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Eurocolour input to the public consultation on the EFSA Draft updated Guidance on the assessment of the safety of feed additives for the users

https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l0900000AIuYo/pc0589

Input online, section by section, 10000 characters per section possible

Section 2.5: Local and systemic toxicity after repeated exposure

Referring to lines 275-278:

> "In case the active substance/agent or the additive is considered an engineered nanomaterial (as set out in Regulation (EU) 2015/2283) or does not meet the definition of engineered nanomaterial but may include particles at the nanoscale, based on the relevant EFSA Guidance (EFSA SC, 2021a and b), the additive is considered a hazard by any relevant route of exposure."

We reject this blanket condemnation of engineered nanomaterial and material containing small particles as being a hazard.

We would like to recall that the definition of nanomaterial based on the size was explicitly established without any reference to a potential hazard. According to the opinion of the Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) of 2010, which the Commission Recommendation of 10 June 2022 on the definition of nanomaterial 2022/C 229/01 still refers to, 'nanomaterial' is a categorization of a material by the size of its constituent parts. It neither implies a specific risk, nor does it necessarily mean that this material actually has new hazard properties compared to its constituent parts or larger sized counterparts.

There is no scientific evidence to regard nanomaterials as a hazard per se.

The definition chosen in the guidance is furthermore not appropriate for the intended purpose: The definition of engineered nanomaterial as set out in regulation (EU) 2015/2283 is related to novel food and has no reference to occupational safety or contact to eye, skin or inhalation effects.

Also, the EFSA Guidance (EFSA SC, 2021a and b) has set a threshold of 500 nm as the upper limit for the range of 'small particles' based on technical considerations (availability of methods for screening and measurement) and gastrointestinal uptake (combined with an uncertainty factor). Being covered by these guidelines only means that a specific assessment at the nanoscale is required, not that there is a hazard in principle. In particular, if the risk assessment shows no additional nano specific risk, there is no reason to assume a general health risk.

Many materials being regarded as nanomaterial have been used safely in the feed industry for decades and have been shown to be safe by extensive scientific studies. It is therefore highly inappropriate and misleading to generalise nanomaterials as a hazard.

As the production of feed additives must comply with occupational health and safety regulations, this should also be the basis for the use of the feed additives.

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Section 3: Exposure assessment

Referring to lines 282-297:

"In the majority of cases, an exposure assessment is not considered necessary based upon the following criteria:

1. When the only identified hazard concerns skin and/or eye irritation, skin and/or respiratory sensitisation, or when the additive is considered an engineered nanomaterial or does not meet the definition of engineered nanomaterial but may include particles at the nanoscale (see Section 2.5), it is assumed that any exposure will be a risk and no quantification of exposure is needed;

2. When a hazard without a threshold has been identified from the background toxicity data of the active substance/agent or the additive (e.g. impurity with a genotoxic potential), it is assumed that any exposure will be a risk and no quantification of exposure is needed;

3. When an occupational exposure limit (e.g., OEL, DNEL) exists, there is the legal responsibility of the operator to ensure compliance with the legal limits;

4. When the physico-chemical properties of the active substance/agent or of the additive exclude the possibility of exposure to substances of toxicological relevance (e.g., encapsulation, dust-free formulations).

As stated in section 2.5, we reject the blanket assumption that nanomaterials pose a risk at any exposure.

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About Eurocolour:

Eurocolour e. V. is the umbrella association for manufacturers of pigments, dyes, fillers, frits, ceramic and glass colours, and ceramic glazes in Europe.

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