

October 21st, 2022

Chemical Sustainability Strategy (CSS) and revision of REACH

Possible impact of on feed additives and their mixtures

The EU [Chemicals Strategy for Sustainability \(CSS\)](#), which is a key commitment of the European Green Deal, announced extending the generic approach to risk management (*i.e.*, in REACH, Article 68(2)) to further [hazard classes and uses](#). This generic approach to risk management (GRA) means that the procedure under [REACH](#) Article 68(2)¹ can be used to restrict the most harmful chemical substances in products for consumer and professional use, while allowing limited exemptions under conditions clearly defined in the law.

A restriction would be proposed based on generic exposure considerations if a substance has certain hazardous properties, and if that substance (on its own or in mixtures) would be used by consumers and professionals. Hence, hazardous properties of the substance and generic exposure considerations are sufficient to substantiate new restrictions. In this regard, risk management is enabled based on a generic assumption of risk, applied as default without the need for further evidence. Requests for allowing exemptions (*i.e.* derogations) of specific substances are envisaged only after the restrictions have been adopted, upon proving that the substance is essential to society. This approach stands in stark contrast to the current restriction process identified in Article 68(1) of REACH, where the socio-economic impact of the restrictions, including the availability of alternatives, should be considered before restricting hazardous.

The planned extension of the generic approach to risk management (GRA), seems to foresee ² the granting of limited derogation:

- *in certain exceptional cases, on the basis of minimal exposure throughout the life cycle*
- *in case of essential uses*

FEFANA is not in favour of introducing additional generic restrictions for feed additives and their mixtures resulting from the proposed generalised extension of the GRA for the following reasons:

1. Pre-market risk assessment and authorisation of feed additives applies and ensures safe use

Hazardous substances can be present in several feed products without these causing harm to users, consumers and the environment because the related risks have been thoroughly assessed during a scientific risk assessment conducted by a specialised, independent EU agency such as - which is the case for feed additives - EFSA. Appropriate risk management decisions are taken by the competent EC services in charge of issuing the respective authorising regulations. The extension of generic approach to risk management to feed additives and their mixtures without considering a risk assessment by EFSA, which is already performed as a standard for every feed additive authorised for use in the EU, may wrongly lead to disproportionate consequences for several feed products, including preparations, premixtures and complex substances such as feed additives of botanical origin.

¹ ARTICLE 68: Introducing new and amending current restrictions

² [Circabc \(europa.eu\)](https://eur-lex.europa.eu/eli/reg/2022/1775/oj)

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A specific condition of the EU authorisation procedure of feed additives is that they must not have an adverse effect on animal health, human health or the environment. The EFSA risk assessment covers these aspects in an exhaustive manner, including assessing the safety for the users. Based on the EFSA assessment, when appropriate, the use of protective measures (*e.g.*, masks and gloves for handling) is detailed in the authorising regulations.

FEFANA cannot see how an extension of the GRA to feed additives and their mixtures would be justifiable as the EU pre-market authorisation system already ensures the safe use of the additive, including laying down specific measures to address any hazards identified during the scientific assessment. This system has been in place for many years at this point, all this time actively contributing to the reduction of the risks to humans, animals and the environment posed by certain hazardous chemicals. Moreover, since the manufacture and use of feed additives and their mixtures is handled by well-trained users, a high-risk exposure scenario is not realistic. As a result, minimal exposure throughout the life cycle is generally expected for feed additives and their mixtures.

2. Essential use of feed additives and their mixtures

The EU strategy also announced a reform of the REACH authorisation and restriction processes, and the definition of essential use criteria to be applied in all relevant EU legislation for both generic and specific risk assessments. Feed additives have been recognized in the [EU Farm to Fork strategy](#) as contributing to more sustainable animal farming practices. According to the Commission³, in line with the action plan of the Farm to Fork strategy, the main aim of the proposal for a revised feed additives regulation is to contribute to a more sustainable food production system by establishing new criteria to promote the authorisation of feed additives with positive effects on animal welfare and on the environment. It will build up mechanisms to promote innovation in feed additives, particularly those contributing to reducing the use of antibiotics and mitigating climate change effects.

Furthermore, some feed additives are essential micronutrients, meaning that animals cannot synthesise them by themselves and would be deficient without supplementation of their diet. Other well-known effects of feed additives are to improve feed properties by enhancing nutritional value, improving flavour, texture, as well as preserving quality, freshness, and wholesomeness of feed. These are all important effects feed additives can have which makes them essential components of animal diets.

All things considered, feed additives certainly do possess all the qualities to be considered substances that have an essential role and place in the EU, not only providing sustenance for farm animals, but consequently to EU consumers as well, all the while contributing to the sustainability of EU production.

FEFANA members call for the exclusion of feed additives and their mixtures from the scope of the extension of the generic approach to risk management (GRA).

We kindly ask decision makers to duly consider our arguments in the ongoing debates around the revision of the REACH legislation.

³ [Carriage details](#) | [Legislative Train Schedule \(europa.eu\)](#)