Assessment of user safety for feed additives

Issues faced by the risk manager and control authorities:

A Member State perspective

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Risk management based on risk assessment

Hazard for the user may come from:

- **The active substance itself** (e.g. formaldehyde, essential oils)
- **Another component** (e.g. 14% methanol in formaldehyde)
- **The form** of the additive (liquid VS powder: dusting potential)
- **Impurities** (e.g. endotoxins)

=> A proper study of the hazard for the user should, theoretically, take into account all these parameters (composition, form).

=> **Very detailed authorisations**!

… In theory
User safety depends on the composition

=> **Composition**: as detailed as possible … ?
%ages for all major components, max for hazardous impurities, etc.

➢ **Authorisation not specific enough** => too much variability in the composition => **unassessed risk**

BUT:

➢ **Authorisation too specific**:
- **Feasible in practice**? Technical variations, notably for plant extracts, clays, etc.
- Can be tested in official controls?
- **Too detailed** => only the applicant matches the specifications
⇒ **No longer generic**!
⇒ **Economic issue, competition issue**

=> **Find the right balance**
The safety data provided by the applicant holds only for the additive as prepared by the applicant.

Ex :
- The applicant’s process ensures a low level of impurities …
- The additive produced by the applicant has low dusting potential …

But not necessarily true for other operators!
Different process, different moisture level …

=> How restrictive should the autorisation be ? (see previous slide)

➢ What about preparations ?
- Another layer of unknown
- Increase or decrease the risk ?
- Can the applicant provide « preparation scenarii » ?
Data provided by the applicant

One of the points where application dossiers are, consistently, the weakest: no data provided (or very limited data)

⇒ EFSA and SCoPAFF use « general » scientific knowledge of the substance and its hazards, including assessment under other legislations

« EFSA could not conclude on the safety for the user » → deny authorisation ? Request supplementary data from the applicant ? Do without ?
Data to be taken into account (2)

- **Risk assessment under other legislations (notably REACH)**:
  Safety data sheet, ECHA opinion …

→ **PRO**: it makes sense to avoid *redundancies* or *contradictions* between scientific authorities

→ **CON**:
  - **Same product?** (« feed-grade ») **Same applicant/manufacturer?**
  - REACH assessment follows *exposure scenarii in areas other than feed*: *do they really match the use in the feed industry?* (Dosage, frequency of use, industrial equipment, form/composition … ?)
  - **Differing methods** between assessing authorities (feed additives, REACH, PPP …)
Hierarchization of risk management measures

Parallel to article 6 directive 89/391/CE:

➢ **Eliminate/substitute**: no autorisation for a dangerous additive when other, less dangerous, options, are available

➢ **Combat the risk at source**: specifications in the autorisation (form, max content in impurities …) ; ALARA principle

➢ **Risk management by the operator**: Operational procedures, organisational measures, protection equipment

⇒ **How to assess the availability and suitability of alternatives on the market?** Technically and economically viable substitutes

⇒ What is a *proportionate level* of risk management measures?
Risk management by the operator / the user (1)

« Generic/usual » paragraph in « other provisions »

Loses some of its impact

Labelling ? Shall it appear in the instructions for use ? Redundancy with CLP labelling ?

Variability between operators : control, case-by-case appreciation ?
(The CA for feed additives is not the main CA for worker safety => hard to assess)
Risk management by the operator / the user (2)

« User » is usually intended to mean a worker at a feed additive / premixture producer or a feed mill

- **Farmers** ?
- **Pet owners** ? (additives marketed directly to the final consumer)

Different exposure scenarii, different operational procedures

(+ Final users => CLP does not apply)
Thank you for your attention