# 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**

# Generic additives : extrapolation of applicant data

**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 to be taken into account (1)

- **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 …

→ **<u>PRO</u> :** it makes sense to **avoid** **redundancies** or **contradictions** **between scientific authorities**

→ **<u>CON</u> :**

- **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