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Industry's views on the implications of the EFSA Nano guidance documents in feed additives applications

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- IMPLEMENTATION OF THE GUIDANCE DOCUMENTS – IDENTIFIED ISSUES AND QUESTIONS

GENERAL VIEWS OF INDUSTRY

Since the publication of the Guidance on Particle - Technical Requirements (TR) and the Guidance on Nano - Risk Assessment (RA) in August 2021, feed additives applicants and CROs are still **relatively inexperienced on their implementation and practical use**.

- Risk of studies not being performed according to guidance docs. (deviating methodologies and reporting standards)
- Dialogue and opportunities for exchange are very much appreciated to support both, applicants and laboratories
- The possibility of asking questions during the risk assessment would be welcome to ensure a successful application procedure and to avoid additional investment

IMPLEMENTATION OF THE GUIDANCE DOCUMENT

***Note*: feedback provided on the Guidance on Particle - Technical Requirements (TR)**

General aspects:

- Reported difficulties on the identification of laboratories able to do the tests described in the guidance
    - A list of experienced and accredited laboratories would facilitate the process
- Is there a way to avoid lengthy justifications for some product groups, or to define exceptions for which the assessment may be omitted? Examples:
    - How to deal with whole microorganisms? (=i.e., micronrange)
    - Enzymes or proteins (biological, biodegradable/digestible substances) which are formulated with (oligo- or poly-)saccharide substances which are soluble (e.g., maltodextrin, inulin etc.)

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2.3. Appraisal routes using solubility and dissolution rate

2.3.1. Solubility in water

- Solubility threshold ≥ 33.3 g/L

  Is it possible to apply a certain minimum ratio Solubility: Max dosage? Relevance in case of low inclusion rate additives (e.g., vitamins)

- Solubility of a substance at a certain pH value and temperature is very much an intrinsic characteristic and not dependent on the actual form of the substance

  Will literature sources be sufficient instead of own studies?

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2.3.2. Dissolution rate in water

Protocol and cut-off proposed in the Guidance are based on human physiological conditions (e.g., dissolution conditions in the gut), for the assessment of feed additives *the protocol should be adapted in order to consider the physiological characteristics of each target species* (based on GIT volume; pH; time to reach the small intestine)

- What does this mean for calculation of max. concentration in water?

  Suggestion to use minimum water:feed ratios to translate max. feed levels to max. water concentrations

- What physiological conditions are to be followed?

  No official standards available

- How do physiological conditions translate into an alternative protocol?

- Is there a need to do studies per animal species conditions, or is a study linked to only the most critical species sufficient?

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2.3.3. Confirmation of absence of particles for liquid materials

The physical state of a substance (solid, liquid or gas) is an intrinsic property and only ruled by ambient temperature (2nd law of thermodynamics).

- Will literature information be sufficient in those cases to defend that the substance is a true liquid?

IMPLEMENTATION OF THE GUIDANCE DOCUMENT

4. Evidence to be submitted on safety studies conducted without documented consideration of the properties of small particles

Two requirements set simultaneously for existing toxicological *studies that were not originally designed to specifically consider the presence of a fraction of small particles:*

- Rather demanding, especially for older studies when many of the cited methodologies were not available or commonly used
- This could lead to a large number of existing studies being rejected during the risk assessment by EFSA
- Section 4.3 establishes *criteria for requiring new studies and setting the assessment and assessment strategy* and specific examples… will these provide sufficient perspective to applicants for preventing additional animal studies?

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THANK YOU!