FEFANA

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SUSTAINABILITY

INNOVATION

FEED SAFETY

ANIMAL HEALTH AND WELFARE

SAFE FOOD

Industry's views on the EFSA Guidance on the assessment of the safety of feed additives for the user – update

Contents

GENERAL VIEWS OF INDUSTRY

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- We appreciate EFSA's constant effort to update and streamline the guidance documents
- Feed additive regulation requires the assessment of "user/worker safety"
- Requirements of Reg. (EC) No 429/2008 do not take into consideration how feed additives are handled in practice and the measures taken by FBOs:
  - Importance to take into account legislations on worker safety and their implementation by industry to assess if other measures have to be proposed in the authorisations
  - Need to differentiate between products/substances (fully) regulated by Health & Safety legislation and/or by REACH) and those not (fully) covered by existing legislations
- We consider that the starting point for defining efficacy assessment should be the Regulation (EC) 429/2008

ASPECTS TO BE CONSIDERED

ASPECTS TO BE CONSIDERED – By risk managers

How can the legal framework (Reg. (EC) No 429/2008) be amended to be more "fit for purpose"?

Who are the users/workers in scope of the assessment?

The purpose of the assessment and subsequent risk management measures/applicable legislative framework depend on whom we are willing to protect

- Workers: in feed additives/premixtures plants? In feed mills?
- Final user (farmers, pet owners): in scope?

ASPECTS TO BE CONSIDERED – By risk assessors

Exposure assessment

Worker's exposure model needs to reflect real situations and practical use conditions including the effects of protective measures and not on the worst-case scenario

Data packages, applicable protocols, and measures for risk managers?

- How to address data gaps?
- EFSA's expert judgment and recommendation on the protocols would be key for the process (same situation as for of efficacy or tolerance studies).
  - What are the relevant protocols to be used for each kind of FA?
  - How to determine if they are fit for purpose (e.g., microorganisms, enzymes?)
  - What safety recommendations may be proposed in case of data gaps vs protocols non 'fit for purpose' vs 'safety issue' identified based on the safety studies?

ASPECTS TO BE CONSIDERED

USER/WORKER SAFETY ASSESSMENT OF MICROBIAL FEED ADDITIVES

Current requirements possibly not fully applicable to microorganisms.

1. Most (if not all) *in vitro* OECD protocols have been developed for chemicals and are unlikely to be applicable to micro-organisms
    - e.g., LLNA / skin sensitization[1]
    - Technically, it is not possible to use micro-organisms as such, on cellular test systems that require culture media
2. Microorganism do not penetrate skin barriers: likelihood for microorganism to induce *per se* acute dermal or eye irritation/corrosion is very small (if not null) (microorganisms as such are unlikely to be irritant/corrosive/sensitive)
3. Is it relevant to perform *in vivo* and/or *in vitro* testing for micro-organisms as per existing OECD protocols?

[1] *Report of the 7th biopesticides steering group seminar on sensitisation potential of micro-organisms, OECD – ENV/JM/MONO(2017)8*

ASPECTS TO BE CONSIDERED – By risk assessors

Importance of other legislative frameworks

e.g., REACH, CLP, worker safety legislation

Holder vs non-holder specific additives

EFSA evaluated product may/will not reflect the ones placed in the market

Dustiness

What is a high vs low dusting potential? Could EN 15051 be applicable to FA assessment?

CONCLUSIONS

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- Weaknesses in current approach impact all stakeholders – EFSA, EC, MS, Applicants… And efficient and fit for purpose system is required.
- Industry own measures and existing ‘worker safety’ frameworks must be considered
- Open questions
  - Target: whom do we want to protect the most ?
  - End-points (skin, eye, respiratory system): applicability of protocols to the different types of FA and measures to be proposed based on conclusions
  - How to facilitate the use of existing studies (e.g., from REACH)

THANK YOU!