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THE POTENTIAL RISKS ARISING FROM NANOSCIENCE AND NANOTECHNOLOGIES ON FOOD AND FEED SAFETY

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NANOTECHNOLOGY IN THE FOOD CHAIN
Opportunity & Risks
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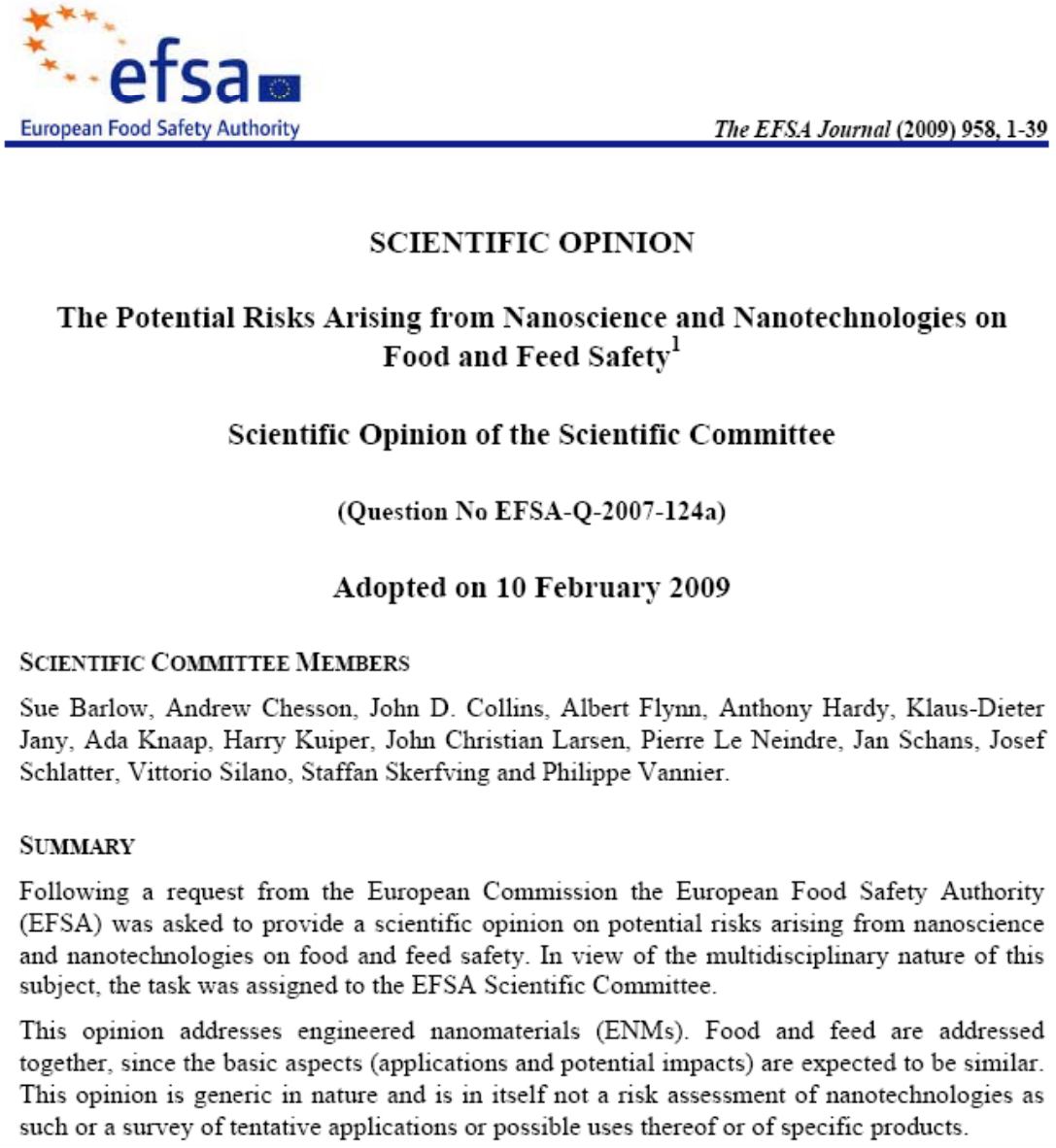
Organized by Federal Agency for the Safety of the Food Chain in the frameworkof Belgian EU Presidency

Overview

- **What are the health & safety issues of nanoparticles in food?**
  - EFSA's 2009 Opinion
  - Risk assessment of applications
- **Which risk assessment issues need to be addressed for nanotechnology in food?**
  - Preparation of guidance on nanomaterials
- **Is there a prioritisation with respect to research needs?**
  - Challenges & uncertainties

What are the health & safety issues of nanomaterials in food?



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The EFSA Journal (2009) 958, 1-39

SCIENTIFIC OPINION

The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety[1]

Scientific Opinion of the Scientific Committee

(Question No EFSA-Q-2007-124a)

Adopted on 10 February 2009

SCIENTIFIC COMMITTEE MEMBERS

Sue Barlow, Andrew Chesson, John D. Collins, Albert Flynn, Anthony Hardy, Klaus-Dieter Jany, Ada Knaap, Harry Kuiper, John Christian Larsen, Pierre Le Neindre, Jan Schans, Josef Schlatter, Vittorio Silano, Staffan Skerfving and Philippe Vannier.

SUMMARY

Following a request from the European Commission the European Food Safety Authority (EFSA) was asked to provide a scientific opinion on potential risks arising from nanoscience and nanotechnologies on food and feed safety. In view of the multidisciplinary nature of this subject, the task was assigned to the EFSA Scientific Committee.

This opinion addresses engineered nanomaterials (ENMs). Food and feed are addressed together, since the basic aspects (applications and potential impacts) are expected to be similar. This opinion is generic in nature and is in itself not a risk assessment of nanotechnologies as such or a survey of tentative applications or possible uses thereof or of specific products.

EFSA 2009 opinion

- **The opinion is generic in nature, is not a risk assessment of nanotechnologies, of applications or of specific products.**

- **It considers Engineered Nanomaterials (ENM) and identifies issues such as existing limitations on exposure and data availability and main uncertainties.**

Conclusions of the 2009 opinion

- The nanospecific properties and characteristics of ENM are likely to affect their toxicokinetic behaviour and toxicity profile
- The risk assessment of ENM has to be performed on a case-by-case basis, based on proper identification and comprehensive characterization of the ENM as used in food / feed, and on exposure data
- For certain applications there may currently be specific difficulties to generate requested data.

Risk Assessment of Applications

- **Based on EFSA March 2009 opinion, EFSA has preparedness to assess applications.**
- **EFSA risk assessors will not be able to conclude unless sufficient data is submitted.**
- **No consensus guidance for risk assessment have yet been produced at the international level for the food and feed area.**

EFSA risk assessment of ENM

Two assessments have been provided by EFSA on risks of specific nanomaterials in food and feed:

- **CEF Panel: No safety concern for titanium nitride for use as food contact material on the basis of proven absence of migration into food.**

- **ANS Panel: Submitted data were insufficient to adequately characterise silver hydrosol and the Panel could not provide an opinion.**

No new applications have been received by EFSA.

ANS: Panel on Food Additives and Nutrient Sources added to Food
CEF: Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids

Preparation of guidance

2009 Request – Terms of Reference

EFSA is requested to **prepare a guidance document**...including food additives, enzymes, flavourings, food contact materials, novel foods, feed additives and pesticides...

...This document should **provide practical recommendations for the risk assessment** of food related applications of nanotechnology **to the extent possible with current knowledge**...

Scientific Committee Working Group

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Experts in nanoscience, nanotechnologies, risk assessment

Mona-Lise Binderup, Qasim Chaudhry, Wim De Jong, Corrado Galli, David Gott, Rolf Hertel, Akihiko Hirose, Wolfgang Kreyling, Hermann Stamm and Stefan Weigel

Meetings during 2010

Minutes are published on EFSA website

Guidance under development

- Focus on oral administration
- Case-by-case assessment
- Information and data needs related to exposure and use scenarios
- Complement to current guidance documents available for various areas/sectors
  - Provide guidance on nano specific considerations that need to be assessed in addition to conventional aspects

General scenarios

- **Reformulation of already used and approved food / feed / ingredients**
  - **Assess if available information can be used**

- **Novel food / feed / ingredients not previously used in food / feed**
  - **Additional data needs for a full evaluation**

Physico-chemical characterisation

- **Comprehensive characterisation needed**
  - **E.g. size, size distribution, morphology, surface chemistry, catalytic activity, stability / shelf life, volume specific surface area (for dry powders).**
  - **Concentration, dispersion medium, agglomeration-aggregation state**
  - **Information on method of production, intended use, batch to batch variation**

Characterisation at several steps

- Prior to use in food / feed
- As used in food / feed
- As used during toxicological testing
  - Acknowledged that characterisation can be difficult in certain matrixes.
  - Methods used need to be carefully selected and described

Exposure scenarios

- **Outline anticipated exposure scenarios as this will influence the extent of the hazard characterisation.**
  - **Direct or indirect addition to food / feed**
  - **Certain applications may give rise to a very limited exposure**
  - **Where nano-form exposure is not detected by appropriate methods, conventional risk assessment should be performed**

Toxicity testing strategies

- ***In vitro*** **tests not yet validated. Provide screening and initial understanding of biological effects.**
  - **Genotoxicity and mutagenicity tests**

- ***In vivo*** **test**
  - **ADME**
  - **90-day rodent repeat oral toxicity, considering extended endpoints (e.g. endocrine activity and immuno- and reproductive toxicity)**

- **Additional tests triggered by initial results**

Public Consultation

- Openness and public involvement
- Scientific comments are addressed by the experts
- Comments enhance the scientific quality and clarity
  - All comments are published

Assessing New Technologies - Uncertainties and challenges

- **Complications**
  - **Information gaps**
  - **Scientific publications not designed to answer risk assessment questions**
  - **Lack of guidance documents**

Benchmark with the Risk Assessment Paradigm

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HAZARD IDENTIFICATION

- Identification of adverse health effects
  - Animal-based toxicological studies
  - *In vitro* toxicology data
  - Structure-activity consideration
  - Human data

HAZARD ASSESSMENT

- Quantification of adverse health effects
  - Dose-response for critical effect
  - Selection of critical data
  - Mode/mechanism of action
  - Kinetic variability
  - Dynamic variability

EXPOSURE ASSESSMENT

- Active principle
  - Dose of toxicant
  - Dose in individuals
  - Dose in special population groups
  - Max/min, chronically/occasionally

RISK CHARACTERISATION

"Risk = hazard x exposure"

Main uncertainties and challenges

- Analytical limitations in the measurement of nanomaterials in various matrices make assessment of toxicity and exposure data difficult.
- More testing experience with nanomaterials is needed to establish optimal approaches.
- Long term oral exposure information is missing and extrapolation from shorter exposure is not yet reliable.
- Bioaccumulating and persistent nanomaterials are likely to end up in the food / feed chain as contaminants.

Safety and risk assessment issues

- **Some nanomaterials may be of low safety concern whereas others, especially if persistent and highly reactive, may be of a higher risk.**

- ***In vivo* toxicity data are needed for most assessments. Currently no validated *in vitro* methods available.**

- **Limited practical risk assessment experience in the food area.**

Addressing safety and risk assessment issues

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- Risk assessment of nanomaterials needs to be on a case-by-case basis.
- The information requirements to perform a risk assessment will vary depending on the properties and intended use, and less data is expected where no significant exposure is shown to take place.
- Exchange of data and evaluation criteria as well as cooperation over sectors and preventive approaches are beneficial.

Looking ahead

- **A rise of applications concerning nanomaterials in different food and feed sectors is expected both inside and outside EU.**

- **An intensive learning curve of potential risks of nanotechnology applications is expected over the coming years with possible refinement of relevant risk assessment methodologies.**

Thank you