Governing Nano Foods

Principles-Based Responsive Regulation

EFFoST Critical Reviews #3

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PREFACE AND ACKNOWLEDGEMENTS

This book is an updated and much revised version of a study that has been written to contribute to discussions at the FAO Round Table Sessions at NANOAGRI 2010 in São Pedro, Brazil.[1] UN Food and Agriculture Organization (FAO) requested the initial study. However, the analyses and opinions expressed are those of the authors. They do not necessarily reflect FAO's positions. FAO holds the copyrights of the 2010 study, but authorised the authors to publish the information contained therein. This publication is endorsed by the European Federation of Food Science & Technology (EFFoST) and the Global Harmonization Initiative (GHI).

This book primarily targets at an interdisciplinary audience. This is why the language and content of this book largely deviates from what an audience socialised in the respective science might expect from such a topic. We tried to strike a balance between presenting the core issues of the respective disciplines in a language understandable to an interdisciplinary audience on the one hand, while displaying the main topics from the respective disciplines related to the topic of the book in a most comprehensive way on the other. It will be on the reader to judge if we succeeded.

We are grateful for the trust FAO has placed in the food law team at Wageningen University. The following experts have contributed in various ways to this study:

Gerrit Alink (Wageningen University), Sourav Bhattacharjee (Wageningen University), Arnout Fisher (Wageningen University), Scott Geyer (Massachusetts Institute of Technology), Frans Kampers (Wageningen University), Maryvon Noordam (RIKILT Institute of Food Safety), Onno Omta (Wageningen University) and Merel van der Ploeg (Wageningen University). Other people who helped to make it possible to produce this study are Patrick van Veenendaal and

[1]See <www.nanoagri2010.com> and Caue Ribeiro et al., 2010. International Conference on Food and Agriculture Applications of Nanotechnologies, São Pedro.

Ingeborg Oude Lansink at the Liaison Office of Wageningen University.

FAO has initiated development of a publication in collaboration with Monash University on Nanotechnology Applications in Food and Agricultural Sectors: Principles and Guidance for Food Safety Regulation. With the permission of FAO, parts of the text from this draft publication have been included in the appendix of this paper.

Bernd van der Meulen

Wageningen 15 October 2013

EXECUTIVE SUMMARY

The objective of this book is to help to test and improve existing regulatory infrastructures – or if need be to build new ones – in such a way that they can ensure food safety in general in the face of the challenges posed by nanotechnologies.

This book argues for a principles-based regulatory framework for nanotechnologies. In contrast to most conventional regulatory wisdom that identifies gaps in existing regulatory systems with a view of filling them with detailed rules specifically related to the risks emerging from nanotechnology,[1] this book subscribes to research on the ineffectiveness of such rule-based regulation. Instead, and in line with insights from research mainly from the sector of financial regulation,[2] we argue for a more responsive and thus effective principles-based framework to deal with nanotechnology in the food sector. Such a framework may provide an instrument to benchmark existing regimes and to design new or improved structures.

This study builds on existing principles of food safety regulation and the interpretation of these principles at national and regional levels. The study works from the bottom-up to build a regulatory system for addressing the risks connected to nanotechnology applications in food production, despite the fact that profound knowledge on the impact of nanotechnologies is still lacking. The primary objective of the proposed regulatory system is to protect the health and safety of consumers of foods that are likely to contain substances obtained by nanoscale chemosynthesis or engineered nanoparticles. This relates not only to substances included in the food but also to substances that may leave traces in food due to their use at various stages of the food chain. Examples of such substances may be pesticides, equipment and packaging materials.

[1]See Appendix C.

[2]See *inter alia* Julia Black, Martyn Hopper and Christa Band, 2007. Making a success of principles-based regulation. Law and Financial Markets Review, 191–206.

There are existing and generally agreed principles on which regulatory approaches to food safety regulation are based. The proposed structure chooses responsibility including liability of food businesses as an underlying principle. Likewise, nanotechnologies applied to foods – nanomaterial in packaging or nanoproducts used in food preparation – may require appropriate safety studies. The core of nanofood safety regulation is a case-by-case premarket approval requirement for foods to which nanotechnologies have been applied. Where premarket approval is required, the sponsor of the product to which nanotechnology has been applied must provide methods of detection and scientific proof of safety of the product at issue. The scientific community and public authorities must develop and agree on methods of risk assessment. To ensure that this principle can be implemented in the context of problems stemming from the foods applications of nanotechnology, registration is desirable of at least all those businesses that bring such foods to the market. Furthermore businesses are required to have systems in place that enable the traceability of such foods. To protect property rights and enable food businesses to benefit from approved applications, applicants should enjoy an exclusive right for a certain period from the moment of approval on. After this exclusivity period, the approval should become generic to avoid obstruction of innovation and unnecessary suffering that may result from a repetition of safety testing on humans or animals.

The leading risk assessment authorities and the international community are called upon to come to understandings regarding cooperation and mutual recognition that ensure world-wide market access for approved applications of nanotechnologies in the food sector and protect businesses from the need to submit to multiple approval procedures. Taken together the proposed measures constitute a regulatory framework capable of ensuring the safety of foods to which nanotechnology has been applied.

ABBREVIATIONS

ADI	acceptable daily intake
BSE	bovine spongiform encephalopathy
CAC	Codex Alimentarius Commission (FAO/WHO)
CCP	critical control point
CFR	Code of Federal Regulations (USA)
EFFL	European Food and Feed Law Review
EFSA	European Food Safety Authority
ENMs	engineered nanomaterials
ENPs	engineered nanoparticles
EPA	Environmental Protection Agency (USA)
EU	European Union
FAO	Food and Agriculture Organization (UN)
FCM	food contact material
FDA	Food and Drug Administration (USA)
FFDCA	Federal Food, Drug and Cosmetic Act (USA)
FSA	Food Standards Agency (UK)
FSAI	Food Safety Authority of Ireland
FSANZ	Food Standards Australia New Zealand
GATT	General Agreement on Tariffs and Trade (WTO)
GI-tract	gastrointestinal tract
GMO	genetically modified organism
GRAS	generally recognized as safe (USA)
HACCP	hazard analysis and critical control points
ICCPR	International Covenant on Civil and Political Rights (UN)
ICESCR	International Covenant on Economic, Social and Cultural Rights (UN)
INS	International Numbering System
ISO	International Organization for Standardization
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
JMPR	Joint FAO/WHO Meeting on Pesticide Residues
NM	nanomaterials
nm	nanometre

NP	nanoparticles
NT	nanotechnology
MRL	maximum residue limit
OECD	Organisation for Economic Co-operation and Development
PARNUTS	foods for particular nutritional uses
PHS Act	Public Health Services Act (USA)
RA	risk assessment
RDA	recommended daily allowance
RFID	radio frequency identification
SPS Agreement	Agreement on the Application of Sanitary and Phytosanitary measures (WTO)
UK	United Kingdom
UN	United Nations
USA	United States of America
USC	United States Code
USDA	Department of Agriculture (USA)
WHO	World Health Organization
WTO	World Trade Organization

CONTENTS

CHAPTER 1

Introduction

1.1 WHY REGULATE THE APPLICATION OF NANOTECHNOLOGIES IN FOOD?

Regulatory intervention in product markets such as trade in foods is based on the insight of the imperfection of markets.[1] If nanotechnologies would be subject to the humble forces of markets alone, the risk that negative externalities and information asymmetry would lead to unwanted outcomes would be too high to leave nanotechnology unregulated. However, highly regulated markets may face a detriment in a competition with laxer-regulated markets in the world (so-called Delaware effect[2]). This would mean that businesses that offer nanofoods may be more likely to offer their products in legal regimes where they face a more favourable regulatory framework. The stricter regulation would cut consumers off from getting access to the benefits such a new technology would provide. If the regulated market is big enough, however, strict regulation can also lead to a form of *de-facto* standard setting, which drives other, laxer-regulated regimes to comply with the regulatory standard of the highly regulated regime (California[3]- or Brussels Effect[4]). Hence, regulatory regimes also compete for effectiveness of their methodology across borders. In any way, regulatory regimes shall have an interest in finding an optimal level of regulation, which on the one hand provides for the safety of consumers but gives them access to new technologies, which have the potential to make their life better, on the other. Not regulating nanofoods at all is hence not a viable option, but their prohibition is also not the right way to go. Like in any kind of product safety regulation, the main dilemma for policy makers in regulation of nanofoods is to find the optimal level of regulation in product safety.

[1]See Arcuri, 2000.
[2]Coffee, 1987, 761–763.
[3]Vogel, 1995.
[4]Bradford, 2012.

In the food and agricultural sectors, regulatory intervention is framed in human rights obligations, which addresses these shortfalls of imperfect markets from a legal perspective. The vast majority of states in the world has committed themselves to the progressive realisation of the human right to adequate food. As per 10 October 2013, 160 states are party to the United Nations (UN) International Covenant on Economic, Social and Cultural Rights (ICESCR).[5] State parties' responsibility regarding adequate food encompasses diverse dimensions. In order to realise the right to food, states have to solve the dilemma to find an optimal level of regulation: States should on the one hand regard favourably technological and other developments that may contribute to the nutrition of the population in general and of vulnerable groups in particular.[6] On the other, they shall protect[7] people from adverse substances[8] in food.[9]

Nanotechnologies may be relevant from both perspectives: the perspective of providing the world with improved possibilities for sustainable agricultural production to better meet nutritional needs, but also the perspective of hazards and risks from which consumers should be protected. The challenge for governments is to strike the right balance in creating, enabling and protecting regulatory environments.

1.2 APPLICATIONS OF NANOTECHNOLOGIES IN FOOD AND AGRICULTURE

In recent years, properties of substances and processes at nanoscale command scientific attention within a converging field of physics, chemistry, biology, materials sciences and other disciplines. This attention leads to increased understanding regarding existing products and processes, but also to the development of new technologies and

[5]See <http://treaties.un.org/Pages/ViewDetails.aspx?src = TREATY&mtdsg_no = IV-3&chapter = 4&lang = en>.

[6]Article 11(2)(a) ICESCR.

[7]On the state obligations to respect, *protect* and fulfil, see General Comment 3 on the nature of State parties' obligations, of the UN Committee on Economic, Social and Cultural Rights.

[8]On the concept of adequacy encompassing, food in a quantity and quality sufficient to satisfy the dietary needs of individuals, free from adverse substances and acceptable within a given culture, see General Comment 12 on the right to adequate food.

[9]On the implementation of the human right to adequate food, see also Voluntary Guidelines, to support the progressive realisation of the right to adequate food in the context of national food security, adopted by the 127th Session of the FAO Council November 2004, Food and Agriculture Organization of the United Nations, Rome, 2005.

substances. While there are is controversy about a legal definition of nanomaterial,[10] nanotechnology can be thought of as any technology which either incorporates or employs nanomaterials or involves processes performed at the nanoscale.[11] Nanotechnologies are generally seen as new and fast emerging fields that involve the manufacture, processing and application of structures, devices and systems by controlling shape and size at the nanometre scale.

Nanotechnologies have the potential to impact many aspects of food and agricultural systems, as nano-enabled technologies can be applied along the entire food production chain from production to consumption (e.g. during cultivation – nanopesticides, food processing, packaging, pathogen detection, etc.).

During a FAO/WHO Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications (June 2009), the following broad categories of nanotechnology applications in the food and feed sector were identified on the basis of the analysis conducted by Chaudhry et al. (2008):[12]

1. Where nanotechnology processes and materials have been employed to develop food contact materials (FCMs). This category includes nanomaterial-reinforced materials, active FCM designed to have some sort of interaction with the food or environment surrounding the food and coatings providing surfaces with nanomaterials or nanostructures.
2. Where food/feed ingredients have been processed or formulated to form nanostructures. This category includes applications that involve processing food ingredients at nanoscale to form nanostructures or enhance taste, texture and consistency of the foodstuffs.
3. Where nano-sized, nano-encapsulated or engineered nanomaterial (ENM) ingredients have been used in food/feed. This category includes nanoscale ingredients, including additives (such as colourants, flavourings and preservatives) and processing aids (including nano-encapsulated enzymes) that can be produced for a variety of uses.

[10]See Bowman et al., 2010; D'Silva, 2011.

[11]Her Majesties Government, UK Nanotechnologies Strategy, Small Technologies, Great Opportunities, 2010, p. 6.

[12]Based on the extensive review by Chaudhry et al. (2008), Chau et al. (2007) and FAO/WHO (2009).

4. Biosensors for monitoring condition of food during storage and transportation. This category includes packaging which include indicators.
5. Other indirect applications of nanotechnologies in the food and feed area, such as the development of nanosized agro-chemicals (including fertilizers, pesticides, etc.), or veterinary medicines.

1.3 THE CHALLENGE TO REGULATE NANOTECHNOLOGY IN FOOD

Nanotechnologies are the latest in a series of scientific advances that, when applied to the food supply, can both deliver benefits for consumers *and* challenge the ability of regulators to evaluate and ensure safety. There are three main factors that underlie the challenges.

1. **A wide diversity of potential food applications of nanotechnology.**
   'Nanotechnology' is not one thing but rather a set of tools for manipulating matter at the molecular and atomic level. At this 'nanoscale' familiar substances (like silica, carbon and clay) take on new properties that have a wide range of potential application and each new application of nanotechnology can raise new, application-specific scientific and regulatory questions.
2. **The same novel properties of nanomaterials that can convey benefits are also likely to raise new safety questions.**
   The consensus of scientific opinion is that *nanoscale material cannot be assumed to be safe* based on what is known about the same substance at conventional, bulk scale. At least until there is a better understanding of the safety issues in general, each food application will need to be assessed carefully to ensure safety.
3. **The scientific tools used today to evaluate the safety of conventional-scale food substances may not be fully applicable to nanoscale substances.**
   For example, the expression of dose levels in animal toxicity studies in terms of mass per unit of body weight may not work for nanoscale particles, for which toxicity could be a function of the ratio of surface area to mass rather than the absolute mass of the substance being tested. In addition, the potential for nanoscale materials to be distributed in the body and to interact at the cellular level differently than conventional-scale materials may require adaptation of existing toxicity test protocols or entirely new study designs.

In short, *to* perform the product-specific safety assessments required for nanoscale materials, food safety regulators may need scientific tools that do not presently exist including methods of detection.

These scientific challenges and uncertainties do not mean that the hands of food safety regulators are tied or that they cannot do their job of protecting food safety while enabling the free movement of foodstuffs. The principles underlying existing practices for evaluating and regulating the safety of substances added intentionally to food provide a strong basis for moving forward. This study highlights the benefits of a food safety framework which is based on such a principles-based regulation instead of rules-based. We will also highlight the limits and possible adjustments of such a framework (i.e. a functional definition, see Appendix B).

1.4 OBJECTIVES, METHODS AND SCOPE OF THE STUDY

This study highlights the benefits of a food safety framework which is principles based. Given the gaps in knowledge and the uncertainties regarding risks of food applications of nanotechnologies, we argue that its regulation shall be based on principles rather than on rules. We build our claim on the insights of research formulated by Julia Black on principles-based regulation, which aims to cope with the limitations of the capacity of traditional rule-based regulation to manage the challenges arising in complex markets with uncertain risks.[13] Principles-based regulation, as developed in financial market regulation, consists of three elements:[14]

1. broad-based standards in preference to detailed rules
2. outcomes-based regulation
3. increasing senior management responsibility.

One main element is the switch in perspective of regulation: Rules-based regulation tries to prescribe the content of the regulated behaviour to a maximum extent, avoiding regulatory gaps that leave room for interpretation. In principles-based regulation, however, principles deliberately allow for such gaps, which are then filled by application: 'Regulatory conversations as to the meaning and application of the rules take centre stage as their meaning and application is elaborated

[13]Black, 2008, 425.
[14]See Black et al., 2007, 191.