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# Regulatory aspects of nanotechnology in the agri/feed/food sector in EU and non-EU countries☆

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ABSTRACT

Nanotechnology has the potential to innovate the agricultural, feed and food sectors (hereinafter referred to as agri/feed/food). Applications that are marketed already include nano-encapsulated agrochemicals or nutrients, antimicrobial nanoparticles and active and intelligent food packaging. Many nano-enabled products are currently under research and development, and may enter the market in the near future. As for any other regulated product, applicants applying for market approval have to demonstrate the safe use of such new products without posing undue safety risks to the consumer and the environment. Several countries all over the world have been active in examining the appropriateness of their regulatory frameworks for dealing with nanotechnologies. As a consequence of this, different approaches have been taken in regulating nano-based products in agri/feed/food. The EU, along with Switzerland, were identified to be the only world region where nano-specific provisions have been incorporated in existing legislation, while in other regions nanomaterials are regulated more implicitly by mainly building on guidance for industry. This paper presents an overview and discusses the state of the art of different regulatory measures for nanomaterials in agri/feed/food, including legislation and guidance for safety assessment in EU and non-EU countries.



## 1. Introduction

The rapid development of nanotechnology has opened the door for innovation in many industrial sectors, including agricultural production, animal feed and treatment, food processing, and food contact materials (hereinafter referred to as agri/feed/food). Some applications (Fig. 1) are already merchandised while many more are currently under research and development (Chaudhry et al. 2008; Parisi, 2014; RIKILT and JRC, 2014). Expected benefits of nanotechnology-enabled products in these sectors include increased efficacy of agrochemicals, enhanced bioavailability of nutrients or more secure packaging material. Such new products or ingredients may, however, also pose a risk to human health and the environment due to their specific properties and to the potential widespread use and exposure.

There are efforts worldwide to address and regulate the production and safe handling/use of nanomaterials (NMs) and nanotechnology either by legislation or by (non-binding) recommendations and guidances (van der Meulen et al. 2014). There is currently no piece of legislation entirely dedicated to regulation of NMs, neither in the EU nor in any other country (Arts et al. 2014). Current legislation is considered by many countries sufficient and specific enough to regulate NMs and nanotechnology (European Commission, 2012; OECD, 2013b); however, amendments have been suggested by several stakeholders, including the European Parliament (European Parliament, 2009) and non-

☆ The opinions expressed in this publication are those of the authors only and do not represent JRC's, EFSA's or RIKILT-Wageningen UR's official position.

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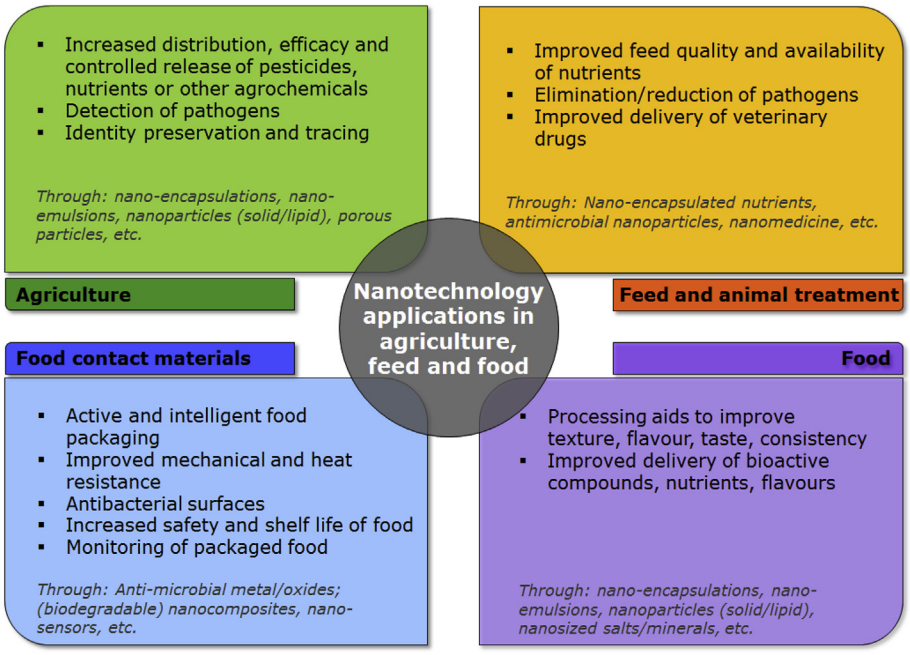


**Fig. 1.** Applications of Nanotechnology and nanomaterials in the agriculture, feed and food sector.

governmental organisations (NGOs) (BEUC et al. 2014). The need for additional guidance to assess the potential risk and for recommendations to ensure the safe use of NMs has been identified, and several expert bodies are active in this field, such as the EU Scientific Committees and Agencies, the Organisation for Economic Cooperation and Development (OECD), the International Standard Organization (ISO) or the US Food and Drug Administration (FDA). Relevant regulatory issues to be considered for NMs include a definition of the term "nanomaterial", registration or authorisation procedures, specific information requirements for risk assessment, risk management and provisions to increase the transparency and traceability on the commercial use, by e.g. labelling or by notifying to a register for products containing NMs (Falkner and Jaspers, 2012; Aschberger et al. 2014).

In this review we aim to provide an overview of existing legislation, and guidances for risk assessment as well as other relevant documents with regard to NMs and nanotechnology in agri/feed/food in EU and non-EU countries. Relevant information was gathered from peer-reviewed publications through a dedicated search in on-line bibliographic databases, websites of the European Commission, European Agencies/Authorities, the Official Journal of the European Union, national governments, national and international organisations and institutions during the period April to August 2013. Additional information was collected through a questionnaire on "Regulation and safety assessment of nanomaterials in agri/feed/food applications" issued in October 2013 (RIKILT and JRC, 2014). Information on non-EU legislation was mainly retrieved from recent reports, such as those published by WHO/FAO (FAO/WHO, 2013) or OECD (OECD, 2013b) and from other relevant sources. Here we present and discuss the results by taking into account also the latest developments (until May 2015) in the area of regulation and safety assessment of nanomaterials in the agri/feed/food sector. Furthermore, we will discuss some of the properties of nanomaterials used in agri/feed/food and the impact of such properties on environmental safety in agricultural applications and on consumer safety for food and food contact materials (FCMs). Issues surrounding the safe use of nanomaterials in the workplace are not within the scope of this paper.

## 2. Nanotechnology applications in agri/feed/food and potential impacts on safety

Nanotechnology in the agri/feed/food sector enables the development and production of products or ingredients at the nanometre scale with new beneficial properties (RIKILT and JRC, 2014) (as summarised in Fig. 1). The same properties that are beneficial for certain applications may, however, also have an impact on health and environmental safety (Chaudhry and Castle, 2011; Cushen et al. 2012).

In agriculture, nanotechnology can contribute to improved pest management and crop protection through better efficacy of pesticides and other agrochemicals such as fertilisers, hormones or growth agents (Chaudhry and Castle, 2011; Bucheli et al., 2013; Kah and Hofmann, 2014). Other agricultural applications include genetic engineering, identity preservation, sensors to monitor soil conditions as well as veterinary medicine (Gogos et al. 2012), which are, however, not the focus of this review. Enhanced efficacy of pesticides and other agrochemicals can be achieved by different ways (Kah et al., 2012). One way is decreasing the size of poorly soluble active ingredients, consequently increasing their solubility and (bio)availability. The other way is mixing/encapsulating active substances in micro or nano-emulsions and nano-dispersions, therefore allowing a slow/targeted release of the active ingredients and/or prevention of premature degradation. Both strategies enable reducing the dose while achieving comparable or even better performance. Any manipulation intended to improve efficacy and release, however, is also likely to impact the environmental fate and behaviour of pesticides or agrochemicals. Slow release of active ingredients may imply higher persistence and consequently higher risk for non-target organisms and potentially greater numbers of residues on harvest. The increased concentration of solvents and surfactants required for "nanoemulsions" many influence the fate of pesticides or have a direct effect due to soil sorption (Bucheli et al., 2013; Kah and Hofmann, 2014). On the other hand a reduced concentration of active ingredients in pesticide products may result in a better environmental safety profile due to lower environmental exposure and lower traces of residues