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Bottlenecks faced in the industry and multi-disciplinary approach in risk assessment of nanomaterials: A Regulatory perspective

Stakeholder workshop on nanoscience nanotechnology,
Parma 1-2 April 2019

Dr David Carlander
NIA Director of Regulatory Affairs
2 April 2019

EFSA Journal

GUIDANCE

ENDORSED: 29 May 2018

doi: 10.2903/j.efsa.2018.5327

Guidance on risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain: Part 1, human and animal health

EFSA Scientific Committee,
Anthony Hardy, Diane Benford, Thorhallur Halldorsson, Michael John Jeger,
Helle Katrine Knutsen, Simon More, Hanspeter Naegeli, Hubert Noteborn, Colin Ockleford,
Antonia Ricci, Guido Rychen, Josef R. Schlatter, Vittorio Silano, Roland Solecki,
Dominique Turck, Maged Younes, Qasim Chaudhry, Francesco Cubadda, David Gott,
Agnes Oomen, Stefan Weigel, Melpo Karamitrou, Reinhilde Schoonjans and Alicja Mortensen

Starting with the good!

- Guidance is very comprehensive from a scientific perspective
  - But maybe too comprehensive!?
- The trial period of the GD is appreciated and should be evaluated based on experience of dossiers received
- The possibilities by applicants to use tiered approaches and performing screening is welcome, as well as the distinction between valid and validated methods.

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Not everything is nano!

- Many of the considerations mentioned in the GD are in its nature not nanospecific, but equally applicable to many applications in the food and feed area
  - Indirect genotoxicity is not a nanospecific effect, and is equally applicable for conventional substances that give rise to persistent inflammation
  - Microbiome information
- When will an applicant be outside of the guidance?

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Issues related to Definition

- The definition used in the guidance is pragmatic from a risk assessment perspective but very controversial from a practical and clarity point of view
  - Several definitions are available for nanomaterials

- NIA is urging to only apply the GD for engineered nanomaterials as defined in the Novel Food Regulation

- NIA is strongly against applying different thresholds to define a nanomaterials, and requests that the threshold in the EC recommendation is kept

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Issues related to Definition

- '...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 an engineered nanomaterial on the market!!!

  - Will changes to general/generic guidance be considered?

What is to be tested

- '… the tests as described in this Guidance have to be performed with the **representative material** as used in the agri/food/feed chain and **as present on the market**.'

Is not easily understood with the statement:

- '…testing strategy is selected so that the data could be relevant for the risk assessment of the **fraction in the nanoscale**…'

[Section 1.3]

Unclarity

- Section 4.2.2.
- '…proposed specification for the pristine (as produced) nanomaterial intended to be used in food/feed should be provided by the applicant.'

- Pristine may not be the same as the product intended to be used in the food/feed

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Gov4Nano/WP2/Malta Project for OECD GD/TG

Malta Project is working on 7 tasks (official start 1 Jan 2019):

- Determination of **solubility and dissolution rate** of nanomaterials in water and relevant synthetic biologically mediums (Task 2.2)
- Identification and quantification of the **surface chemistry** and **coatings** on nano- and microscale materials (Task 2.3)
- Scientific protocol(s) underpinning the future development of a **harmonised test guideline for (V)SSA (**Task 2.4)
- Applicability of **the TG 442D *in vitro* skin sensitisation** for nanomaterials (Task 2.5)
- New TG on Determination of the **Dustiness** of Manufactured Nanomaterials (Task 2.6)
- **Abiotic Transformation** of Nanomaterials in Environmental Aquatic Media (Task 2.7)
- Studies on **bioaccumulation of nanomaterials in fish** (Task 2.8)

OECD Test Guideline development

Suggestion for a new TG

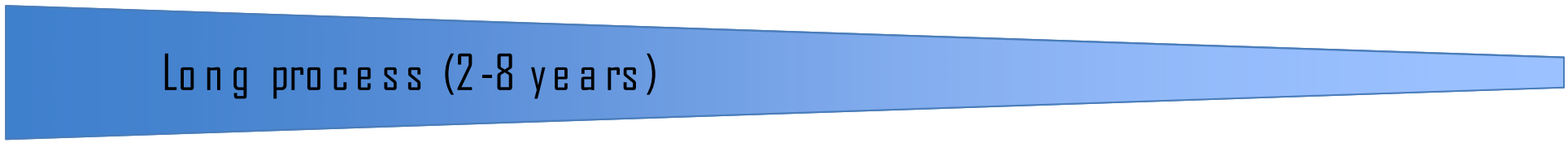
Discussion at WPMN of a Draft SPSF

Discussion at WNT of SPSF to include in OECD Work Program

Approval at WNT of final TG for adoption by OECD Council

Main TG development work, including e.g. round robin testing (several years)

An OECD member takes the lead, with support from other members



SPSF: Standard Project Submission Form used by OECD WNT to receive proposals
WNT: Working Group of National Co-ordinators of the Test Guidelines programme

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Uncertainties for case-by-case and read across

- Case-by-case assessment by EFSA creates additional uncertainty for applicants
  - on e.g. waiving in vitro studies
  - whether read across is properly justified to waive additional tests
- When will these EFSA judgments be communicated during the assessment?
- Uncertainty creates costs!

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Nice to know vs need to know

- Clarification and Description required of what is **need to know vs nice to know** from a risk assessors' perspective
  - microbiome information is nice to know and should not be required.
  - microbiome information is also not nanospecific and should not be part of the GD. This creates confusion and uncertainties

- Provision of confidential business information:
  - Considerable investment in product development

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Practical hurdles to be overcome

- Industry needs to be able to use service providers to generate data for an application dossier
  - An expert team needs to be created to generate a dossier, internal staff, expert consultants, service providers
  - If no service provider available…. A sign of limited market interest… where to turn?
- Applicants have difficulties to understand what is required from risk assessors if guidance is not specific
  - Without agreed test methods, huge burden is placed on applicant to consider validity of methods and broad specific knowhow
- For characterization, the applicant may not necessarily know the final products where the nanomaterial can be used

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Uneven playing field between large and small

- Different realities between large established industries vs small innovation companies
  - Large industries may have internal testing facilities, regulatory support vs small may have just a potential innovative product!

- The more stringent requirements found in a guidance, the more resources are required to bring new products to the market.
  - Too stringent guidance requirements hampers innovations reaching consumers and providing societal benefits

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From EFSA opinion to regulation

- Effect of regulatory decisions: Positive lists vs individual approvals
  - General specification in an annex so everyone can create a product vs a decision for an individual company
  - Detail of specification can be used to influence market access
  - Accurate description of regulatory approval specifications are important!
- EFSA opinion may imply that a product is/contain a nanomaterial by applying the very broad (definition) scope of the guidance
  - This can have severe consequences for a manufacturer and users with regard to e.g. market perception and possible labelling requests

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Conclusions

- Continue the trial period experience of working with the Guidance: Consider publish a best practice document
- Early active communication with applicants to discuss test methods, validity and waiving of tests
  - Reduce uncertainties from case-by-case judgements
  - Consider publishing ‘best practices’ for applicants
- The broad definition is not practical
- Consider carefully what information is need to know for risk assessment!
- Cooperation with other agencies, e.g. ECHA is important
  - Shared language where possible

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Thank you!

Grow your business!

Stay ahead of new regulations!

Strengthen your communications!

Make your voice heard!

Join the NIA family – Become a Member

Nanotechnology Industries Association (aisbl)
143 Avenue de Tervuren
1150 Woluwe-Saint-Pierre, Brussels
Belgium

Dr David Carlander
Director Regulatory Affairs
david.carlander@nanotechia.org