

## Evaluation of the EU feed additive regulation: FEFANA's members experience

The European Commission has launched an Evaluation of [Regulation \(EC\) No 1831/2003](#) on [feed additives used in animal nutrition](#) to assess its fitness for purpose. With the aim to contribute to the Commission's initiative, part of the [Better Regulation](#) agenda, FEFANA undertook a survey of its membership. While it is recognized that the current Regulation assures the safety of products, the outcome of the survey identifies some hurdles especially with regard to fostering innovation, thus delaying access to products that would help solving evolving needs e.g. sustainability, animal welfare and antimicrobial resistance.

### 1. BACKGROUND

In May 2018, FEFANA commissioned a survey of its 96 members to gather information on the practicality of the implementation of Regulation (EC) No 1831/2003 on additives for use in animal nutrition. The findings below are a summary of the replies of 60 participating companies.

#### Collated data

Information and data were sought on:

- Types and sizes of companies
- Experienced timeframes for product authorisation in the EU
- Resources spent on application
- Reasons for withdrawal of applications
- Investments and exports
- Other qualitative feedback.

### 2. KEY FINDINGS

#### 2.1 Fostering entrepreneurship

The survey results show that smaller businesses (SMEs) are generally specialised in feed additives, while larger businesses have wider product portfolios. This information is particularly relevant considering that approximately 2/3 of FEFANA members are SMEs according to their turnover.

#### 2.2 An innovative and dynamic industry

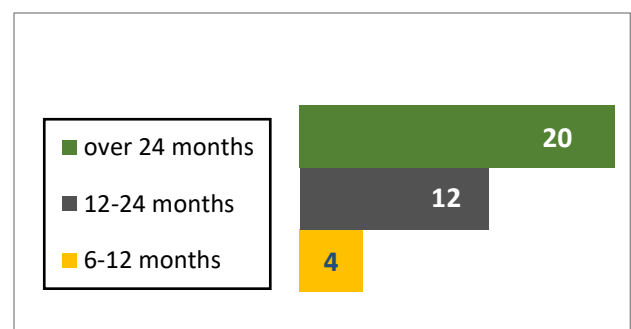
**Innovation is the most significant part of overall investment.** Up to **18%** of total turnover for small businesses is used in research and development for new products. This clearly underlines the highly innovative nature of the EU feed additive sector.

EU companies are also very important **exporters**: exports account for **60%** of annual turnover for SMEs and **42%** for large businesses.

#### 2.3 Lengthy authorisation procedure

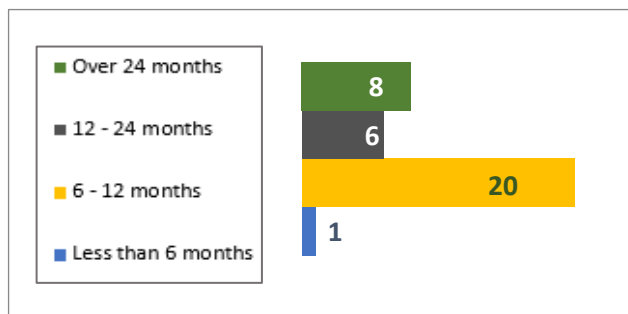
Products to be used as feed additives undergo a thorough pre-market assessment in the EU. The average timeframe for the completion of a product's risk assessment by the [European Food Safety Authority \(EFSA\)](#) is **over 2 years**. Delays are mainly attributable to the way and time supplementary information is requested and sometimes lack of clarity of questions.

**Average timeframe between application and delivery of the EFSA opinion (36 replies):**



An **additional 6 to 24 months** is then required for the mandatory risk management procedure by the [European Commission](#). An authorisation is only granted upon agreement of the Member States meeting in the [committee dedicated to animal nutrition](#).

**Average timeframe between EFSA opinion and EU Commission decision on authorisation (35 replies):**



Delays here are often due to overload of the meeting agenda, requests for confidentiality of the data provided by the applicant, and/or complications in the legal translation of the scientific opinion.

Therefore, on average, it might take up to 3 years for a product to reach the market.

## 2.4 Investments and returns

Ensuring the safety of the products entering the EU market is of paramount importance. The survey also shows that, in contrast to the safety assessment, the efficacy assessment for certain types of feed additives appears disproportionate in terms of study requirements and with no guarantees for return-on-investment, leading to **withdrawal of product applications**.

Lack of protection for **non-holder specific authorisations** is also perceived as a discouraging factor for the applicants, who cover the costs to generate and deliver all required data without however having exclusive rights to such product authorisations.

## 2.5 Other issues

Other main concerns emerging from the survey include:

- Lack of flexibility to take into account the additional benefits of feed additives in the current evolving livestock management and production systems (e.g. sustainability, animal welfare and antimicrobial resistance.);
- Unclear definition of some feed types resulting in uncertain scope;
- Disproportionate, out-of-date provisions for labelling, in need of alignment with other EU legislation.

## 3. CONCLUSIONS

The current EU legislative framework assures feed and food safety but needs to provide an improved setup to ensure continuous innovation in the feed chain and sufficient return to cover the investments. Significant improvements could be obtained by modernising provisions to better reflect progress in scientific knowledge and technology know-how and the evolving societal demands.

This could lead to a reduction of the resources needed for the overall authorisation process (for applicants, EFSA and the EU Commission alike), whilst ensuring that innovative products that support safe, sustainable and efficacious animal nutrition continue to be developed and, most importantly, will reach the EU market.