Eating Nanomaterials: Cruelty-free and Safe? The EFSA Guidance on Risk Assessment of Nanomaterials in Food and Feed

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Summary — Nanomaterials are increasingly being added to food handling and packaging materials, or directly, to human food and animal feed. To ensure the safety of such engineered nanomaterials (ENMs), in May 2011, the European Food Safety Authority (EFSA) published a guidance document on Risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain. It states that risk assessment should be performed by following a step-wise procedure. Whenever human or animal exposure to nanomaterials is expected, the general hazard characterisation scheme requests information from in vitro genotoxicity, toxicokinetic and repeated dose 90-day oral toxicity studies in rodents. Numerous prevailing uncertainties with regard to nanomaterial characterisation and their hazard and risk assessment are addressed in the guidance document. This article discusses the impact of these knowledge gaps on meeting the goal of ensuring human safety. The EFSA’s guidance on the risk assessment of ENMs in food and animal feed is taken as an example for discussion, from the point of view of animal welfare, on what level of uncertainty should be considered acceptable for human safety assessment of products with non-medical applications, and whether animal testing should be considered ethically acceptable for such products.

Key words: alternative test methods, engineered nanomaterials, food and feed safety, nanotoxicology, Three Rs principles, tiered-testing strategy.

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Introduction

Nanotechnology is increasingly being used in industry for the production and processing of human food and animal feed. For example, nanomaterials are added to food contact materials to monitor and improve food quality and freshness. Although food packaging makes up the largest share of current and short-term predicted applications, nanomaterials are also added directly to food to prolong shelf-life, modify its taste, texture, sensation, consistency or fat content, and to enhance nutrient absorption (1). Currently, there are no legal information requirements for assessing the specific risks of nanomaterials in food and animal feed — or in any other area of nanomaterial application.

Following a request from the European Commission (EFSA-Q 2009-00942), early in 2011, the Scientific Committee of the European Food Safety Authority (EFSA) published a draft guidance document on the risk assessment of manufactured nanomaterials to be used in human food and animal feed. This guidance document builds on the EFSA’s Scientific Opinion — Potential Risks Arising from Nanoscience and Nanotechnologies on Food and Feed Safety (1), which considers current toxicity testing approaches as a suitable starting point to assess nanomaterials. It acknowledges that the adequacy of existing test methods has yet to be established, so that any individual risk assessment is likely to be subjected to a high degree of uncertainty.

The draft guidance document underwent a public consultation from 14 January to 25 February 2011. Then, on 9 April 2011, the Scientific Committee adopted a revised version. The finalised Scientific Opinion — Guidance on the risk assessment of the application of nanoscience and nanotechnologies in the food and feed chain was published on 10 May 2011 (2). On the same day, the results of the public consultation were made available on the EFSA website (at: http://www.efsa.europa.eu/de/supporting/pub/126e.htm?wtrl=01).

The EFSA guidance document on risk assessment of nanomaterials in food and animal feed (referred to as the Guidance) encompasses applications of nanotechnologies throughout the entire