Nanotechnology Industries Association

2 March 2018

NIA Comments on the EFSA Draft for Public Consultation Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health

Introduction to document

These final NIA comments are submitted via the electronic submission platform provided by EFSA (http://registerofquestions.efsa.europa.eu/roqFrontend/consultation/doc/105) on 2 March 2018 ahead of the EFSA deadline on 4 March 2018.

General remarks on the Draft Guidance

NIA welcomes the transparency procedures put in place by EFSA which allow for a broad consultation of EFSA stakeholders to provide input to EFSA Guidance documents. We are also welcoming the future publication of Part-2 of the Guidance which will address those aspects that relate to environmental risk assessment.

The Draft Guidance is very comprehensive from a scientific perspective, considering its intended broad coverage of potential products and applications in the food and feed area. It should be mentioned that food and feed, to provide their nutritional effects, are in general degraded/digested in the gastrointestinal tract into smaller sizes that often are in the nanoscale to allow their systemic uptake. Thus, animals and humans alike have a very well adapted system for dealing with various substances in the nanoscale, and there are instances where de novo formation of nanomaterials are naturally produced in the gastrointestinal system. We would like to stress that nanomaterials, as they are also natural and found in nature, are ever-present, and thus will always be found in food/feed products.

We would also like to point out, that the guidance would in most instances and in general be equally applicable to any substance in the food/feed area, and many of its considerations would not be nanospecific. In addition, as commonly known from vast scientific studies, there have not been any nanospecific hazards identified.

The possibilities by applicants to use tiered approaches and performing screening is welcome, as well as the distinction between valid and validated methods.

We like to stress that EFSA Guidance documents are not legally binding documents, but due to their origin are providing a very strong signal to industry on the information EFSA expects to be provided in an application. I.e. if an EFSA Guidance is not followed, an unfavourable opinion from EFSA is more

likely, and thus, a product will likely not be made available on the market. Thus, the more stringent requirements found in a guidance, the more resources are required to bring new products to the market. Too stringent requirements hampers innovations reaching consumers and providing societal benefits. With this said, the risk assessment conundrum 'need to know vs nice to know' is implicitly ever present in wordings used in the Draft Guidance and needs to be dealt with in a balanced and appropriate manner by the risk assessor.

Specific remarks to the Draft Guidance

The specific remarks are referencing, when possible, to the line numbers in the Draft Guidance.

L159: It may not always be possible for the applicant to test the material as it is being used in the final product.

L259: Inadequate tests is not specific nor clear. Information from such tests may still be of value in a weight of evidence approach.

L352: Indeed, smaller molecules migrate faster in FCM polymers, but it has also been shown that nanoparticles are considerable larger than molecules, and thus, their migration is often not observed (as also found in several recent EFSA FCM opinions). Thus, it is suggested to rewrite this statement.

Section 1.2.2 Definition of a nanomaterial

NIA and its Members are aware that several definitions are available for nanomaterials and we are urging for a common definition to be used and would welcome that EFSA strongly emphasises the use of the definition recommended by the European Commission (current under revision).

Section 1.3. Scope of this Guidance and when to apply it

L544: The suggestion by EFSA that also larger particles should be considered when they retain characteristics of the nanoscale is comprehensive and conservative, but it renders a large uncertainty for applicants when and how they should apply this Draft Guidance to their products. This comment is also applicable for L770. Thus, a list of such properties would be valuable. Or this requirement should be considered to be removed in its entirety as it is vague.

L552: This suggestions is not practically feasible and should be removed in its totality. As even stated '…a small fraction (<50%) is always expected to be present with at least one dimension below 100 nm'. If this is implemented, there is likely no solid material that would not be considered to fall under this Draft Guidance. It is a much too conservative approach to require applicants to apply a testing strategy for a nanomaterial, when they are not putting a nanomaterial on the market! This comment is also applicable to L887.

L561: The applicant may not be able to know in what final products its substance will end up being used in.
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L586: For applications that are not applicant specific, but where a general product authorisation is given, the requirement for an applicant to provide a separate physchem characterisation for each

distinct nanomaterial is not feasible as the applicant can only be responsible to provide a characterisation of the materials it is producing itself.

Section 3.1. Characteristic of the nanoscale which may affect toxicity

L695: Studies show that mechanical stress do not release nanomaterials, but larger microsized particles. Therefore, this kind of study should only be required if specific concerns arise.

Section 4.2.2. Specifications and representativeness of the test material

L877: It is not clear what EFSA considers to be the pristine material in this sentence. Theoretically a product to be put on the market can be an aggregate of fused particles, thus in this case, the aggregated particle is the smallest entity although in is made from smaller particles fused together, but these smaller particles can not be separated without destroying the product indented to be put on the market.

L900: The formulation of this sentence borders on risk management, and at least the 'should' should be changed.

Section 6.2.1. In vitro gastrointestinal digestion

L1424: This sentence is scientifically correct, but in practice this can not be required information to be provided by applicants. This effect would instead be considered as natural function of the digestive system or a homeostasis effect. I.e. if the nanomaterial is completely degraded in the conditions of the stomach (L1421) this should not require further nanomaterial specific investigations (however, non-nanomaterial risk assessment may still be required).

Section 6.2.2. Stability in lysosomal fluid

L1456: The pristine material may not always be the most suitable materials for testing the lysosomal stability, and the assessment would preferably be performed, where possible and relevant, with the material to be put on the market, or possibly by the substance expected to constitute the internal exposure.

Section 6.4. In vitro and in vivo genotoxicity testing

L1598: Indirect genotoxicity is not a nanospecific effect, and is equally applicable for conventional substances that give rise to persistent inflammation.

Section 6.8.6. Gut microbiome

L2111: It is the view of NIA that potential impact of the gut microbiome is not yet sufficiently advanced to provide relevant guidance for nanomaterials, nor for conventional substances.

Section 6.9.1. Specific issues for in vitro studies

L2201: The requirement for two independent studies for each individual endpoint is too strong and the final decision on the number of studies to be provided should be up to the applicant. There may be very robust methods, and thus only one method may be needed.

Section 6.9.2. Specific issues for in vivo studies

L2212: This statement is not nanospecific and should be deleted as it is applicable to all chemicals.

Section 9. Conclusions and Recommendations

L2481: NIA is strongly against applying a different threshold to define a nanomaterials, and requests that the threshold in the EC recommendation is kept. Consequently, the definition in the Novel Food Regulation may be adjusted following the revised EC recommendation.
L2482: The SC recommends statement is a risk management suggestion and not risk assessment, and is thus outside the remit of EFSA. Suggest to delete.

Editorial remarks

L2177: The heading is repeated.
L2271: Abbreviation is usually IATA (not IATAS).

The NIA and its Members appreciates the public consultation and the opportunity to provide these comments.

Brussels, 2 March 2018

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Nanotechnology
Industries Association

The Nanotechnology Industries Association

Formed in 2005 by a group of companies from a variety of industry sectors including healthcare, chemicals, automotive and consumer products, the Nanotechnology Industries Association (NIA) creates a clear single voice to represent the diverse industries in the multi-stakeholder debate on nanotechnologies. NIA provides a purely industry-led perspective, derived from the views of the collective membership and forms an interface with government, acting as a source for consultation on regulation and standards, communicating the benefits of nanotechnologies and interacting with the media to ensure an on-going advancement and commercialization of nanotechnologies.

For further information visit http://www.nanotechia.org or contact us on enquiries@nanotechia.org.

The NIA, Nanotechnology Industries Association, is the sector-independent, responsible voice for the industrial nanotechnologies supply chains; it proactively supports the ongoing innovation and commercialisation of nanotechnologies and promotes their safe and reliable advancement.

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