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

Annex 4: Case studies

[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 4: CASE STUDIES

4.1 Introduction

The aim of the case studies was to understand the practical application of the Regulation and its impacts, to identify and explain the underlying factors, and to collect qualitative and quantitative data that expanded on the evidence collected from the survey and desk research. This evidence was used in particular for the analysis of regulatory costs and non-quantitative impacts (other costs; benefits), which underpins the analysis of the effectiveness and efficiency of the Regulation.

The case studies covered **two thematic areas**:

A. The **authorisation process** from application to market. This covered all types of feed additives, focussing on three feed additives (selected from the Regulation's functional groups, to represent three of the most important categories);
B. The **labelling** of feed additives. This covered two feed additives and two pre-mixtures, focussing on **four Member States**.

Although the starting point of the case studies was to investigate two themes, the inclusion of several Member States in combination with several additives from the survey results, resulted in a **considerably wider breadth of scope involving more feed additives**.

Table 1 below collates key criteria used for the selection of the two themes, seven types of products and four Member States (for theme B: labelling); **Table 2** indicates the combination of specific categories, functional groups and types of products on the basis of more specific criteria. The final case study outline was based on further feedback from the industry, in terms of relevance of impacts and data availability.

Table 1: Overview of case study themes, Member States, additives and key selection criteria

		Selection criteria
Themes (2)	**A. Authorisation process**	A core requirement of the Regulation (Article 4), including provisions on modification and re-authorisation. Some of the current procedures (Article 7 to 14) and their implementation have been at the centre of debate, with regards *inter alia* to length, complexity, data protection/ confidentiality issues and, ultimately, their impact on innovation.
	B. Labelling	A core provision of the Regulation (Article 16), which appears to be posing problems in practice (coherence also with Regulation (EC) No 767/2009). Labelling plays a key role in facilitating a competitive market environment in which dynamic, efficient, innovative operators can make full use of labelling to sell their products. In a broader reading, labelling pertains both to: mandatory provisions and encouraging/supporting additional voluntary initiatives; as well as, to the business-to-business (B2B) marketing of livestock feed and business-to-consumer (B2C) of pet food.
Member States *(a)* **(4)**	**BE DE ES FR**	• Include two to three of the five biggest EU feed additive producers: IT, ES, DE, DK, FR; • Geographical balance, reflecting livestock production systems, species focus, as well as importance of pet sector; • Balance of small and large MS: include one small MS.
Additives (A: 3) (B: 2 +2)	See next Table	• Representative of the most important categories/functional groups • Importance in market (applications; authorisations; market share); • Use (species; food producing animals/pets); • Innovation potential.

(a) Selection of Member States mainly of relevance to the second thematic case study (B: Labelling).

The criteria used for the above selection included the importance in terms of number of applications and authorisations, as well as in terms of use and innovation potential. These are detailed within the case studies.

Table 2: Selection of categories/functional groups covered by the case studies

Category	Functional group
A: Authorisation process *(a)*	
3: Nutritional	b. Trace elements
4: Zootechnical	a. Digestibility enhancers
5: Coccidiostats & histomonostats	Coccidiostats & histomonostats
B: Labelling *(b)*	
3: Nutritional	a. Vitamins, pro-vitamins etc.
4: Zootechnical	a. Digestibility enhancers
Premixture for fattening pigs or chickens for fattening (broilers)	
Premixture for cats or dogs	

(a) A: Authorisation case study: cases of authorisation of specific feed additives were considered, taking into account data availability.

(b) B: Labelling case study: cases of authorisation of specific feed additives were considered, taking into account data availability.

In total, **24 interviews** were conducted to cover the two case study themes, of which 20 with industry stakeholders and 4 with Member State Competent Authorities, as follows:

A. **Authorisation**: interviews were conducted with:
   - **Applicants**: companies and consortia that have applied for the authorisation of a feed additive among the above groups. These operators are members of FEFANA, FEFAC, FEDIAF, and Animal Health Europe.

B. **Labelling**: interviews were conducted with:
   - **Operators along the feed chain:** companies manufacturing feed additives, premixtures, compound feed and/or pet food, affected by the Regulation's labelling provisions. These operators are members of FEFANA, FEFAC, FEDIAF, and Animal Health Europe.
   - **Competent Authorities** of the selected four Member States.

In addition, the case studies draw on data collected during the stakeholder survey (Annex 3: consultation synopsis report, section 3.2.2.4).

The approach followed for assessing the regulatory costs is based on the Standard Cost Model recommended in the Better Regulation toolbox #60.

To facilitate cross-referencing, the methodology and data collection is briefly outlined here for each case study.

4.2 Case study A: Authorisation process

4.2.1 INTRODUCTION

The authorisation of feed additives is a core requirement of Regulation (EC) No 1831/2003 (Article 4), including provisions on modification, suspension and revocation (Article 13), as well as the renewal of authorisations (Article 14). Detailed rules for the implementation of these provisions are laid down in Commission Regulation (EC) No 429/2008, as regards the preparation and presentation of applications and the assessment and authorisation of feed additives. It is noted that for additives authorised under Directive 70/524/EEC, their reauthorisation was required within seven years after the entry into force of the Regulation (Article 10). The procedure to be followed for the authorisation of new additives and for the reauthorisation of additives that were originally placed on the market under the Directive are laid down in Article 7. The procedure to be followed for the renewal of authorisations granted under the Regulation (i.e. to renew the authorisation beyond the originally granted 10-year period) are laid down in Article 7.

Some of the current procedures (as laid down in Articles 7 to 14) and their implementation (including EFSA guidance) have been at the centre of debate, with regards *inter alia* to length, complexity, data protection/confidentiality issues and, ultimately, their impact on costs/burden and on innovation.

The authorisation process from application to market has been analysed for the purposes of the case study. The aim has been to assess how the authorisation procedure has been working, to identify issues and difficulties in the process, and to understand the impact of the process on costs and the benefits for applicants. This focussed on three feed additives (selected from the functional groups, to represent three of the most important categories). The selection of additives includes a mix of holder-specific and non-holder-specific authorisations, as follows:

- **Case 1: enzymes.** Enzymes are an important **digestibility enhancer** (**zootechnical additives**: functional group 4(a)). The zootechnical additives category accounts for the largest number of applications for authorisation (292[1] applications of which 112 applications are for digestibility enhancers), and a quarter of all authorisations granted during the evaluation period (2004-17). Authorisations of zootechnical additives are holder-specific and encompass many new types of products. Digestibility enhancers are one of the two most important functional groups in terms of applications and authorisations (the other being gut flora stabilisers); within this group, enzymes are amongst the most commonly used. Enzymes have been increasingly used as a dietary supplement in animal feed over the last decade with many new applications and products, e.g. phytase is increasingly being used for pigs and poultry, providing both economic and environmental benefits, and there is growing interest for their application in aquaculture feed[2]. According to the EU Register, as of December 2017, 72 digestibility enhancers were authorised, and these are mainly enzymes. According to data provided by the industry[3], the EU-28 enzymes market is currently valued

[1] This figure refers to each request for authorisation in each functional group. This is different from the number of Administrative applications.

[2] Phytase is any type of phosphatase enzyme that makes the phosphorus from phytin (an indigestible, organic form of phosphorus that is found in grains and oil seeds) available for animal digestion. They can be derived from a range of sources including animals, plants and micro-organisms, with microbial sources the most promising for the production of phytases on a commercial scale due to their enhanced physio-chemical characteristics and catalytic properties. Benefits include the double effects of reducing the use of expensive inorganic phosphorus in animal feed and the reduction in environmental pollution from excessive manure phosphorus runoff. As of December 2017, 18 phytase feed additives were authorised on the market; they can be distinguished according to the biochemical classification by the International Committee of Biochemical Nomenclature, as 3- or 6-phytases.

[3] Source: RM Associates Report for FEFANA (2018).

at €230 million, which represents approximately 3% of the total EU-28 feed additives market.

- **Case 2: zinc oxide.** Zinc oxide is a major **trace element (nutritional additives**: functional group 3(b)). The nutritional additives category records the third largest number of applications for authorisation during 2014-17 (178 applications) and also includes many new types of additives. Trace elements perform important physiological functions, such as the complex functions in metabolism, and deficiencies can lead to general disorders, which is why they are provided in animal feed to maintain optimal livestock health and performance. Trace elements account for the largest number of applications and authorisations (28 out of 69 authorised nutritional additives, up to December 2017). Within this group, zinc oxide (an essential trace element for the nutrition of animals) accounts for a major market share (one non-holder-specific authorisation, for all species). It is also noted that use of zinc oxide in veterinary medicinal products (VMPs) is due to be phased out by 2022[4].
- **Case 3: coccidiostats**. Coccidiostats are substances intended to kill or inhibit the single-celled Eimeria parasite causing the coccidiosis disease in poultry. They are used as feed additives in a preventive function to control coccidiosis, which is an endemic disease in the EU due to the parasite being universally present. Authorisations for this category of products are holder-specific. Up to December 2017, the EU Register records 27 authorisations, against 35 applications for authorisation submitted during the 2004-17 period. In 2008 the Commission had concluded that no suitable alternatives existed for the functions provided by these substances, consequently it was not considered appropriate at the time that these should be phased out (European Commission, 2008).
- **Other feed additives**: some other additives for which respondents provided costs, e.g. nutritional and technological additives.

4.2.2 METHODOLOGY AND DATA COLLECTION

For this case study, six companies provided data for an enzyme product (zootechnical additives: digestibility enhancers); one consortium for zinc oxide (nutritional additives: trace elements); and, one company for coccidiostats. One other company provided data for holder-specific additives (zootechnical) versus non-holder-specific additives (nutritional), on average across each category. In addition, relevant data/feedback across all additives[5], as provided by applicants in the context of the survey, are also taken into account.

The following impacts were explored: direct costs; indirect costs and losses; and, benefits.

For confidentiality reasons, only anonymised summary data can be presented in this report.

[4] In June 2017, the EU Standing Committee for Medicinal Products for Veterinary Use (CVMP) decided on an EU-wide ban on the use of zinc oxide in VMPs, giving Member States up to five years to phase it out by 2022. The Committee adopted by consensus a final opinion recommending "*the refusal of the granting of the marketing authorisations and the withdrawal of the existing marketing authorisations for veterinary medicinal products containing zinc oxide*.". The Committee concluded that the animal health benefits of zinc oxide used for medicinal purposes do not outweigh the risks for the environment. The Committee also acknowledged that there is a risk of co-selection for resistance associated with the use of zinc oxide but, at the present time, that such risk is not quantifiable.

[5] The survey collected data on costs as an average across all feed additives, while the case studies focused on specific additives. During the case studies, some respondents provided data on the costs of authorisation of some other additives, e.g. nutritional and technological additives, which were not in the scope of the case study. The costs of these cases is taken into account, as they largely also form part of the evidence base provided in the survey.

4.2.3 DIRECT COSTS

The main items identified for the calculation of the **direct costs** of the authorisation process for applicants are the costs of:

1) staff time spent on activities for the preparation of application (by category of staff)[6];
2) studies conducted by applicants to provide the required evidence on the safety and efficacy of the additives; and,
3) external services, notably of any consultants/experts that applicants may involve and of access to data.

With regard to the cost of studies, it is noted that the range of studies required per application depend on the type of additive. For instance, in accordance with Commission Regulation (EC) No 429/2008, for additives aimed to be used in feed for non-food producing animals (e.g. pets) the safety of the additive for consumers and environment does not need to be addressed, as no scientifically-based evidence for concern has been identified by EFSA. Furthermore, EFSA may request supplementary data when the evidence initially provided by applicants is not sufficient ('stop the clock' procedure); the calculation of costs includes the costs of further studies.

The detailed breakdown of direct costs is as follows:

1. Staff costs			
Activities for the preparation of application	**Staff cat**	**Number of man days**	**Costs (€)**
• Identification/characterisation of the additive			
• Preparation of the method of analysis for its evaluation by the EURL			
• Design of post market monitoring plan			
2. Safety and efficacy studies			
	Unit costs (€)	**Number of units**	**Costs (€)**
Safety studies			
• In vitro			
• Laboratory animals			
• Tolerance ruminants			
• Tolerance pigs/poultry/ fish			
• Other species			
Efficacy studies			
• Ruminants			
• Pigs/poultry/ fish			
• Other species			
3. External costs			
	Unit costs (€)	**Number of units**	**Costs (€)**
Fees to consultants for preparation of application			
Fees paid for sharing data (if applicable)			
ALL COSTS: 1+2+3			

[6] Four categories of staff were considered: senior managers (category 1); professionals with university education (category 2); technicians with vocational education (category 3); administrative staff (category 4).

4.2.3.1 Case 1: enzyme (holder-specific)

Data on costs were provided by six companies that have applied for the authorisation of an enzyme of major use as a digestibility enhancer[7]. Of these, two are SMEs (one of which is part of a large company). The total costs of authorisation were estimated at an average €2.5 million per company and per application. The cost indicated by the two SMEs was considerably lower than the above average, but the sample size is too low (two SMEs and four large companies) to draw any conclusions on the extent to which the level of costs bears any relation to company size. One non-SME company provided a considerably higher cost estimate than the above average, which reflects the costs of supplementary work following requests from EFSA for further information/data.

Although the average cost estimate masks a considerable range of costs across companies, in all cases, safety and efficacy studies accounted for the bulk of the cost. In total, safety and efficacy studies accounted for 58% of the total cost. Efficacy demonstration is by far the highest regulatory cost closely followed by safety.

Table 3: Costs of authorisation for an enzyme (zootechnical additives)

	COSTS *(a)*	*% share of total*
***1.* Staff costs: activities for the preparation of application**		
All categories of staff	€ 620,414	*24%*
2. Safety and efficacy studies		
• ***Safety studies***	€ 403,080	*16%*
• ***Efficacy studies***	€ 1,070,000	*42%*
3. External costs (b)		
Fees to consultant for preparation of application	€ 91,667	*4%*
AVERAGE COSTS, per application (1+2+3) *(n=6)*	***€ 2,549,354***	*100%*

(a) Includes all costs provided by six companies. In some cases, companies have submitted several applications for authorisation of this enzyme product: in these cases, they provided the average cost per application, across all of their applications.
(b) This includes only fees provided to consultants for the preparation of application. Three of the six companies incurred such costs; for the remaining companies the costs are negligible, if any. The above cost is based on the three companies that incurred costs.

Source: data collected from applicants during interviews, final calculations by Agra CEAS

Efficacy studies account in all cases for the major share of all study costs: the cost of efficacy studies across six companies is 2.7 times the cost of safety studies. The cost is due to the high number of studies required per species. An important determinant of these costs is the number of studies that need to be carried out, which depends on the number of species for which authorisation is sought and the number of studies required by the legislation. The number of studies required may increase when the information/data is not considered sufficient for the assessment by EFSA and supplementary information/data are necessary. The number of efficacy studies carried out by respondents ranged from 18 to 41. The other major determinant of efficacy costs is the cost per study. This tends to vary per species: in most cases, costs range between €25,000 and €40,000 per study, and in some cases higher costs/study were provided (e.g. for studies on sows). In one case, an applicant noted that they withdrew their application following an EFSA request to provide supplementary data, which would have required additional high cost efficacy studies.

[7] For confidentiality reasons, only anonymised summary data can be presented here.

Nonetheless, applicants noted that the new EFSA efficacy guidance of 2018[8] has improved requirements. Notably, there were two big improvements: a) it is now allowed to extrapolate from broilers to turkeys; b) it is now possible to submit short term studies, which are accepted as sufficient to prove digestibility, whereas long term studies were required previously.

In the case of safety studies, the cost is lower than for efficacy studies, due to the lower number of studies required, ranging from 4 to 17. On the other hand, the required tolerance studies[9] and studies on laboratory animals carry a higher cost/study. Again, this tends to vary per species: in most cases, the costs of tolerance studies range between €15,000 and €40,000 per study, and in some cases higher costs/study were provided (e.g. for studies on sows and on ruminants). For laboratory animals, the available cost range per study is even higher. On the other hand, in vitro studies tend to carry a considerably lower cost: in most cases, a cost lower than €10,000 per study was indicated.

The staff costs related to the preparation of the application were the second most important category, accounting in total for 23% of the costs. The main activity incurring staff costs is the identification and characterisation of the additive. All activities are mainly carried out by cat 1 and cat 2 staff; only one company indicated that some cat 3 staff were also involved. However, staff costs were not important for all companies:

- Some activities were already carried out prior to the application, therefore considered as sunk cost. E.g. in some cases, the method of analysis has previously been in-house validated and verified, and also previously assessed by the EURL for another similar product; one respondent indicated that developing a new in-house method for evaluation by the EURL, would take about 85 days of preparation time as the method requires validation (in product, in feed and in premixtures) followed by method verification (in product, in feed and in premixtures) in a second laboratory.
- Also, in some cases, certain activities are externalised. Half of the companies incurred some costs for fees paid to external consultants, but only in one case these were relatively major, accounting for 45% of the total costs (this included activities related to the preparation of the application and studies).

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

According to all companies, the costs of authorisation in the EU are considerably higher than in non-EU markets due to the high level of requirements in safety and efficacy studies. One company indicated that registration costs for this enzyme in non-EU countries vary from country to country, but in their experience costs range between €500 and €3,000 per dossier and each application process takes between 2 months and up to 18 months to be completed.

[8] https://www.efsa.europa.eu/en/efsajournal/pub/5274

[9] Tolerance studies are performed on the species or categories of animals for which the additive is intended for. These studies evaluated the short term toxicity and establish the margin of safety in case that the additive is consumed at higher doses than recommended.

4.2.3.2 Case 2: zinc oxide (non-holder-specific)

The consortium that applied for the re-authorisation of zinc oxide is composed of three companies (one distributor; one manufacturer; and, one manufacturer of premixtures/distributor). This consortium is managed by the feed additives and premixtures industry association (FEFANA).

According to data submitted by the consortium, the costs of this reauthorisation dossier are relatively low. The total costs are roughly estimated at around €50,000, which includes: staff costs for the identification/characterisation of the additive; and, the fees paid to a consultant for the preparation of the application. As zinc oxide has been studied for a long time, it was possible to use existing studies, therefore the cost of studies was minimal.

FEFANA manage 10 consortia, for which about 100 applications have been submitted over the evaluation period, with some applications covering several feed additives each. Based on this experience, FEFANA notes that zinc oxide is not considered a representative case in terms of costs, which are relatively low. According to data provided by FEFANA to the survey, the average cost of authorisation has been calculated at €372,515 across their consortium applications.

4.2.3.3 Case 3: coccidiostats (holder-specific)

Data on costs were provided by one company that has applied for the authorisation of several coccidiostats[10]. The total costs of authorisation across 2 coccidiostats were estimated at an average €3.4 million per application. This was entirely spent on safety studies; all other costs were negligible (no estimates provided). The high number of studies and cost/study involving laboratory animals accounted for 74% of the total cost, followed by tolerance studies poultry) which accounted for 18% of the total cost.

4.2.3.4 Other cases

- **<u>Average costs of authorisation (Article 4) across all types of additives</u>**

Data on the average direct costs of the authorisation process were collected from applicants through the stakeholder survey, using a similar breakdown of costs as for the case studies (detailed data in Q118 to Q124, Annex 3)[11]. Data on these costs were provided by 31 companies that have applied for the authorisation of feed additives, as an average across all applications submitted. Of these, 10 are SMEs, of which 4 are part of a large company.

The costs of authorisation for the 31 companies across all applications were estimated at just under €1.1 million on average per application. These include the costs of supplementary work following requests from EFSA for further information/data. The cost indicated by the 10 SMEs was slightly lower at just over €1 million, suggesting that the level of costs does not bear any relation to company size.

Although the average cost estimate masks a considerable range of costs across applicants, in all cases, safety and efficacy studies accounted for the bulk of the cost. Safety and efficacy studies account for 67% of all costs, with safety studies having a higher share than efficacy studies. Staff costs account for 24% of all costs, with mainly cat 1 and 2 staff involved (64% and 23% of all staff costs, respectively).

[10] For confidentiality reasons, only anonymised summary data can be presented here.

[11] During the case studies, some respondents provided data on the costs of authorisation/reauthorisation of some other additives, e.g. nutritional and technological additives, which were not in the scope of the case study. The costs of these cases is taken into account, as they largely also form part of the evidence base provided in the survey.

Table 4: Costs of authorisation (all additives)

	COSTS *(a)*	% share
1. **Staff costs: activities for the preparation of application**		
All categories of staff	€ 265,012	24%
○ Cat 1	€ 170,522	
○ Cat 2	€ 60,101	
○ Cat 3	€ 29,922	
○ Cat 4	€ 4,467	
2. Safety and efficacy studies		
Safety studies	€ 402,171	36%
Efficacy studies	€ 345,355	31%
3. External costs		
Total external costs	€ 104,355	9%
of which: external consultants	€ 33,342	
AVERAGE COSTS, per application (1+2+3) *(n=31) (a)*	**€ 1,116,894**	100%
AVERAGE COSTS, per application for SMEs (1+2+3) *(n=10)*	€ 1,031,603	

(a) Includes costs provided by 31 applicants (*n=31*). Companies provided the average cost per application, across all their applications. Due to incomplete data provided in some cases, this average cost may represent a small underestimate. For example, excluding data submitted by 5 external consultants (which are incomplete) marginally increases the average estimate of total costs to €1,127,150.

Source: data collected from applicant responses to the stakeholder survey (Q118 to Q124), final calculations by Agra CEAS

In addition, data provided by one company on an average basis, across holder-specific additives of the zootechnical category versus non-holder-specific additives of the nutritional category, indicate small differences in authorisation costs between the two categories. According to the data, on average, it costs around 2.4 million for the authorisation of a zootechnical additive versus 2.1 million for the authorisation of a nutritional additive. Although the authorisation of a nutritional additive costs 11% less than that of a zootechnical additive, this is mainly due to the species covered by the additive authorisations considered in the calculation. In particular, in this case the nutritional additives target ruminants, which involves higher costs for safety (tolerance) studies (ratio of total costs in ruminants vs pigs/poultry is 3:1, due to the higher unit cost/study for the former), while the zootechnical additives target pigs/poultry, which involves higher costs for efficacy studies (ratio of total costs in ruminants vs pigs/poultry is 1:3.3, due to the higher number of studies required for the latter).

- **Average costs of renewal of authorisation across all types of additives**

Data on the average direct costs of the process for the renewal of an authorisation were collected from applicants through the stakeholder survey, using a similar breakdown of costs (detailed data in Q125 to Q131, Annex 3). Data on these costs were provided by 18 companies that have applied for the renewal of an authorisation, as an average across all applications submitted. Of these, 7 are SMEs, of which 2 are part of a large company.

The costs of authorisation for the 18 companies across all applications were estimated at an average €216,357per application. This figure, which includes the costs of supplementary work following requests from EFSA for further information/data, represents roughly 20% of the cost of authorisations under Article 4. The average cost indicated by the 7 SMEs was nearly double, but this is due to the relatively high costs indicated by the 2 SMEs that are part of a large company; excluding those, the average cost per renewal application for SMEs drops significantly. It is noted though that the average cost per application varies significantly depending on the type of additive for which renewal was requested by applicants and studies required, rather than the applicant company's size.

Again, although the average cost estimate masks a considerable range of costs across applicants, in all cases, safety and efficacy studies accounted for the bulk of the cost. Safety and efficacy studies account for 88% of all costs, with efficacy studies having a considerably higher share than safety studies. Staff costs account for 9% of all costs, with mainly cat 1 and 2 staff involved (27% and 66% of all staff costs).

Table 5: Costs of renewal of an authorisation (all additives)

	COSTS (a)	% share
***1.* Staff costs: activities for the preparation of application**		
All categories of staff	€ 18,606	9%
○ Cat 1	€ 5,111	
○ Cat 2	€ 12,257	
○ Cat 3	€ 615	
○ Cat 4	€ 623	
2. Safety and efficacy studies		
Safety studies	€ 71,042	33%
Efficacy studies	€ 118,750	55%
3. External costs		
External consultants	€ 7,959	4%
AVERAGE COSTS, per application (1+2+3) *(n=18) (a)*	**€ 216,357**	100%
AVERAGE COSTS, per application for SMEs, including those that are part of a large company (1+2+3) *(n=7)*	€ 673,374	
AVERAGE COSTS, per application for SMEs (1+2+3) *(n=5)*	€ 94,270	

(a) Includes costs provided by 18 applicants (*n=18*). Companies provided the average cost per application, across all their applications.

Source: data collected from applicant responses to the stakeholder survey (Q125 to Q131), final calculations by Agra CEAS

Operators along the feed chain are questioning whether the authorisation period of 10 years and renewal of authorisation thereafter is justified for all types of products; in particular, additives for which there is an extensive body of scientific knowledge on adverse impacts and the identified risk is low. Examples of additives for which the 10-year authorisation period is not considered relevant as it is not risk-based: additives that are authorised for use in food (technological, flavourings, nutritional) and that have a long-established history of safe use in animal nutrition.

In such cases, according to operators, the renewal obligation creates unnecessary burden for all involved (Commission/PAFF; EFSA; Member State Competent Authorities; and, the industry). An example put forward by operators is the case of vitamins, the renewal of which has created unnecessary burden especially when it is non-holder-specific and some companies have to assume the burden for the benefit of the wider industry. In an effort to safeguard the return on that investment, companies define the product to the highest possible level of precision, e.g. in terms of purity criteria, to ensure that only these companies can produce to this specification.

The industry noted that 700 feed additives are coming up for renewal (due to start in 2024); many of these relate to applications originally submitted under consortia managed by FEFANA. This means, on average, 70 feed additive renewals to be processed per year from 2024 onwards. The great majority of these additives are authorised in food (a high number of which are flavourings). Furthermore, controls in the member States can demonstrate whether there has been a problem with the use of these additives in animal nutrition. According to the industry, there should be a more flexible approach when the risk profile of the products is low and not changing; unless there is a scientific basis raising

concern on the use of these additives, renewal may not be required or could be streamlined/fast tracked. This would reduce the burden for all involved.

4.2.4 INDIRECT COSTS AND LOSSES

The main items identified to generate additional **indirect costs and losses** are those stemming from delays in the deadlines foreseen by the Regulation for the authorisation process, including the requests for supplementary data by EFSA ('stop the clock' procedure) and the final Commission decision regarding the authorisation.

Nearly all applicants complained of the '*unpredictability'* of the authorisation process, in their responses to the stakeholder survey, the OPC and interviews. This refers to a combination of: 1) unexpected requests for supplementary data by EFSA and undue delays in these requests (e.g. beyond six months); 2) delays in the final Committee (PAFF) procedure for a decision; and, 3) other delays (e.g. mandate to EFSA; validation of dossier). Although not all applicants have incurred such delays, several examples of such cases were provided[12]. Furthermore, average delays experienced across all feed additives have been collected from companies in an internal recent survey by FEFANA reported below. These delays also exert negative impacts further down the feed chain as reported below by users.

4.2.4.1 Case 1: enzyme (holder-specific)

The delays incurred by most applicants are caused by the EFSA requests for supplementary data ('stop the clock' procedure). These are: delays in request for information; and/or, delays after the 6-month legal limit foreseen for the EFSA assessment. These delays bear the biggest impact on the overall timeframe, according to applicants. The delays, beyond the legal limit of 6 months, varied depending on the complexity of the dossier, but ranged from 9 months to 2.5 years.

Delays due to the Committee procedure for authorisation and other delays are also common, but less impacting in terms of the overall timeframe of the process.

Four of the six applicants that provided data had incurred delays, and for two of them the overall time required form submission of application to Committee decision was roughly 3 years. On the other hand, two of the six applicants experienced minor delays.

It was not possible for applicants to monetise the cost and losses of these delays. The main issue for applicants is that the authorisation process is not predictable with regards to the timeframe and potential final cost, leading to a situation where the business case no longer holds as in the initial business plan. Although eventually, in case the authorisation is granted, it will be for a 10-year authorisation period, the operators will have lost valuable time for launching the product on to the market and this erodes the sales potential. Meeting the customer expectations on the timing of the launch is a big factor, especially for innovative products, for which it is important to bring to market quickly, not to lose the momentum of innovation. Normally, communication with customers starts when the product is expected to be close to the end of the authorisation process. If the product is launched several months, or even years, later than expected, it is not certain that the initial projection on potential sales can be fully recovered.

[12] The focus here is on the case study sectors. Apart from the case of enzymes reported here, delays were also experienced by applicants in the case of Coccidiostats, but these cannot be detailed further for confidentiality reasons.

The delays in EU authorisation also impact market access and sales in non-EU countries, as for a product's registration in most countries it is necessary to have an authorisation in the producing country of the feed additive, and this requires prior approval in the EU.

4.2.4.2 Other cases: impacts across all types of additives

According to an internal survey conducted by FEFANA amongst its members in 2019[13], for Article 4 authorisations, the average time taken between the submission of application and delivery of the EFSA opinion is over 2 years. The Committee procedure for authorisation takes an additional 6-12 months, although it can extend to over 1-2 years in some cases. Therefore, on average, it might take up to 3 years for a product to reach the market; and for some products, the authorisation procedure has taken considerably longer.

According to EFSA data, the deadline between the reception of a valid application and the adoption of the EFSA opinion shows for Article 4 that 40% of applications were adopted within 9 months, 52% within 12 months and 73% within 18 months. To compare those data with the information provided by FEFANA in the internal survey, it is necessary to sum 41 days for the validation of the application to the EFSA data. The period to validate an application is less than or equal to 41 days and for 71% of applications less than or equal to 35 days.

Although the data provided by FEFANA are not as precise as the actual data provided by EFSA they are not in contradiction although the actual EFSA data shows that more than 50% of Article 4 dossiers applications are adopted within 9 months after a valid application.

According to applicant responses to the stakeholder survey, interviews and the OPC, a major problem currently is that in practice there is a series of 'stop the clock' events throughout the procedure. Due to this, it can be on average 1.5 years from the EFSA mandate to the EFSA opinion. One applicant indicated that for one dossier the series of questions took nearly 4 years to complete in total. Applicants therefore believe that if EFSA could collect all clock-stop-questions and send them in one go to the applicant, the delays could be significantly reduced.

EFSA noted that: there is extensive guidance by EFSA (including on stop-the-clock timelines[14]); it has also improved its approach on 'application desk services' in recent years; and, it has established a catalogue of support initiatives[15] during the life-cycle of applications for regulated products to facilitate the assessment process.

According to applicants, although these initiatives are helpful, the lack of possibility for a pre-submission meeting with applicants to clarify technical issues is an important hindrance to the smooth roll-out of the process. This would allow clarifications on the specific data requirements that need to be prepared to support an application; e.g. to clarify the end points for innovative products when these are not yet established and that the intended technical approach will satisfy the EFSA requirements. It was also indicated that such a process exists in the case of VMPs and in the case of human medicines[16]. An

[13] http://fefana.org/wp-content/uploads/2019/08/2019-08-30-FEF_factsheet_data_collection_Survey.pdf

[14] The timelines for the provision of supplementary information follow the administrative guidance for the processing of applications for regulated products (update 2019), to ensure a harmonised approach between EFSA between scientific units. EFSA (2019). https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2018.EN-1362

[15] Under this initiative, whenever EFSA requests supplementary information during the risk assessment, applicants have the possibility to request for a clarification conference in order to clarify the basis for the request and ensure common understanding. EFSA (2019). https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2016.EN-1025

[16] The European Medicines Agency (EMA) has a system of early (advance) notification by applicants, which is used for planning purposes. Six to seven months before submission, applicants should notify the EMA of their intention to submit an application and include a statement on the intention to request a conditional marketing

example was provided of an enzyme with an innovative mode of action and type of benefits (end points) based on latest scientific developments, for which the EFSA assessment took 2.5 years and then still had to undergo the EC Committee procedure, which on average takes 6-12 months. This is considered too long for innovation to come to market.

At the level of the Committee procedure for a decision on the authorisation, delays are often due to overload of the meeting agenda and/or complications in the legal translation of the scientific opinion. In the past, delays were also caused by requests for confidentiality of the data provided by the applicant, but this issue is now addressed[17]. Meeting agendas tend to be full and there is not enough time to address; if not addressed, the applicant can lose more time, because the Committee meets mostly every 2 months.

Finally, applicants complained of other delays due to the lack of a fixed timeframe in the Regulation for: a) the Commission to mandate EFSA for the dossier assessment; b) for EFSA to accept the mandate; and, c) for EFSA to do the completeness check of an application dossier, i.e. the time required from mandate to EFSA to validation of the dossier. Applicants noted that the mandate from Commission to EFSA and acceptance by EFSA take on average 3-4 months, and the validation of dossier can take a further couple of months. This view is not supported by the data on average delays provided by EFSA and the Commission. These data indicate that: the Commission forward the application to EFSA in less than 15 working days; EFSA acknowledge receipt of the application in 15 working days; and, the completeness check is complete (dossier validated) in 32 working days for 60% of Article 4 applications and in 33 working days for 50% of Article 10 applications. The whole duration of the process (including dossier validation) therefore takes on average less than 3-4 months. Although slightly longer for Article 10 applications, the products are on the market, which reduces the impact of the delay. In more recent years, the workload created by the renewal of authorisations adds to the backlog of applications being processed by EFSA and the delays in processing applications. In this context, operators along the feed chain (feed additive producers, traders and users) are questioning the extent to which the renewal process is relevant across all types of feed additives (see above section 'costs of renewals').

According to users of feed additives, delays in the authorisation and renewal of authorisation also exert impacts further down the feed chain in terms of ensuring the availability of feed additives for pre-mixtures and feed formulations. In certain cases, the renewal procedure creates uncertainty and unpredictability on the future availability of feed additives for the feed chain, since there is no obligation for former applicant(s) to submit an application for renewal (e.g. for non-holder-specific authorisations) The renewal for non-holder-specific authorisations can be requested by any interested operator. For holder-specific authorisations, the renewal must be done by the holder of authorisation or it successor. In such cases, considering that an application for renewal might not be submitted on time and taking also into account the product's importance for the feed chain, a conditional period would be useful to ensure continuity in the production of pre-mixtures and feed.

4.2.5 COSTS VERSUS BENEFITS[18]

Although authorisation costs are an important upfront investment, in addition to R&D costs that also need to be borne in advance, all feed additive companies indicated that they only

authorisation (https://www.ema.europa.eu/en/pre-submission-request-form). EFSA has indicated that a similar system could help EFSA plan ahead.

[17] In the past, EFSA did not publish the opinion until the confidentiality decision was taken by the Commission (with only a short summary published in the meantime); this delayed the decision making process. This is no longer a problem as EFSA can publish the opinion with the confidential parts hidden, therefore it does not need to wait until the confidentiality decision is taken by the Commission.

[18] This section focuses on costs versus benefits for the feed additives industry. The wider benefits of the Regulation are outlined in the main body of the Report (EQ3).

decide to proceed to an application for authorisation if they expect a satisfactory return on their investment (ROI).

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

Nonetheless, the first few years of the investment are harder, particularly for SMEs, as the company need to invest in the R&D and authorisation costs involved with no revenue. Depending on the financial support a company may have, e.g. on the R&D budget, the start-up costs can be a significant barrier, particularly for SMEs. Hence, due to the considerable costs involved, it is rare to have more than one product going through an application for authorisation process at any time. Ultimately, each company has to make a strategic decision based on its structure and funding support; e.g. to start with an application for authorisation covering fewer species to save on costs (as this requires fewer studies) and expand to more species when possible.

For these reasons, SMEs - particularly the smaller companies - either tend to specialise in a few products to develop a niche or tend to rely on generic, non-holder-specific authorisations. However, from the experience gained in practice with the non-holder-specific authorisations, they have two important drawbacks:

1. The lack of protection for these authorisations is generally perceived as discouraging applicants, who need to cover the costs to generate the required data without however having exclusive rights to product authorisations; and,
2. It tends to be the case that the leading applicant covers all/most costs, with other participants contributing proportionately less or minimally.

Both drawbacks create a *'free-rider'* effect on the non-holder-specific authorisation segment of the feed additives market. In practice, this means that those companies that bear the costs (or the highest share of the costs) to get the authorisation do not necessarily reap the benefits (or the highest share of the benefits), as the benefits are typically shared with the wider industry (both feed additive manufacturers and feed additive users).

The industry illustrated the challenges for non-holder-specific additives with the case of the withdrawn application for authorization of the antioxidant Tertiary-Butylhydroquinone (TBHQ) as technological feed additive, due to the *'free-rider'* effect versus high costs (which are also due to other relevant considerations). As a consequence, TBHQ could not be authorised and, hence, it cannot be used in the EU feed chain which limits the portfolio of available antioxidants as critically important substances to preserve feed safety and quality, as also highlighted by feed producers and users.

Cost-sharing is an important aspect for ensuring a more equitable and fair distribution of costs. In the case of holder-specific authorisations, it can ensure that companies with less access to financial resources/support (e.g. SMEs) can contribute to the investment and participate in the benefits created by the innovation. In the case of non-holder-specific innovations, it can ensure a fairer distribution of costs vs benefits amongst participants and non-participants. Cost-sharing can thus encourage innovation and the availability of

products in the market. The available evidence suggests that successful cost-sharing initiatives in commercial partnerships (e.g. joint dossier funding, joint applications, royalties for data sharing) have been developed (e.g. FEFANA has organised 10 consortia[19]), although according to the industry these remain relatively specific initiatives.

According to the industry, the new Regulation on the transparency and sustainability of the EU risk assessment in the food chain[20] could make the situation more complicated. The Regulation, which will become applicable on 27 March 2021, will provide public access to studies and information submitted by applicants in the risk assessment process whilst respecting data confidentiality. Although it is not yet clear how this will be implemented in practice, there is concern amongst the industry that companies may become even more reluctant to invest in carrying out studies that will become public data.

[19] http://fefana.org/eu-legislation/authorisation-consortia/

[20] 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. For more information: https://ec.europa.eu/food/safety/general_food_law/transparency-and-sustainability-eu-risk-assessment-food-chain_en

4.3 Case study B: Labelling

4.3.1 INTRODUCTION

Labelling is another core provision of the Regulation (Article 16). Labelling plays a key role in facilitating a competitive market environment in which dynamic, efficient, innovative operators can make full use of labelling to sell their products. It also plays an important role in the transmission of information to users of the products that is necessary to enable the protection of workers, animals and the environment.

While labelling rules were also previously laid down in the Directive, the requirements were standardised and more detailed under the Regulation. The requirements included directions for use, the identification number, batch reference number and date of manufacture, as well as additional requirements by category (Annex III) and/or for specific authorisations. The establishment of more detailed labelling rules was meant to enable feed business operators, pet owners and farmers to protect workers, consumers, animals and the environment. For example, the label may contain a provision indicating that gloves are necessary to manipulate the additive or may establish a maximum dose to prevent health problems to animals from over-dosage or to consumers of food of animal origin, if the additive or its residues accumulate in a way that may pose a risk to human health.

Labelling rules apply to both additives and premixtures. Some requirements (e.g. business name, directions for use, batch reference number and date of manufacture), do not apply to the feed additives incorporated in pre-mixtures (Article 16.1; this provision was introduced following the adoption of Regulation (EC) No 767/2009).

It is noted that Regulation (EC) No 767/2009 lays down rules for labelling of feed materials. This makes a distinction between the concept of 'label' (information present on the packaging) and 'labelling' (information present on any medium and in any form accompanying the product, including e.g. on the internet and advertising), which is missing from Regulation (EC) No 1831/2003.

The aim of the case study is to explore the impact of the labelling provisions on costs/burden for operators along the feed chain, from producers of feed additives and pre-mixtures to producers of compound feed and pet food. To this end, the case study focussed on two feed additives and two pre-mixtures, as follows:

- **Feed additives:**
  - **Vitamins.** Vitamins, pro-vitamins and chemically well-defined substances having similar effects are the second major group of nutritional additives, 58 applications (functional group 3(a)). The nutritional additives category records the third largest number of applications for authorisation during 2014-17 (174 applications) and includes many new types of additives. Vitamins are an important additive widely used in the form of premixtures in feed supplementation both for pets and food-producing animals.
  - **Digestibility enhancers.** Digestibility enhancers (functional group 4(a)) are one of the two most important groups of zootechnical additives. Authorisations of zootechnical additives, which account for the largest number of authorisations granted during 2004-17 (271 applications) are holder-specific and encompass many new types of products. Digestibility enhancers are an important additive widely used in premixtures and expected to increase considerably in use and share of the EU market.
- **Premixtures**. The focus on pre-mixtures aims to understand the costs generated by the labelling of a feed additive in terms of the transmission of information to products using/containing the feed additive. The needs and drivers for the use of feed additives in feed destined for food-producing animals are different from those for their use in pet-food; this was addressed for the first time by the Regulation (i.e. not previously addressed by the Directive). The selection of two groups of premixtures reflects this

consideration, to allow understanding whether labelling costs are adapted to the needs of the two different uses:

- Premixtures for fattening pigs or broilers
- Premixtures for cats or dogs

4.3.2 METHODOLOGY AND DATA COLLECTION

For this case study, 12 companies provided data for a range of feed additives and pre-mixtures. Although the focus has been on four Member States, companies operating in a broader range of Member States contributed their feedback. Relevant data/feedback provided by the industry in the context of the survey are also taken into account. For confidentiality reasons, only anonymised summary data can be presented in this report.

4.3.3 COSTS: OVERVIEW

The costs collected apply to labelling changes due to regulatory requirements, not the initial labelling for placing products on the market. The main items identified for the calculation of the **costs** of the labelling provisions are the costs of:

1) Staff time spent on label translation, design and application of labels (by category of staff)[21];
2) External services, notably of any service providers that companies may involve for translation, printing of labels etc.
3) Disposal of labels; disposal of products.

These costs cover the following activities:

1. Staff costs	**Staff cat**	**Number of man days**	**Cost (€)**
• Design labels and/or accompanying documents due to a change in the authorisation of a feed additive			
• Change of formulations (premixtures/compound feed) to adapt to new EU requirements on feed additives			
• Comply with traceability requirements			
2. External services	**Unit cost (€)**	**Number of units**	**Cost (€)**
• Translate labels and/or accompanying documents for placing product on market			
• Print labels for placing product on market			
3. Disposal costs			**Cost (€)**
Total			
ALL COSTS: 1+2+3			

The use of internal staff time and external services involves activities that need to be carried out to design and apply labels. Labels need to be changed each time there is a change in an authorised product, e.g. the scope of the species covered or conditions of use. Changes to the authorisation of a feed additive are the first reason why companies change labels (according to 22 out of 30 respondents to the stakeholder survey, Q134). These adaptations need to be performed on the label of the feed additive concerned, as

[21] Four categories of staff were considered: senior managers (category 1); professionals with university education (category 2); technicians with vocational education (category 3); administrative staff (category 4).

well as on the label of the premixture product containing it, and on the label of compound feed and/or pet food that contains the additive and/or the premixture.

These costs depend on the following key factors:

(a) **Frequency of changes**: the need for changes increases for pre-mixtures containing several feed additives. The higher the number of additives on which regulatory changes have occurred the higher the need for changes and the resulting costs. Generally, the labels of feed additives are changed less frequently: respondents to the stakeholder survey indicated that labels of feed additives change every 2-5 years on average, while labels of premixtures may need to be changed from 1-2 times[22] per year on average triggered by feed additive re-authorisations and/or renewals.

(b) **Number of product references[23]**: this will depend on product and operator. The higher the number of product references, the higher the costs:
   - This is related to product range (whether additives or premixtures) and customer range (number of countries, whether EU and non-EU). Premixtures contain several additives and are therefore more exposed to labelling changes with any change in the regulatory status of each additive; depending on the extent to which an additive is commonly used in premixture formulations, a large number of products may be affected by the change. They are also often tailor made according to customer specifications. For all these reasons, a large number of premixture product references may be affected by label changes.
   - This is not related to company size or volume of operations. A large company producing large volumes may have a relatively low number of product references than an SME that produces a large range of tailor-made products at small volumes for specific customers and selling to a large range of markets/customers.

(c) **Number of languages on the label**: this tends to be higher for feed additives (often up to 24 languages, for the EU market) and lower for premixtures (typically 3-4)[24]. The higher the number of languages the higher the need for translation costs. It should be clarified that the obligation of the Feed Additives Regulation is that the label is translated into one official language of the country of destination; the number of languages that are necessary on the label are a function of the number of countries to which products are destined, which is determined by operators' production and marketing strategies.

(d) **Level of automation**. Advanced technologies can be used to automate certain labelling/printing operations which improves efficiency (e.g. by allowing the production line to move faster) and reduces costs (particularly staff costs). Companies will seek to find a balance between investing in automated systems vs staff costs. Several companies indicated that they adopted such technologies in the past few years; although this increases costs in the first few years due to the required investment, once the investment is written off in 3-4 years, costs are reduced longer term.

[22] The case of 6 times per year was also indicated by 5 out of 24 respondents to the survey (Q132). However, during interviews, companies clarified that although regulatory changes affecting their premixture products may happen 6 times a year, they tend to bring these changes together to perform a label change twice or once per year, taking advantage of the transitional period provided (typically 6 months).

[23] Or stock keeping units (SKUs). This refers to number of products/formulations multiplied by number of packaging per product/formulation (different sizes and types of packaging for the same product/formulation) multiplied by number of label versions/packaging. Types of packaging may include carton box, bags, liquid forms depending on the product/formulation. All these aspects depend on customer requirements.

[24] For premixtures, there is a trade-off between number of languages and number of SKUs. Not all EU languages can be combined on the label of a premixture, due to the large quantity of information that is required on the labels. Hence, several labels are needed, depending on the EU countries to which the product is destined. This leads to the need for more SKU's with a multiplication of inventory costs as a result.

A regulatory change, even small, usually triggers label layout changes, which are the most expensive. According to data collected through the survey, on average across 23 respondents, the staff time spent on label translation, redesign and application of labels was **20 hours or €602 per label change**[25]. This average cost reflects a range in the number of languages used on the labels of products across respondents (parameter (c)).

The average cost per label change needs to be multiplied by the frequency of changes (parameter (a)) and the number of product references (parameter (b)) to derive the total cost of labelling changes over a period. Given the amount of information currently required on the label, the frequency of changes and the number of product references, labelling costs can become important. This is simulated in the calculation below; this indicates that, although the unit costs involved per product reference are relatively low, these increase substantially with a high number of changes and product references. The case of 10 product references can be used as a proxy for the labelling of a single feed additive, while the case of 100-200 (or more) product references can be used as a proxy for the label of premixtures affected by the change in a single feed additive[26].

Table 6: Costs of label changes (estimates) (a)

Frequency of change	Cost per product reference *(b)*	Total cost		
		10 product references	*100 product references*	*200 product references*
2x per year	€ 1,204	€ 12,044	€ 120,441	€ 240,881
1x per year	€ 602	€ 6,022	€ 60,220	€ 120,441
1x per 2 years	€ 301	€ 3,011	€ 30,110	€ 60,220
1x per 5 years	€ 120	€ 1,204	€ 12,044	€ 24,088

(a) This calculation is a simulation that aims to indicate how costs increase with the increase in the underlying parameters and does not represent an average across the industry. It assumes a proportionate increase in costs as frequency of changes and number of product references increase. There may be significant potential savings from economies of scale and/or automation and/or other strategies potentially followed by companies to reduce costs (e.g. product reformulation, export to non-EU countries etc.).

(b) Calculation based on an average €602 per label change, i.e. 20 hours of staff time spent on label translation, redesign and application of labels (average across 23 respondents to the survey). Includes internal and external staff costs; in the interviews, companies specified most staff costs are internal.

Source: calculations by Agra CEAS based on data collected from responses to the stakeholder survey.

All operators agreed that the costs of changes on the labelling on feed additives (which are induced by regulatory changes in the additive's authorisation status as such), are relatively low. On the other hand, the costs induced by such changes on the labelling of premixtures and feed containing typically several feed additives can be more important. For this reason, the costs are presented separately below, for feed additives and for premixtures/feed.

4.3.4 COSTS: LABELLING OF FEED ADDITIVES

Due to the relatively low frequency of changes and number of product references, the costs of changes on the label of single feed additives due to regulatory changes as such

[25] Average across cat 1 to cat 4. The staff categories mainly involved in labelling changes are cat 1 to cat 3.
[26] Theses proxies are drawn from the information and data submitted to the stakeholder survey and interviews.

are relatively minor. Data collected from 9 manufacturers of feed additives indicate minimal-negligible costs.

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

Currently there is a lot of information provided on the label. This includes both mandatory regulatory requirements (points I to iii below: EU; point iv: non-EU) and voluntary information (point v below):

i. The information required by Article 16 of Regulation (EC) No 1831/2003 (including product name/functional group, business name/address, net weight / volume, batch number, production / expiry date, directions of use).
ii. The specific information that appears in the column 'other provisions' of the specific Regulation on the approval of an additive.
iii. The safety data sheet (SDS) required under the CLP legislation[27]. This requires specific wording (concerning user/worker safety).
iv. For products also marketed outside the EU, mandatory regulatory requirements in non-EU countries need to be included on the label.
v. In addition, labels typically include some internal quality standard information, which includes safety warnings, user instructions etc.[28].

For the labelling of premixtures, some of this information needs to be provided for each additive contained in the premixture, although less information is required[29].

The above information is more complex to include on a label that is available in several languages; therefore, the cost increases as the number of languages increases. Typically, feed additive and premixture manufacturers target several countries with the same packaging, which therefore needs to provide the information on the label in several languages. The objective generally is to standardise the label, so as to target many countries both EU and non-EU. This business model is very common across the industry. Out of 28 respondents to the survey, 10 typically had more than 10 languages on the label of their products and 8 of these even had 23-30 languages (Q132, stakeholder survey).

The industry noted that customers on the market are increasingly sensitive to regulatory compliance as regards the information that needs to be provided on the label. Furthermore, the information particulars provided on the label pursuant to mandatory regulatory requirements include some repeat information provided by other means; notably, the product specification sheets used by the industry in B2B transactions, ahead of the product's purchase to ensure that the product conforms to the technical specifications required by the buyer. Hence, a number of Codes of good labelling practices have been developed:

[27] This is required only for cases that are not excluded in Article 2(6) of REACH and Article 1(5) of CLP.
[28] Suppliers to the feed industry are required to have a quality and feed safety system in place, including a HACCP system, where risk assessment and management of supplied ingredients, ensure that these products comply to the applicable legislation and agreed specifications. It is quite common that these suppliers and manufacturers have quality systems implemented like FAMI-QS, GMP+, OVOCOM, UFAS, FEMAS, QS, or similar systems. See FEFANA code of practice for pre-mixtures: http://fefana.org/wp-content/uploads/2018/02/2013-05-03_booklet_premixtures.pdf
[29] According to Article 16(1) of the Feed Additives Regulation, most of the information under point i and ii above do not need to be labelled for the feed additives incorporated in the premixtures.

- The labelling information to be provided on the label and in the product specification sheets for feed additives and premixtures is described in a joint Code of practice for the application of the labelling rules laid down in Article 16 of Regulation (EC) No 1831/2003, which is issued by FEFANA/FEFAC/EMFEMA[30].
- Further down the chain, for the implementation of the labelling provisions on feed that are laid down in Article 26 of Regulation (EC) No 767/2009:
    - A joint EU Code of good labelling practice for compound feed for food producing animals has been issued by FEFAC/Copa-Cogeca[31]; and,
    - FEDIAF has updated a Code of good labelling practice for pet food, which was originally published by the Commission in 2011 – the updated code was endorsed by the PAFF in September 2018[32].

The feed additives industry has been discussing for many years the issues and problems stemming from the current obligations on labelling, especially after the adoption of Regulation (EC) No 767/2009 on the placing on the market and use of feed. The feed Regulation makes a distinction between a feed 'label' (the document attached to each pack) from 'labelling' (general documentation using any medium). This allows the information to be provided e.g. by electronic means. Hence, there is a strong perception amongst the feed additives industry that Regulation (EC) No 1831/2003 and Regulation (EC) No 767/2009 are not fully aligned with regard to the labelling provisions. According to the industry, the main questions that arise in relation to the information required by Regulation (EC) No 1831/2003 on the physical product label are:

I. *Who needs what information?* The information is needed by feed operators down the chain using the feed additive in feed, including end-users (farmers using the feed and pet-owners buying the pet food). At the level of feed operators, a distinction is made between nutritionists and workers. All these recipients of information have different information needs.
II. *When is it relevant to have the information?* Depending on who needs the information and what are their needs, information may be required before, at or after purchase of the feed additives.
III. *Where is it relevant to have the information?* Depending on the previous two points, some information may be relevant to be provided on the label while some information may be relevant to be provided on the product specification sheet which is used in B2B transactions ahead of the purchase of the feed additives.

According to the industry, more flexibility should be provided in the Regulation as to how the information can be provided on the label. For instance, electronically readable labels such as a matrix barcode (e.g. the QR Code trademark) have important advantages for the transmission of information along the chain, operational efficiency (warehousing/processing operations), as well as allowing the additional information if required, and having the potential to facilitate the tasks of control authorities. Other means to provide the information, such as pictograms (e.g. safety warnings, storage info) and using international standard units (e.g. for net weight/volume) can also make improve the efficiency of information provision as they save space on the label and do not need translation. For instance, the CLP regulation foresees the use of pictograms for safety warnings; also, some companies indicated that in other industries e.g. pharmaceuticals, the label includes pictograms for batch number, manufacturing date, expiration date etc. All these alternative ways to present some of the information on the label ensure improved efficiency without compromising traceability.

[30] Joint EMFEMA / FEFAC / FEFANA: Code of Practice for the application of the labelling rules laid down in Regulation (EC) No 1831/2003 for feed additives and premixtures. September 2011, Version 8. https://www.fefac.eu/files/36438.pdf .

[31] COPA-COGECA / FEFAC Code of Good labelling practices for compound feed for food producing animals. Version of May 2016 (ADA(10)5244:6). Available to download at: https://copa-cogeca.eu/Download.ashx?ID=1539350

[32] FEDIAF: Code of Good Labelling Practice for Pet Food, October 2018. http://www.fediaf.org/images/FEDIAF_Labelling_Code_October_2018_online_final.pdf

A further factor that triggers costs is differential understanding between national Competent Authorities (NCAs), as to the level of implementation required by the labelling provisions laid down in Article 16 of Regulation (EC) No 1831/2003. Requests of Member State authorities (e.g. based on their interpretation of additional requirements or worker safety information) are the second and third most important reason why operators change labels (according to 23 out of 30 respondents to the stakeholder survey, Q134).

Companies complain of a perceived 'gold-plating' by authorities, over and above the requirements of the Regulation. Examples provided include: some NCAs require all information to be available in all languages, while other NCAs provide some flexibility for some of the information to be available in the main EU languages; some NCAs require larger font size although this is not specified in the legislation; some NCAs insist on listing a representative company in their country, whereas already a European operator is indicated on the label; some NCAs accept listing a "minimum" content on the label while others insist on listing a fixed value; and, differences in implementation for additives which are produced from GMOs with some countries being very strict in listing the statement "*produced from GMO*" on the product label while other countries are not.

To address these issues, the industry would welcome a set of guidelines on labelling, to enable a common understanding amongst authorities and operators for the interpretation of the labelling provisions of Regulation (EC) No 1831/2003.

NCAs identified some more technical issues pertaining to more general aspects of the Regulation (and other applicable legislation) which may create differential understanding and interpretation of labelling requirements by authorities across the EU. Examples provided include: use of additives in drinking water (the use of additives/premixtures is not authorised via drinking water, but complementary feed can be used in drinking water); the approach to claims on the label with regard to the effects of an additive (extent to which these are restricted to the specific function for which the additive is authorised, as stated in the authorising Regulation); extent to which quantity of carriers is to be declared on the label (not explicitly required by Article 6 of Regulation (EC) No 1831/2003) versus the extent to which carriers are to be included in the list of feed materials used in compound feed (implementation of Article 17 of Regulation (EC) No 767/2009).

4.3.5 COSTS: LABELLING OF PREMIXTURES

As discussed, in view of the range of factors that determine labelling costs (see points a to d, under 'costs: overview), the costs for the labelling changes that need to be performed on the label of premixtures due to the Regulation vary considerably depending on the case. It is therefore not possible to provide an average range of costs across the entire premixtures industry that would capture the whole range of situations that may prevail in practice. To illustrate better these costs, four representative cases are presented below.

Common observations that can be drawn from the cases on premixtures are as follows:

- Changes to the regulatory status of feed additives that are commonly/ widely used in premixtures result in higher costs due to the increased number of product references that contain the additives and are therefore affected by the change. Recent examples, of regulatory changes over the last 3-4 years, widely used and frequently mentioned by companies include: vitamin, flavourings and trace elements re-authorisations; copper re-authorisation in 2018 with reduction in max limits; suspension of *ethoxyquin*[33] *in September 2019*.

[33] *Ethoxyquin* is a common preservative (technological additives: functional group 1(a)), widely used in premixtures. On a precautionary basis, due to the incomplete data submitted for the reauthorisation of this additive, it has been suspended (not withdrawn) in feed use, after a transitional period which expired at the end of September 2019. It is noted that all companies interviewed faced some label changes and/or disposal costs from the suspension of *ethoxyquin*, due to the common use of this additive as a preservative.

- Companies indicated that to some extent the costs are due to the timings of the regulatory changes, e.g. reauthorisation of common additives contained in the premixtures. Combining/ synchronising reauthorisations of commonly used additives of the same type helps reduce costs: this was the case for example with the reauthorisation of flavourings; if followed with the forthcoming reauthorisation of organic acids, it could help significantly cut down on costs. On the other hand, vitamins and trace elements have not been re-authorised at the same time Completing re-authorisations simultaneously helps to make labelling changes at once, especially because these are common ingredients in premixtures.
- The size of packaging has an impact on labelling. Pre-mixtures are typically sold in a wide variety of packaging sizes (1 kg; 5 kg; 25 kg; up to 500 to 1000 kg bags). Complementary feed may be sold in individual units smaller than 1kg. The information that needs to be contained on the label of premixture products (combined effect of Regulation (EC) No 1831/2005 and the CLP Regulation) causes a problem of room on the labels and readability of the information. Generally, the complexity/cost is expected to be proportionately higher for smaller packs than for larger packs.
- No impacts on the labelling process and costs were identified in relation to the presentation of the product (liquid vs solid form).
- Costs of disposal/destruction of labels/products that become obsolete due to a regulatory change tend be low. In some cases, the label is printed directly on the packaging (pre-printed bags[34]); regulatory changes may therefore cause some cost for destruction of the packaging and/or in more rare cases, destruction of the pre-mixture products. Overall, however, these costs are relatively low.
- Although relatively low, companies consider these costs to be higher than in non-EU countries. One of the companies with global activities compared the costs of labelling changes to costs in other regulated developed countries and concluded that labelling changes result in higher costs in the EU: according to their internal calculations, in the EU costs are €2.25/t compared to Canada (€0.25-0.35/t; and US: €0.40-0.50/t).

Other impacts of changes in the regulatory status of products - in case when additives are not authorised/reauthorized and/or their scope and conditions of use change – include: the need for product reformulation; and/or reliance on a lower number of suppliers (including suppliers from non-EU countries) hence increased prices for procuring certain feed additives. The case of amino acids and vitamin B12, for which respectively 75% and 100% of EU demand is imported from Asia[35], were indicated as examples.

An overview of the four cases of premixture companies is provided below:

Type of company	Number of references	Cost of labelling changes	Disposal costs; losses
Case 1: large	~180 product references (standard model)	€140,000/year (since 2019, *automated* systems: €80,000/year)	disposal of labels: €2,000 (on average)
Case 2: medium (part of large)	large number of product references (tailor-made model)	€144,000/year	destruction of unsold products: €24,000 in product value disposal of labels: €13,500

[34] This is expected to be the case mostly for special premixtures in small packaging, complementary feed, and for special compound feed (e.g. for companion animals).
[35] Data provided by one operator, based on their own experience.

Type of company	Number of references	Cost of labelling changes	Disposal costs; losses
Case 3: medium (part of large)	large number of product references (tailor-made model)	€91,000/year	destruction of unsold products: €40,000 in product value
Case 4: large	large number of product references (tailor-made model)	€114,000/year (plant with a *high* level of automation) €223,000/year (plant with a *low* level of automation)	minimal

4.3.5.1 Case 1: manufacturer of premixtures

Context: This case refers to a large company, manufacturing additives and premixtures destined both for pet food and feed for food producing animals. The company follows a standardisation model for the production of formulations, with a total ~180 product references. During the last 6 years the company had to change the labels 14 times, of which 2 changes were due to authorisation decisions and 4 were due to other regulatory requirements under Regulation (EC) No 1831/2003; the remaining 8 changes were due to Member State competent authority interpretation of the EU regulatory requirements (with different approaches noted in some cases) and the company's own decision.

Costs: In this case, the average annual cost of performing labelling changes due to regulatory requirements (6 changes) was estimated at approximately €140,000 over the past 3 years. The company subsequently invested in automated systems, which will reduce the cost from 2019 onwards to €80,000 on an annual basis. According to the company, harmonisation of interpretation across Member States and greater flexibility in the provision of information within Regulation (EC) No 1831/2003 would bring important savings on labelling costs.

The company notes that any further increase in labelling requirements would mean a change of labels, as there is no space left on the current labels. Furthermore, the current production model may need to shift away from standardisation to 'make to order' packaging/labelling, which would significantly cut the return on investment (ROI).

Disposal costs/losses: Costs and losses are minor, as transitional periods (typically 6 months) tend to suffice. Any costs/losses incurred concern the destruction/disposal of the label, not of the product. Common business practice is to keep a 3-year stock of labels; with the typical 6 months of transition period provided (e.g. suspension of *ethoxyquin*[36]), the worst case could be 2.5 years of labels. This cost is relatively low in any case (about €2,000 on average).

4.3.5.2 Case 2: manufacturer of premixtures

Context: This case refers to a medium size company (part of a large company) manufacturing additives and premixtures both for pet food and for feed destined to food producing animals. This company has a large number of product references, due to sales to a large number of markets and customers and tailor-made formulations. The company

[36] *Ethoxyquin* is a common preservative (technological additives: functional group 1(a)), widely used in premixtures. On a precautionary basis, due to the incomplete data submitted for the reauthorisation of this additive, it has been suspended (not withdrawn) in feed use, after a transitional period which expired at the end of September 2019. It is noted that all companies interviewed faced some label changes and/or disposal costs from the suspension of *ethoxyquin*, due to the common use of this additive as a preservative.

had to perform several changes on the label in recent years due to regulatory and authorisation changes under Regulation (EC) No 1831/2003.

Costs: In this case, the average annual cost of performing labelling changes due to regulatory requirements under Regulation (EC) No 1831/2003 was estimated at approximately €144,000 in the past 3 years (net cost including savings generated by a shift to automated systems). This cost represents 0.4% of production costs.

Disposal costs/losses: total costs and losses due to multiple regulatory changes were estimated at €24,000 in product value (for the destruction of 15 tonnes of unsold products) and disposal costs at €13,500; despite the transitional periods provided, customers were reluctant to buy the products in some cases, hence resulting in products remaining unsold.

Products not sold at the end of the transitional period (e.g. containing *ethoxyquin*) can only be exported outside the EU if the products are registered in a non-EU country. In this case, products have to be stored for a longer time if new product registrations are required in the third countries; assuming the product is granted registration in non-EU countries, there will be some (minor) storage costs (in addition to the registration costs for each non-EU country). However, in some cases, a product's registration may last beyond the product's expiry period, resulting in product destruction.

4.3.5.3 Case 3: manufacturer of premixtures

Context: This case refers to a medium size company (part of a large company) manufacturing premixtures for food producing animals (poultry and pigs). This company has a large number of product references, due to sales to a large number of markets and customers and tailor-made formulations. The company had to perform several changes on the label in recent years due to regulatory and authorisation changes under Regulation (EC) No 1831/2003.

Costs: In this case, the average annual cost of performing labelling changes due to regulatory requirements under Regulation (EC) No 1831/2003 was estimated at approximately €91,000 in the past 3 years; this includes costs generated by a change in some cases in the products' formulation due to a regulatory change in the additives. In 75% of all cases, the change related to a regulatory update (of these: 12% involved a formula change and 63% involved a label change only).

Disposal costs/losses: This company faced almost no disposal costs to date, being prepared for the change. The only case when costs were incurred was the recent suspension of *ethoxyquin,* which resulted in 20 tonnes of unsold products that had to be destroyed, at a cost of €40,000 (including the value of the destroyed product and destruction costs).

4.3.5.4 Case 4: manufacturer of premixtures

Context: This case refers to a large company manufacturing premixtures. With several plants across the EU, this company has a large number of product references, due to sales to a large number of markets and customers and tailor-made formulations. As an indication, two of its plants produce around 1500 formulations of premixtures that are tailor made according to customer needs. The company had to perform several changes on the label in recent years due to regulatory and authorisation changes under Regulation (EC) No 1831/2003.

Costs: In this case, the average annual cost of performing labelling changes due to regulatory requirements under Regulation (EC) No 1831/2003 in the past 3 years was estimated at approximately €114,000 for a plant with a high level of automation; and, €223,000 for a plant with a low level of automation. At company level (as an average across plants), this cost represents 3.4% of the sales profit. In 40% of all cases, the change related to a regulatory update; while in the other 60% of cases it may be customer

driven but also triggered by a regulatory change. This includes costs generated by a change in some cases in the products' formulation due to a regulatory change in the additives.

In total, all business administrative activities related to regulatory matters on labelling, including those induced by changes in the authorisation of feed additives, represent about 25% of all activities related to compliance activities across the company.

Disposal costs/losses: This company faced almost no disposal costs to date, being prepared for the change. However, the transition periods typically provided (6 months) is not sufficient for premixtures. Usually 3-4 months at least are needed for stock clearance, depending on the shelf life of products. Sometimes customers may push for change, as they are aware of the forthcoming change and do not want to be left with stocks of older products. These factors narrow the window for making label changes to maximum 2 months, which does not allow e.g. to combine the re-labelling work on various re-authorization acts in one run.

4.3.6 COSTS: LABELLING OF PET FOOD

Data were collected from three pet food manufacturers. Due to the large number of product references potentially affected by a regulatory change, the costs can be significant. For example, if an additive is removed from the product due to change in its regulatory status, the label must change to reflect this. Typically, the withdrawal of a declared additive or the imposition of a new content limit that requires declaration can affect many hundreds of items of packaging. Companies specified that they generally try to reduce complexity in recipes, by relying on a smaller number of key ingredients, including feed additives. If the regulatory change affects a major critical additive, e.g. a nutritional additive such as a vitamin, a change could affect thousands of packaging units with over €1 million in re-labelling costs, in addition to reformulation costs.

One company indicated reformulation costs of €30,000 (which roughly represents 100 working days of cat 1 and 2 staff), across a range of 2,000 products; and, re-labelling costs which can reach up to €1 million in case labels need changing across the 2,000 products. These costs relate to an additive with a declarable maximum, widely used across the company's multiple brands.

According to data provided by two companies on another case of a feed additive widely used in the pet food industry, which was recently withdrawn from the market, reformulation costs are expected to reach in excess of €3-4 million. In addition, there are important re-labelling costs and at least 10% of the production volume is expected to be destroyed at an expected cost of €15,000 - €20,000 (this is the cost of destruction only; it excludes the loss in product value)[37].

A sufficiently long transition period for pet food (e.g. 24 months) would negate the cost of losing the stock of 3-6 months. Granting in such cases a longer transitional period is important to ensure both re-labelling and inventory management and reduce costs.

It is noted that these costs reflect the wider product range of pet food manufacturers, in terms of the number of: products/formulations; packaging per product/formulation (different sizes and types of packaging for the same product/formulation); and, the number of label versions/packaging. It also reflects the fact that pet food has standard,

[37] The transition period given for the withdrawal of products containing this additive is 6 months to produce and 12 months to sell; after this period, the products can no longer be on sale and need to be recalled. One of the companies indicated that it is impossible to sell through all stocks during the transition period. Given a product shelf life of 2 years and assuming a very skilled inventory management, at least 10% of the production volume (an estimated 15-20 tonnes) needs to be destroyed.

more sophisticated, packaging, with information printed directly on the package. Thus, the above costs may represent an over-estimate of the actual costs of labelling changes. In the case of food producing animals the feed is prepared upon request and labelled at that moment; this increases flexibility to accommodate changes and is therefore expected to imply lower costs for manufacturers of compound feed for food-producing animals, in comparison to pet food manufacturers.

4.3.7 COSTS VERSUS BENEFITS[38]

According to all consulted parties, the information available on the product's label (from feed additives to feed) is important to ensure traceability and controls, as well as to inform users along the feed supply chain and end users.

The main point where views differ is on the amount of information and the form in which it is required on the product's physical label:

- Competent authorities tend to argue that the information and the form in which it is currently required is the most relevant for allowing the authorities to perform verification checks.
- On the other hand, the industry along the feed chain tends to argue that the requirement to provide this information on the product's physical label creates an unnecessary burden that is disproportionate and does not add any benefits, or has any added value, in terms of traceability. In particular, the benefits of traceability are already conferred through the use of other means by which this information is provided in B2B transactions (product specification sheets), in line also with industry standards and codes of practice. This enables, for example, the efficient recall of products along the chain in case any issues arise with any feed additive.

According to the industry, the labelling information can be provided in a more efficient way, that is better aligned to Regulation (EC) No 767/2009, through the use of other media (e.g. electronically readable labels) that reduce the costs of the information provision on the physical label. Furthermore, the industry would welcome a set of guidelines, to enable a common understanding amongst authorities and operators for the interpretation of the labelling provisions of Regulation (EC) No 1831/2003.

These actions would improve the cost-benefit balance of the **implementation of labelling provisions** of Article 16 of changes/updates under Regulation (EC) No 1831/2003.

Although the costs of label changes triggered by regulatory changes/updates under Regulation (EC) No 1831/2003 – notably a change in the authorisation status of a feed additive - are relatively low, these costs multiply with the increase in product references as the feed additive moves down the feed chain, i.e. used in premixtures and (used as a feed additive or contained in premixtures) in complementary feed and compound feed. Hence, even a small change in the authorisation status of a feed additive can result in important costs in labelling and/or reformulation of existing products. Significant savings can be made in these costs by reducing the frequency of the changes required on labels. This can be ensured by:

- Synchronising the timings of authorisation/renewals of similar types of additives (e.g. as has been the case with the reauthorisation of flavourings);
- Reducing deadlines in authorisations and renewals;
- Providing longer transition periods, particularly for users of feed additives (pre-mixtures and feed/pet food) that require a longer time to perform adaptations.

[38] This section focuses on costs versus benefits for the feed supply chain. The wider benefits of the Regulation are outlined in the main body of the Report (EQ3).

These actions would improve the cost-benefit balance of **labelling adaptations that are due to regulatory changes/updates** under Regulation (EC) No 1831/2003.