TECHNICAL REPORT

Annual report of the EFSA Scientific Network of Risk Assessment of Nanotechnologies in Food and Feed[1] for 2014

European Food Safety Authority[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

In accordance with EFSA's strategy for cooperation and networking with Member States, a Network for Risk Assessment of Nanotechnologies in Food and Feed was established in 2010. The overall goals of this Network are to facilitate harmonisation of assessment practices and methodologies; to enhance exchange of information and data between EFSA and MS; and to achieve synergies in risk assessment activities. The Annual reports of the Network inform the public and the EFSA Advisory Forum about its specific activities and achievements. During 2014, the Network followed-up on its priority areas and contributed to the making of inventory lists of applications of Nanomaterials already present in the food/feed chain. During its meeting in 2014, the Network dedicated most of its discussions on relevant research results for possible toxic effects following the oral route of exposure. The Network exchanged views on the technical aspects and implications of the definition for Nanomaterial. The network also shared its views on the ongoing and upcoming risk assessments of EFSA on applications comprising implicitly or explicitly nanoforms. The Network updated its list with national research and contact details of national laboratories that can analyse nanomaterials in complex matrices.

KEY WORDS

Nanotechnology, nanomaterial, food, feed, toxicology, genotoxicity, detection

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SUMMARY

Developing networking and stronger co-operation with the Member States and strengthening EFSA's relationship with its institutional partners (EU and international) and stakeholders are among the key recommendations formulated by EFSA's Management Board. In accordance with EFSA's strategy for co-operation and networking with Member States, the Scientific Network for Risk Assessment of Nanotechnologies in Food and Feed (hereafter referred to as 'Nano Network') was launched. The Nano Network had its inaugural meeting in February 2011 and following this, one meeting per year is scheduled.

The overall goals of the Nano Network are to provide a forum for dialogue among participants; build mutual understanding of risk assessment principles; enhance knowledge on and confidence in the scientific assessments carried out in EU; and to provide increased transparency in the current process among Member States and EFSA on nanotechnology. All this with the aim to raise the level of harmonisation of the risk assessments developed in the EU on nanotechnology.

The Network is composed of representatives from 21 Member States and Norway. In addition, observers to this Network represent the Former Yugoslav Republic of Macedonia, Turkey and Montenegro. There is also representation from the European Commission (DGSANTE and JRC), from the EFSA Scientific Committee and the relevant Units/Panels.

During 2014, the Network followed-up on its priority areas and contributed to the making of inventory lists of applications of Nanomaterials already present in the food/feed chain.

At its 2014 meeting the Network focussed again on updates of research results from toxicological studies relevant for the oral route of exposure. Member States representatives presented relevant studies. The type of nanomaterials that are now occurring in the food/feed chain are mainly Titaniumdioxide (TiO_2) and Synthetic Amorphous Silica (SAS). The evidence bases for oral toxicity and for conducting comprehensive risk assessments of these two materials is building up, but more research remains needed. Challenges to draw firm risk assessment conclusions reside in (1) the intake estimation (2) the possible worst-case absorption and the dose-dependence of absorption (3) the potential irrelevance of high dose oral toxicity studies for risk assessment (4) the extrapolation of kinetic data from rat to man (5) the nanoparticle determination in tissues, and (6) the many differences between the types of nanoforms of one nanomaterial (e.g. in kinetics and toxicity). Some differences in behaviour of different nanoforms have been observed, but there is no clear overview. A new issue of concern is that absorption is not linear with dose: high dose studies are often used for tox testing for estimation of safe dose, while the high dose may result in aggregation, agglomeration, gelation and as a consequence dose-dependent absorption.

Challenges also remain to exist regarding the technical aspects for considering a material as a nanomaterial (NM) for the regulatory purpose of food labelling. The NanoDefine project (FP7) is expected to deliver by 2017 an implementable test-scheme for regulatory purposes to distinguish nano from non-nano.

The Network agreed that regardless the current challenges and regardless the % of nanoforms in the bulk material (particle size% or mass%), EFSA should assess the nano-fraction, no matter how small. Food law, as being implemented by the EFSA Panels is covering nanomaterials. Nanomaterials are addressed mainly by cross-referring to the Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain (EFSA Scientific Committee, 2011 http://www.efsa.europa.eu/en/efsajournal/doc/2140.pdf).

The Network also updated its list with contact details of national laboratories that have equipment and know-how for analysing certain nanomaterials in complex matrices.

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BACKGROUND AS PROVIDED BY EFSA

In accordance with EFSA's strategy for cooperation and networking with Member States (MS)[4], a Network for Risk Assessment of Nanotechnologies in Food and Feed was established in 2010. The overall goals of the Network for Risk Assessment of Nanotechnologies in Food and Feed are to facilitate harmonisation of assessment practices and methodologies; to enhance exchange of information and data between EFSA and MS, and to achieve synergies in risk assessment activities.

In 2010, the EFSA Scientific Committee adopted its scientific opinion on "The Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety"[5]. In this opinion, the Scientific Committee concluded that EFSA would be in a position to assess possible future applications on a case-by-case basis and that it would be able to reach a conclusion only if sufficient data is submitted for such a risk assessment. There is however still a lack of data, and a lack of harmonized and validated methodologies on crucial elements of the risk assessment. Upon request from the European Commission, the Scientific Committee subsequently provided in April 2011 guidance for assessing the potential risks arising from applications of nanoscience and nanotechnologies to food, feed and pesticides. Practical recommendations and provisions for such risk assessment were given to the extent possible with current knowledge, allowing industry to submit dossiers for nanotechnology food applications.

EFSA is closely following developments in the area of nanotechnologies in food and feed in order to address the need to provide further specific guidance where possible. The scientific network for risk assessment of nanotechnologies in food and feed was established in 2010 and has helped to strengthen the scientific cooperation for risk assessment of application of nanotechnologies and products thereof in the relevant areas within EFSA's remit. It aims at anticipating and reducing the duplication of activities and avoiding divergence of opinions. The network is an environment to share data and methodologies facilitating harmonisation of assessment practices and assist in anticipating emerging risks in the EU.

[4] http://www.efsa.europa.eu/EFSA/resource_EFSA/about/core/mb_strategy_28thmeet_en_6a.pdf?ssbinary=true
[5] http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902361968.htm

TERMS OF REFERENCE AS PROVIDED BY EFSA

The Terms of Reference for the first 3 years had been discussed and agreed with the Scientific Committee and the Advisory Forum in 2010. The EFSA Advisory Forum decided en 2013 to renew the Nano Network. For this renewal, the charter "14_ SCER-03_A_00_NanoNetwork, version 2" was developed and the Network itself has been consulted on the below Terms of Reference and action plan. This renewal of activities will be registered in the EFSA Register of Questions under mandate number M-2014-0144.

The specific objectives of this EFSA Scientific Network for Assessment of Nanotechnologies in Food and Feed are to:

Facilitate harmonisation of assessment practices and methodologies:

- Share best practices of risk assessment of applications of nanotechnologies between EFSA and MS.
- Discuss ongoing issues of risk assessment of applications of nanotechnologies or new opinions adopted.
- Share and discuss on-going risk assessment of applications of nanotechnologies to avoid duplication and divergent opinions.
- Discuss new guidance under development or developed for risk assessment of applications of nanotechnologies.
- Share and discuss priorities for risk assessment activities of nanotechnologies at national and EU level.
- Discuss new scientific developments in risk assessment activities of nanotechnologies and their implications on risk assessment practice.
- Identify and prioritise common research needs that support progress in risk assessment.
- Identify common themes and areas for mutual cooperation for risk assessment activities of nanotechnologies.

Enhance exchange of information and data between EFSA and Member States of the European Union:

- Sharing risk assessment of applications of nanotechnologies through the EFSA information exchange platform.
- Discussing issues of availability and quality of data required for risk assessment purposes of applications of nanotechnologies.
- Sharing information and experience in data collection and surveillance of applications of nanotechnologies.
- Identifying and mapping expertise in specific areas and on specific issues for risk assessment of applications of nanotechnologies.

EFSA may entrust certain tasks to the network, such as collection of data and identification of emerging risks, or some preparatory work for future guidance development.

MEMBERS

Countries	Nominated Member Organisation	Appointed expert	Appointed alternate
Austria	Austrian Agency for Health and Food Safety - Österreichische Agentur für Gesundheit und Ernährungssicherheit GmbH	Johann Steinwider	
Belgium	Veterinary and Agrochemical Research Centre (VAR)	Jan Mast	
Bulgaria	Department of Biotechnology, University of Food Technologies	Angel Angelov	Nadezhda Sertova Risk Assessment Center, Bulgarian Food Safety Agency
Croatia	Croatian Food Agency	Darko Mikec	Darja Sokolic-Mihalak
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Estonia			
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Sweden			
UK	Food Standards Agency	David Gott	Manisha Upadhyay

OTHER MEMBERS/OBSERVERS

Norway	Norwegian Institute for Public Health-Scientific Committee for Food Safety	Ragna Bogen Hetland	
FYR of Macedonia	Food and Veterinary Agency	Nijazi Salija	Suzana Popovska
Turkey	Ministry of Food, Agriculture and Livestock	Nurseren Budak	Nevra Ozcan
Montenegro	Ministry of Health	Zorica Đekic	

ACTIVITIES

The following sections highlight the most important activities of the Network during 2014.

1. Follow-up from Annual meeting 2013

The Network maintained its four priorities and updated them as follows:

- Need for inventory of nanomaterials in products on the market:
  - Was addressed by EFSA procurement contract "NanoInventories" and MS initiatives for legal registers.
  - Priority might expire when the labelling legislation comes into force end 2014.
- Analysis and monitoring of products under development and on the market:
  - Priority remains for next term of the network
  - One example is the monitoring of products on the market comprising SiO_2 (within the NanoLyse project)
- Need for suitable measuring methods:
  - Being addressed by JRC and research project including NanoLyse, NanoDefine and NanoREG
- Need for validated test methods *in vitro* and *in vivo*
  - Priority remains but requires a pragmatic approach on the basis of reasonably foreseen possibilities.

2. Annual meeting 2014

The fourth meeting of the Nano Network was held on 21-22 October 2014 in Parma and attended by 17 out of 22 scientific experts from Member States organisations and from Norway, 1 EFSA Scientific Committee expert, 1 hearing expert from SCENIHR, 4 European Commission experts and 8 EFSA scientific staff members (2 from of the Scientific Committee and Emerging Risks Unit (SCER), 2 from the Advisory Forum unit (AFSCO), 1 from the FEED Unit, 1 from the FIP unit and 2 from the pesticides Unit (PRAS)). The minutes of that meeting are published on EFSA's website http://www.efsa.europa.eu/en/events/event/141021a.htm. The following topics and actions were discussed.

2.1. National cooperation and network coordination

The procedures for the renewal of the EFSA Scientific Networks mandate, the nominations of representatives and the Terms of References of the Networks were discussed with the EFSA AFSCO colleagues. As an outcome of a review carried out in 2013, a new provision is incorporated in the updated mandates for all networks: it specifies that Member States representatives in this Network shall commit to liaise as appropriate at national level before and after each Network meeting. For the coordination of the networks at the national level, Focal Points are appointed to assist Network representatives in preparation for meetings and should receive a copy of the agenda of the nominated representative. Focal Points have the possibility to organise events at the MS level to 'network' between representatives.

2.2. EFSA Procurement Nanomaterial inventory

The contractors (RIKILT and JRC) delivered the outcomes of the EFSA outsourcing project "Inventory of nanotechnology applications in the agricultural, feed and food sector" that were published on the EFSA website in July 2014: http://www.efsa.europa.eu/en/supporting/pub/621e.htm. The purpose of this inventory was to predict upcoming applications for EFSA. The results for nanotechnology applications show that nano-encapsulates, silver and titanium dioxide have the highest number of records in the Nano Inventory and that food additives and food contact materials are the most indicated current applications. Potential future developments are expected in the field of nano-encapsulates and nano-composites in applications such as novel foods, food/feed additives, biocides, pesticides and food contact materials. The query on toxicological data shows that most information is available for silica, titanium dioxide and silver to characterise their potential human hazard, including

cytotoxicity, genotoxicity, repeated dose toxicity, and biokinetics. The inventory includes only a limited set of records for the risk assessment status of nanomaterials used in agri/feed/food applications showing that only a few materials have been evaluated according to the available literature. Finally, the review of legislation and regulation in the EU as well as in non-EU countries shows that currently a few EU legal acts incorporate a definition of a nanomaterial to enable specific provisions for nanomaterials. In many non-EU countries a broader approach with limited nanomaterial specific legislation and/or legally binding definition of nanomaterials is applied which mainly builds on guidance for industry.

The members of the network welcomed the work delivered by the external contractors for EFSA and acknowledged the challenge to distinguish what is confirmed on the market and what is claimed or envisaged to be marketed. It was reminded that this is of great importance for consumers who should be able to distinguish what is now already in food and what is under development. France and Belgium are also working on national registries of Nanoparticles.

2.3. Nano Definition and issues around measurement

The technical aspects for considering a material as a nanomaterial (NM) for the regulatory purpose of food labelling were discussed in detail. Technical challenges exist particularly for particles with external dimensions in the lower nanometer range (below approximately 30nm), for nanoparticles embedded in complex matrices (such as food and feed), and for representative sampling. The formation of aggregates and the measurement of constituent particles in such aggregates deserves particular attention. The conversion of mass-based particle size distributions to number-based particle size distributions in the nanometre-scale is very problematic, and hence particle size measurements need to take into account the required number-based metrics. These challenges are being addressed in continued method development, with the goal of validating methods, including sample preparation, for specific purposes. One step forward would be to agree if the definition should be applied to the pristine state of the ingredient (rather than the final product) and whether it covers solid particles only (soluble or non-soluble). Exclusion from the definition is envisaged under food-law for natural, soft, and degradable nanomaterials. The NanoDefine project (FP7) is expected to deliver by 2017 an implementable test-scheme for regulatory purposes.

2.4. Updates on toxicity tests from the Member States

2.4.1. DE - What mode of action do Nanomaterials have in Liver and Intestine?

German research results showed that the accumulation in enterocytes is lower for Ag-Pure NP than for Ag-PVP corona. The molecular effects were monitored and showed a Ag NP dose response with upregulation of 2134 genes and downregulation of 2918 genes. These nano-effects were confirmed with RT-PCR. The involved pathways are oxidative stress, loss of cell-cell contacts and cell-matrix contacts, and remodelling of cytoskeleton. Silver nanoparticles may indeed overcome the gastrointestinal juices in their particulate form without forming large aggregates. Silver particles can reach the intestinal epithelial cells after ingestion with only a slight reduction in their cytotoxic potential. Further research results are to be presented in 2015: an on-going NL-DE project is expected to unravel the influence/protection of food matrix components and digestion on the cytotoxicity of NP; an on-going DE-FR research is expected to unravel the influence on uptake and toxicity of solubility (Al -NP) versus non-solubility (TiO_2).

2.4.2. IT - 90 day oral toxicity study on SAS within the NanoReg project

A Repeated-Dose 90-day Oral Toxicity Study on Synthetic Amorphous Silica (E551) is in progress under the NanoReg project and aims at comprehensive test results useful for risk assessment. The global market volume of SAS is 1.5 million tons a year (i.e. not limited to food applications) and dietary exposure of the general population to nanosized SiO_2 occurs and could increase in the near future. The results of SAS toxicokinetics of two different nanoforms showed that they had different kinetics, whereas common features were low oral bioavailability and relatively slow tissue elimination. The goals of the 90-day study are to identify hazards and obtain dose-response data. The

pyrogentic SAS nanoform is used with a soluble counterpart (silicic acid) as comparator. The endpoints of this ongoing study include tissue deposition, general toxicity, histopathology, genotoxicity, reproductive toxicity and immunotoxicity. The results will be available in 2015.

2.4.3. NL - research on SAS TK and SAS RA

Novel insights into the risk assessment of the nanomaterial SAS in food were presented. There are a lot of uncertainties and assumptions that make it difficult to draw firm conclusions on (1) Intake estimation (based on measurement in 27 products and worst case but on other hand not all product groups included) (2) Absorption (Worst case based on NanoGenotox data, not RIKILT data, Dose dependent, and SAS-type dependent) (3) Relevance of high dose oral toxicity studies for risk assessment (4) Extrapolation of kinetic data from rat to man (Allometric scaling and absorption) (5) Silica in tissues determined by measuring Si and assumed to be present as particles (control corrected), and (6) Differences between types/forms of silica (kinetics and toxicity).

Initial concerns about nanomaterials are their potential slow elimination and accumulation as well as the potential variation and lack of information in behaviour between various forms/types. Therefore, assessment of the combination of potential for accumulation and low oral absorption for realistic exposure by kinetic model should be explored. Some differences in behaviour of different nanoforms have been indeed observed, but there is no clear overview.

A new issue of concern is that absorption is not linear with dose: high dose studies often used for tox testing for estimation safe dose and the high dose may result in aggregation, agglomeration, gelation and as a consequence dose-dependent absorption. Absorption may therefore decrease with increasing oral dose, leading to a potential underestimation of risk. High dose oral studies must only be applied with caution for nanomaterials. Focusing risk assessment on internal exposure in the target organ is a way forward to accommodate these issues.

2.4.4. FR - Évaluation des risques liés aux nanomatériaux Enjeux et mise à jour des connaissances

France reviewed the state of the art on nanomaterial risk assessments, not limited to food applications.The focus was to determine what are the substances already on the market that should be risk assessed. This was a challenging task due to limited information sources, high variability in collected information and variability in quality of the data. There are methodological progresses needed in all domains relevant for risk assessment: higher quality in physico-chemical characterisations, set-up or adaptation of (eco-)toxicology testing, realistic exposure and a higher degree of harmonisation and standardisation of the methods.

One of the major issues to be considered in risk assessment of nanomaterials is the evolution of these materials all along their life cycle: oxidation state, dissolution or precipitation in a mineral form different than the initial, homo & hetero aggregation, adsorption, etc.. Another issue it the need for a multidisciplinary approach: for instance though discussions between experts of atmospheric pollution & nanomaterials. Many recommendations were made to help advance the scientific knowledge and address the needs for risk assessment, to steer risk management evolutions and legislation.

2.5. SCENIHR opinion on Nanosilver

DG SANTE Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) published its risk assessment opinion on Nanosilver. This opinion details the different nanoforms, the role of solubility on their toxicity and the different exposure routes and levels. During the discussion with the Nano Network, special attention was given to the main risks due to toxic potential for nano-Ag and the selection for Ag resistant micro-organisms. The main conclusion is that over the already widespread and increasing use of silver containing products, additional effects caused by widespread and long term use of Ag-NPs cannot be ruled out. More data and more long term-exposure studies are needed.

2.6. Food additives re-evaluation programme

The EFSA FIP Unit is dealing with the food additives re-evaluation programme to be finalized by 2020 and a picture of the current situation was discussed with the Nano Network. With respect to nanomaterials used as food additives, the Regulation (EC) No 1333/2008 Art 12 clearly mentions that if there is a change in particle size, for example through nanotechnology, the food additive shall be considered as a different additive. The ANS Panel evaluated nanomaterials (characterisation and identification, toxicity testing) mainly with cross-reference to the Guidance of the EFSA Scientific Committee of April 2011 ("Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain", http://www.efsa.europa.eu/en/efsajournal/doc/2140.pdf). A definition of "engineered nanomaterial" is specified in Regulation (EU) 1169/2011 and more clarity on the definition of "nanomaterial" and its characteristics is expected from the revision of the Recommendation of 18 October 2011 (EC OJ L 275/38). In the applications received by EFSA, there has been a clear distinction between adventitious particles and declared nanomaterial; and in the near future other food additives that could be in a nanoform will be assessed. Particular attention on this aspect will be paid.

3. Outputs of the Nano Network

3.1. Briefing on Nanoplastics for the EFSA CONTAM Unit

The Nano Network was consulted and invited to collect from the Member States information on
(1) MS activities to develop detection methods for micro/nano plastic particles in food
(2) possible occurrence data from sampling food for micro/nanoplastics and
(3) ongoing national or European research projects that address micro/nano plastics particles in food.
The Network's feedback was transmitted to the EFSA CONTAM Unit.

3.2. Operational outputs

Detailed minutes of the 21-22 October 2014 meeting were published on the Network's dedicated website, http://www.efsa.europa.eu/en/events/event/141021a.htm.

The online platform for the Network (https://dms.efsa.europa.eu/) is used to share information in between the annual meetings of the Network. This information and also the continuously updated Nanonetwork nominations, are accessible to the EFSA Advisory Forum.

Summaries from MS national activities in the area of food and feed as well as relevant scientific papers to share with the Network were uploaded to the DMS platform. Highly relevant documents or regulatory developments were shared among the Network per e-mail.

The Network also updated its tables with Feedback of the Nano Network on the Tasks of the Terms of Reference and ongoing activities in Member States relevant for risk assessment of nanotechnologies in food and feed. This ensured exchange of best practice (relevant work on applications and guidance documents), streamlining common research needs (ongoing research projects and research needs), identification of new expertise and areas where cooperation is required.

The members of the Network also updated the list of national laboratories that are competent to analyse food samples upon request and that are able to verify the presence of and characterise nanoparticles. The list provides details on the physicochemical/analytical methodologies used in those labs, and the nature of the nanomaterials tested.

4. Planned Network activities for 2015

The next yearly meeting is scheduled on 7-8 July 2015, Parma. Candidate topics for discussionwill be forwarded by the Network members.

Food law is being implemented by the EFSA Panels. Nanomaterials are covered and addressed by cross-referring to the Nanomaterial Guidance from the Scientific Committee published in 2011. Food and feed additives currently comprise nano-fractions, but nano-specific data are not always provided. The EFSA Nano Network advises EFSA to assess the nano-fraction, no matter how small in % of the bulk material (particle size% or mass%).

The EFSA Nano Network also made the suggestion that EFSA could help in giving steer to research activities, especially on how to generate data useful for RA: e.g. low doses should be used in toxicity studies, and exposure assessment should be based on internal dose (not only external dose).

The EFSA Nano Network reminded about the useful work delivered by the former EFSA WG on nano and underlined new developments that could trigger new activities. There is a growing body of evidence showing that NP act very differently from the non-NP (both as hazard, fate in the environment and life cycle) and can cause harm. EFSA could clarify the role of solubility and dissolution in toxicity and also take a position on soft nanomaterials.