15/06/2022

User/worker safety assessment in the feed additive authorisation process
Industry views

Who are we?

FEFANA (EU Association of Specialty Feed Ingredients and their Mixtures) is the united voice of the specialty feed ingredients business in Europe. Our membership comprises manufacturers and traders of feed additives, functional feed ingredients, premixes and other mixtures of specialty ingredients that enter the food chain via feed.

IMA-Europe represents the European producers of bentonite, borates, calcium carbonate, cristobalite, diatomite, dolomite, feldspar, kaolin, kaolinitic clays, lime, mica, quartz, sepiolite, talc and vermiculite - i.e., around 500 mineral companies or groups operating more than 700 mines and quarries and 750 plants throughout Europe. Some of these industrial minerals are used and approved as feed additives.

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- How is industry applying worker safety measures?
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General views from industry on user/worker safety

General views of industry

- We appreciate EFSA's initiative to re-activate the discussion on user/worker safety
- Feed additive regulation requires the assessment of "user/worker safety".
- However, requirements set in the guidelines do not take into consideration how FA are handled in practice and the measures taken by FBOs:
  - Importance to take into account existing legislations on worker safety and how it is implemented by industry to assess if additional measures have to be proposed in the authorisations
  - Need to differentiate between two categories of FA: highly regulated products (e.g., those covered by Health & Safety legislation and/or by REACH) and those not (fully) covered by existing legislations
- Identified worker safety risks are controlled by precautionary measures.

General views of industry

The discussion paper nicely describes the current situation and raises several points to be considered:

- By risk managers: How can the legal framework be amended to be more “fit for purpose”?
- By risk assessors: Which data packages need to be provided, which protocols apply (e.g., chemically defined substances vs microorganims), and which measures are to be proposed to risk managers?
- Importance of other legislative frameworks (e.g., REACH, CLP, worker safety legislation)
- Target: Who are the users/workers in scope of the assessment?
- Dustiness: What is a high vs low dusting potential? Could EN 15051 be applicable to FA assessment?

Target: 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?

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 should we determine if they are fit for purpose (e.g., microorganisms – see annex to the presentation)?
  - How will EFSA conclude and what safety recommendations may be proposed?

EFSA proposal for a stepwise approach

Step 1: Hazard identification and characterization

- Existing knowledge:
  - We appreciate the general line to derive information from existing (e.g., CLP) classifications
  - What to do when the whole data package is not available and only abstracts are publicly available (e.g., from IUCLID)?
  - Could publicly available abstracts be considered as valid alternative to full data package?
  - Applicability of a "*QPS like approach*" for user/worker safety based on experience acquired to multi-assessment of regulated products
- Experimental data:
  - For potential contaminants/impurities, model calculations on potential maximum hazard (max. level in the additive; expected hazard class) before deciding on the need for experimental data generation.

Step 2: Exposure assessment

- Situations are highly variable in terms of FA handling. It creates a dilemma for the precise appreciation of exposure risks ruled by the precautionary principle.

- General instructions on precautionary measures (like P-phrases from CLP, or specific safety provisions when no CLP classification applies) may be the best approach.

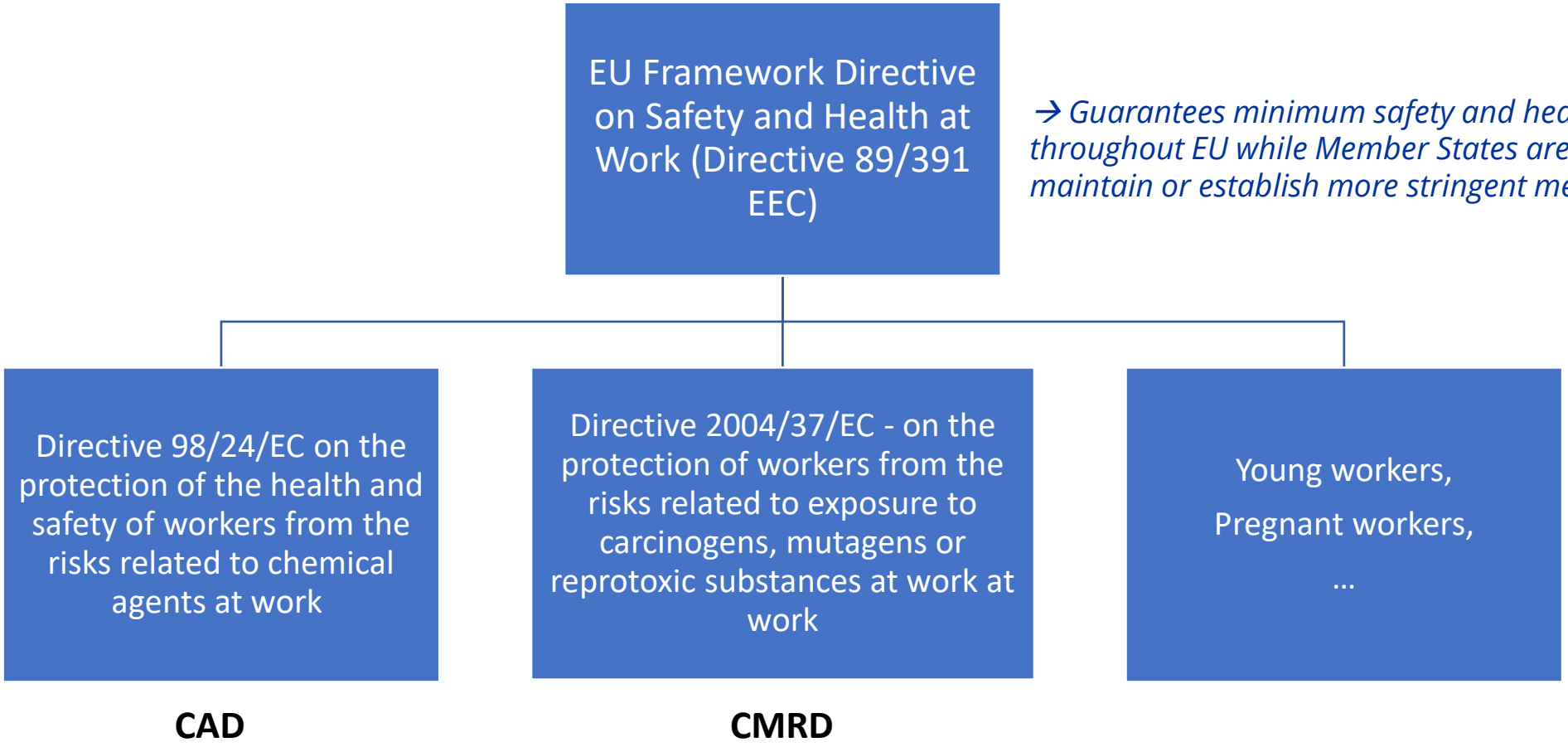
- We suggest the following to assess worker exposure:
  - Establishing safe level(s), if none are already existing: industry to establish management measures to handle the product below the safe level(s) (e.g., OELs, DNELs)
  - A dual approach is suggested when the additive is available both in powder and granulated form → uniform threshold criteria for 'granulated' products need to be established (max. amount of fines of a certain size; minimum mean particle size). Granulated/coated products would benefit from certain data waivers and/or receive risk management measures.

How is industry applying worker safety measures?

Management in a feed additive and in a premixture production plant

The management of worker safety in a feed additive production plant

Health & Safety (H&S) is a top priority for Industry and is already highly regulated at EU and national level.



→ *Guarantees minimum safety and health requirements throughout EU while Member States are allowed to maintain or establish more stringent measures.*

The management of worker safety in a feed additive production plant

Managing safety when handling substance and mixtures

→ ***Stepwise approach:***

1. Hazard assessment to identify hazard(s) related to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be use (e.g. CLP Regulation) –
2. Identify the No Adverse Effect Level
3. Consider safety factors where relevant and establish the safe exposure level
4. Implement Risk Management Measures to keep with confidence exposure below the safe level through collective measures (e.g. close systems, exhaust ventilation, time shifts…) or PPE at last resort
5. Monitor exposure levels and keep records

Example for feed additive E559 kaolin

Presence of respirable crystalline silica (RCS) identified as a hazard (covered by CMRD)

Binding EU OEL set for RCS: 0,1 mg/m³

See next slide for an example
EU Good practices (www.nepsi.eu)

Dust monitoring programme launched in 2002
More than 30,000 measures compiled

The management of worker safety in a feed additive production plant

Before implementing Risk Management Measures

After implementing Risk Management Measures

The management of worker safety in a premixture production plant

- General: precautionary measures taken on basis of applicable Occupational health legislation, applying P-phrases of CLP legislation and/or Feed additive Other precautionary provisions

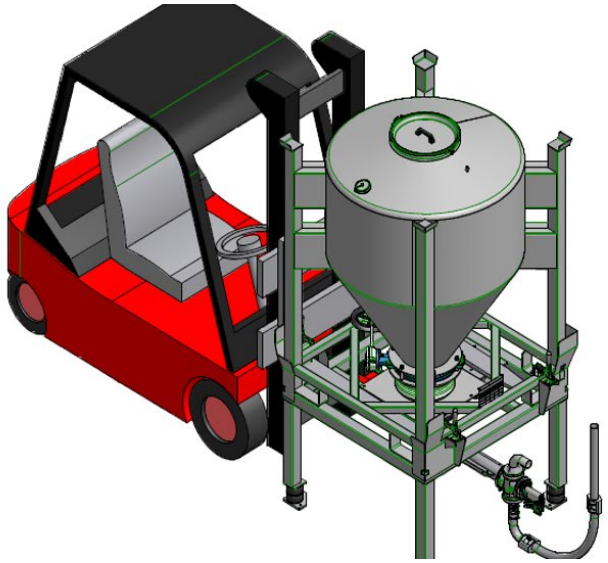
- Example of personal protection: dust exposure measures per risk category based on Threshold limit value, Time-weighted average (TLV-TWA). Level of personal protection linked to risk category:

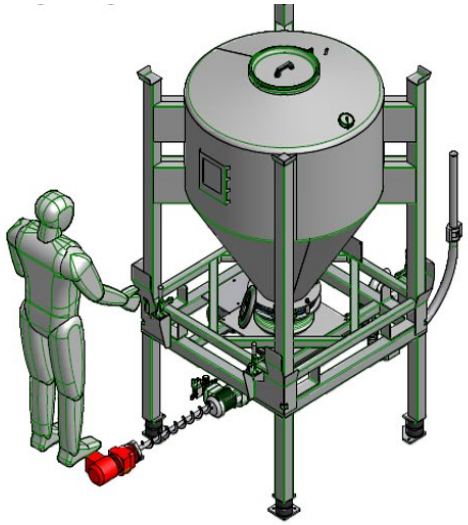
  - 1 – high risk products (TLV < 0.02 mg/m^3), e.g. Cobalt carbonate
    Powered Air Purifying respirator = PAPR) with at least PP3/N99 dust filter

  - 2 – risk products (TLV between 0.02 mg/m^3– 1 mg/m$^{3)}$, e.g. certain vitamins
    Breathing protection minimum type FFP3/N99 (but recommended: FAPR)

  - 3 – nuisance products (TLV > 1 mg/m^3), e.g. Wheat meal
    Breathing protection minimum type FFP2/N95

The management of user/worker safety in a premixture production plant (continued)





Example of innovative solution to exclude manual handling and dust formation:
Mobile bins delivered with content (e.g., cat. 1 risk products like Cobalt salts); return to supplier when empty

Conclusions

Conclusions / aspects to be considered

- Efficient approach is needed for all actors involved in the risk assessment/risk management process
- 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!

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. Hence, one can question the relevance of *in vivo* and/or *in vitro* testing for micro-organisms

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

Management of user safety measures in feed additives authorisations

- In **feed additives authorisations** specific provisions referring to personal protective equipment (breathing protection, glasses and gloves shall be used during handling) are replaced by a general provision that is somewhat adapted to EFSA's conclusions :

> *"For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection".*

- The provision is barely changed no matter the **conclusions reached by EFSA or the data submitted during the assessment** → a *de facto* "generic" sentence with low practical significance for feed additives, premixtures, compound feed operators and/or farmers.
- There is also a lack of harmonisation on how this provision should be "labelled".