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

Annex 1: Intervention logic

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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 1: INTERVENTION LOGIC

The Regulation was adopted in 2003 as part of the actions contained in the White Paper on Food Safety, which aimed to ensure the highest standards of food safety in the EU. The provisions laid down by the previous legislative framework (Directive 70/524/EEC) were complex and subject to uneven implementation. New rules on feed additives were also needed to better address the rise of antimicrobial resistance. There was significant scope to improve protection of humans, animals and the environment from unsafe feed additives. The Regulation also aimed at fostering innovation in livestock farming and sought to take better account of scientific and technological developments while ensuring consumers' interests were protected.

The sections below outline the needs identified and the objectives pursued by the Regulation, together with the different actions and the positive results to which they were expected to lead.

Objective: Address the rise of antimicrobial resistance

Identified needs: The use of antibiotics as feed additives to promote the growth of animals contributes to the antimicrobial resistance (AMR) of pathogens carried both by animals and by people eating food originating from those animals. In addition, the excessive or inappropriate use of antimicrobials leads to the increasing emergence and spread of multi-resistant bacteria in the environment, which also contributes to the spread of AMR.

- **Actions**: Ban the use of antibiotics as feed additives (growth promoters).

Expected results: By banning the use of antibiotics as feed additives (growth promoters), the Regulation was expected to contribute to reducing the threats posed by AMR to citizens, animals and the environment.

Objective: Simplify the rules governing the authorisation of feed additives

Identified needs: Under the previous framework, the rules governing the authorisation of feed additives were complex, unclear and often resulted in undue delays for applicants. For instance, the assessment of applications involved all the MS, with one MS designated as rapporteur. In addition, the Directive was not uniformly transposed across the MS, which created disparities between the national rules followed in different countries (See Judgements of the Court on the interpretation of certain provisions of the Directive in relation to the provisions adopted by the MSs[1].)

- **Actions**: To address these shortcomings, the Regulation established a single harmonised authorisation procedure, with a centralised risk assessment performed by EFSA and predefined timelines to be respected for the different steps of the procedure. In addition, the Commission adopted detailed rules to help applicants prepare their dossiers including strict data requirements. This allows applicants to

[1] Case 29/87 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A61987CJ0029);
Case C-145/02 (https://eur-lex.europa.eu/search.html?qid=1552030785137&text=Case%20C-145/02&scope=EURLEX&type=quick&lang=en)
Case 28/84 (https://eur-lex.europa.eu/search.html?qid=1552030843921&text=Case%2028/84&scope=EURLEX&type=quick&lang=en)

know precisely the requirements they have to fulfil. A single application form was also established.

Expected results: Taken together, these measures were expected to result in a simpler, faster and more predictable authorisation process and also to contribute to a better functioning of the internal market in feed additives.

Objective: Protect humans, animals and the environment from unsafe feed additives

Identified needs: Feed additives may pose a risk to human health both through direct exposure – that is, "occupational exposure for workers" and exposure for other users such as farmers or pet owners (e.g. irritation of the skin or respiratory tract) - and through indirect exposure by the consumption of products of animal origin if the additive or its residues persist in the food. Animals are directly exposed to additives through the consumption of feed. In addition, the active substance(s) contained in the additive may be excreted either as such, or as metabolites, which can lead to significant environmental impacts. The environmental impact is all the more important as feed additives are usually administered over long periods of time, and often to large groups of animals. The health of humans and animals may be further affected through exposure to such environmental contamination.

To address these needs, the following set of actions were set out and results expected per action:

- **Actions**: The Regulation provides for the risk assessment function to be under the responsibility of the EFSA, while risk management is performed by the Commission, which takes the final decision on whether or not a feed additive should be authorised and on what conditions.

Expected results: This separation of competences was introduced to ensure that the potential risks of feed additives are assessed in an independent manner and following a clear procedure.

- **Actions**: The establishment of clear safety criteria is of paramount importance in the risk assessment process. The Regulation introduces a comprehensive set of criteria to assess risks for humans, animals and the environment. These include new safety criteria for new categories of feed additives, as well as more comprehensive criteria to protect the environment beyond the livestock production site (i.e. effects on ground water).

Expected results: The application of these criteria was expected to result in the placing on the market of feed additives that are less hazardous for animal and human health, and which have fewer negative impacts on the environment.

- **Actions:** A 10-year time limit applicable to all authorisations was introduced to allow for the timely reassessment of the safety of feed additives, as scientific knowledge of their effects and impacts evolves.

Expected results: It was expected that this time limit would also encourage the development of feed additives with a better safety profile.

- **Actions**: The Regulation provides for detailed labelling rules mirroring those applicable to food. Feed additives must be used in specific ways in order to ensure the safety of animals, consumers, workers and other users and the environment. For example, a maximum dose should be indicated on the label if higher doses may be toxic for animals or lead to the accumulation of toxic residues in animal products.

The directions for use on the label should also include, where appropriate, information about measures to protect workers handling them, and/or about how to manipulate the additive so as to reduce its impact on the environment.

Expected results: These labelling rules were expected to facilitate the safer use of feed additives along the feed chain and thus ensure a high level of protection of human health, animal health and the environment.

- **Actions**: Implementation and enforcement must be efficient and consistent. To facilitate enforcement the Regulation established the corresponding European Union Reference laboratory (EURL) supported by a network of National Reference Laboratories (NRLs). The main role of the EURL is to validate the methods of analysis for the additives proposed by the applicants for control purposes. It also provides scientific and technical support to the Commission and is an important forum where difficulties in the implementation of such methods can be discussed and resolved in collaboration with the Member States. Another instrument provided by the Regulation is the obligation for the applicants to provide a monitoring plan for certain categories of additives. During the assessment, EFSA will decide if a monitoring plan is relevant or not. The additive may be safe, but there may still be unforeseen effects that require further monitoring to identify, as is the case, for example, with some long-term effects. The authorisation of such additives is linked to an individual applicant (the authorisation holder) who is obliged to implement the monitoring plan and report on its results to the Commission and to the Authority. A case in point is lanthanum carbonate octahydrate, a synthetic additive intended to be used for adult cats to restrict the intestinal absorption of phosphorus. EFSA pointed out that the product was intended for administration over the entire adult life of cats, yet the consequences of chronic exposure had not so far been investigated directly. They therefore recommended a monitoring plan to ensure that any evidence of chronic adverse effects will be detected and reported. Reliable methods of analysis allow effective identification and quantification of additives in feed and facilitate traceability through the feed chain; in this way, control should be improved. Monitoring plans were also expected to contribute to the early detection of potentially harmful effects so that corrective measures could be put in place.

Expected results: Taken all together, these provisions should contribute to better protection of human health, animal health and the environment.

- **Actions**: The Regulation also recognises the need to better address the specific issues facing pet animals and their owners. Guidelines for applicants, including clear and comprehensive data requirements, were set up to reduce the need for testing on pets by implementing other testing strategies, and to take into account the potential hazards of additives for pet owners. A full demonstration of an additive's efficacy is also now a requirement for them to be placed on the market.

Expected results: These measures should mean that additives in pet food are safer for both the animals and their owners. Pet owners should also not be misled, since only additives that really deliver on the claims that are made for them will be available for sale within the EU.

Objective: Foster innovation in livestock farming by taking into account scientific and technological progress

Identified needs: A good environment to promote innovation serves society. The relationship between animal nutrition and the protection of the environment, the protection of animal wellbeing, the increase of productivity and the quality of animal products has been addressed significantly through innovation in feed additives.

- **Actions**: The Regulation establishes a comprehensive classification system for additives according to their intended use, including clear criteria and data requirements. This seeks to streamline applications in particular for innovative additives that can have a positive impact on the environment, increase productivity or contribute to the wellbeing of animals (so-called "zootechnical additives"). For these additives, the holder of the authorisation benefits from marketing exclusivity for the whole period of authorisation. This is to promote innovation and encourage the industry to fund research by improving the prospects for future profits from sales of the new product. Unlike the Directive that preceded it, the Regulation includes certain new categories of additive (amino acids, silage agents and urea and derivatives). It permits the use of additives in water for drinking; and provides a procedure for establishing criteria for new types of additive in the future, as required by scientific or technological developments. Authorisations are periodically reviewed (every 10 years) so as to allow applicants to consider if it is necessary to invest in the renewal of an additive that has been replaced on the market by other more efficacious additives.

Expected results: By streamlining the application process for innovative additives, it was expected these measures would lead to increased productivity and animal well-being, promote the use of environmentally-friendly additives and increase the availability of innovative feed additives.

- **Actions**: The Regulation establishes guidelines for applicants, including clear and comprehensive data requirements to demonstrate the efficacy. New additives are now assessed for efficacy (amino acids, silage agents, urea and derivatives some vitamins and colourants).

Expected results: This action was expected to increase the availability of more efficacious feed additives.

- **Actions**: To increase transparency a register of feed additives was set up. The Register lists all the additives that have been authorised in the EU and provides access to the Regulations authorising feed additives.

Expected results: This action was expected to increase transparency for FeBOs and for competent authorities and citizens and thus promote innovation by making operators more aware of those additives that are at the forefront of the industry. As a result, it was expected that operators and citizens would be better informed and more aware of the latest developments in the industry. This should also help ensure a level playing field for FeBOs.

Innovation and transparency are key elements that contribute positively to the better functioning of the internal market.

Objective: Protect consumers' interests

Identified needs: Protecting consumers' interests means ensuring that only safe and efficacious additives are used in feed.

- **Actions**: Addressing this need requires a predictable, trustworthy and transparent regulatory system from the authorisation to the final user (livestock farmer or pet food owner). This system should prevent the use of feed additives that could pose a risk for the consumers of animal products and should also ensure that the consumer is not misled on the quality of the food (as when, for example, a feed additive gives a flavour to the food of animal origin that is not characteristic of such food). The Regulation also takes into account other aspects related to the needs of society, or the right of consumers to be informed. Appropriate labelling rules are also important

to protect consumers so full information is available throughout the whole chain on the proper use of additives. For example, the use of additives is restricted in certain methods of production such as organic farming. The information provided in the labelling enables livestock farmers to use the right additives and to produce foods in accordance with the consumer's expectations.

Expected results: These measures were expected to ensure that consumers would not be misled as to the quality or characteristics of food that they purchase.

Figure A2.1: Intervention logic for Regulation (EC) No 1831/2003