EUROPEAN
COMMISSION

Brussels, 28.2.2024
SWD(2024) 47 final

COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE EVALUATION

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

{SWD(2024) 46 final}

The purpose of the evaluation is to assess how well the Feed Additives (FA) Regulation[1] has performed based on the five evaluation criteria of the Better Regulation Guidelines: effectiveness, efficiency, coherence, relevance and added value.

This analysis is based on data gathered through a public consultation, an external study, a literature review, targeted surveys, case studies and interviews with stakeholders, national competent authorities and representative associations. The main limitations encountered were: the lack of official statistical data on production, value and trade of feed additives and feed products including them; the difficulty of obtaining economic data from industry; and the absence of a previous evaluation/impact assessment of the relevant legislation to better define the baseline.

This evaluation is part of the combined evaluation/impact assessment to inform decisions on the revision of the FA Regulation, which is one of the actions foreseen under the Farm to Fork Strategy. The Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system[2] is one of the key actions of the European Green Deal[3], an ambitious EU initiative to move towards a clean circular economy, restore biodiversity and cut pollution.

Feed additives are products such as vitamins, antioxidants, microorganisms, amino acids or enzymes, used in animal nutrition to keep animals in good health, to improve their productivity and welfare or to reduce the environmental impacts of animal farming. Feed additives can in particular exert positive effects on animal welfare, for instance, by reducing the stress for farm animals when transitioning to a different production stage (e.g. lactating pigs to fattening pigs), and on animals' health and well-being, by stabilising their intestinal flora and reducing the need for medicinal treatments (e.g. antimicrobials) and the likelihood of manure contamination.

Before they can be placed on the EU market, feed additives must undergo a safety and efficacy assessment by the European Food Safety Authority, through a centralised procedure aiming to protect animals, humans and the environment from potentially harmful effects and to ensure that EU farmers and animal keepers can access safe, nutritious and high-quality feed products. The 2003 FA Regulation replaced a Council Directive of 1970, and particularly sought to improve feed additives' safety for humans, animals and the environment. Combating the rise of antimicrobial resistance was a key objective of the FA Regulation, as was fostering innovation in livestock farming. The Regulation also sought to simplify the authorisation process, while ensuring rigorous and independent risk assessment, and setting-up clear rules for the labelling of feed additives. Finally, the Regulation also sought to address the specific needs of pets and their owners.

[1] Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. OJ L 268, 18.10.2003, p. 29.

[2] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - A Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system. COM (2020) 381 final.

[3] Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions - The European Green Deal. COM (2019) 640 final.

The evaluation shows that the FA Regulation has generally functioned well, and that its **objectives** remain **relevant**. There are three main areas in which there is clearly room for improvement: more could be done to encourage innovation in feed additives, in particular those that can improve the sustainability of livestock farming; there is still scope to reduce administrative and regulatory burden generated by the authorisation process; and steps should be taken to further enhance animal welfare.

Fostering **sustainability** of animal farming is a new overarching objective that was not prominent when the 2003 FA Regulation was framed. The existing Regulation has largely addressed sustainability in livestock production although the potential of the Regulation to contribute to a more sustainable farming was not maybe fully realised. There is room for improvement, for instance by creating a specific category of additives promoting sustainability and decoupling zootechnical effects from sustainability effects and thus, raising more awareness on the positive effects of some additives for a sustainable livestock farming.

The FA Regulation has clearly made a significant positive contribution to the fight against **antimicrobial resistance**. However, there remains more to be done in this area, so this objective is still of relevance, and the measures addressing this problem should be developed further.

In general, the authorisation system for feed additives has proven **efficient and effective** and ensures a high level of protection of human health, animal health and the environment, along the food and feed chain.

Although the FA Regulation has brought significant progress towards the objective of **simplification and harmonisation** of the authorisation system when compared to the situation under the 1970 Directive, the evaluation identifies a number of possible measures that could help reduce delays further and improve the clarity and coherence of the authorisation process.

The reduction of **administrative and regulatory burden** could also be pursued further. For example, changes in the holder of an authorisation should be handled through a simpler procedure. Also, extending the duration of the authorisation period, at least for certain types of additives, could bring benefits of this kind.

In addition, a number of provisions in the relevant legislation would benefit from some improvement in terms of **clarity and coherence**, which would also help reduce burden by avoiding possible divergent interpretations of those provisions. Better coherence with other legislative provisions, such as the CLP Regulation[4], could also reduce both time periods in the authorisation process and costs for operators. As an example of improved clarity to be provided, the FA Regulation should better clarify that the environmental risk assessment for farmed non-food producing animals is to be carried out in the same manner as for food-producing animals.

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

There are certain areas where **reduction of costs** would be possible (e.g. extending the duration of the authorisation period, or reforming the system of non-holder-specific authorisations). A review of the non-holder specific authorisation system could increase the availability of certain essential additives, but its impact on SMEs would need to be assessed. There is also room to reduce administrative costs for the Commission and Member States.

As regards **information and labelling**, the FA Regulation has been successful in conveying safety messages, and in general worked well. A number of areas would benefit from greater coherence with other legislation, or from more modern alternatives to physical labels. Harmonised rules (e.g. labelling, identification) for feed additives that are imported/exported should also be considered when revising the Regulation.

The **enforcement** of the FA Regulation has been generally successful. Nevertheless, some weaknesses with regard to **enforcement and traceability** were identified concerning imports from third countries, and feed additives only intended for export to third countries.

The FA Regulation addresses **the specific needs of pet animals and their owners** through a comprehensive set of rules that are tailored to this particular sub-sector, especially those governing the risk assessment phase of the authorisation process.

As regards the **encouragement to innovation**, the evaluation found a high level of innovation in certain areas – in particular, additives used as an alternative to antibiotics, additives improving the digestibility of feed (better use of resources), and additives increasing the performance of animals. However, the FA Regulation has not kept pace with innovation in other areas, and in particular with the potential of feed additives to promote sustainability, by helping mitigate the environmental impact of livestock farming, or improving animal welfare.

This is mainly due to the limitations of the current additives' categorisation system.

A number of other barriers to innovation have also been identified (e.g., some difficulties with the interpretation of EFSA guidance, some insufficient definition of endpoints for new additives, etc.), while some measures, such as the establishment of holder-specific authorisations, have clearly encouraged greater investment in innovation (with some limitations for SMEs however). A number of possible areas for improvement to promote innovative additives, notably related to sustainability aspects, are clearly identified in the report.

On the other hand, it is also clear that non-holder specific authorisations have generated some unintended negative effects, and this has led to a shortage in the supply of certain essential additives, such as vitamins, that are very important for animal health and welfare. This matter would need to be addressed on the occasion of the revision of the FA Regulation.

It is clear, then, that the FA Regulation has brought significant **added value** through the harmonised EU authorisation procedure and labelling rules, and has substantially advanced the objectives pursued by the legislation. In order to strengthen the functioning of the internal market and ensure a level-playing field, however, there remains scope for additional harmonisation/clarification in certain areas.