safety and efficacy, e.g. transitional periods, generally works well but could be more systematic and less case by case. Potential benefits (e.g. responding to the needs of animal production and animal health) are not sufficiently taken into account and tend to be overruled by potential risks, especially when the EFSA assessment is non-conclusive, thus leaving little room for the Commission to apply more weight to other elements in its final decision. One NCA indicated that this undermines the availability on the market of a wider range of additives that respond to current needs, e.g. hygiene condition enhancers, microorganisms as gut flora stabilizers and preservatives in the form of acids.

Member States also appear overall satisfied with the **re-evaluation process** (Article 10.2). In particular, the process has helped adapt the future renewal of authorisations to new requirements (21 NCAs); has provided applicants with enough flexibility to adapt to technological and scientific progress (20 NCAs; 1 NCA disagreed); and, has helped additives that are safer for farm animals and for pet animals to be placed on the market (22 and 20 NCAs, respectively). For each of the above aspects, only 3 to 5 NCAs did not provide a definite answer. Furthermore, the burden of the new safety and efficacy requirements for re-evaluation has been proportionate to the benefits, according to 15 and 13 NCAs, respectively; although 1 NCA disagreed, and several NCAs (9 and 11, respectively) did not provide a definite answer.

Key comments provided by those NCAs that disagreed or did not provide a definite answer on the above aspects of the re-evaluation process are:

- Flexibility to adapt to technological and scientific progress is provided as long as the substance is the same, e.g. when there is a change in the production process, but not in other cases. 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.
- Currently, very few additives specifically authorised for pet food have been re-evaluated.
- In relation to the burden of the re-evaluation process, several NCAs were not in a position to express an opinion. One NCA indicated that EFSA guidelines were not always clear for applicants; another NCA commented that efficiency could be improved if EFSA addressed its questions to the operators on the scientific and technical evolution, one year before the authorisation expires.

Similarly, the different deadlines foreseen by the Regulation (authorisation, re-evaluation, renewal, modification, suspension and revocation - Articles 4, 10 and 13) are considered reasonable by 19 NCAs, although 1 NCA disagreed and 5 NCAs did not provide a definite answer. Consequently, according to 18 NCAs, the procedure for authorisation does not need to be modified significantly, although 1 NCA disagreed and 6 NCAs did not provide a definite answer. On the other hand, NCAs are rather divided on whether the procedure for the renewal of the authorisation needs to be updated to prevent problems: according to 12 NCAs the procedure needs to be updated, while according to 12 NCAs it does not.

A key comment provided by those NCAs that disagreed or did not provide a definite answer is that, at the moment, there are a number of feed additives in the EU Register for which the original authorisation has expired, applications for reauthorisation have been submitted, and there is no final decision yet on their reauthorisation. Furthermore, there are feed additives for which no applications are submitted due to the costs involved, although these may be of wider benefit. In addition, concerning the renewal process, several NCAs highlighted the workload created for EFSA, the Commission and Member States and that an appropriate procedure should be provided to ensure that only technical and scientific innovations are subject to renewal.

NCA views were more varied on the 10-year authorisation period. Although a majority found this period adequate to promote innovation (17 NCAs), both for holder-specific (18 NCAs) and non-holder-specific additives (14 NCAs), 2-3 NCAs disagreed. Also, the 10-year authorisation period is considered necessary to ensure safety by most NCAs (17), although 3 NCAs disagreed. For each of the above aspects, it is noted that several NCAs (4 to 6, depending on the aspect) did not provide a definite answer.

Key comments provided by those NCAs that disagreed or did not provide a definite answer are: a 10 year authorisation can be too short to encourage innovation, particularly for smaller companies in view of the difficulties to secure funding; the period could be adapted by type of additive, e.g. level of scientific/technical progress and safety risk. For feed additives of lower risk, a period of 20 years could be more appropriate; for feed additives of higher risk, the current 10-year period is generally appropriate.

Updating the method of analysis is considered necessary for the renewal of authorisation by 22 NCAs; only one NCA disagreed, commenting that the aim is the standardisation of analytical methods, not a continuous adaptation to new analytical techniques when this does not serve a specific purpose e.g. to allow better controls. On the other hand, the role of the EU-RL is adequately defined in the Regulation according to 22 NCAs; only one NCA disagreed, commenting that the EU-RL competence could be enhanced, e.g. to support the national laboratories with the development and/or execution of analysis, as well as the NCAs whenever needed.

3.3.2.3 Labelling and placing on the market

Most NCAs (19) consider labelling requirements to be fit for purpose; only 3 NCAs disagreed and the remaining 3 NCAs did not provide a definite answer. A key comment by those NCAs that disagreed or did not provide a definite answer is that the labelling could be modernised, with certain indications potentially provided in a separate document (other than the label).

In terms of innovation, 12 NCAs believe that innovative feed additives can be placed on the market, but 4 NCAs disagreed and 9 NCAs did not provide a definite answer. 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 the main issues raised by those NCAs that disagreed or did not provide a definite answer.

3.3.2.4 Costs versus benefits

Due to the need to respect confidentiality, data collected from the survey were analysed and presented jointly, in the Report.

Most NCAs consider current implementation of the Regulation to be efficient. In particular, as already indicated in the previous section on the authorisation procedure:

- The burden of new safety and efficacy assessment requirements for re-evaluation has been proportionate to the benefits, according to most NCAs (15 and 13, respectively), although several NCAs (9 and 11, respectively) did not provide an answer and 1 NCA disagreed. Overall, most NCAs appreciate the benefits of the process as the first authorisations took place a long time ago, and the re-evaluation led to the removal of potentially unsafe feed additives from the EU market.
- The different deadlines foreseen by the Regulation (authorisation, re-evaluation, renewal, modification, suspension and revocation, i.e. Articles 4, 10 and 13) are overall considered reasonable by 19 NCAs.

On the other hand, according to 10 NCAs, the **administrative burden** (e.g. for obligations relating to change of authorisation holder, modification of authorisation for non-holder-specific additives) can be reduced; although 12 NCAs did not provide a definite answer and 3 NCAs disagreed. Key aspects raised to improve the administrative burden are: changing the format of the feed additive Register to a web-based platform with searchable criteria, e.g. to allow updates and finding more easily the status of each additive; and, the procedure to follow for changes in the modification of authorisation holder (as this is currently included in the authorising regulation).

3.3.2.5 Suitability of the Regulation

A substantial majority of NCAs consider that the **needs/objectives** identified at the time of the drafting of the Regulation to be still highly to fully relevant for feed additive legislation today (the number of NCAs varies between 20 and 23 NCAs, depending on the need/objective, but it is always a majority of respondents).

At the same time, 15 NCAs identify new needs/objectives for the EU feed additive legislation, which emerged since the Regulation was adopted, while the remaining 10 NCAs do not identify any. In most cases, the identified issues refer to needs and objectives that are already addressed by the Regulation. Amongst genuinely new or emerging needs, taking into consideration animal welfare and climate change are those most frequently/consistently mentioned.

The Regulation is considered by most NCAs sufficiently suitable in its current form to address **scientific and technical progress**. The aspect on which some concern was expressed by few NCAs was whether the definitions in the Regulation (3 NCAs) and criteria used for authorisation of feed additives (2 NCAs) are in line with the current state of scientific and technical progress (while 6 and 3 NCAs respectively did not provide a definite answer). Key comments provided by those NCAs that disagreed or did not provide a definite answer are:

- Definitions: updating the definitions in the Regulation to update reference to old legislation, align with other recently revised legislation (e.g. Regulation No.2019/6 on veterinary medicinal products) and with scientific and technical progress; clarifying definitions to better distinguish between feed additives, premixtures, feed material, processing aids and veterinary medicines; and, adding a definition for preparations.
- Criteria for authorisation: developing a broader range of performance end-points for the assessment of efficacy, to allow innovation and address current needs.

Furthermore, 10 NCAs are aware of feed additives that cannot be placed on the market because they cannot be authorised by the Regulation, for instance because they do not match with the list of functional groups or because the use in water for drinking is not allowed (e.g. organic acids that can have a preservative function, or even some nutritional additives such as vitamins) or for other reasons. One NCA commented that a number of zootechnical additives cannot be approved because it is not possible to demonstrate efficacy with the currently accepted performance parameters ('end-points'), although these additives may provide benefits in terms of animal welfare of reducing the use of antibiotics; and that, generally it is a problem that performance parameters for zootechnical feed additives for non-food producing animals are non-existing.

Regarding **trade**:

- **Exports:** 17 NCAs are aware of feed additives that are not authorised for placing on the market in the EU, but which are still produced in the EU only for export; and, 19 NCAs have taken action to prevent that feed additives and premixtures non authorised in the EU and intended for export end up on the EU market. These actions include: registration of operators handling such additives; monitoring production, use (incorporation in premixtures) and exports, e.g. through obligation for operators to report movement and/or risk-based routine controls and random checks; import controls; obligation to notify all additives/premixtures before placing on the market; notification to the NCA of destination when sending such products to other MS; and, obligation to label ('only for export'). The actions reported by NCAs were generally considered effective and no problems were identified, except in the case of import controls (see next point). 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.
- **Imports**: 11 NCAs consider imports of feed additives into the EU to be adequately controlled; while 14 NCAs consider them to be partially controlled. The main concerns raised by the latter NCAs are: there is no EU list of third countries establishments from which feed additives can be imported; the lack of CN codes for additives that are intended for food and feed use complicates import controls, while for substances imported for food, feed or technical use, the competent authority for such imports (Customs administration) is not designed to support food or feed safety control; there are deficiencies with regard to the labelling of imported feed additives and it is not possible for Member States to control certain aspects of the authorisation of a product manufactured in third countries without controlling the production process; and, exports of non-authorised feed additives are not always and not uniformly controlled across the EU (see previous point), hence their potential re-import cannot be excluded.

3.3.2.6 Coherence

Most NCAs did not identify any contradictions/inconsistencies between Regulation (EC) No 1831/2003 and other EU legislation, with the exception of the legislation on feed material in general (Regulations EC No 767/2009, EU No 68/2013) for which 14 NCAs identified at least 1 or 2 contradictions/inconsistencies.

Within Regulation (EC) No 1831/2003, the main contradictions/issues identified (by 9 NCAs) were absent definitions and/or key terms.

Although most NCAs are not aware of any differences between Member States with regard to the interpretation of EU legislation, which create issues of coherence for feed additives on the EU market, several NCAs were aware of such differences. The extent of differences in interpretation was perceived to be most prevalent in the case of other feed legislation (EC No 767/2009; EU No 68/2013; EEC 90/167; EC 2001/82; GMO legislation; other feed and hygiene legislation) for which 9 NCAs indicated they are aware of differences, followed

by Regulation (EC) No 1831/2003 itself (8 NCAs), and less for legislation on food and chemicals (EC No 178/2002; EC No 1272/2008; EC No 1907/2006) (2 NCAs).

3.3.2.7 EU added value

For nearly all NCAs, harmonisation of the feed additive rules at EU level achieves better results than action at national level. This is the case both with the harmonised authorisation procedure and labelling rules. Hence, EU level intervention in the area of feed additives needs to continue, according to all 25 NCAs.

3.4 Open public consultation

The OPC ran from 12 December 2018 to 3 April 2019 in EU survey and the questionnaire was available in 24 languages. Respondents were invited to respond to 26 open and closed questions, plus provide further information on their background.

The OPC targeted a broad range of stakeholder groups, which were identified in the consultation strategy as potentially affected by the REFIT of Regulation (EC) No 1831/2003. This included: individual citizens, economic operators, pet owners, business organisations, workers and their representative organisations, non-governmental organisations, advisory bodies and public administrations.

To ensure a broad coverage, the European Commission directly invited 70 umbrella organisations representing the different stakeholder groups, including animal welfare and environmental NGOs, consumer organisations, farmer and trade associations, to respond to the OPC. The targeted organisations were selected based on their outreach to the wider network of the stakeholder groups that they represent. This included: the 2 most representative organisations at EU level representing consumers; the EU umbrella organisation for animal welfare, representing 68 organisations across the EU; 5 environmental organisations, representing a broad network of environmental NGOs and civil society organisations; 9 umbrella organisations representing farmers; and, in relation to worker safety issues, an EU umbrella organisation representing 120 trade unions related to agriculture and food. The link to the OPC was also posted in the SANTE website[3].

3.4.1 PARTICIPANTS

In total, **110 responses were recorded** (no duplicates identified). The overall response rate is sufficiently high for a consultation on a Regulation covering a specialist product sector. The number of respondents to the OPC, by stakeholder group, is as follows:

- 52 companies/business organisations
- 24 business associations
- 16 EU citizens
- 12 public authorities
- 6 'other' organisations, of which 2 consultants, 2 veterinarians, 1 academic/ research organisation and 1 NGO (the Federation of Veterinarians of Europe - FVE).

In addition, 7 respondents provided 7 papers in attachments to the OPC. Of these, 5 documents (submitted by 6 respondents) are position papers on the use of coccidiostats as feed additives; the remaining 2 documents (submitted by the same respondent) are proposals for revisions to the Regulation.

There is a relatively high share of responses received from business stakeholders (70% of the total). This has included responses by the main organisations representing the industry, including FEFANA, FEFAC, FEDIAF, Animal Health Europe and their members, but also farming organisations. Amongst companies (manufacturers, traders), many responses were received from SMEs. It is noted that that 39 of the 76 business associations/companies that responded to the OPC also provided feedback to the targeted stakeholder survey. This includes some organisations of large outreach, such as for example the umbrella organisation representing European agriculture (Copa-Cogeca, covering 60 organisations from the EU-28 Member States and 6 partner organisations from EEA countries/Turkey).

[3] https://ec.europa.eu/food/safety/animal-feed/evaluation-eu-legislation_en

Despite the Commission's extensive dissemination efforts, relatively limited feedback was received from organisations representing consumers, worker unions, environmental organisations and animal welfare organisations responded to the OPC. It is recalled that feed additives are a specialist sector, sitting at the top part of the food supply chain as a provider of important inputs into animal feed for food producing animals; as well as, in supplying non-food sectors including pet food and feed for other non-food producing animals. At the same time, it is interacting with a broad and diverse range of non-food supply chains for sourcing raw materials, including e.g. chemicals, minerals and plant extracts. As such, although the feed additives sector potentially exerts a broad range of impacts – including, e.g. to animal welfare, health and safety, food safety, the environment - it is likely to be not widely known to the broader citizenship or to be considered too 'distant' from the food sector or societal issues/challenges affecting citizens today. This is also reflected in the relatively low share of responses received from citizens (15% of the total).

3.4.2 OUTCOME

An overview of the OPC response was provided by the Commission in a **factual summary report**[4]. A concise analysis of the OPC results is provided below. The text differentiates between types of respondents, to the extent that a difference in views prevails. Overall, this does not happen in many cases.

The feedback provided in the open questions has been taken into account and synthesised when addressing the relevant judgement criteria and evaluation questions in the main Report. It is noted that, for organisations that responded both to the OPC and the survey of stakeholders (39 of the 76 business associations/companies), there is considerable overlap on the feedback provided to the open questions.

3.4.2.1 Safety and efficacy of feed additives

The majority of respondents believe feed additives to be safe and efficacious, with some slight variation depending on the aspect of safety or efficacy; e.g. from 72% of all respondents agreeing that the ban on antibiotics introduced by the Regulation played an important role in preventing antimicrobial resistance (AMR); to 91% believing that feed additives are safe for animals.

Companies were almost unanimous in their belief, but views of respondents other than companies were more nuanced (Q1). Citizens in particular provided nearly all of the "*Don't know*" answers to this question. For example, citizens were disproportionately likely to either not know or disagree with the statement that feed additives authorised in the EU are safe for the environment and tended not to agree or disagree with the statement that feed additives help to improve animal welfare. In summary, as might be expected, by often not expressing a view, citizens clearly do not consider themselves to be as well informed on the safety and efficacy aspects of feed additives as other respondents.

The one NGO that replied to the OPC disagreed that the ban of antibiotics in feed introduced by the Regulation plays an important role in preventing antimicrobial resistance (AMR) because of its lesser relevance, as the main contribution to AMR in humans is driven by the use of antibiotics in humans. The organisation commented that although antibiotics in feed were banned and the use of antimicrobial medicines in animals was reduced significantly, no effect of such measures on the use of antimicrobials in animals is observed yet. On the other hand, nearly all of public authority respondents, as well as the one academic/research institute that responded, either agreed or strongly agreed the Regulation plays an important role in preventing AMR.

[4] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1483-Evaluation-of-the-feed-additives-Regulation/public-consultation

Similarly, 90% of respondents believe the safety assessment of feed additives carried out by the European Food Safety Authority (EFSA) has helped make feed additives safe for human health, animal health and the environment (Q2). Two thirds of EU citizen respondents share this view; while the remaining one third did not know (the "*Don't knows*" were largely accounted for by citizens).

3.4.2.2 Authorisation, re-evaluation and renewal procedures

Although respondents across all groups overwhelmingly believe there is an added value in having a harmonised, centralised authorisation procedure for feed additives at EU level (Q6), they are divided on some aspects of implementation of the Regulation; but the large number of *"Don't knows"* is noted in some cases. In particular:

- Just over half of respondents believe that the Regulation does not make it easier to place new innovative additives on the market when compared with the former Directive 70/524/EEC (Q5). Most notably, only 10% of companies/business organisations and 21% of business associations believe that the Regulation makes it easier; while 42% of public authorities think it does. Common issues identified by those respondents that express a negative view are the complexity, cost and time taken to complete authorisations, particularly for SMEs. Several respondents highlighted the example of the efficacy assessment for zootechnical additives, noting that the performance criteria (end-points) set by the Regulation to assess efficacy require a range of studies that are not always appropriate in a real market context. According to those respondents, the result of these difficulties is that only commercially high value additives come to market, leading to the reduction in the range of additives available in certain categories.
- For a slight majority of respondents across all respondent groups, the information available in the publicly accessible Register of Feed Additives provides sufficient information on feed additives for interested parties, with most respondents noting that the Register has been a great improvement compared to the previous situation (Q7). Nonetheless, around 1/4 of respondents believe it does not and would like to see further improvements. Negative views on the Register focused mainly on useful information that is currently not provided (e.g. conditions of use; link to the EFSA Register of Questions) and on the current pdf format of the Register which does not allow users to search by key criteria (e.g. by name and type of additive, functional group, species, maximum use levels, etc.). Respondents indicated that providing the Register as an online database with a consolidated version and a search function would be a more practical format for users.
- Respondents were divided on whether the definitions in the Regulation are clear, relevant and up to date, with almost half believing them to be, compared to just under 30% who believe they are not (Q8). More than half of the business associations, public authority respondents, and the academic/research institute that responded felt the definitions are clear, relevant and up to date. Companies/business organisations had a more mixed response; the NGO expressed a negative view. Although no comments were provided on this specific question, elements underlying these responses can be found in comments to other questions. On the positive side, several respondents noted that the Regulation allows for more flexibility than the Directive, such as the definition of new functional groups (e.g. substances for the reduction of mycotoxin contamination). On the negative side, few respondents noted that the whole approach for defining categories and functional groups is outdated and needs rethinking (one private consultancy provided a list of suggestions on this); and that definitions should be clarified and completed (e.g. active substance vs. feed additive, preparations, premixtures vs. mixtures of feed additives, use in water, etc.), as well as better aligned with the feed catalogue and other feed regulations. However, the majority of respondents with negative views focused mostly on specific implementation issues rather than the definitions as such.

- Views on the suitability of procedures set out in the Regulation vary (Q9), but the large number of *"Don't knows"* is noted. For almost 3/4 of respondents that provided an answer, having a centralised authorisation procedure ensures equal treatment of all applicants and common requirements, and the procedure for submitting an application is fit for purpose (compared to 14% who believe it is not). However, respondents were less positive about the suitability of data requirements for renewing an authorisation; with just over a third of those providing an answer believing requirements to be suitable, compared to almost a quarter who believe they are not; with business associations particularly negative on the suitability of data requirements. Regarding the procedures for granting, modifying, suspending and revoking an authorisation companies/business organisations and business associations were much more equivocal on whether these are fit for purpose, with a higher proportion than for other respondent types neither agreeing nor disagreeing.
- Similarly, although for most respondents the authorisation procedure set out in the Regulation involving EFSA and the Commission is still fit for purpose (Q10), and the risk assessment carried out by EFSA allows for sound decision making (Q11), companies/business organisations were the most negative on these aspects. Furthermore, respondents, particularly business associations, were less positive about the suitability of data requirements for renewing an authorisation. Issues posing challenges with the implementation of the current authorisation process, that are commonly identified by most respondents, include: delays, e.g. due to the fact that the Comitology process do not start until the EFSA public opinion is issued; absence of possibility to communicate with the applicants involved at critical points in the process, which may result in further delays and other impacts (e.g. through pre-submission meetings with EFSA-FEEDAP experts to clarify scientific questions on the study protocols; for editorial review by the applicant prior to publication of implementing authorising regulations to avoid occasional errors in content); disproportionate requirements for efficacy studies (e.g. requiring *in vivo* studies; EFSA assessment based on Article 5 of the Regulation, i.e. general feed additive effects, rather than the actual definition of the specific functions in Annex I).
- Over half of respondents were not able to say whether data protection rules are effective in relation to the cost of preparing dossiers and the benefits provided by the 10-year protection (Q12); and whether data-sharing rules are effective in reducing costs and animal testing (Q13). Among those respondents who were able to answer, roughly 2/3 (i.e. a third of total respondents) believe the implementation of these aspects not to be effective, with business associations and companies/business organisations particularly negative about the data protection rules. According to these respondents, the 10-year data protection does not ensure sufficient return on investment in relation to the costs involved for bringing a product to market, whether of holder-specific or non-holder-specific additives, especially for innovative feed additives and/or those requiring a high R&D cost. For non-holder-specific authorisations in particular, there is an additional issue that the data protection rules as set in the Regulation do not provide any protection to the applicant/s (i.e. once the authorisation is granted, any feed business operator can market the product in the EU if it complies with the provisions of the authorising regulation), while the authorisation costs are shouldered only by the applicant/s. Furthermore, respondents noted that data sharing has been used on very few occasions during the assessment of feed additives, and only for non-holder-specific additives. Concerns were also raised by several respondents on the extent to which the data protection rules can offer protection following the forthcoming implementation of the new Regulation on the transparency and sustainability of the EU risk assessment in the food chain[5], as after submitting an application the dossier

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

and all studies will be available to competitors worldwide. These issues are identified as particularly challenging for SMEs.

3.4.2.3 Labelling and placing on the market

A majority of respondents believe that the labelling of feed additives and premixtures is informative and helps prevent their misuse along the feed chain, but the Regulation should also allow for information through other channels than the product label (Q17).

Respondents were more divided on whether the information provided on the label relating to the safe use of the additive is clear and enables measures necessary for worker protection to be applied effectively: just over half of respondents believe that the information is clear and effective, while about a quarter believe that it is not, particularly amongst companies/business organisations, business associations, and EU citizens.

Those respondents that expressed negative views believe there is a need to make labelling requirements more practical, facilitating the information flow along the feed chain, to be coherent with other legislation, for instance the feed marketing legislation (Regulation (EC) 767/2009). With regards to worker protection, some industry respondents believe that the rules laid down in the CLP Regulation are sufficient.

3.4.2.4 Costs versus benefits

Regarding the costs and benefits of the Regulation, respondent views vary, with business associations particularly negative (Q19):

- For most respondents (59%), particularly public authorities and business associations, the Regulation has been effective in preventing food/feed crises and losses. In particular, guaranteeing a high level of protection of human and animal health, protecting against misleading practices, and ensuring that decisions relating to safety are supported by a sound scientific basis are very important elements appreciated by the majority of respondents, including business stakeholders.
- Nonetheless, fewer respondents (36%) believe the cost of labelling feed additives/premixtures is justified by the value of information provided to the user. While a majority of public authorities believe the cost is justified, business associations are more divided, and companies/business organisations tend to believe that the cost is not justified, mainly because of the practicalities of providing the information under current rules (see earlier section on labelling, Q17).
- Only 12% of respondents believe the cost of applications for getting a feed additive authorised in the EU market to be proportionate to the benefits. This is mainly due to the issues raised by those that expressed negative views on the authorisation process (see earlier section on authorisation procedures), in particular: the 10-year duration of the authorisation which is considered insufficient (Q12 and Q13), as well as the challenges of completing the assessment of efficacy and the issues surrounding non-holder-specific authorisations (costs borne by applicant/s while benefits enjoyed by all operators putting the authorised feed additive on the EU market) (Q5, Q10, Q11). Companies/business organisations and business associations were particularly negative about these points.

On the other hand, respondents overwhelmingly believe that EU harmonised conditions for placing feed additives on the market ensures fair competition within the EU and facilitates trade (Q18); and that EU level intervention in this sector is still warranted (Q20). Nonetheless, respondents, in particular companies/business organisations and business associations, are divided as to whether the Regulation positively or negatively affects the competitiveness of the EU feed additives sector (Q20); public authorities were more likely to agree (67%), while companies/business organisations and business associations were more likely to disagree (36% and 32% respectively).

3.4.2.5 Suitability of the Regulation

Respondents are divided as to whether the authorisation of feed additives should consider, and sufficiently considers, (a) societal needs and (b) economic aspects as well as safety and efficacy; although the relatively large number of "*Don't know*" answers (nearly a quarter of respondents) is noted in this case (Q3). Citizens are slightly more inclined to indicate that societal factors are not sufficiently taken into consideration; companies/business organisations and business associations were, perhaps expectedly, more likely than other respondent types to consider that economic aspects are not sufficiently taken into account.

The main aspect that respondents put forward was improving the authorisation procedure to foster innovation and to take into account scientific progress, by ensuring the procedure takes place in a timely manner (Q4). In particular, common needs that several respondents (across all types of respondent) identify as not sufficiently considered by the current authorisation process (Q3; Q4) are:

- Ensuring innovation, especially by SMEs, on new product development aiming to address evolving societal needs (e.g. further reducing the use of antibiotics, improving meat quality, addressing animal welfare and conditions of breeding; improving sustainability, reducing environmental impact).
- Enabling authorisations which do not have large commercial support, such as for additives intended for a limited market, e.g. for pet food, bait feed, food-producing animals such as rabbits, etc.
- Avoiding the economic impact (caused by the disruption to supply and innovation) of the withdrawal of a feed additive, based on 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 this impact to reach more proportionate decisions.
- Avoiding unnecessary animal testing, which – according to some respondents – is imposed by the large number of trials required to assess efficacy in particular.

Amongst only half of respondents that could answer certain questions on the **scope** of the Regulation:

- A small minority (18%) of respondents believe that the Regulation is sufficiently flexible to adapt to new scientific and technical developments (Q14). A majority (59%) of public authorities agree with the statement; and the academic/research institute agreed, while the NGO disagreed. On the other hand, the Regulation is not considered sufficiently flexible by an important share (38%) of respondents, especially among business associations (41%) and companies/business organisations (52%).According to disagreeing respondents, science and technology evolves at a much faster pace than regulatory developments, with the industry research and development efforts focusing on innovative new products to meet current challenges (e.g. alternatives to use of antibiotics, more sustainable food production, reducing the impact of farming practices on the environment, improving animal welfare, etc.). The current framework lacks the flexibility to adapt to scientific and technological advancements. A key issue identified is the efficacy assessment of innovative products, for which the mode of action and demonstration of efficacy are often based on new scientific developments, which are not included in the EFSA guidance or are not fully reflected in the conditions for authorisation (Article 5) of the Regulation. Beyond the development of new/innovative feed additives as such, there are further innovations in relation to analytical methods (e.g. to assess efficacy: in vitro methodologies for demonstration of mode of action, as well as non-invasive measurements for specific performance criteria or 'end-points') and for labelling (use of new technologies, e.g. bar codes or QR codes), which are currently not sufficiently addressed or encouraged by the Regulation.

- Some 45% of respondents believe that there are new categories of feed additives and/or functional groups that need to be considered by the Regulation (Q15), with plant extracts and additives for animal welfare mostly cited as new categories that need to be considered. Business associations, companies/business organisations and public authorities were more likely to state that new categories need to be considered. Some business organisations proposed to add an "other" functional group to each feed additive category to allow greater flexibility and innovation; the newly created group of physiological condition stabilisers was cited as an example which demonstrates that the current process to establish a new functional group does not have the pace that is needed to develop solutions for new societal needs and scientific progress.
- Almost 40% of respondents believe that the use of additives in drinking water needs to be clarified (Q16), in particular it should be made clear which additives can be used in drinking water and which cannot. Amongst those that favour clarification, the issue most commonly cited is the interaction of additives in drinking water, in particular technological additives e.g. preservatives, with the legislation on biocides. The problem lies in that 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, but the approach is different. Public authorities were more likely to say that clarification is needed, followed by companies/business organisations; the NGO also argued for more clarification. However, the large proportion of respondents not expressing an opinion (44%), particularly amongst citizens (79%), should be noted.

3.4.2.6 Other comments and uploaded documents

The responses to the final open question and the uploaded documents reflect the views, opinions of respondents as depicted by their answers to closed questions and level of agreement with the statements described above, which also largely depend on the extent of relevance of the Regulation for the respondents' profession or interests. For example, respondents either identify a problem of implementation and call for a "more flexible" approach or they demand more consideration of factors other than safety and efficacy and an even stricter authorisation procedure.

In total, 7 documents were uploaded by 7 respondents to the EU survey. Of these documents, 5 are position papers on the use of coccidiostats as feed additives (submitted by 6 of the 7 respondents). The following organisations are authors of each of these 5 papers: a) the working group anticoccidials of the PVSG (Veterinary Poultry Specialists in the EU); b) ELPHA-AVEC; c) Zentralverband der Deutschen Geflügelwirtschaft e.V.; d) the Association of Veterinary Consultants (AVC); and, d) a private company (manufacturer of coccidiostats).

These position papers maintain that coccidiostats and histomonostats must remain within the scope of the Feed Additives Regulation, as preventive use of coccidiostats in poultry production remains necessary in modern animal husbandry in the EU and is best applied via feed as feed additives. In particular, the papers raise the continuous challenge of coccidiosis in poultry and recognize 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 papers cite evidence that coccidiostats as feed additives are not critical to the development of antimicrobial resistance in humans, as they are only used in animals and not in human medicine (e.g. are not rated by the WHO as important to human health). On the other hand, by controlling coccidiosis and maintaining intestinal health in poultry, they can help in subsequently decreasing the number of therapeutic antibiotic treatments which may be needed and thus positively contributing to reducing the risk for antibiotic resistance development.

The remaining 2 documents (submitted by 1 business organisation, a private consultancy providing services in the feed additives sector) are proposals for: revising the definition of categories and functional groups; and, a series of recommendations on other aspects of the Regulation and its implementation

3.5 Interviews

3.5.1 PARTICIPANTS

At the structuring phase of the study, exploratory interviews were carried out with key stakeholders to ensure a good understanding of the important issues, establish data availability and identify any challenges related to the evaluation. These interviews helped to finalise the methodology, consultation strategy and data collection activities.

During the main phase of data collection for the study, as a follow-up to the online surveys, interviews were conducted with stakeholders, Member State Competent Authorities, EFSA, the EURL and the EC, to further investigate and clarify several aspects of the study. **The interviews mainly aimed to collect further quantitative and qualitative data, in particular on the costs and impacts of Regulation (EC) No 1831/2003.** They also provided stakeholders with the opportunity to highlight their experience, raise key issues that may not have been covered through the online surveys, and clarify some information/data already provided through the surveys. The list of the interviewed organisations is provided below:

List of EU level interviews carried out *(a) (b)*

	Organisation	Stage of the feed supply chain
1	FEFANA *(b)*	Feed additive/premixtures manufacturers
2	Animal Health Europe *(b)*	Manufacturers of coccidiostats/histomonostats
3	FEFAC *(b)*	Feed additive users: manufacturers of compound feed/premixtures
4	FEDIAF *(b)*	Feed additive users: pet food manufacturers
5	EMFEMA	Feed minerals/on-farm mixtures
6	AVC	Association of Veterinary Consultants
7	Copa-Cogeca	Farmers (users)
8	AVEC	Poultry sector (users)
9	FEAP	Federation of European Aquaculture Producers (users) *(c)*
	Organisation	**Role**
10	DG SANTE	Commission services
11	EFSA	Risk assessment
12	EU RL (JRC)	Supporting the process of feed additives authorisation/re-authorisation

(a) To allow appropriate depth/focus, key organisations (e.g. FEFANA) required several interview meetings.
(b) Excludes interviews conducted in the context of the case studies with: individual operators; organisations representing the different stage of the feed chain; and, Member State Competent Authorities (4 MS).
(c) Interview conducted with Italian member of FEAP.

The list **excludes 24 interviews conducted in the context of the case studies** with: a) operators (manufacturers of feed additives, premixtures, coccidiostats/histomonostats, compound feed, pet food); and, b) Competent Authorities in four Member States (Belgium, France, Germany and Spain). In view of the confidentiality concerns over the provisions of sensitive data on costs and company information which were raised by individual operators, the initial number of planned interviews was extended to include a larger number of companies. Thus, more than 30 interviews were conducted in the main phase of the study (including 24 interviews in the context of the case studies; of which 20 with the industry and 4 with the Competent Authorities of the selected Member States).

Interview guidelines were developed following the structure of the evaluation questions, sub-questions of the study and the judgement criteria used. The questions were tailored for each interview and sent to the interviewee in advance. The interviews were held mainly

in English and were conducted in person mostly in Brussels, while some interviews were done via telephone. All interviews reports were validated with interviewees. The qualitative/ quantitative data collected were assembled in spreadsheets in order to process the results for analysis.

3.5.2 OUTCOME

All interviewed stakeholders and Member State Competent Authorities generally agree that the current Regulation (EC) No 1831/2003 has been effective in meeting objectives, i.e. ensuring that feed additives placed on the market are efficacious and safe for animals, humans and the environment. They also agree that, central to the achievement of a high safety standard, also in comparison to the former legislation (Directive 70/524/EEC), is the implementation of the authorisation procedure set out in the Regulation.

At the same time, according especially to stakeholders from the feed additives and premixtures sector, the achievement of these objectives has come at a high cost. These stakeholders highlighted several obstacles that affect the effectiveness of the legislation. In particular, the EU industry tends to believe that the competitiveness and innovation ability of the EU feed additives sector is undermined by the relatively strict requirements of the Regulation and the delays and 'unpredictability' of the authorisation process (Articles 4, 10 and 14). For instance, the functioning of the efficacy assessment, which is affected by incomplete dossiers, EFSA requests for supplementary data, hence unpredictability over the duration, costs and final outcome of the authorisation process.

The occurrence of delays is supported by the quantitative data available from EC/EFSA data on the timelines of approvals. The record to date in meeting the legal deadlines in Regulation (EC) No 1831/2003, both in the case of new authorisation and reauthorisation procedures, is considered a challenge by both the feed additives sector and Competent Authorities in some Member States. However, the industry and Member States tend to take different views as to the reasons for the delays. According to applicants, a key obstacle is the perceived rigidity of the requirements to assess efficacy and insufficient flexibility in the Regulation to adapt to scientific and technical progress; e.g. creation of new functional groups takes too long, definition of end points is too focused on performance targets etc. According to Member State Competent Authorities, key reasons are applicants' insufficient understanding of the (efficacy) requirements and data availability/cost to perform the required studies.

Despite the differences in views as to the reasons for the delays, both the industry and Member States raise particular concerns in the context of renewals of several important groups of substances that are due to occur in coming years. Moreover, stakeholders representing end users raised their concerns for the EU to maintain its current level of competitiveness; e.g. livestock farmers and the aquaculture industry fear that fewer products may be available for use in the future.

Certain other aspects, e.g. the approach on exports not authorised in the EU and premixtures/feed containing them (so-called NAFA products) also adversely affect the level-playing field between EU operators, in that the absence of a harmonised approach leads to rules being set in some Member States and not in others. Some industry stakeholders stressed that the absence of legal provisions in Regulation (EC) No 1831/2003 obstructs the level-playing field on exports of NASA products, whereas others do not consider the harmonisation of rules to be necessary.

Also, according to both the industry and Member State Competent Authorities, EU producers are particularly disadvantaged in the case of non-holder-specific authorisations, as all operators (whether EU or non-EU) have access to the EU market for the authorised product, although the investment in the generation of data required for the risk assessment process is largely financed by EU producers.

The industry highlighted that, from an efficiency perspective, the potential benefits are not yet fully realised. For example, completing the authorisation procedure in one year as foreseen by the Regulation is considered a realistic target within the scope of a 10 year authorisation period; the delays and additional requests lead to increased costs and undermine the final return on investment (ROI). The reauthorisation and renewal procedures lead to an increased workload in new safety and efficacy studies while not considering the nature of substances (e.g. substances with a long history of safe use and no new evidence emerging on the safety aspects could be considered as safe). Regarding the labelling rules (Article 16), 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, and this important cost implications for operators. Also, the simplified procedure for the authorisation of additives already authorised in food, and the procedure for the extension of authorisation of additives for minor uses are not perceived to be working well.

Generally, there is consensus between Competent Authorities and business stakeholders that Regulation is internally and externally coherent; and, that the needs identified at the time of the Regulation's drafting remain relevant. They also agree that the Regulation plays a positive role in reducing/containing anti-microbial use, hence supporting the wider policy target to reduce AMR threats from livestock production. However, their views differ on the extent to which the Regulation allowed adaptation to technical and scientific progress, with business stakeholders remaining more sceptical on this, in line also with their views on the negative impacts from the implementation of the authorisation procedure in practice on competitiveness and innovation.

Competent Authorities of the selected four Member States generally tend to have a more positive view on the implementation of the Regulation, including coherence and relevance of the objectives, in line also with the more general picture that emerged from the survey (to which 25 MS CAs responded). Nonetheless, they agree with business stakeholders that over the years both the level of complexity of the procedures and the workload this has created have increased; and, according to some Member State Competent Authorities, some simplification is required where possible (e.g. renewals of additives with long history of safe use).

Finally, there is unanimous agreement among Member State Competent Authorities and business stakeholders that the current legislation adds great value. Overall, the stakeholders along the feed chain and Member State Competent Authorities share the opinion that an EU intervention is key to ensure the protection of animals, humans and the environment. 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.