24 November 2022

Update of the Guidance on studies concerning the safety of use of the additive for users/workers

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Outline

- User safety in the context of feed additives assessment
- From the old to the new Guidance - Limitations and needs for improvements
- New Guidance – work in progress

User safety in the context of feed additives assessment

Safety evaluation of a feed additive

Authorisation process of a feed additive:

- Safety for the target species
- Safety for the consumers
- Safety for the environment
- **Safety for the users**

Evaluation of the safety for the users

- Main criteria in the Implementing Regulation (EC) No 429/2008

- Relevant toxicological aspects:

→ effects on the **respiratory system** (irritancy and sensitisation, toxicity by inhalation)

→ effects on **eye** (irritancy) **skin** (irritancy and sensitisation)

→ systemic toxicity

Exposure:

→ topical or by inhalation

→ quantitative assessment (from all routes), where possible

- Risk assessment based on the toxicological information + exposure

- Precautionary measures to control exposure

EFSA Guidance on the assessment of user safety

European Food Safety Authority

EFSA Journal 2012;10(1):2539

SCIENTIFIC OPINION

Guidance on studies concerning the safety of use of the additive for users/workers[1†]

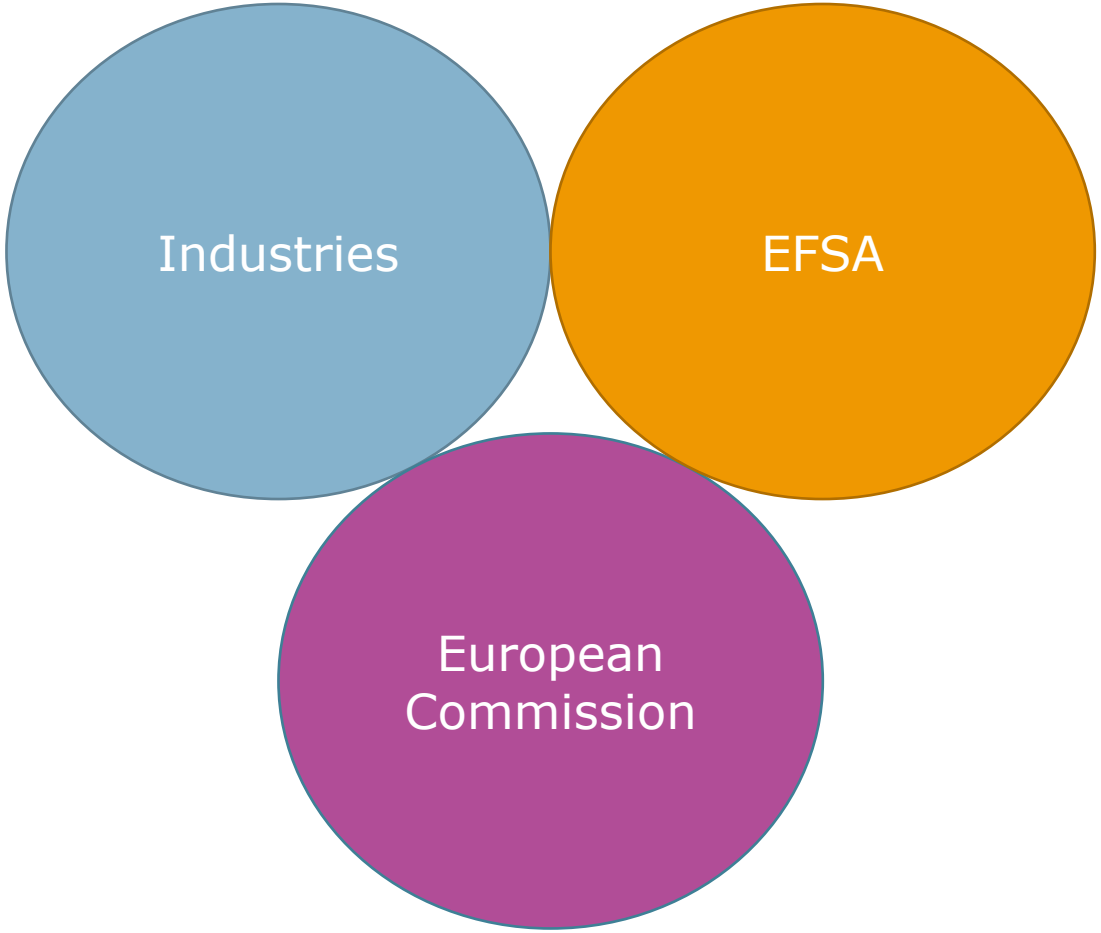
EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)[2,3]

European Food Safety Authority (EFSA), Parma, Italy

https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2012.2539

From the old to the new Guidance – Limitations and needs for improvements

First steps in the Guidance updates



- Info-session (November 2019)
- Ad-hoc technical meeting with industries (June 2022)

Objective

To find a pragmatic approach to the assessment of user safety which

- fulfils the needs of the risk managers
- keeps the requirements for applicants and industry proportionate

WG Toxicology – User Safety sub-group

WG Experts

- Paul Brantom
- Andrew Chesson
- Birgit Dusemund
- Alberto Mantovani
- Francesca Marcon
- Ruud Woutersen

FEEDCO Unit staff

- Jaume Galobart
- Paola Manini
- Fabiola Pizzo

Preparatory document – June 2022

- Developed by the WG on Toxicology (User safety sub-group)
- Presented to the stakeholders and EC during a technical meeting on June 2022
- Used as basis for the discussion with industry and EC and for the drafting of the updated Guidance

Definition of workers/users

- Who are the users/workers? Professionals who are exposed to feed additives in the working environments (e.g., premix plant and feed mill workers and farmers)

- Could the pet owners be considered under "users" definition?

Exposure scenarios

Exposure variable	Premix factory worker	Feed mill worker	Farmer	"Owner"
Sources	Additive Premix	Additive Premix Feed	Additive Premix Feed	Additive Feed
Routes	Respiratory Topic Oral	Respiratory Topic Oral	Respiratory Topic Oral	Respiratory Topic Oral
Location	Indoors	Indoors	Indoors Outdoors	Indoors
Technology	High	High	Low	-
Use of protective measures	Likely	Likely	Likely/Unlikely	Very unlikely
Duration	High	High-medium	Medium-low	Low

Issues to be considered:

lack of data - different scenarios
all the users are unprotected, worst-case scenario → not reflect the real situations

Two categories of additives

Holder Specific products

(zootechnical additives and coccidiostats) single authorised final formulation and product consistency

- Presumption of risk from identified hazards
- Rarely perform exposure assessment (needs specification of who is to be protected)

Generic products

no specific authorised formulation, apart from the active principle

- Reluctance to provide data
- Data, if available do not cover all potential forms of the additive

Data requirements

- Harmonisation with other regulatory frameworks (ECHA – CLP – REACH, EFSA pesticides)
- Possibility to use existing data/assessments, including human data
- Principle of "One substance one assessment"
- New challenges: exposure to genotoxic impurities and nanomaterials
- For some end-points and products there are no validated methods: inhalatory sensitisation, skin sensitisation for microorganisms

New Guidance – work in progress

General principles (not yet endorsed by the Panel)

- Users = workers (no pet owners)

- Data source
  - → 3R principle and animal welfare (existing assessments/data, NAMs, *in vitro* studies)
  - → Harmonisation with other regulatory frameworks

  One substance one assessment

- For generic additives → assessment of the active substance

- Identification of exclusion criteria for hazard identification (e.g. microorganisms and sensitisation)

Exclusion criteria – Exposure assessment

Step-wise approach

1. Hazard identification

2. Exposure assessment would not be needed for all the feed additives but should be performed case by case based on the toxicological profile

<u>No exposure assessment is necessary:</u>

- When no hazards have been identified
- When a hazard exists, it is assumed that exposure will be a risk
- When there is an occupational limit (e.g., OEL, DNEL)
- When the physico-chemical properties of the additive exclude the possibility of exposure
- When a HBGV does not exist or when systemic toxicity is not expected

Timeline - Planning

- 18 March 2022 → Mandate accepted by the ED (deadline: 30 June 2024)
- November 2023 → Tentative endorsement from the FEEDAP Panel
- December 2023 → Public consultation launching
- March 2024 → Discussion on the outcome of the public consultation - (Tentative adoption)
- June 2024 → Adoption

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