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User safety assessment of feed additives

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Trusted science for safe food

efsa
European Food Safety Authority

Scope and purpose

Objective

To find a pragmatic approach to the assessment of user safety

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

Who are the users?

Users are defined as the persons who may be exposed to the additive while handling it, when incorporating it into premixtures or feedingstuffs or using a feedingstuff supplemented with the additive.

Issues for consideration - 1

Two categories of additive

Holder Specific products

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

Issues for consideration - 2

Nanomaterials

- Specific requirements for a risk assessment if there may be exposure of users

Relevance of REACH

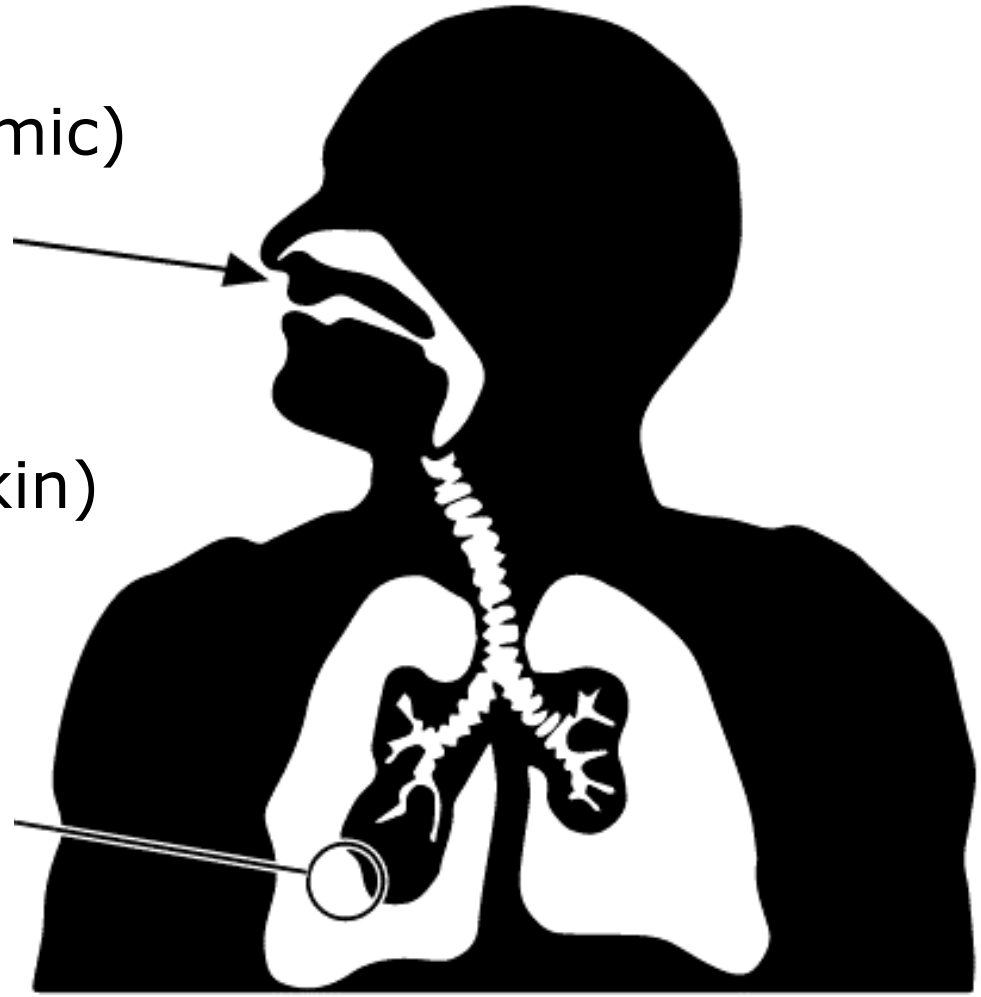
- Alignment with CLP which includes the identification and characterisation of hazards for each chemical entity.
- Harmonisation of guidance?
- Principle of “One substance one assessment”

Routes of exposure

Oral (Systemic)

Topical
(eyes and skin)

Respiratory



Step 1 - Hazard identification and characterisation

- Effects on:
  - Respiratory system (inhalation toxicity; sensitization)
  - Eye/skin (irritation , sensitization, phototoxicity)
- Systemic toxicity (all routes and endpoints)
- Pathogenicity and/or Endotoxin production or content

Step 1 - Hazard identification and characterisation

- Sources of information:
  - Existing assessments:
    - CLP classification
    - ECHA assessment by REACH (RAC opinions) or any other EU scientific body
    - Occupational limits; when available
  - Prior knowledge:
    - Studies available elsewhere but not assessed by an EU body
    - Case study reports or manufacturing plant experience
    - Where relevant QSAR and read-across to assess whether further studies are needed
    - Experimental data with the active substance(s)/agents/additive

Note: *wherever data are cited attention should be given to ownership and access to the original studies*

Step 2 – Exposure assessment

- No exposure assessment is necessary when:
  - no hazards have been identified in Step 1
  - an irritancy or sensitization hazard exists
  - there are occupational exposure limits
  - the physico-chemical properties exclude the possibility of exposure

Step 2 – Exposure assessment

- Where there is evidence of systemic toxicity:
  - Exposure calculation for all routes on a case-by-case basis
    - Holder specific – based on all forms of final additive
    - Non-holder-specific – based on worst-case scenario (maximum exposure to active substance)

***Question** – for which scenarios should an assessment model be developed?*