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)

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SCIENTIFIC COMMITTEE MEMBERS

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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.

It is claimed that nanotechnologies offer a variety of possibilities for application in the food and feed area – in production/processing technology, to improve food contact materials, to monitor food quality and freshness, improved traceability and product security, modification of taste, texture, sensation, consistency and fat content, and for enhanced nutrient absorption. Food packaging makes up the largest share of current and short-term predicted markets.

Formulation at the nanosize may change the physico-chemical characteristics of materials as compared to the dissolved and micro/macroscale forms of the same substance. Their small size, high surface-to-mass ratio and surface reactivity are important properties, both for new applications and in terms of the associated potential health and environmental risks.

Current uncertainties for risk assessment of ENMs and their possible applications in the food and feed area arise due to presently limited information on several aspects. Specific uncertainties apply to the difficulty to characterize, detect and measure ENMs in food/feed and

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biological matrices and the limited information available in relation to aspects of toxicokinetics and toxicology. There is limited knowledge of current usage levels and (likely) exposure from possible applications and products in the food and feed area.

The risk assessment paradigm (hazard identification, hazard characterization, exposure assessment and risk characterization) is considered applicable for ENMs. However, risk assessment of ENMs in the food and feed area should consider the specific properties of the ENMs in addition to those common to the equivalent non-nanoforms. It is most likely that different types of ENMs vary as to their toxicological properties. The available data on oral exposure to specific ENMs and any consequent toxicity are extremely limited; the majority of the available information on toxicity of ENMs is from *in vitro* studies or *in vivo* studies using other routes of exposure. The risk assessment of ENMs has to be performed on a case-by-case basis.

Current toxicity-testing approaches used for conventional materials are a suitable starting point for risk assessment of ENMs. However, the adequacy of currently existing toxicological tests to detect all aspects of potential toxicity of ENMs has yet to be established. Toxicity-testing methods may need methodological modifications. Specific uncertainties arise due to limited experience of testing ENMs in currently applied standard testing protocols. Additional endpoints presently not routinely addressed may need to be considered in addition to traditional endpoints.

For hazard characterization, the relationship of any toxicity to the various dose metrics that may be used is currently discussed and several dose metrics may need to be explored in addition to mass.

The different physicochemical properties of ENMs compared to conventional dissolved and micro/macroscale chemical counterparts imply that their toxicokinetic and toxicity profiles cannot be fully inferred by extrapolation from data on their equivalent non-nanoforms.

Appropriate data for risk assessment of an ENM in the food and feed area should include comprehensive identification and characterization of the ENM, information on whether it is likely to be ingested in nanoform, and, if absorbed, whether it remains in nanoform at absorption. If it may be ingested in nanoform, then repeated dose toxicity studies are needed together with appropriate *in vitro* studies (e.g. for genotoxicity). Toxicokinetic information will be essential in designing and performing such toxicity studies. For ENMs which are intended to increase the bioavailability of incorporated substances (i.e. ENM carrier systems), the changes in bioavailability should be determined.

Although, case-by-case evaluation of specific ENMs may be currently possible, the Scientific Committee wishes to emphasise that the risk assessment processes are still under development with respect to characterisation and analysis of ENMs in food and feed, optimisation of toxicity testing methods for ENMs and interpretation of the resulting data. Under these circumstances, any individual risk assessment is likely to be subject to a high degree of uncertainty. This situation will remain so until more data on and experience with testing of ENMs become available. The limited database on assessments of ENMs should be considered in the choice of appropriate uncertainty factors.

The Scientific Committee makes a series of recommendations; in particular, actions should be taken to develop methods to detect and measure ENMs in food/feed and biological tissues, to survey the use of ENMs in the food/feed area, to assess the exposure in consumers and livestock, and to generate information on the toxicity of different ENMs.

Key words: Nanotechnologies, Nanotechnology, Nanoscience, Engineered Nanomaterial, ENM, Nano, Food, Feed, Agro-chemical, Food Contact Material, Exposure, Toxicokinetics, Toxicity, Environment, Risk Assessment, Guidance