European Commission

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

Annex 6: Costs Methodology

[Written by Food Chain Evaluation Consortium - FCEC]
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Contact: [First name Last name]

E-mail: […]*@ec.europa.eu (functional e-mail if existing, or)*
[First name.Last name]*@ec.europa.eu*

European Commission
B-1049 Brussels

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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

This report has been prepared by:

Agra CEAS Consulting Ltd (BE)

Maria Christodoulou, Director (Project Manager)

Dylan Bradley, Director

John Nganga, Senior Consultant

Areté s.r.l. (IT)

Alberico Loi

Mario Gentile

Arcadia International EEIG

Francesco Montanari

Methodology and Data

1 Analysis of regulatory costs

The section below describes the process for the analysis of the regulatory costs for the affected stakeholders and Member State Competent Authorities. The analysis of regulatory costs is presented in the two case studies, on authorisation and labelling, in Annex 4.

The assessment of administrative and compliance costs stemming from the Regulation was based on the identification of relevant obligations and required actions, as defined in the standard cost model (SCM) (**Table A1**).

During the structuring phase, the various obligations laid down in Regulation (EC) 1831/2003 were identified and checked with the industry during the exploratory interviews (**Table A2.16**). This process revealed that the main (most burdensome) obligations for FBOs stemming from the Regulation are related to the authorisation process (including the detailed implementing rules of Commission Regulation (EC) 429/2008) and to the labelling obligations (Article 16 of Regulation (EC) 1831/2003, as well as the detailed rules of Commission Regulation (EC) 429/2008, and rules established by Regulation (EC) 767/2009 on the placing on the market of feed). Complying with these obligations (A) requires FBOs to take a number of actions (B) (**Table A1)** which entail costs.

In assessing the costs of the obligations, a distinction was made between information that would be collected and processed by businesses even in the absence of the legislation (which generates business-as-usual (BAU) costs) and information that is solely collected because of the legal obligation (which generates additional costs). Thus, **all costs are calculated on an additional basis**, i.e. excluding business-as-usual (BAU) costs.

Table A1: Identification of costs according to the Standard Cost Model (SCM)

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

Table A2: Obligations for FBOs, as defined in Regulation (EC) No 1831/2003

Operator	Obligation	Reference (Reg. 1831/2003) *(a)*	Importance (cost-wise) *(major/minor) (b)*
Holder of the authorisation	Implement a post-market monitoring plan (if requested)	**Preamble** (20)	Minor
Any person seeking an authorisation	Submit an application	**Authorisation** Article 4	Minor
Applicant	Adequate and sufficient demonstration of conditions set out by the Regulation	**Conditions of authorisation** Article 5	**Major**
Applicant	Deliver the necessary documents to EFSA	**Application of authorisation** Article 7	**Major**
Applicant	Deliver the supplementary information to EFSA (if requested)	**Opinion of the Authority** Article 8	**Major/**Minor *(depends on questions or not from EFSA)*
The holder of the authorisation	Ensure that monitoring is carried out and to submit reports to the Commission (rarely requested)	**Supervision** Article 12	Minor
The holder of the authorisation/applicant	Re-submit an application, if changing the terms of the authorisation + data supporting the request for the change	**Modification, suspension and revocation of authorisations** Article 13	**Major**
Producer, packer, importer, seller or distributor (within the EU)	Responsibility for proper labelling actions	**Labelling and packaging** Article 16	**Major/**Minor *(depends on producer logistics)*
Applicant	Take all necessary steps to reach agreement on sharing the use of information	**Data protection** Article 20	Minor
Applicant	Should contribute to supporting the cost of the tasks of the Community Reference Laboratory and the consortium of National Reference Laboratories	**Reference laboratories** Article 21	Minor
Applicant	Adequate and sufficient information for renewal	**Renewal of authorisation** Article 14	**Major**
Member States	Member States shall lay down the rules on penalties applicable to infringements of the Regulation	**Penalties** Article 24	*This is not a cost as such for operators. The analysis covered the extent to which penalties apply and severity of penalty.*

(a) Article 10.2 revaluation of existing products; and, Article 15 urgent authorization: these aspects were not considered to incur 'major' costs by the industry

(b) Minor/major costs in this context is meant to provide the relative importance of the costs (i.e. whether they constitute 'major' or 'minor' costs for an operator). The purpose of this table has been to provide an initial understanding of the importance of these costs for operators.

Source: Agra CEAS, based on the SCM and exploratory interviews with the industry.

1. Costs of authorisation process

The authorisation process (Articles 4, 5, 7, 8, 12, 13) involves a sequence of actions generating costs; these can be broken down into three main headings:

a) **Submission of application;**
b) **Submission of method of analysis including fees and reference samples to the Community Reference Laboratory to validate the method of analysis;**
c) **Dossier preparation and completion** (note: this includes response to requests for supplementary information). Two of the main actions of dossier preparation relate to the generation of specific data (actions #3 to #5) through testing:
    i) Safety tests / studies
    ii) Efficacy tests / studies

These three headings are closer to the obligations resulting from the Regulation as seen from the point of view of the industry. The relationship between the articles and these obligations is set out below:

Article / obligation	Submission of fees	Submission of application	Dossier preparation and completion (tests / studies)
4 (Submit an application)	X	X	
5 (Demonstration of conditions)			X
7 (Deliver documents to EFSA)			X
8 (Deliver supplementary info)			X
12 (Ensure monitoring)			
13 (Resubmit application and data)	X	X	X
14 (Reauthorisation)	X	X	X

Note: reauthorisation (Article 14) has been added to the list of obligations.

With regards to these three headings:

a) **Submission of fees** is a fixed cost: €6,000 paid to the EURL, plus the cost of sample (which has been indicated by the industry as relatively 'minor').
b) **The submission of an application** is an administrative obligation which can be quantified on the basis of staff time, staff category and unit costs[1].
c) The extent of **costs for dossier preparation and completion** is driven by (i) the number of tests / studies requested, and (ii) the complexity of tests / studies required. In order to quantify this, efforts were made to determine the average unit cost of studies and identify the average number of requested studies. This included the additional costs created by requests for supplementary data, beyond the data already available through existing tests carried out by FBOs at their own initiative, to the extent that these are essential to demonstrate the safety/efficacy of the product.

Total costs for a single case of authorisation and renewal of authorisation were calculated based on the three quantifications above. These was then contextualised through the collection of data on production costs and/or turnover.

In addition, **indirect costs and losses** were analysed, with the focus on:

d) **Reformulation costs**: costs incurred by users of feed additives (i.e. compound feed manufacturers; pet food manufacturers) for product reformulation, in the event that feed additives are withdrawn or conditions of use change (dosage; species).

[1] Staff costs: costs of internal company staff and/or external experts (consultants, lawyers).

e) **Loss of sales**: foregone revenue, in the event of undue/unjustified delays beyond the normally foreseen/justified timeline from application to authorisation.

2. Costs of labelling

Article 16 requires various information to be indicated on the feed additive product label; in some cases, there are additional communication requirements laid down in the detailed rules of Commission Regulation (EC) 429/2008, and rules established by Regulation (EC) 767/2009 on the placing on the market of feed, as well as in the REACH and CLP legislation. This information is destined to be transmitted downstream the supply chain, to, where applicable, FBOs that are feed additive buyers/users (i.e. compound feed and pre-mix producers, pet food producers, traders, retailers).

A key disadvantage of the current rules in Regulation (EC) No 1831/2003, according to operators, is that this information needs to be indicated on the product label, resulting in excessively long labels and costs of adapting these labels when information changes. Furthermore, the information indicated on the label is not ultimately used neither by product buyers (i.e. central procurement managers in companies downstream the supply chain) nor by product users (i.e. staff operating at plant level). Thus, the main costs analysed are **additional costs of labelling when label changes** (i.e. costs that would not be incurred by using other means of transmitting the information, such as through bar codes):

a) Adaptation of packaging and/or labels/labelling process. This includes labelling, packaging and storage costs, stock management of labels/final packaged products, label/packaging waste.

These costs include both time required (staff time; staff category; unit costs) and the costs of materials and equipment. Potential cost overlaps and/or mitigation of requirements imposed by other legislation (e.g. CLP) were considered to the extent appropriate.

In addition, **indirect costs and losses** were analysed, with the focus on reformulation costs and, other costs/losses, as in the case of authorisation costs.

3. Costs for MS CAs (control costs)

The following types of costs were investigated for MS CAs:

a) Cost of controls: the costs borne by national enforcement authorities for performing controls. These costs include both time required (staff time; staff category; unit costs[2]) and the costs of materials and equipment. They may be partly compensated by the imposition of fees on FBOs.
b) Cost of management: attending the standing committee, study of draft regulations for approval, contact stake holders (questions, meetings etc.), approval of feed establishments for additives and premixtures, approval of importers of feed additives.

2 Monetisation of costs

In all cases:

[2] Staff costs: costs at the level of the competent authority performing the controls, and costs of national food agency or official control laboratory staff (to the extent thy are involved).

- Earnings are adjusted for overhead costs[3];
- The conversion of annual or monthly earnings to daily rates is based on 215 working days/year[4] and 8 hours/working day.

Costs for the EU institutions:

Costs were estimated for the European Commission (DG SANTE), the EURL and EFSA to fulfil their tasks under the Regulation.

The costs were calculated on the basis of the number of days spent by each of the three institutions on their tasks, multiplied by the average daily rate (adjusted for overhead costs). The daily rate is calculated on the basis of the 2019 rates of remuneration of EU officials, as published in OJ C 451, Volume 61, 14 December 2018[5].

Costs of NCAs:

Data were collected on staff time (for staff categories 1 to 4) spent on the following activities that directly stem from the obligations of the Regulation for national competent authorities:

(a) participation to the meetings of the Standing Committee in Brussels
(b) controls carried out to perform inspections and verification checks
(c) other legal and administrative obligations

All data on staff time were collected as an average annual number of days during 2016-18 for each of the above three activities. These data were collected through the survey (which targeted all EU-28 Member States) and interviews conducted during the case studies (which targeted four countries: Belgium, France, Germany and Spain).

The staff time expressed in number of days was multiplied by the average daily rate to calculate the total costs in €. The daily rate was calculated on the basis of the Eurostat dataset on mean annual earnings by economic activity and educational attainment [dataset: earn_ses14_30][6] for public administration for each Member State and for each of the staff categories 1 to 4 (adjusted for overhead costs).

Costs for operators:

Costs were monetised using the Eurostat dataset on mean annual earnings by economic activity and educational attainment [dataset: earn_ses14_30][7] for industry (except construction), as an average across the EU-28 and for each of the staff categories 1 to 4 (adjusted for overhead costs). The use of the average EU-28 earnings neutralises the impact of the location of companies' operations on costs.

[3] According to Better Regulation toolbox #60: addition of 25% overhead on staff costs
[4] Working days: https://ec.europa.eu/eurostat/documents/10186/7970019/Guideline-unitcosts.pdf
[5] The same rates are assumed for all institutions (Commission, EFSA, EURL). AD rate is based on AD/AST, grade 10, step 1; AST rate is based on AST/SC, grade 4, step 1.
[6] https://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=earn_ses14_30&lang=en
[7] https://appsso.eurostat.ec.europa.eu/nui/show.do?dataset=earn_ses14_30&lang=en

Analysis of benefits

The importance of the benefits depends on the extent to which the Regulation's provisions are successful in meeting the expected results/outcomes, as set out in the intervention logic (section 2.1.2.1)**.** All of the outlined results/outcomes constitute potential benefits, for the different stakeholders expected to be affected by the legislation. The benefits (qualitative and quantitative) include the advantages of having in place a common framework at EU level (EU added value).

The actual benefits are generally not possible to quantify, and even less to monetise; this is due both to their non-quantifiable nature, and the presence of confounding factors which mean that lack of a basis for attributing causality cannot be isolated and attributed to the Regulation alone. This is the case for all of the expected benefits for human health, animal health and welfare, and the environment: for all these aspects, benefits were analysed qualitatively, in terms of the extent to which they are considered to have been achieved by the different groups of stakeholders, bearing in mind the need to attribute causality to the Regulation. This analysis was supported, where possible, by evidence provided on an exemplary basis (i.e. best examples of benefits actually obtained).

Efforts were also made to collect more quantitative indicators of the benefits of the Regulation for business operators and for MS Competent Authorities, in terms of potential costs savings and generated market value. Only in few cases, operators provided data in terms of the share of regulatory costs as a percentage of production costs or turnover.

Cost savings	a. Extent to which costs of compliance are lower under the Regulation, compared to the Directive: business operators: savings in compliance costs (differentiating between operators at different stages along the supply chain); MS CAs: savings in control and management costs
	b. Extent to which authorisation costs would have been higher under a national authorisation scheme: potential savings from the fact that a common, centralised authorisation scheme is in place. This benefit is relevant both for business operators and MS CAs.
Market value	c. Additional value generated by the centralised EU authorisation enabling sales to multiple markets. This benefit cannot be directly compared to the costs of the authorisation process (which are additive-specific); where possible, the turnover generated by the authorised type of additives in broad magnitude terms, in order to ccontextualize the relative iimportance of the costs (authorisation; labelling).

3 Data confidentiality issues/concerns

In view of confidentiality issues and concerns raised by the industry during the main phase of the study, consultation and data collection, especially on the costs of the Regulation, has been difficult and has encountered some delays.

To ensure that essential quantitative data could be collected for the purposes of the study, in consultation with the Commission, the confidentiality concerns have been addressed mainly through:

- Relevant confidentiality statements to ensure non-disclosure of sensitive data and of the owner of the data[8]. These were run by the Commission before being added to tools or shared with data owners;
- Use of multiple tools for data collection (surveys; interviews; case studies); and,

[8] Notably feed additive/premixtures/feed producers and applicants for authorisation.

- Enlarging the coverage of participant operators/companies to the data collection activities. For case studies, this necessitated an important extension to the number of interviews completed with companies.

As a result, there are constraints to the provision of some content details in this Report:

- Replies to EQs (section 5 to 9 of the main Report; and, the case studies in Annex 4): the presentation of results by source (company/applicant product group/name) is constrained in some cases (e.g. data on costs) by confidentiality statements;
- The level of detail in stakeholder responses and data calculations followed for certain aspects, particularly on costs, are also subject to confidentiality restrictions.