

## **TECHNICAL REPORT OF EFSA**

### **Outcome of Public Consultation on the EFSA Draft Nanotechnology Opinion<sup>1</sup>**

**Prepared by EFSA**

**(Question No EFSA-Q-2007-124b)**

**Issued on 5 March 2009**

#### **BACKGROUND**

On the 14 of October 2008, the EFSA Scientific Committee endorsed a draft opinion of the Scientific Committee on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed safety and the Environment. The draft opinion had been prepared by an EFSA Scientific Committee Working Group composed of external experts and member of the Scientific Committee.

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from the scientific community and stakeholders on its work, EFSA engages in public consultations on key issues. The work on nanotechnologies is such an issue and on 17<sup>th</sup> October 2008 the draft opinion was published for public consultation until the 1<sup>st</sup> of December, 17:00 CET. EFSA has committed to publish the comments received as well as a short report on the outcome of the consultation (see appendix 1).

#### **COMMENTS RECEIVED**

At the deadline EFSA had received 208 submissions, from about 30 interested parties (individuals, non-governmental organisations, industry organisations, academia and national assessment bodies). All comments received were scrutinized and subsequently tabulated with reference to the contributor and the section of the draft opinion to which the comment referred. There were a number of submitted comments received outside the electronic form which thus did not fulfil the EFSA submission criteria (See annex 1). However, those comments were still considered and have been inserted in the table of comments. Duplicate comments received from the same contributor appear only once in the table and comments submitted by individuals on a personal capacity are listed anonymously. Comments submitted formally on behalf of an organization appear with the name of the organization. The table of all comments is published as a separate document on the EFSA web site [http://www.efsa.europa.eu/EFSA/efsa\\_locale-1178620753812\\_1211902361968.htm](http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902361968.htm).

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<sup>1</sup> For citation purposes: Technical Report of EFSA on Outcome of Public Consultation on the EFSA Draft Nanotechnology Opinion. *EFSA Technical Report (2009) 235, 1-5*

## **SCREENING AND EVALUATION OF COMMENTS RECEIVED**

### **1. General**

There were several comments that supported the general view of the opinion and others which were in disagreement with the general view of various sections. Several comments were related to nanotechnology or nanotechnologies in general and were as such not specifically related to the remit of EFSA or the terms of reference of the opinion. A number of comments expressed the need for additional and more research. Some comments were related to political or management issues and as such these comments were considered to be outside the scientific remit of EFSA and were not addressed. A few comments provided references to scientific publications or provided arguments for different interpretations compared to the ones expressed in the draft opinion by the Scientific Committee. There were also suggestions for editorial improvements and clarifications.

#### **1.1. Types of comments**

Several comments asked for the opinion to provide a definition of nanomaterials, and thus expand the terms used in the opinion and some asked that the terminology used reflects the recent ISO publication TS 27687. Also, demarcation versus nanomaterials long used in food/feed (micelles in milk, mayonnaise etc) should be clearer.

Some comments addressed the uncertainties of the future potential application of nanotechnologies in the food and feed area as well as the possible products placed on the market.

The lack of suitable methods for hazard identification and characterisation, exposure assessment and of detection/analysis of specific applications were acknowledged by several commentators, including the limited availability of validated *in vitro* methods. Comments were also provided for the environmental section, and suggestions to perform life cycle analysis.

Some comments were related to the strength of the evidence base on which to reach conclusions as there is limited information available on toxicity of orally administered nanomaterials. There were questions about how the Scientific Committee was able to reach conclusions on risk assessment procedures on such limited data.

Several commentators agreed that the general risk assessment paradigm is applicable and the information needed for the risk assessment need to be provided on a case-by-case basis, from appropriately designed studies.

Some comments stressed the likely variation in toxicity between different engineered nanomaterials.

#### **INCORPORATION OF COMMENTS IN THE OPINION**

The comments were all discussed by the EFSA Scientific Committee working group on nanotechnology at a dedicated meeting. Although a substantial number of comments appeared to be on issues outside the remit of the Scientific Committee and, consequently were not considered in the revised draft opinion, many comments received were very appropriate and

of high value for the Scientific Committee. These were all incorporated and strongly contributed to enhancing the scientific quality and clarity or to providing better understanding of the opinion.

#### **ACKNOWLEDGEMENTS**

This report was prepared by the Scientific Committee and Advisory Forum Unit.

## APPENDIX 1

The text below is from the EFSA website of the public consultation:

### **Public consultation on the Draft Opinion of the Scientific Committee on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed safety and the Environment**

Deadline: 1 December 2008

EFSA is launching a public consultation on its draft scientific opinion on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed safety and the Environment. The work follows a request from the European Commission (EC) to EFSA for advice on this issue in 2007. EFSA's opinion will help inform consideration of any future EU measures in relation to nanotechnologies in the food and feed area.

EFSA's Scientific Committee (SC) has led this work and has been assisted by a Working Group of scientists with relevant expertise to consider the different aspects of the Commission's request. In order to receive relevant information EFSA launched a call for data in January 2008 on its website and via its Advisory Forum.

In line with EFSA's policy on openness and transparency and in order for EFSA to receive comments from the scientific community and stakeholders on its work, EFSA engages in public consultations on key issues.

In this respect EFSA would be grateful to receive relevant comments on its Draft Opinion of the Scientific Committee on the Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed safety and the Environment.

Interested parties are invited to submit comments and pertinent scientific information by means of the electronic form available on this page by **1st December 2008, 17:00 CET**, following the instructions below.

If interested parties wish to contribute scientific studies or data to support a particular comment, these should be preferably have been published or accepted for publication and clear reference to where the supporting information is found should be made.

A submission will not be considered if it:

- is submitted after the deadline set out in the call;
- is presented in any other form than the instructions and template provide for;
- contains comments which do not relate to the contents of the document;
- contains information on individual cases;
- contains complaints against institutions, personal accusations, irrelevant or offensive statements or material;
- is related to policy or risk management aspects, which is out of the scope of EFSA's activity.

EFSA looks at the scientific evidence and data relevant to its specific risk assessment remit. Important and relevant feedback will be any further evidence or data that EFSA may not have been able to access that should be considered in the final opinion. Views on wider issues, for example ethical or other societal issues, are not part of EFSA's remit.

EFSA will assess all relevant comments from interested parties which are submitted in line with the criteria above. The comments will be further considered by the EFSA Scientific Committee and taken

into consideration where these will enhance the scientific quality or understanding of the document. Following this exercise EFSA will publish the relevant comments received, as well as a short report on the outcome of the consultation. In addition to the above criteria, for the publication of the comments the following information should be noted;

- Repeated comments received from the same contributor will appear only once.
- Comments submitted by individuals acting in a personal capacity will be published anonymously.
- Comments submitted formally on behalf of an organization will appear with the name of the organization.

[Frequently Asked Questions \(FAQs\) on Nanotechnology](#)

[Key Topics on Nanotechnology](#)

**Reference document:**

[Draft Opinion on Nanotechnologies](#)  (0.2Mb)

Publication date: 17 October 2008