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OECD Science, Technology and Industry Policy Papers No. 4

# Regulatory Frameworks for Nanotechnology in Foods and Medical Products

## SUMMARY RESULTS OF A SURVEY ACTIVITY

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# FOREWORD

Nanotechnology applications have been reported across a number of specific product areas, including foods and medical products. Food and medical products are subject to regulatory oversight in many countries to ensure their safety and, in some cases, effectiveness. As nanotechnology develops, countries/regions have begun to develop, refine, and/or articulate regulatory approaches for foods and/or medical products, and invest in regulatory science and other research efforts to support the responsible development of nanotechnology in these areas.

In 2010, the OECD Working Party on Nanotechnology (WPN) began a project, the objective of which was to provide an inventory, summary, and overview of regulatory approaches, legislative regimes, and government-sponsored regulatory science research and other research programmes, institutions, and infrastructure in foods and medical products that involve the application of nanotechnology. This survey activity was carried out from early 2011 to early 2012; responses were then analysed and compiled in the current report.

The development of this project was based on the active participation of 12 WPN delegations: Australia, Canada, European Union, France, Germany, Japan, Korea, the Netherlands, Norway, Poland, the Russian Federation and the United States.

The Committee for Scientific and Technological Policy (CSTP) agreed to the declassification of this report in January 2013.

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## ACRONYMS

| | |
|---|---|
| EC…… | European Commission |
| EHS……. | Environmental, Health, and Safety |
| ENP……. | Engineered Nanoparticle |
| EU…… | European Union |
| FDA…… | Food and Drug Administration (United States) |
| FSIS……. | Department of Agriculture's Food Safety and Inspection Service (United States) |
| HC…… | Health Canada |
| HPFB……. | Health Products and Foods Branch |
| INRA…… | Institut National de la Recherche Agronomique (France) |
| KEMA…… | Keuring Van Electrotechnische Materialen (Netherlands) |
| MIP…… | Molecularly Imprinted Polymers |
| NANOMAT programme | NANOscience, nanotechnology and MATerials (Norway) |
| NIFA…… | National Institute of Food and Agriculture (United States) |
| NNI……. | National Nanotechnology Initiative (United States) |
| OECD……. | Organisation for Economic Co-operation and Development |
| RIVM…….. | National Institute for Public Health and the Environment (Netherlands) |
| TPD…….. | The Therapeutic Products Directorate (Canada) |
| US……... | United States |
| WPMN…… | OECD Working Party on Manufactured Nanomaterials |
| WPN…… | OECD Working Party on Nanotechnology |

## EXECUTIVE SUMMARY

In 2010, the Organisation for Economic Co-operation and Development (OECD) Working Party on Nanotechnology (WPN) began a project, the objective of which was to provide an inventory, summary, and overview of regulatory approaches,[1] legislative regimes,[2] and government-sponsored regulatory science research and other research programmes, institutions, and infrastructure in foods and medical products that involve the application of nanotechnology.

The project entitled "Regulatory Frameworks for Nanotechnology in Food and Medical Products" is based on a survey, for each of the food and medical product areas, that addressed questions related to: 1) the regulatory frameworks being used to provide oversight for the use of nanotechnology in the relevant field; 2) the legislative frameworks relevant to these regulatory frameworks; and 3) relevant government-supported research programmes and institutions. The survey activity was carried out from early 2011 to early 2012; responses were then analysed and put together in the present report. This survey activity was not intended to prioritise or rank responses from any one delegation or region but to better inform intergovernmental discussions among delegations. To that end, data collection in areas of shared interest in this survey may help support and inform future intergovernmental discussions and research-related activities on foods and medical products. The survey activity is specifically intended to provide a snapshot of current activities across OECD WPN delegations, with respect to regulation, legislation, and government sponsored regulatory science research and other research activities relevant to nanotechnology.[3]

The development of this project was based on the active participation of twelve WPN delegations: Australia, Canada, European Union, France, Germany, Japan, Korea, the Netherlands, Norway, Poland, the Russian Federation, and the United States. These twelve delegations responded to either the survey on foods, the survey on medical products, or to both surveys (see Table 1).

[1] For purposes within this report, the term 'Regulatory Frameworks' covers the approaches to regulate product areas such as the types of products, the effective status of the regulation, scope and applicability.

[2] For purposes within this report, the term 'Legislative Regimes' covers relevant statutory authorities, their effective status, key legal provisions, and the administrative bodies that provide oversight.

[3] This report is for information purposes only and provides an overview of some of the regulatory frameworks applicable to food and medical products that may contain nanomaterials or may otherwise involve the application of nanotechnology. It is not intended to provide guidance or recommendations related to the regulation of nanotechnology-derived food or medical products. Nor does it include a list or summary of all relevant requirements established by national or regional regulatory authorities. Product manufacturers and distributors are advised to refer to applicable legal requirements as well as any recommendations issued by regulatory authorities. Products intended for sale in a specific country or region must comply with and otherwise not conflict with requirements established for that country or region.

**Table 1. Delegations that responded to questionnaires in foods and medical products**

| | Foods | | | Medical Products | | |
|---|---|---|---|---|---|---|
| | **Regulatory frameworks** | **Legislative regimes** | **Government-sponsored regulatory science research and other research activities** | **Regulatory frameworks** | **Legislative regimes** | **Government-sponsored regulatory science research and other research activities** |
| **Australia** | • | • | | | | |
| **Canada** | • | • | • | • | • | • |
| **European Union** | • | • | • | • | • | • |
| **France** | • | • | • | • | • | |
| **Germany** | • | • | | • | • | |
| **Japan** | | • | • | • | • | |
| **Korea** | • | • | • | | | |
| **Netherlands** | • | • | • | • | • | • |
| **Norway** | • | • | • | • | | • |
| **Poland** | • | • | • | • | • | • |
| **Russian Federation** | • | • | • | • | • | • |
| **United States** | • | • | • | • | • | • |

For the foods survey, eleven delegations responded to the regulatory frameworks survey component, twelve delegations responded to the legislative regimes survey component, and ten delegations responded to the government-sponsored regulatory science research and other research activities survey component. For the medical products survey, ten delegations responded to the regulatory frameworks survey component, nine delegations responded to the legislative regimes survey component, and seven delegations responded to the government-sponsored regulatory science research and other research activities survey component.

Responses received from participating delegations were analysed and a number of observations were drawn from this analysis. Delegations reported: 1) general regulatory approaches for foods and medical products to oversee products that may contain nanomaterials or otherwise involve the application of nano-technology; 2) various legislative regimes relevant to foods and medical products; and 3) government-sponsored regulatory science research and other research activities. Delegations also reported mechanisms to guide experts, the public and regulated entities in the foods and medical product sectors.

To the foods survey, some delegations reported regulatory approaches for foods, including regulation of products that may contain nanomaterials or otherwise involve the application of nanotechnology. Delegations also reported having published or articulated regulatory approaches to nanotechnology. Variations in the type, nature, and extent of the review process depended on the statutory authority governing the food substance/product and the products current regulatory status. Several delegations reported existing government-sponsored regulatory science research or other research activities that focused on food packaging, food additives, food contact materials, and nutrition, and more than three delegations reported metrology and analytical methods, toxicology, exposure, nutrient bioavailability, and food preservations as the most studied food areas.

To the medical products survey, some delegations reported regulatory approaches for medical products, including regulation of products that may contain nanomaterials or otherwise involve the application of nanotechnology. Most delegations also identified existing legislation for medical product areas and, in most cases, the existing legislation was also applicable to products that may contain nanomaterial or otherwise involve the application of nanotechnology. Delegations reported support and guidance for regulated entities primarily via organisation websites or having published or articulated regulatory approaches to nanotechnology. Variations in the type, nature, and extent of the review process also depend on the statutory authority governing the medical product and its regulatory status. Most delegations reported government-sponsored regulatory science research or other research activities in the medical product areas. Exposure science was reported across all delegations. Metrology and analytical methods and toxicology were reported by a majority of delegations. All delegations reported collaborations in various areas of regulatory science research or additional research activities with academia, other government agencies within their country, or other government agencies internationally. Some delegations also reported collaborations with industry.

Analysis of responses received from participating delegations indicated that foods and medical products that may contain nanomaterials or otherwise involve the application of nanotechnology are covered under existing national and/or regional legislative and regulatory frameworks that are relevant and applicable to foods and medical products. Several delegations identified regulatory frameworks for the same foods products (food additives, food contact materials) and medical products (drugs, medical devices). Delegations also reported similar regulatory scopes for foods and medical products (i.e. manufacturing, importation, and commercialisation/marketing), and the development of regulatory approaches for nanotechnology. The primary purpose of this inventory is to better inform intergovernmental discussions among delegations. To that end, data collection in areas of shared interest in this survey may help support and inform future intergovernmental discussions and research-related activities on foods and medical products.

# INTRODUCTION

The Organisation for Economic Co-operation and Development (OECD) refers to nanotechnology as a set of technologies that enables the manipulation, study or exploitation of very small structures and systems.[4] Nanotechnology allows scientists to work at the nanoscale to create, explore, and manipulate the biological and material worlds for a number of uses, including diverse applications such as electronics, energy, environmental remediation, medicine, security, and space[5] (NNI, 2011). The field of nanotechnology is multidisciplinary, spanning biology, material science, chemistry, physics, and engineering. Application of this new field has already led to the development of novel materials, medical products, and electronics to name a few; and future advances have the potential to affect virtually every area of economic activity and aspect of daily life.

Nanotechnology applications have been reported across a number of specific product areas, including foods (such as enhanced protection offered by improved food packaging materials[6], or improved delivery of a functional ingredient or a nutrient in food[7] and medical products (such as increased bioavailability, decreased dosage, or increased potency of a drug product[8] and decreased toxicity of a drug product[9]). Foods and medical products are subject to regulatory oversight in many countries to ensure their safety and, in some cases, effectiveness. Nanotechnology can pose new challenges to governments to support its responsible development when used in food and medical products, through an appropriate and balanced oversight.

As nanotechnology develops, countries/regions have begun to develop, refine, and/or articulate regulatory approaches for foods and/or medical products, and invest in regulatory science and other research efforts to support the responsible development of nanotechnology in these areas.

4 OECD description of nanotechnology (accessible online at: www.oecd.org/sti/nano).

5 See for example, NNI (National Nanotechnology Initiative) (2011), Environmental, Health, and Safety Research Strategy, Executive Office of the President, http://nano.gov/node/681.

6 Chaudhry, Q., M. Scotter, J. Blackburn et al. (2008), "Applications and implications of nanotechnologies for the food sector", *Food Additives and Contaminants*, Vol. 25, pp. 241-258.

7 See for example, Chen L, G.E. Remondetto, and M. Subirade (2006), "Food protein-based materials as nutraceutical delivery systems", *Trends in Food Science & Technology*, Vol. 17, pp. 272-283; and IOM (Institute of Medicine) (2009), Nanotechnology in food products: Workshop Summary, Washington, DC: The National Academies Press.

8 Merisko-Liversidge, E.M. and G.G. Liversidge (2008), "Drug nanoparticles: formulating poorly water-soluble compounds", *Toxicologic Pathology*, Vol.36, pp. 43-48.

9 Paciotti, G.F., L. Myer, D. Weinreich et al. (2004) Colloidal gold: a novel nanoparticle vector for tumor directed drug delivery, *Drug Delivery*, Vol.11, pp. 169-183.

In 2010, the OECD Working Party on Nanotechnology (WPN) (see Box 1) agreed to a survey activity that would help provide an inventory, summary, and overview of regulatory approaches, legislative regimes, and government-sponsored regulatory science research and other research programmes, institutions, and infrastructure, in foods and medical products that involve the application of nanotechnology[10]. Twelve volunteer delegations were surveyed over 2011 and early 2012 - Australia, Canada, European Union, France, Germany, Japan, Korea, the Netherlands, Norway, Poland, the Russian Federation, and the United States.

Results of the survey are reported in this paper.

**Box 1. Role of the OECD Working Party on Nanotechnology**

The OECD Working Party on Nanotechnology (WPN) was established in March 2007 to advise upon emerging policy issues of science, technology and innovation related to the responsible development of nanotechnology. It is a subsidiary group of, and receives its mandate from, the Committee for Scientific and Technological Policy (CSTP).

The WPN works co-operatively with other OECD groups, including the Working Party on Manufactured Nanomaterials (WPMN, subsidiary to the Chemicals Committee); the Working Party on Biotechnology (WPB); the group of National Experts for Scientific and Technological Indicators (NESTI) and their parent committees. (For more information, please visit: www.oecd.org)

## Purpose of the inventory

The development and analysis of this inventory is designed to address three goals.

- First, to generate an inventory, summary, and overview of regulatory approaches, legislative regimes, and government-sponsored regulatory science research and other research programmes, institutions, and infrastructure for nanotechnology in the foods and medical products areas.
- Second, to inform WPN discussions, by enhancing the understanding of different approaches used across delegations participating in the WPN as well as among public stakeholders and industry.
- Third, to identify areas of shared interest through the collection of specific data sets (i.e. inventory of regulatory frameworks, legislation, and government-sponsored activities).

[10] This report is for information purposes only and provides an overview of some of the regulatory frameworks applicable to food and medical products that may contain nanomaterials or may otherwise involve the application of nanotechnology. It is not intended to provide guidance or recommendations related to the regulation of nanotechnology-derived food or medical products. Nor does it include a list or summary of all relevant requirements established by national or regional regulatory authorities. Product manufacturers and distributors are advised to refer to applicable legal requirements as well as any recommendations issued by regulatory authorities. Products intended for sale in a specific country or region must comply with and otherwise not conflict with requirements established for that country or region.

## Survey focus

The project is based on a survey for each of the food and medical products areas. Both product sectors have observed advances in government approaches in the research, development, application, and commercialisation of nanotechnology. Surveys addressed questions related to: 1) the regulatory frameworks being used to provide oversight for the use of nanotechnology in the relevant field; 2) the legislative framework relevant to these regulatory frameworks; and 3) relevant government-supported research programmes and institutions. Each survey section is detailed below and a description of the areas of survey focus is available in Box 2.

**Box 2. The focus of the survey**

**Regulatory frameworks**: For the purposes of this document, regulatory frameworks consist of the standards and rules which regulate a particular class of persons, acts, or items promulgated by government agencies pursuant to authority granted by statute.

**Legislative frameworks:** For the purposes of this document, legislative frameworks refer to the specific acts passed by a country's federal legislature and pertaining to the regulation of foods and medical products which may contain nanomaterials or otherwise involve the application of nanotechnology. Legislative acts, once passed, are codified as statutes, which either authorise a regulatory agency to regulate a class of persons, acts, or items, or which themselves regulate a class of persons, acts, or items.

**Regulatory science research and other research activity frameworks:** For the purposes of this document, research activities consist of regulatory science research and other research activities sponsored by government organisations and their affiliates to support or inform assessments needed by government organisations for regulatory or other purposes.

For the foods area, this survey sought to identify regulatory frameworks, legislative regimes, and government-sponsored regulatory science research and other research programmes, institutions, and infrastructure that encompass or specifically address nanotechnology in foods. The survey targeted information regarding regulation of various food substances such as food ingredients, food additives, colourings, and food contact substances.

For the medical products area, this survey also sought to identify regulatory frameworks, legislative regimes, and government-sponsored regulatory science research and other research programmes, institutions, and infrastructure that encompass or specifically address nanotechnology in drugs, medical devices, biological products, and 'combination products' (i.e. products that can combine attributes of multiple medical product categories).

The survey section covering regulatory frameworks gathered information on regulatory approaches relevant to nanotechnology by asking delegations about the types of products being regulated, the effective status of the regulation, and the scope and applicability of regulation. The survey also gathered descriptive information about various approaches to regulation such as working definitions, review of requirements and procedures, guidance available to manufacturers, and the extent of public engagement and stakeholder input.

The survey section covering legislative regimes explored information about legislative regimes, including relevant statutory authorities, their effective status, key legal provisions and the administrative bodies which provide oversight that serve as the basis for the development and implementation of regulatory approaches.

The survey section covering regulatory science, research and other research activities focused on programmes, institutions and infrastructure established to support the development or regulation of nanotechnology in the foods or medical product areas. The survey explored government-sponsored regulatory science research activities and other research, with a focus on areas of study, collaboration with stakeholders and the administrative or sponsoring bodies.

Definitions of the key terms used in the surveys are provided in Annex 2 to this report.

## SUMMARY OF RESPONSES ON CURRENT LEGISLATION AND REGULATIONS ESTABLISHING OVERSIGHT

Government authorities have published documents elaborating their current thinking related to the regulation of nanotechnology products.[11] Private entities have also published reports on governance and research approaches as well as the potential benefits and risks associated with nanomaterials.[12,13]

Approaches to regulation continue to evolve and countries continue to develop statements relevant to the regulation of products in the foods and medical products sectors that may involve nanomaterials or otherwise involve the application of nanotechnology. The following section presents a summary of current legislation and regulations establishing oversight of nanotechnology among twelve OECD-WPN delegations.

### Legislation and regulation relevant to food products

#### *Legislation relevant to food products*

Overall, eleven of the twelve participating delegations responded to the survey section entitled, 'Description and summaries of legislation for foods'; Table 2 provides a summary of those responses. All of the eleven delegations reported at least one legislative act was in effect. Most delegations reported legislation that was applicable to nanotechnology. Several delegations reported more than one legislative mandate or more than one organisation responsible for statutory implementation. Annex 3a provides additional descriptions of participating delegation's food legislation.

[11] See for example, EC (2011), Commission Recommendation on the Definition of Nanomaterial, Brussels, http://ec.europa.eu/environment/chemicals/nanotech/pdf/commission_recommendation.pdf; Health Canada (2011), Policy Statement on Health Canada's Working Definition for Nanomaterial, http://www.hc-sc.gc.ca/sr-sr/pubs/nano/pol-eng.php; NICNAS (Australia National Industrial Chemicals Notification and Assessment Scheme) (2010), Adjustments to NICNAS new Chemicals Processes for Industrial Nanomaterials, http://www.nicnas.gov.au/Publications/Chemical_Gazette/pdf/2010oct_whole.pdf#page=14; and NNI (National Nanotechnology Initiative) (2011), Policy Principles for the US Decision-Making Concerning Regulation and Oversight of Applications of Nanotechnology and Nanomaterials, http://www.whitehouse.gov/sites/default/files/omb/inforeg/for-agencies/nanotechnology-regulation-and-oversight-principles.pdf.

[12] See for example, Chatham House (2009), Securing the Promise of Nanotechnologies: Towards Transatlantic Regulatory Cooperation, www2.lse.ac.uk/internationalRelations/centresandunits/regulatingnanotechnologies/nanopdfs/REPORT.pdf.

[13] See for example, FAO/WHO (2010), Expert Meeting on the Application of Nanotechnologies in the Food and Agriculture Sectors: Potential Food Safety Implications, Meeting Report, http://whqlibdoc.who.int/publications/2010/9789241563932_eng.pdf; Regulatory Governance Initiative (2009), International Approaches to the Regulatory Governance of Nanotechnology, www.nanolawreport.com/uploads/file/Nanotechnology_Regulation_Paper_April2009[1].pdf; and National Academies of Sciences (2009), Nanotechnology in Food Products: Workshop Summary, the National Academies Press, Washington, DC, http://www.nap.edu/openbook.php?record_id=12633.

Variations in the type, nature, and extent of the review process depend on the statutory authority governing the food substance/product and its regulatory status. In most cases, delegations reported legislation for foods, in general, including those that contained nanomaterials or otherwise involved the application of nanotechnology.

**Table 2. Description and summaries of legislation for foods**

| **Delegation (Responsible Organisation)** | **Existing legislation** | **Summary** |
|---|---|---|
| **Australia** (Foods Standards Australia New Zealand) | Food Standards Australia New Zealand Act | Established the Food Standards Australia New Zealand and authorises it to regulate food. |
| **Canada** (Health Canada) | Food and Drugs Act | Authorises Health Canada to regulate, among other products, food and drugs. |
| **European Union** (European Commission [EC], European Food Safety Authority [EFSA]) | General Food Legislation (EC 178/2002) | Established the EFSA and establishes food safety requirements. |
| | Novel Food (EC 258/97), | Established safety requirements for foods which had no significant consumption prior to 1997. |
| | Food Additives Regulation (EC 1333/2008), | Regulates the use and labelling of food additives. |
| | Plastics Regulation (EC 10/2011) | Regulates the use of plastic materials and articles intended to come into contact with food. |
| | Active and Intelligent Materials Regulation (EC 450/2009) | Regulates the use of active and intelligent materials and articles intended to come into contact with food. |
| | Labelling Regulation (EC 1169/2011) | Regulates the labelling of foods for the purposes of consumer protection. |
| **France –** (Ministry of Agriculture/ General Directorate on Food, European Commission, European Food Safety Authority) | Grenelle II Law<br>Decree n° 2012-232<br>Order of 6 august 2012 | Establish a system of compulsory declaration for all nanomaterials. |
| | Applicable European Commission Regulations (see EC legislation above) | See EC legislation above. |
| **Korea** (Korea Food and Drug Administration) | Food Sanitation Act | Authorises the Ministry of Health and Welfare to regulate foods for the purposes of national health. |
| | Health and Functional Food Act | Authorises the Ministry of Health and Welfare to regulate and license the production of health and functional foods. |
| | Framework Act on Food Safety | Authorises the regulation of food for the purpose of safety. |

| | | |
|---|---|---|
| **Germany** (Federal Ministry of Food, Agriculture and Consumer Protection, European Commission, European Food Safety Authority) | German Food and Feed Code (LFGB) | Implements the provisions of EU Regulation 178/2002. |
| | Applicable EC Regulations (see EC legislation above) | See EC legislation above. |
| | Cellulose Film Directive (Directive 2007/42/EC) | Regulates the use of cellulose film based materials and articles that come into contact with food. |
| **Japan** (Ministry of Health, Labor, and Welfare) | Food Sanitation Law (Law no. 233) | Authorises the regulation of foods by the Ministry of Health, Labour, and Welfare for the purposes of health and safety. |
| **Netherlands** (European Commission, European Food Safety Authority) | Applicable EC Regulations (see EC legislation above) | See EC legislation above. |
| **Norway** (European Commission, Norwegian Food Safety Authority, European Food Safety Authority) | Applicable EC Regulations (see EC legislation above) | See EC legislation above. |
| **Poland** (European Commission, European Food Safety Authority) | Applicable EC Regulations (see EC legislation above) | See EC legislation above. |
| **Russian Federation** (Federal Service for Surveillance on Consumer Rights Protection and Human Well-being, Ministry of Health and Social Development of the Russian Federation) | "Federal Law of 21 of November, 2011, on the Fundamentals of Protection of the Public Health" and others | Implements the following provisions, among others: Methods of classification of products and nanoindustry technologies in terms of their potential danger; Guidelines on selection order for the for the nanomaterials control sampling; Control for nanomaterials applied in food products, used in the chemical industry, in packaging materials, and applied in agriculture; and various testing for nanomaterials in the tissues of animals and plants. |

| | | |
|---|---|---|
| **United States (US)** (Food and Drug Administration [FDA], Department of Health and Human Services [HHS]; and Food Safety and Inspection Service [FSIS], Department of Agriculture [USDA]) | Federal Food, Drug, and Cosmetic Act, as amended | Authorises the Secretary of Health and Human Services (who acts through the FDA) to regulate, among other products (most relevant to this report), foods, drugs, and medical devices, including drugs and medical devices that are biologics. |
| | Public Health Service Act | Authorises HHS to license biological products, and also authorises the conduct and support of public health research by HHS. |
| | Federal Meat Inspection Act | Authorises the FSIS to regulate livestock and related meat products. |
| | Poultry Products Inspection Act | Authorises the FSIS to regulate poultry products. |
| | Egg Products Inspection Act | Authorises the FSIS to regulate egg products. |
| | Note: The US Consumer Product Safety Commission (CPSC) has regulatory authority over consumer products, including products with food contact surfaces (such as food containers, and food cooking, eating, and preparation articles). However, FDA regulates such products with respect to any migration of a substance from the contact surface to the food. | |

Overall, ten of the twelve participating delegations responded to the survey section titled 'Food areas covered under regulatory frameworks'; Table 3 provides a summary of those responses. Each delegation reported regulatory approaches for one or more food product areas. Australia, Canada, European Union, Germany, Netherlands, the Russian Federation, and the United States reported a regulatory framework for additional product areas not specifically identified in the survey (e.g. natural health products, novel foods, and contaminants). All delegations identified as currently having in place regulatory approaches for foods, including approaches for product areas that may contain nanomaterials or otherwise involve the application of nanotechnology (also see Table 5).

**Table 3. Food areas covered under regulatory frameworks**

| Delegation | Food Ingredients | Food Additives | Colorings | Food contact materials | Nutrients | Other product areas covered |
|---|---|---|---|---|---|---|
| **Australia** | • | • | • | • | • | • |
| **Canada** | • | • | • | • | • | • |
| **European Union** | • | • | • | • | • | • |
| **Korea** | • | • | • | • | • | |
| **Germany** | • | • | • | • | • | • |
| **Netherlands** | • | • | • | • | • | • |
| **Norway** | • | • | • | • | • | |
| **Poland** | • | • | • | • | • | |
| **Russian Federation** | • | • | • | • | • | • |
| **United States** | • | • | • | • | • | • |

### *Regulatory frameworks for food products*

Overall, nine of the twelve delegations responded to the survey section entitled, "Scope of regulatory frameworks for foods"; Table 4 provides a summary of those responses. Nine delegations reported manufacturing, importation, and commercialisation/marketing requirements for product areas containing nanomaterial or otherwise involving the application of nanotechnology. Two delegations reported additional oversight and other areas of responsibility (e.g. clinical trials, labelling, packaging, storage, and distribution).

**Table 4. Scope of regulatory frameworks for foods**

| Delegation | Manufacturing | Importation | Commercialisation / marketing | Additional oversight, other areas of responsibility |
|---|---|---|---|---|
| **Australia** | • | • | • | |
| **Canada** | • | • | • | • |
| **European Union** | • | • | • | |
| **Korea** | • | • | • | |
| **Germany** | • | • | • | |
| **Netherlands** | • | • | • | |
| **Norway** | • | • | • | |
| **Poland** | • | • | • | |
| **United States** | • | • | • | • |

Overall, nine of the twelve delegations responded to the survey section titled, "Scope of review processes for foods"; Table 5 provides a summary of those responses. Some delegations reported premarket approval, premarket notification, post-market notification, and post-market surveillance regulatory processes. Some delegations also reported having issued regulatory statements on nanotechnology.

**Table 5. Scope of review processes for foods**

| Delegation | Published (or articulated) a regulatory approach to nanotechnology | Premarket approval | Premarket notification | Post-market notification | Post-market surveillance | Other |
|---|---|---|---|---|---|---|
| **Australia** | • | • | | • | | |
| **Canada** | • | • | • | • | • | • |
| **European Union** | • | • | | | | |
| **Korea** | | • | • | • | • | |
| **Germany** | • | • | | | | |
| **Netherlands** | • | • | | | | |
| **Norway** | • | • | | • | • | • |
| **Poland** | • | • | | | | |
| **United States** | • | • | • | • | • | • |

For example, some delegations have published statements on nanotechnology relevant to foods that may include working definitions for nanomaterials,[14] points to consider when determining if products such as foods contain nanomaterials or otherwise involve the application of nanotechnology, [15] or new processes for industrial nanomaterials.[16] Examples of regulatory statements include:

[14] See for example, EC (2011), Commission Recommendation on the Definition of Nanomaterial, European Commission, http://ec.europa.eu/environment/chemicals/nanotech/pdf/commission_recommendation.pdf.

[15] See for example, FDA (2011), Draft Guidance: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology, www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm257926.htm; and FDA (2011), Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives, www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm300661.htm.

- Australia's Department of Health and Ageing, Adjustments to NICNAS (National Industrial Chemicals Notification and Assessment Scheme) new chemicals processes for industrial nanomaterials (accessible online at: www.nicnas.gov.au/Current_Issues/Nanotechnology/FAQs_Nano_Adjustments_for_New_Chemicals_Processes_Dec_2010.pdf).
- Recommendation from the European Union on the definition of a nanomaterial (accessible online at: http://ec.europa.eu/environment/chemicals/nanotech/pdf/commission_recommendation.pdf; also see Communication from the Commission to the European Parliament, The Council and the European Economic and Social Committee, the Second Regulatory Review on Nanomaterials http://ec.europa.eu/nanotechnology/pdf/second_regulatory_review_on_nanomaterials_-_com(2012)_572.pdf).
- Policy Statement on Health Canada's Working Definition for Nanomaterial (accessible online at: www.hc-sc.gc.ca/sr-sr/pubs/nano/pol-eng.php).
- United States Draft Guidance: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology (accessible online at: www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm257926.htm); Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives (accessible online at: www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodIngredientsandPackaging/ucm300661.htm).

To summarise, foods that may contain nanomaterials or otherwise involve the application of nano-technology are generally governed by existing national and/or regional legislative and regulatory frameworks, and in some cases more than one organisation is responsible for statutory implementation. All delegations reported oversight for various food areas (see Table 6), while some delegations reported oversight for additional product areas, such as natural health products and novel foods.

**Table 6. Food areas covered under regulatory frameworks**

| All Delegations | Food ingredients | Food additives | Colourings | Food contact materials | Nutrients | Other product areas |
|---|---|---|---|---|---|---|
| Number=12 | 10 | 10 | 10 | 10 | 10 | 7 |

Delegation Reporting Key: 1-3 White 4-6 Light Gray 7-9 Gray 10-11 Medium Gray 12 Dark Gray

Delegations also reported varying pre- and post-market review processes for foods (see Tables 7 and 8).

[16] See for example, NICNAS (Australia National Industrial Chemicals Notification and Assessment Scheme) (2010), Adjustments to NICNAS new Chemicals Processes for Industrial Nanomaterials, http://www.nicnas.gov.au/Publications/Chemical_Gazette/pdf/2010oct_whole.pdf#page=14.

**Table 7. Scope of regulatory frameworks for foods**

| All Delegations | Manufacturing | Importation | Commercialisation/ Marketing | Additional Oversight, Other Areas of Responsibility |
|---|---|---|---|---|
| Number=12 | 9 | 9 | 9 | 2 |

Delegation Reporting Key: 1-3 White 4-6 Light Gray 7-9 Gray 10-11 Medium Gray 12 Dark Gray

**Table 8. Scope of review processes for foods**

| All Delegations | Published (or articulated) a regulatory approach to nanotechnology | Premarket approval | Premarket notification | Postmarket notification | Postmarket surveillance | Other |
|---|---|---|---|---|---|---|
| Number=12 | 8 | 9 | 3 | 5 | 4 | 3 |

Delegation Reporting Key: 1-3 White 4-6 Light Gray 7-9 Gray 10-11 Medium Gray 12 Dark Gray

Several delegations reported existing regulatory frameworks for foods in general. Some delegations reported regulatory approaches for foods, including regulation of products that may contain nanomaterials or otherwise involve the application of nanotechnology. Most delegations reported manufacturing, importation, and commercialisation /marketing requirements for product areas containing nanomaterial or otherwise involving the application of nanotechnology. Some delegations reported published statements relevant to foods.

Delegations also reported online resources to support and provide guidance to regulated entities and to share information with the public and other stakeholders on nanotechnology applications in foods, mostly via organisation websites (See Annex 1; also relevant to medical products).

## Legislation and regulation relevant to medical products

In the medical products survey, responses were received from ten of the twelve participating delegations (see Table 9). Annex 3b provides additional descriptions of participating delegations' medical product legislation.

### *Legislation relevant to medical products*

Nine delegations responded to the survey section entitled, "Description and summaries of legislation for medical products". Each delegation responded that at least one such legislative act on the regulation of medical products was in effect, and some delegations reported multiple such acts. Some delegations reported more than one legislative mandate or organisation responsible for implementation of legislation on the regulation of medical products. Most delegations identified existing legislation for medical product areas. In most cases, the existing legislation was also applicable to products that may contain nanomaterial or otherwise involve the application of nanotechnology.

**Table 9. Description and summaries of legislation for medical products**

| Delegation – (Responsible Organisation | Existing Legislation | Purpose |
|---|---|---|
| **Canada – (**Health Canada) | Food and Drugs Act | Authorises Health Canada to regulate, among other products, food and drugs. |
| | Natural Health Products Regulation | Authorises Health Canada to regulate natural health products. |
| **European Union** – (European Commission, European Medicines Agency) | Medicinal Products Regulation (EC Regulation 726/2004) | Establishes European Medicines Agency and regulates supervision of medicinal products for human and veterinary use. |
| | Orphan Medicinal Products Regulation (EC Regulation 141/2000) | Regulates the development and authorisation of medical products designed for use by not more than 5 in 10.000 persons. |
| | Medicinal Products for Children Regulation (EC Regulation 1901/2006) | Regulates the development and authorisation of medical products designed for pediatric use. |
| | Advanced Therapy Medicinal Products (EC Regulation 1394/2007) | Regulates the development and authorisation of medicinal products designed for advanced therapies, and implements incentive programmes for small and medium sized enterprises. |
| **France – (**Ministry of Environment / General Directorate for Risk Prevention / Department of chemical products, diffuse pollution and agriculture, European Commission, European Medicines Agency) | Grenelle II Law<br>- Decree n° 2012-232<br>- Order of 6 august 2012 | - A sweeping package of environmental reforms and regulations with incidental impact on production of medical products.<br><br>- Establish a system of compulsory declaration for all manufactured nanomaterials |
| | Applicable European Commission Regulations (see EC legislation above) | See EC legislation above. |
| **Germany** | Applicable European Commission Regulations (see EC legislation above) | See EC legislation above. |
| **Japan – (**Ministry of Health, Labor, and Welfare) | The Pharmaceutical Affairs Law | Authorises the Ministry of Health, Labour, and Welfare to regulate drugs and medical devices. |
| **Netherlands** – (Medicines Evaluation Board;), European Commission, European Medicines Agency) | Applicable European Commission Regulations (see EC legislation above) | See EC legislation above. |
| **Poland**<br>(European Commission, European Medicines Agency) | Applicable European Commission Regulations (see EC legislation above) | See EC legislation above. |
| **Russian Federation (**Federal Service for Surveillance on Consumer Rights Protection and Human Well-being, Ministry of Health and Social Development of the Russian Federation) | Federal Law of 12 April, 2010 N 61-FZ on the Circulation of Medicines (with amendments of 27 July, 11 October, 29 November 2010, 6 December 2011. | Applies to all pharmaceuticals and medical purpose products, irrespective of use/non-use of nanotechnology components in its composition. The control over medical products, manufactured using nanotechnologies is performed in the form of state registration by an authorised Russian Federation state agency, also in the form of licensing the manufacture of appropriate products. |
| **United States –** (FDA, HHS) | Federal Food, Drug, and Cosmetic Act, as amended | Authorises the Secretary of Health and Human Services (who acts through the US FDA) to regulate, among other products (most relevant to this report), foods, drugs, and medical devices, including drugs and medical devices that are biologics. |
| | Public Health Service Act | Authorises HHS to license biological products, and also authorises the conduct and support of public health research by HHS. |

Regulatory frameworks for medical products

Overall, ten of the twelve participating delegations responded to the survey section entitled 'Medical product areas covered under regulatory frameworks'; Table 10 provides a summary of those responses.

**Table 10. Medical product areas covered under regulatory frameworks**

| Delegation | Drugs | Medical devices | Biological products | Combination products | Published (or articulated) a regulatory approach to nanotechnology |
|---|---|---|---|---|---|
| **Canada** | • | • | • | • | • |
| **European Union** | • | • | | | • |
| **France** | • | • | | | • |
| **Germany** | | • | | • | • |
| **Japan** | • | • | • | • | • |
| **Netherlands** | • | • | • | • | • |
| **Norway** | • | • | • | • | • |
| **Poland** | • | • | | | • |
| **Russian Federation** | • | • | • | | • |
| **United States** | • | • | • | • | • |

Several delegations reported existing regulatory frameworks for a number of medical product areas, including those that may contain nanomaterials or otherwise involve the application of nanotechnology. Nine delegations reported regulatory approaches for both drugs and medical devices; all delegations reported regulatory approaches for medical devices. Some delegations reported having regulatory frameworks in place for other product areas such as biological products (N=6) and combination products (N=6). Other delegations also reported oversight of other product areas (e.g. natural health products).

Overall, nine of the twelve participating delegations responded to the section titled 'Scope of Regulatory Frameworks for Medical Products'; Table 11 provides a summary of those responses.

**Table 11. Scope of regulatory frameworks for medical products**

| Delegation | Manufacturing | Importation | Commercialisation / marketing | Additional oversight, other areas of responsibility |
|---|---|---|---|---|
| **Canada** | • | • | • | • |
| **European Union** | • | • | • | |
| **France** | • | • | • | |
| **Germany** | • | • | • | |
| **Japan** | • | • | • | |
| **Netherlands** | • | • | • | |
| **Norway** | • | • | • | |
| **Poland** | • | • | • | |
| **United States** | • | • | • | • |

All delegations reported existing requirements governing the manufacture, importation, and commercialisation/marketing for medical product areas relevant to nanotechnology. Two delegations reported additional oversight responsibilities (e.g. advertising, complaint handling and mandatory problem reporting, compliance monitoring and enforcement activities, investigational use, labelling packaging, storage and distribution, recall, and special access [e.g. Emergency Use Authorisation]).

Overall, ten of the twelve participating delegations responded to the survey section entitled, "Scope of Review Processes for Medical Products"; Table 12 provides a summary of those responses. All delegations reported publishing (or articulating) a regulatory approach to nanotechnology. Delegations reported regulatory approaches that included pre-market approval, premarket notification, post-market notification, and post-market surveillance regulatory processes. Four delegations reported additional activities related to the review of medical products where nanotechnology is involved (e.g. investigational testing, special access, additional reporting requirements, or additional information related to regulatory frameworks for nanotechnology).

**Table 12. Scope of review processes for medical products**

| Delegation | Published (or articulated) a Regulatory Approach to Nanotechnology | Premarket approval | Premarket notification | Post-market notification | Post-market surveillance | Other |
|---|---|---|---|---|---|---|
| **Canada** | • | • | • | • | • | • |
| **European Union** | • | • | | • | • | |
| **France** | • | • | | • | • | • |
| **Germany** | • | • | • | • | • | • |
| **Japan** | • | • | • | • | • | |
| **Netherlands** | • | • | • | • | • | |
| **Norway** | • | • | • | • | • | |
| **Poland** | • | • | | • | • | |
| **Russian Federation** | • | | | | | |
| **United States** | • | • | • | • | • | • |

In parallel to responses in the foods inventory, some delegations reported published statements on nanotechnology, including working definitions for nanomaterials and points to consider when determining whether products (such as medical products) contain nanomaterials or otherwise involve the application of nanotechnology. Examples of regulatory statements include:

- Recommendation from the European Commission on the definition of a nanomaterial (accessible online at: http://ec.europa.eu/environment/chemicals/nanotech/pdf/commission_recommendation.pdf; also see Communication from the Commission to the European Parliament, The Council and the European Economic and Social Committee, the Second Regulatory Review on Nanomaterials http://ec.europa.eu/nanotechnology/pdf/second_regulatory_review_on_nanomaterials_-_com(2012)_572.pdf).
- Policy Statement on Health Canada's Working Definition for Nanomaterial (accessible online at: www.hc-sc.gc.ca/sr-sr/pubs/nano/pol-eng.php).
- United States Draft Guidance: Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology (accessible online at: www.fda.gov/ScienceResearch/SpecialTopics/Nanotechnology/ucm257926.htm).

To summarise, medical products that may contain nanomaterials or otherwise involve the application of nanotechnology are generally covered under existing national and/or regional legislative and regulatory frameworks. Variations in the type, nature, and extent of the review process depend on the statutory authority governing the medical product and the products current regulatory status (See Table 13).

**Table 13. Scope of review processes for medical products**

| All delegations | Published (or articulated) a regulatory approach to nanotechnology | Premarket approval | Premarket notification | Post- market notification | Post-market surveillance | Other |
|---|---|---|---|---|---|---|
| Number=12 | 10 | 9 | 6 | 9 | 9 | 4 |

Delegation Reporting Key: 1-3 White 4-6 Light Gray 7-9 Gray 10-11 Medium Gray 12 Dark Grey

Across delegations, legislative regimes range from none specifically identified for medical products to current legislation in place. Those with legislative regimes in medical products indicated that they are also applicable to products that may contain nanomaterials or otherwise involve the application of nano-technology. Delegations also reported varying pre- and post-market review processes and several delegations reported manufacturing, importation, and commercialisation/marketing requirements for medical product areas relevant to nanotechnology (see Table 14 and 15).

**Table 14. Scope of regulatory frameworks for medical products**

| All Delegations | Manufacturing | Importation | Commercialisation / marketing | Additional oversight, other areas of responsibility |
|---|---|---|---|---|
| N | 9 | 9 | 9 | 2 |

Delegation Reporting Key: 1-3 White 4-6 Light Gray 7-9 Gray 10-11 Medium Gray 12 Dark Grey

**Table 15. Medical product areas covered under regulatory frameworks**

| All Delegations | Drugs | Medical devices | Biological products | Combination products |
|---|---|---|---|---|
| N | 9 | 10 | 6 | 6 |

Delegation Reporting Key: 1-3 White 4-6 Gray 7-9 Lt. Gray 10-11 Medium Gray 12 Drak Gray

Similar to the foods survey, all delegations reported having published (or articulated) approaches to nanotechnology. Published documents relevant to medical products included working definitions for nano-materials or points to consider when determining whether products contain nanomaterials or otherwise involve the application of nanotechnology (see Table 12).

All delegations reported regulatory frameworks that are applicable to medical products, including those that may contain nanomaterials or otherwise involve the application of nanotechnology. Similar to foods, delegations also reported online resources to support and provide guidance to regulated entities and to share information with the public and other stakeholders on nanotechnology applications in medical products, mostly via organisation websites (see Annex 1).

## SUMMARY OF RESPONSES ON GOVERNMENT-SPONSORED REGULATORY SCIENCE AND OTHER RESEARCH ACTIVITES IN FOODS AND MEDICAL PRODUCTS

An increasing number of research reports examining the application of nanotechnology in the foods and medical products sectors are emerging in the published literature. Some research involves technical assessments by government organisations to support the responsible development of nanotechnology (regulatory science research), while other government-sponsored research investigates the application of nanotechnology and potential new uses. This survey is intended to provide additional information on government-sponsored regulatory science and other research activities in foods and medical products for nanotechnology.

### The foods sector

Delegations reported a number of applications being investigated, including the development of new or enhanced food products, food contact materials, and the delivery of bioactive compounds in foods.[17] Delegations also reported government-sponsored regulatory science research and other research activities in food subcategories (e.g. food ingredients, food additives, colourings, food contact materials, nutrients, food pathogens/contaminants, food packaging, and other categories - see Annexes), as well as novel applications of nanotechnology. Annex 4a provides additional descriptions of delegations' food related government-sponsored regulatory science research and other research activity.

#### *Government-sponsored regulatory science research and other research activities for foods*

Overall, ten of the twelve participating delegations responded to the survey section titled, 'Food Activities Covered by Government-Sponsored Research Programmes, Institutions, and Infrastructure'; Table 16 provides a summary of those responses. Seven delegations reported research programmes relevant to nanotechnology in the foods sector. Specific emphasis varied across delegations and included food additives, food contact materials, food ingredients, food pathogens/contaminants, nutrients, reference materials, and standards.

[17] See for example, the Institute for Food Technologists Conference (accessible at: http://live.ift.org/2011/05/05/nanotechnology- heats-up/).

**Table 16. Foods activities covered by government-sponsored research programmes, institutions, and infrastructure**

| Delegation | Research programmes | Institutions | Infra-structure | Other | Product areas of specific emphasis |
|---|---|---|---|---|---|
| **Canada** | | | | • | Reference material and standards activities |
| **European Union** | • | | | | Food ingredients, food additives, food contact materials, nutrients, food pathogens / contaminants, packaging, other (generic/potentially all areas) |
| **France** | | • | | | Food ingredients, food additives, food contact materials, nutrients, food packaging |
| **Korea** | • | | | | Food ingredients, food additives, colorings, food contact materials, nutrients, packaging |
| **Japan** | • | | | | Food ingredients, nutrients |
| **Netherlands** | • | | | | Food ingredients, food additives, nutrients, food packaging |
| **Norway** | • | | | | Food contact materials, vaccination of fish in aquaculture |
| **Poland** | | • | | | Food ingredients, food additives, food contact materials, nutrients, food packaging |
| **Russian Federation** | • | | | • | Food ingredients, food additives, food contact materials, nutrients |
| **United States** | • | • | • | | Food ingredients, food additives, food contact materials, nutrients, food packaging |

Overall, ten of the twelve participating delegations responded to the survey section entitled, 'Scope of regulatory science research and other research activities'; Table 17 provides a summary of those responses. Most delegations reported a variety of programmatic areas of interest relevant to foods. At least six delegations reported areas of multilateral interest including metrology and analytical methods, toxicology research, and nutrient bioavailability and efficacy.

**Table 17. Scope of regulatory science research and other research activities**

| Delegation | Metrology & analytical methods | Toxicology research | Expo-sure science | Risk assess-ment, risk management | Pathogen detection | Nutrient bioavail-ability & efficacy | Food preser-vation | Other |
|---|---|---|---|---|---|---|---|---|
| **Canada** | • | | | | | | | |
| **European Union** | • | • | • | • | • | • | • | • |
| **France** | • | • | • | | • | • | • | |
| **Korea** | • | • | | | | | | |
| **Japan** | • | | | | | • | | |
| **Netherlands** | • | • | • | • | | • | | • |
| **Norway** | | • | | • | | | • | |
| **Poland** | | | • | | | | | |
| **Russian Federation** | • | • | • | • | • | • | | |
| **United States** | • | • | • | • | • | • | | • |

To summarise, a number of government-sponsored regulatory science research and other research programmes, infrastructure, and institutions support foods product evaluations as well as research and development applications. Active government-sponsored regulatory science research and other research programmes, institutions, and infrastructures are on-going and target specific areas of inquiry (e.g. Metrology and Analytical Methods). Delegations also reported government-sponsored regulatory science research or other research programmes, institutions, or infrastructure, with several common areas of interest. Six areas of multilateral interest include metrology and analytical methods, toxicology research, exposure science, pathogen detection, nutrient bioavailability and efficacy, and food preservation.

Overall, most delegations reported either existing research programmes or institutions. Several delegations reported existing government-sponsored regulatory science research or other research programmes that focused on food packaging, food additives, food contact materials, and nutrition. At least six delegations reported the most studied foods area to be metrology and analytical methods, toxicology, exposure, and nutrient bioavailability and efficacy.

## The medical products sector

Within the area of medical products, specific applications of nanotechnology such as medical devices and drugs are being investigated. The majority of delegation responses reported activities in metrology, analytical methods, and exposure science, whereas multilateral interest in shared areas can potentially identify areas for future co-operation and collaboration. Annex 4b provides additional descriptions of delegations' medical product related government-sponsored regulatory science research and other research activity.

### *Government-sponsored regulatory science research and other research programmes, institutions, and infrastructure*

Overall, six of the twelve participating delegations responded to the section titled, 'Medical product activities covered by government-sponsored research programmes, institutions, and infrastructure'; Table 18 provides a summary of those responses. Six delegations reported having regulatory science research and other research programmes focused on the application of nanotechnology to medical products. Three delegations identified specific, but varied areas of emphasis: bio/nano interface and biophysical interactions with proteins, bionanotechnology, and nanomedicine.

**Table 18. Medical products activities covered by government-sponsored research programmes, institutions, and infrastructure**

| Delegation | Research programmes | Institutions | Infra-structure | Other | Product areas of specific emphasis |
|---|---|---|---|---|---|
| **Canada** | • | | | | Bio/nano interface and biophysical interactions with proteins |
| **European Union** | • | | | | Generic/potentially all areas |
| **Netherlands** | • | • | • | • | Bio-nanotechnology, nanomedicine |
| **Poland** | • | • | | | |
| **Russian Federation** | • | | | | |
| **United States** | • | • | • | | |

Overall, six of the twelve participating delegations responded to the survey section entitled, 'Scope of government-sponsored regulatory science research and other research activities'; Table 19 provides a summary of those responses. Delegations reported a variety of programmatic areas of interest relevant to the application of nanotechnology to medical products. At least four delegations identified metrology and analytical methods, toxicology research, risk assessment, risk management, exposure science, and pathogen detection as areas of interest.

**Table 19. Scope of government-sponsored regulatory science research and other research activities**

| Delegation | Metrology & analytical methods | Toxicology research | Exposure science | Risk assessment, risk management | Pathogen detection | Efficacy |
|---|---|---|---|---|---|---|
| **Canada** | • | | • | • | | |
| **European Union** | • | • | • | • | • | • |
| **Netherlands** | • | • | • | • | • | |
| **Poland** | | | • | | | • |
| **Russian Federation** | • | • | • | | • | |
| **United States** | • | • | • | • | • | • |

### *Medical products government-sponsored regulatory science research and other research programmes, institutions, and infrastructure*

All delegations reported collaborations with academia, other government agencies within their country, and/or other government agencies internationally. Most delegations reported government-sponsored regulatory science research or other research programmes in medical product areas. Four areas of multilateral interest include metrology and analytical methods, toxicology research, exposure science, and risk assessment and risk management. Some, but not all, delegations reported collaborations with industry. A number of government-sponsored regulatory science research and other research programmes, infrastructure, and institutions support medical product evaluation as well as medical product research and development.

# CONCLUSION

In 2010 the OECD WPN agreed to review the current landscape of regulatory frameworks and regulatory science activities surrounding nanotechnology applications in foods and medical products. The project "Regulatory framework for nanotechnology in foods and medical products" was developed in response to this issue. The WPN then developed a survey activity that would help provide an inventory, summary, and overview of regulatory approaches, legislative regimes, and government-sponsored regulatory science research and other research programmes, institutions, and infrastructure in foods and medical products that involve the application of nanotechnology. The survey activity was intended to better inform intergovernmental discussion.

The results provide detailed information from twelve delegations. The responses revealed shared interests or areas where participating delegations have taken a similar approach to address applications of nanotechnology, providing an insight into current thinking and government investments (e.g. government-sponsored regulatory science research) relevant to nanotechnology internationally. The survey activity also suggests potential areas for more focused discussions and potential collaboration between delegations/regions with a similar focus on government sponsored regulatory science research or additional research activities in foods and medical products.

The survey activity is specifically intended to provide a snapshot of current activities across OECD WPN delegations, with respect to regulation, legislation, and government sponsored regulatory science research and other research activities relevant to nanotechnology. Regulatory approaches, legislative regimes, and government sponsored regulatory science and other research activities are anticipated to continue to evolve and develop as the science matures. A list of observations based on one or more of the topics (legislation, regulation, and regulatory science and other research activities) examined in this report is provided below:

- Several delegations reported general regulatory approaches applicable to foods and medical products, which are also applicable to products that may contain nanomaterials or otherwise involve the application of nanotechnology. Variations in the type, nature, and extent of the review process depend on the statutory authority governing the product and its regulatory status.
- Delegations reported legislative regimes governing foods and medical products, which are also applicable to products that may contain nanomaterials or otherwise involve the application of nanotechnology, and in some cases more than one organisation was responsible for implementation of legislative acts.
- Delegations reported government-sponsored regulatory science research or other research programmes, institutions, or infrastructure, with several common areas of interest in foods or medical products categories.
- Several delegations identified regulatory frameworks for the same product areas in foods (food additives, food contact materials) or medical products (drugs, medical devices).
- Some delegations have published or articulated regulatory approaches, such as published statements and regulatory guidance documents that provide advice to the regulated foods and medical products industries, the public, or other stakeholders.

- Delegations reported information sharing, regulatory guidance, and regulatory science research and other research activities for regulated entities primarily via organisation websites.

The survey also identified areas of shared interest among delegations on regulatory approaches, legislative regimes, and government-sponsored regulatory science research and other research programmes, institutions, and infrastructure. In a majority of categories (See Tables 6-8, 13-15), eight or more delegations reported similar areas of interest or approaches to foods and medical products that may be applicable to nanotechnology. Similarly, in a majority of regulatory science research and other research categories (see Tables 17 and 19), three or more delegations reported similar areas of interest or government investment in nanotechnology. These shared areas of interest in regulatory approaches, legislative regimes, and government-sponsored regulatory science research and other research activities may further inform future intergovernmental discussions.

# ANNEX 1: DELEGATION REGULATORY FRAMEWORKS AND LEGISLATIVE REGIMES WEBLINKS

| **Australia** | |
|---|---|
| Foods | Online resources |
| **Regulatory frameworks**<br>• Regulations for each state, territory, and New Zealand (www.foodstandards.gov.au/foodstandards/foodenforcementcontacts/)<br>**Legislative regimes**<br>• The Food Standards Australia New Zealand Act, as amended (www.comlaw.gov.au/Details/C2011C00117) | **Food Standards Australia New Zealand website**<br>• "Food Standards Australia New Zealand (FSANZ) is an independent statutory agency established by the Food Standards Australia New Zealand Act 1991" (www.foodstandards.gov.au/)<br>**ComLaw**<br>• "ComLaw contains the only database of Australian Government legislation that is authoritative for the purposes of legal proceedings" (www.comlaw.gov.au/) |

| Canada | | |
|---|---|---|
| Foods | Medical products | Online resources |
| **Regulatory frameworks**<br>• Food and Drug Regulations *(*www.laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870/*)*<br>**Legislative regimes**<br>• Food and Drugs Act *(*http://laws-lois.justice.gc.ca/eng/acts/F-27/page-8.html#s-30*)* | **Regulatory frameworks**<br>• Food and Drug Regulations, Table of Contents (see Part C, Drugs, Part G, Controlled Drugs) *(*www.laws-lois.justice.gc.ca/eng/regulations/C.R.C.%2C_c._870/*)*<br>• Natural Health Product Regulations, Table of Contents *(*http://laws-lois.justice.gc.ca/eng/regulations/SOR-2010-171/index.html*)*<br>• Medical Devices Regulations, Table of Contents *(*www.laws-lois.justice.gc.ca/eng/regulations/SOR-98-282/index.html*)*<br>**Legislative regimes**<br>• Food and Drugs Act, Table of Contents (see part I, Foods, Drugs, Cosmetics, and Devices) *(* http://laws-lois.justice.gc.ca/eng/acts/F-27/page-8.html?texthighlight=devices+device#s-30*)* | **Health Canada website**<br>• "Health Canada is the Federal department responsible for helping Canadians maintain and improve their health" *(*www.hc-sc.gc.ca/index-eng.php*)*<br>**Justice Laws website**<br>• "The Justice Laws Website is "the online source of the consolidated Acts and regulations of Canada" *(*http://laws-lois.justice.gc.ca/eng/*)* |

| **European Union (also applies to France, Germany, Netherlands, Norway, and Poland)** | | |
|---|---|---|
| Foods | Medical products | Online resources |
| **Legislative regimes**<br>• General Food Legislation (EC 178/2002) *(*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF*)*<br>• Novel Food (EC 258/97)*(*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1997R0258:20090120:EN:PDF*)*<br>• Food Additives Regulation (EC 1333/2008) *(*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:en:PDF*)*<br>• Plastics Regulation (EC 10/2011) *(*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF*)*<br>• Active and Intelligent Materials Regulation (EC 450/2009) *(* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:135:0003:0011:EN:PDF*)*<br>• Labelling Regulation (EC 1169/2011) *(*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:135:0003:0011:EN:PDF*)* | **Legislative regimes**<br>• Medicinal Products Regulation (EC 726/2004) *(*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:136:0001:0033:en:PDF*)*<br>• Orphan Medicinal Products Regulation (EC 141/2000) *(*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:018:0001:0005:en:PDF*)*<br>• Medicinal Products for Children Regulation (EC 1901/2006) *(*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:378:0001:0019:en:PDF*)*<br>• Advanced Therapy Medicinal Products (EC 1394/2007) *(*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:324:0121:0137:en:PDF*)* | **European Commission website**<br>• "The European Commission is the EU's executive body and represents the interests of Europe as a whole (as opposed to the interests of individual countries)" (http://ec.europa.eu/legislation/index_en.htm)<br>• On 3 October 2012, the Commission adopted the Communication on the Second Regulatory Review on Nanomaterials *(*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0572:FIN:en:PDF*).* It describes the Commission's plans to improve EU law and its application to ensure their safe use and is accompanied by a Staff Working Paper on nanomaterial types and uses, including safety aspects, which gives a detailed overview of available information on nanomaterials on the market, including their benefits and risks (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2012:0288:FIN:EN:PDF). |

| France | | |
|---|---|---|
| Foods | Medical products | Online resources |
| **Regulatory frameworks**<br>• http://agriculture.gouv.fr/FAQ-Aliments-et-nanotechnologies<br>**Legislative regimes**<br>• General Food Legislation (EC 178/2002) *(*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF*)*<br>• Novel Food (EC 258/97)*(* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1997R0258:20090120:EN:PDF*)*<br>• Food Additives Regulation (EC 1333/2008)*(* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:en:PDF*)*<br>• Plastics Regulation (EC 10/2011) *(* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF*)*<br>• Active and Intelligent Materials Regulation (EC 450/2009) *(* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:135:0003:0011:EN:PDF*)*<br>• Labelling Regulation (EC 1169/2011) *(*http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:135:0003:0011:EN:PDF*)*<br>• Decree n° 2012-232 *(*www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025377246&fastPos=4&fastReqId=897013844&categorieLien=id&oldAction=rechTexte*)*<br>• Order of 6 august 2012 *(*www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000026278450&fastPos=28&fastReqId=609676040&categorieLien=id&oldAction=rechTexte*)* | **Regulatory frameworks**<br>• http://www.developpement-durable.gouv.fr/<br>**Legislative regimes**<br>• www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000022470434<br>• Decree n° 2012-232 *(*www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000025377246&fastPos=4&fastReqId=897013844&categorieLien=id&oldAction=rechTexte*)*<br>• Order of 6 August 2012 *(* www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000026278450&fastPos=28&fastReqId=609676040&categorieLien=id&oldAction=rechTexte | **Compulsory declaration system:**<br>• www.developpement-durable.gouv.fr/Risques-emergents-la-declaration.html<br>• *www.r-nano.fr/* |

| **Japan** | |
|---|---|
| Medical products | Online resources |
| **Regulatory frameworks**<br>• www.mhlw.go.jp/english/index.html | **Ministry of Health, Labour, and Welfare**<br>• "Ministry of Health, Labour and Welfare implements measures so that people can live a healthy life" (www.mhlw.go.jp/english/policy/health-medical/health/index.html) |

| **Korea** | | |
|---|---|---|
| Foods | Medical products | Online resources |
| **Regulatory frameworks**<br>• http://eng.kfda.go.kr/index.php | **Regulatory frameworks**<br>• http://eng.kfda.go.kr/index.php | **Korea Food and Drug Administration website**<br>• "Sufficient Protection, Speedy Response and Smart Support for Promotion of National Health Protection and Security of Food and Drug Safety" (www.kfda.go.kr/eng/index.do;jsessionid=RS9Cgn1liUkgnchv3DpA1oHTPYu3Ca0UyFB2Bh042l3XwaRseugGRIO4n9HS40SX) |

| **Netherlands** | | |
|---|---|---|
| Foods | Medical products | Online resources |
| | **Regulatory frameworks**<br>• www.cbg-meb.nl/cbg/en/default.htm<br>• *www.kema.com* | • "The Medicines Evaluation Board (MEB) assesses and monitors the efficacy, risks and quality of human and veterinary medicinal products. It also assesses the safety of novel foods for human consumption.<br>• DNV KEMA Energy and Sustainability is a global, leading authority in business and technical consultancy, testing, inspections and certification, risk management, and verification, along the energy value-chain." |

| **Norway** | |
|---|---|
| Foods | Online resources |
| ***Regulatory frameworks***<br>• www.mattilsynet.no | ***Norwegian Food Safety Authority*** *(*www.mattilsynet.no*)*<br>• *"The Norwegian Food Safety Authority (NFSA) is a governmental body, operating on a national basis, whose aim is to ensure that food and drinking water are as safe and healthy as possible for consumers".* |

| ***Poland*** | |
|---|---|
| Foods | Medical products |
| ***Regulatory frameworks***<br>• www.mz.gov.pl/<br>www.minrol.gov.pl/pol/ | ***Regulatory frameworks***<br>• www.mz.gov.pl/ |

| **Russian Federation** | |
|---|---|
| Foods | Medical products |
| **Regulatory frameworks**<br>• www.crc.ru/gosreg/reestr/ | **Regulatory frameworks**<br>• http://grls.rosminzdrav.ru/GRLS.aspx |

| **United States** | | |
|---|---|---|
| Foods | Medical products | Online resources |
| **US Food and Drug Administration (FDA)**<br>**Regulatory frameworks**<br>• Title 21 of the Code of Federal Regulations *(*www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=cfr&utm_content=1*)*<br>**Legislative regimes**<br>• Federal Food, Drug, and Cosmetic Act *(*www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm*)*<br>• Public Health Service Act *(*www.fda.gov/RegulatoryInformation/Legislation/ucm148717.htm*)*<br><br>**USDA Food Safety and Inspection Service (FSIS)**<br>**Regulatory frameworks**<br>• Title 9 of the Code of Federal Regulations<br>**Legislative regimes**<br>• Federal Meat Inspection Act *(*www.fsis.usda.gov/regulations_&_policies/Federal_Meat_Inspection_Act/index.asp<br>• Poultry Products Inspection Act (www.fsis.usda.gov/regulations_&_policies/Poultry_Products_Inspection_Act/index .asp*)*<br>• Egg Products Inspection Act *(*www.fsis.usda.gov/regulations_&_policies/Egg_Products_Inspection_Act/index.asp*)* | **US Food and Drug Administration (FDA)**<br>**Regulatory frameworks**<br>• Title 21 of the Code of Federal Regulations (www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?utm_campaign=Google2&utm_source=fdaSearch&utm_medium=website&utm_term=cfr&utm_content=1*)*<br>**Legislative regimes**<br>• Federal Food, Drug, and Cosmetic Act (www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm*)*<br>• Public Health Service Act (www.fda.gov/RegulatoryInformation/Legislation/ucm148717.htm*)* | **FDA website**<br>(www.fda.gov/default.htm*)*<br>• "FDA is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, [the] nation's food supply, cosmetics, and products that emit radiation"<br><br>**FSIS website**<br>(www.fsis.usda.gov/*)*<br>• "The Food Safety and Inspection Service (FSIS) is the public health agency in the US Department of Agriculture responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labelled and packaged" |

## ANNEX 2. DESCRIPTIONS OF TERMS USED IN THE SURVEYS

**Biological products:** Generally, made from a variety of natural sources (human, animal or microorganism). Similar to the description of drugs, some biological products are intended to treat diseases and medical conditions. Other biological products are used to prevent or diagnose diseases

**Colourings:** Generally, a dye, pigment, or other substance which, when added or applied to a foods product, will result in changing or imparting the colour of the foods product in question.

**Combination products:** Generally, a product composed of any combination of a drug, medical device, and/or a biological product.

**Drugs:** Generally, a substance recognised by an official pharmacopoeia or formulary, a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, a substance (other than food) intended to affect the structure or any function of the body.

**Food additives:** Generally, a substance which, as a result of its intended use will, or will likely, become a component of a food product, and which is not generally recognised as having been shown to be safe through scientific testing.

**Food contact materials:** Generally, a substance, the intended use of which (such as manufacturing, packaging, or transport) will result in touching of the foods product, but which is not intended to have any specific effect on the foods product.

**Food ingredients:** Generally, any substance which is part of a food product.

**Legislation:** For the purposes of this document, legislation refers to the specific acts passed by a country's federal legislature and pertaining to the regulation of foods and medical products which may contain nanomaterials or otherwise involve the application of nanotechnology. Legislative acts, once passed, are codified as statutes, which either authorise a regulatory agency to regulate a class of persons, acts, or items, or which themselves regulate a class of persons, acts, or items.

**Legislative frameworks:** For the purposes of this document, legislative frameworks refer to the specific acts passed by a country's federal legislature and pertaining to the regulation of foods and medical products which may contain nanomaterials or otherwise involve the application of nanotechnology. Legislative acts, once passed, are codified as statutes, which either authorise a regulatory agency to regulate a class of persons, acts, or items, or which themselves regulate a class of persons, acts, or items.

**Medical devices:** Generally, an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals, or intended to affect the structure or any function of the body of humans or other animals, and which does not achieve any of its primary intended purposes through chemical action within or on the body of a human or other animals and which is not dependent upon being metabolised for the achievement of any of its primary intended purposes.

**Medical products:** In this survey, medical products include drugs, medical devices, biological products, and combination products.

**Nutrients:** Generally, a substance necessary for the body's nutritional and metabolic processes.

**Regulation:** For the purposes of this document, regulation refers to specific rules or standards, pertaining to foods and medical products which may contain nanomaterials or otherwise involve the application of nanotechnology, implemented by a regulatory agency pursuant to a legislative act.

**Regulatory frameworks:** For the purposes of this document, regulatory frameworks consist of the standards and rules which regulate a particular class of persons, acts, or items, promulgated by government agencies pursuant to authority granted by statute.

**Regulatory science research and other research activities:** For the purposes of this document, research refers to regulatory science research and other research activities sponsored by government organisations and their affiliates to support either: 1) evaluating products which may contain nanomaterials or otherwise involve the application of nanotechnology for regulatory decision making; or 2) advancing the knowledge and understanding of nanotechnology in product sectors.

## ANNEXES 3 AND 4[18]

ANNEX 3a – Foods legislation descriptions from delegations

ANNEX 3b – Medical product legislation descriptions from delegations

ANNEX 4a – Foods related government-sponsored regulatory science research and other research activity descriptions from delegations

ANNEX 4b – Medical product government-sponsored regulatory science research and other research activity descriptions from delegations

[18] The following annexes are statements directly submitted by individual delegations about their own legislation, regulatory approaches, and government-sponsored regulatory science research and other research activities in the area of foods and medical products.

## ANNEX 3a. FOOD LEGISLATION DESCRIPTIONS FROM DELEGATIONS

This section provides delegations' statements on legislation relevant to foods products.

**Statement from Australia**
**General statement:** The object of the Food Standards Australia New Zealand Act (1991) is to ensure a high standard of public health protection throughout Australia and New Zealand
**Implementation:** A joint body called Food Standards Australia New Zealand focuses on the following goals: 1) a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand; 2) an effective, transparent and accountable regulatory framework within which the food industry can work efficiently; 3) the provision of adequate information relating to food to enable consumers to make informed choices; and 4) the establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards applying to public health and consumer protection.

**Statement from Canada**
**General Statement**: The Food and Drugs Act is a consumer protection statute dealing with foods, drugs, cosmetics and medical devices.
**Implementation:** The Food and Drugs Act establishes minimum health and safety requirements, as well as provisions preventing fraud and deception for all food sold in Canada. 'Sell' as defined in the Food and Drugs Act means to offer for sale, expose for sale, and have in possession for sale and distribution, whether or not the distribution is made for consideration. Regulations contain food labelling requirements and standards of identity, composition, strength, potency, purity, quality or other properties for several classes of foods.[19]

**Statement from European Union**
**General statement:** Overall, it can be concluded that current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework. However, current legislation may have to be modified in the light of new information becoming available, for example as regards thresholds used in some legislation.[20]
**Implementation:** Foods and food ingredients not used for human consumption to a significant degree in the European Union (EU) before 15 May 1997 are "novel foods" and "novel food ingredients". Novel foods and novel food ingredients must be: 1) Safe for consumers; and 2) adequately labelled to not mislead consumers. Regulation EC 258/97 sets the rules for the marketing of novel foods and novel food ingredients. Companies must apply for authorisation and present the scientific information and safety assessment report to market a novel food or novel food ingredient to an EU country authority. Novel foods and novel food ingredients are assessed before they reach the market. An EU country's competent authority assesses the application and decides if additional assessment is necessary; and it allows the

[19] Statement from Health Canada (additional information accessible online at: http://laws.justice.gc.ca/en/f-27/).

[20] Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee (additional information accessible online at: http://ec.europa.eu/nanotechnology/pdf/comm_2008_0366_en.pdf).

marketing of the product if no additional assessment is necessary and if the European Commission and EU countries do not object. All other cases require an authorisation decision.[21]

**Statement from France**

**General statement:** Insofar as the food regulation is harmonised at the European level, one should refer to the statement of the European Union to get an insight of the applicable regulation. Moreover, in France, a system of compulsory declaration has been put into place. This system, also applicable to food, is explained under the section relevant to Medical Products.

**Statement from Germany**

**General statement:** Relevant provisions, including those concerning foods products such as ingredients in the nanoscale, are generally harmonised at the European level.

**Implementation:** In Germany, specific national legislation does not exist with regard to the use of nanotechnology/nanomaterials in food. Apart from the general food legislation, the following EU provisions are applicable also in Germany on the use of engineered nanomaterials in foods: Regulation (EC) No 258/97 (novel food), Regulation (EC) No 1333/2008 (food additives), Regulation (EU) No 1169/2011 (labeling).

**Statement from Poland**

**General statement:** Several obligatory regulations exist concerning food, the food industry and food packaging.

**Implementation:** *1)* Minister of Health Order of 18 February 2011 (Polish Official Journal 2011, No. 52, item 272) concerning extraction solvents which can be used in food industry; *2)* Minister of Health Order of 16 September 2010 (Polish Official Journal 2010, No. 174, item 1184) concerning enriching substances as addition to food, it means vitamins, salt, folic acid in proper concentrations; *3)* Minister of Health Order of 16 September 2010 (Polish Official Journal 2010, No. 180, item 1214) concerning special nutrition items for special purposes, like for new-born babies, dietetically products; *4)* Minister of Agriculture and Rural Area Development Order of 10 July 2007 concerning labelling and packaging of nutrition agents. It is obligatory to give name of the agent, content of the agent, expiry date, mode of preparation, detailed description of packaging conditions (like use of neutral gases), sugar addition, conservative agents, solvents, etc. Above mentioned regulations are based between others on the following directives of the European Commission and Council: 87/250 of 15 April 1987 (WE L 113 of 30.04.1987, p.37; 2001/101/WE of 26 November 2001 (WE L 310 of. 28.11.2001, p.19); 2003/89/WE of 10 November 2003 (UE L 308 of 25.11.2003, p. 15); 2007/68 /WE of 27 November 2007 ( UE L 310 of 28.11.2007, p. 11); 2008/5/WE of 30 January 2008 ( UE L 27 of 31.01.2008, p. 12); 2000/13/WE of 20 March 2000 (WE L 109 of 06.05.2000, p. 29); *5)* Act on commercial values of agricultural - food articles, of 21 December 2000 (Polish Official Journal 2001, No.5 item.44) gives specific description about required quality, classification, packaging and labelling of commercial food articles; and *6)* President of Poland Act of 22 October 2010 about safety of food and nutrition (Polish Official Journal 2010, No. 230, item 1511) which is based on European Parliament directive WE No.767/2009 of 13 July 2009; European Commission directive 82/475/EWG of 23 June 1982 (WE L 213 of 21.07.1982, p. 27); European Council directive 90/167/EWG of 26 March 1990 (WE L 92 of 07.04.1990, p.42); European Council directive 98/51/WE of 9 July 1998 (WE L 208 of 24.07.1998, p. 43); European Commission directive 98/68/WE of 10 September 1998 ( WE L 261 of 24.09.1998, p. 32); European Parliament and Council directive 2002/32/WE of 7 May 2002 (WE L 140 of 30.05.2002, p. 10); European Commission directive 2008/38/WE of 5 March 2008 ( UE L 62 of 06.03.2008, p. 9).

[21] Statement from the European Commission (additional information accessible online at: *http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm*).

**Statement from the United States**

**General statement:** The Federal Food, Drug, and Cosmetic Act (FD&C Act) provides the United States Food and Drug Administration (FDA) with broad regulatory authority over food that is introduced or delivered for introduction into interstate commerce.

**Implementation:** FDA promotes and protects the public's health by ensuring that the food supply is safe, sanitary, wholesome, and properly labelled. Statutory regimes and implementing regulations require premarket authorisation for colour additives and food additives, unless such food additives are generally recognised as safe. These authorities impose other requirements for manufacturers of food, including for the use of current good manufacturing practices, maintenance of records, registration of food facilities, and prior notice for imports. They establish penalties for violations of requirements, and provide FDA with enforcement and other oversight authorities to ensure compliance with statutory and regulatory requirements.[22]

In addition, the USDA's FSIS protects the United States food supply ensuring that meat, poultry, and egg products are safe, wholesome, and accurately labelled. Its statutory authority resides in three Acts: Federal Meat Inspection Act (FMIA), Poultry Products Inspection Act (PPIA), and Egg Products Inspection Act (EPIA). Among the many provisions of these Acts, an underlying principle outlined in each Act that may be relevant to any nanotechnology issues in foods safety indicates that FSIS is authorised to prevent products from entering commerce that are adulterated or misbranded. Key provisions that address this principle can be found for instance in FMIA Section 601(m) and (n), PPIA Section 453(g) and (h), and EPIA Section 1033(a) and (l).

[22] Federal Food, Drug, and Cosmetic Act (additional information accessible online at: www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/default.htm).

## ANNEX 3b. MEDICAL PRODUCT LEGISLATION DESCRIPTIONS FROM DELEGATIONS

This section provides delegations' statements on legislation relevant to medical products.

**Statement from Canada**
**General statement:** The Food and Drugs Act applies to foods, drugs, biologics, natural health products, cosmetics and devices, and includes a description for administration and enforcement of the Act. **Implementation:** Canada's Food and Drugs Act and its regulations govern the sale of a range of therapeutic products regulated by the Health Products and Foods Branch (HPFB). The Therapeutic Products Directorate (TPD) is responsible for regulating: 1) pharmaceuticals (prescription and non-prescription drugs); and 2) medical devices, such as medical and dental implants, medical equipment and instruments, test kits for diagnosis, and contraceptive devices. The Medical Devices Regulations apply to medical devices as defined by the Act, and include requirements for establishment licenses, medical devices licenses, custom devices, devices sold or imported through the special access programme (authorisation for emergency use), and investigational testing (clinical trials). The regulations further describe requirements pertaining to export certificates and risk classification rules for Canadian medical devices.[23]

**Statement from France**
**General statement:** France's regulations are based on European level regulatory frameworks. Besides, a system of compulsory declaration has been put into place. This system, also applicable to Medical Products, was implemented following a commitment by the Environment Round Table (*Grenelle de l'environnement*) relating to the anticipation of risks associated with nanomaterials, particularly through a declaration of the presence of nanoparticles in products available to the general public.
**Implementation:** This scheme aims to improve knowledge: *i)* of nanomaterials and their uses, particularly the traceability, viewed as information along the supply chain of substances and products containing nanomaterials; and *ii)* of the market and the volumes sold. This scheme is also a way to collect available information on toxicological and eco-toxicological properties. This system consists of requesting simple data concerning the nanomaterials that they manufacture, import or distribute whatever the field of application (drugs, medical devices, cosmetics, etc.). This does not consist of a prerequisite for the activities concerned, which can continue without obstacle.

**Statement from Germany**
**General statement:** Legislation relevant for health, safety and environment aspects of nanomaterials (including those contained in medical products) can be grouped under chemicals, worker protection, products, and environmental protection, as needed.

[23] Statement from Health Canada (additional information accessible online at: www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/index-eng.php accessible online at http://laws.justice.gc.ca/eng/F-27/20110104/page 0.html?rp2=HOME&rp3=SI&rp4=all&rp5=food%20and%20drugs%20act&rp9=cs&rp10=L&rp13=50#idhit1; http://laws.justice.gc.ca/eng/C.R.C.-C.870/page-2.html#anchorbo-ga:l_C; accessible online at: http://laws.justice.gc.ca/PDF/Regulation/C/C.R.C.,_c._870.pdf; accessible online at: http://laws.justice.gc.ca/PDF/Regulation/S/SOR-95-424.pdf; http://laws.justice.gc.ca/PDF/Regulation/S/SOR-98-282.pdf.

**Implementation:** In general, current legislation covers to a large extent risks in relation to nanomaterials and those risks can be dealt with under the current legislative framework.[24]

**Statement from Poland**

**General statement:** Poland's regulations are based on European level regulatory frameworks and on following European regulations: 1) Council directive on the unification of law regulations concerning medical devices of active settlement 90/385/EWG of 20 June 1990 (European Community Official Journal WE L 189 of 20.07.1990, pp. 17) in case of active medical devices for implantations; 2) Council directive concerning medical devices 93/42/EWG of 14 June 1993 (European Community Official Journal WE L 169 of 12.07.1993, pp. 1); and 3) Council directive concerning medical devices for *in vitro* diagnostics 98/79/WE of 27 October 1998 (European Community Official Journal WE L 331 of 07.12.1998, pp. 1). Additional Acts for medical devices exists for other kinds of medical devices not mentioned before.

**Statement from the United States**

**General statement:** FDA regulates a broad range of products, including medical products, under the FD&C Act and the Public Health Service Act (PHS Act).

**Implementation:** The FD&C Act establishes requirements for the development, manufacture, and marketing of drugs and devices to ensure the safety and effectiveness of these products. Biological products are subject to the licensure requirements of the PHS Act (and the requirements contained in the license), as well as to most provisions of the FD&C Act, to ensure the safety, purity, and potency of these products. Sponsors are required to obtain marketing authorisation/premarket review from FDA to market most drugs, devices, and biological products, including combination products. These requirements address the safety and effectiveness of the product, including a review of labelling to ensure that practitioners and other users know how to administer these products and are familiar with safety and other considerations. These authorities also impose other requirements, including: the use of current good manufacturing practice; the reporting of adverse events; and the maintenance of records. The authorities also establish civil and, in some case, criminal penalties for violations of requirements, and provide FDA with enforcement and other oversight authorities to ensure compliance with statutory and regulatory requirements. FDA has the authority to withdraw product approvals and take other actions to address safety or effectiveness concerns identified for medical products on the market.

[24] Statement from Germany (additional information accessible online at: http://ec.europa.eu/nanotechnology/pdf/comm_2008_0366_en.pdf).

## ANNEX 4a. FOOD RELATED GOVERNMENT-SPONSORED REGULATORY SCIENCE RESEARCH AND OTHER RESEARCH ACTIVITY DESCRIPTIONS FROM DELEGATIONS

This section provides delegations' statements on nanotechnology activities relevant to foods products.

**Statement from Canada**

**General statement:** Health Canada's work focuses on establishing suitable reference materials and developing methods for detecting and characterising engineered nanoparticles (ENPs) in complex media.
**Implementation:** The Canadian contribution to work outlined focuses on the preparation and characterisation of well-defined ENP reference materials. The methods investigated throughout the NanoLyse research programme may be divided into four groups: 1) reference materials; 2) rapid imaging/screening methods; 3) coupled separation/characterisation methods for inorganic ENP; and 4) coupled separation/characterisation methods for functionalised and organic ENP.

**Statement from France**

**General statement:** The French authorities are able to provide the answers of 2 institutions (INRA and Institut LaSalle Beauvais). They would like to underline that this reply is by no means exhaustive.
Institut National de la Recherche Agronomique (INRA) carries out mission-oriented research for high-quality and healthy foods, competitive and sustainable agriculture and a preserved and valorised environment.
**Implementation:** In the field of nanotechnology the main objective of INRA is to perform research on: how nanotechnology applications in food science can contribute to the well-being of the consumer; the safety of nanotechnology in food products; and governance of emergence of nanotechnologies.
INRA food scientists and technologists worked with naturally existing nanomaterials and nanoscale phenomena long before 'nanotechnology' emerged as a generic term for science and technology on the nanometer scale. INRA research benefits from the combined expertise of food engineers, food chemists and physicists, nutritionists, toxicologists and social scientists. Major themes are the development of: 1) nutrient delivery systems; 2) nanosensors for detecting odours or pathogens; 3) packaging materials; and 4) *in vivo* and *in vitro* toxicological assessment of intestinal barrier function. In this last field, the government plans to evaluate different projects aiming at investigating 1) the disposition of these compounds in rats following oral exposure; 2) the genotoxicity of these substances, using in vivo approaches and tests on blood cells of exposed animals; and 3) metabolomic approaches based on NMR and MS analyses of urine, blood samples and other target tissues from animals exposed at different doses, and appropriate multivariate statistical analyses. Additionally, governance of emerging technologies entails: public perception and public debate; cost benefit analysis; technological mapping, and production of standards for risk management.
Institut Polytechnique LaSalle Beauvais is currently working on the development of biomimetic sensors for measuring mycotoxins. The goal of this project is the development of novel, versatile and high performance bio-sensors, based on the use of molecularly imprinted polymers (MIPs) to measure mycotoxins in complex food matrices. MIPs are synthetic polymeric materials containing recognition sites which are complementary in size, shape and functional groups to template molecules which were used to created them. These artificial fingerprints replace favourably the specific recognition sites of true biomolecules, which makes possible the development of robust sensors suitable for harsh environments. The sensors are based on the use of optical fibers covered by nanomaterials which in turn are enclosed by the synthetic polymer containing the specific fingerprints of the target molecule. Nanomaterials offer their increased surface/volume ratio to improve the sensitivity of sensors. The sensor measurements (coupled to a fiber optic fluorimetric system) are precise, cheap and very sensitive. Simultaneous measurements over several samples and *in-situ* measurements are possible thanks to the miniaturized analytical instrument. Possible applications resulting from this research project are multiple, and can be extensive to the areas such as biomedicine and environment.

**Statement from Japan**
**Implementation:** Government focus areas include development of: 1) methods for making fine rice powder or flour and analysis of physical characters of the products; 2) a method for making nano-size emulsion with nutrients and analysis of bioavailability on experimental animals and stability of the products; and 3) an analytical method suitable for food ingredients.

**Statement from the Netherlands**
**General statement:** NanoNextNL is the large nanotechnology research programme of The Netherlands. It covers many topics, e.g. nano-electronics, nanomaterials, food, nanomedicine and risk analysis and technology assessment. Researchers of NanoNextNL use the facilities of NanoLabNL (the national nanotechnology research infrastructure) to conduct their research. The food theme has four focus areas: 1) addressing the challenge of measuring quality and guarding the safety of food products resulting in better control over specific quality parameters. With a project to detect man-made nanostructured materials in complex matrices it also contains a connection to the risk assessment theme of NanoNextNL; 2) elucidating and understanding the interactions that give rise to molecular and supramolecular structure in food will enable food scientists to develop new functionality in products; 3) developing new food products and the associated processes can also provide better sustainable routes for fine protein-based foods, and by providing healthy components making them bio-available; and 4) microdevices for Food Processing exploit the remarkable behavior of fluids in microchannels in creating new food processing concepts.

The Dutch Food and Consumer Safety Authority has a small research programme called 'knowledge questions'. Two of those knowledge questions have been about nanotechnology and food over the last year: 1) a study that uniquely describes the risk assessment process for the use of one specific nanomaterial in food products. The aim was to identify gaps in essential knowledge and the difficulties and uncertainties associated with each of these steps; and 2) a study on detection and risk information of nanoparticles in food. Observation of trends about nanomaterials in food. Experimental research of the analysis of the presence of nanoparticles in food and aimed at exposure, kinetics or toxicology of nanoparticles in food.

**Statement from Norway**
**General statement:** Government programmes are focused on a generic approach towards research activities associated with nanotechnology and nanomaterials.
**Implementation:** Norway has funded six projects on improvement of food contact, one on vaccination of fish and one on ethics in relation to nanotechnology.

**Statement from the United States**
**General statement:** For purposes of this report, three government agencies focus on foods: FDA, National Institutes of Health (NIH), and United States Department of Agriculture (USDA). Within the FDA, regulatory science research investments include studies evaluating the application of nanotechnology in foods. Regulatory science research activities are focused on the promotion of, and participation in, research and other efforts to increase scientific understanding and to facilitate assessment of data needs for FDA-regulated products, including data needs for those that may contain nanomaterials or otherwise involve the application of nanotechnology.
**Implementation:** Regulatory science research activities include: 1) developing improved methods and tools to detect and measure the physical structure, chemical properties, and safety of nanomaterials in FDA-regulated products; and 2) developing and evaluating *in vitro* and *in vivo* assays and models to assess safety and/or efficacy of nanomaterials in FDA-regulated products; 3) targeting research in FDA-regulated product areas for potential applications of nanotechnology where risk characterisation information would help to enhance the understanding of hazard identification, exposure science, and risk modeling; 4) enhancing the state of knowledge and scientific evidence to support potential development of generalised class-based approaches to risk assessment of FDA-regulated products containing nanomaterials; and 5) improving risk

communication associated with FDA regulated product areas in which products either contain nanomaterials or otherwise involve the application of nanotechnology.

Within the NIH, foods programmes target identifying food preservation and product tracking; nano-filtration; nano-bioreactors; and real-time monitoring and regulation of delivery of nanosensors.

Within the USDA/National Institute of Food Agriculture (NIFA), investment areas include nanoscale science, engineering, and technology research that addresses a broad range of critical challenges and opportunities facing agriculture and food systems, as well as innovative ideas to develop nanotechnology-enabled solutions for global food security through improving productivity and quality, adaptation and mitigation of agricultural production systems to climate changes, improving nutritional quality of foods, and development of biology-based products and energy solutions. The programme scope includes, but is not limited to, novel uses and products of nano-biomaterials of agricultural origins for food and non-food applications, nanoscale-based sensing mechanisms and devices for early detection of diseases and monitoring of physiological biomarkers for optimal agricultural production, precision agriculture technologies including ones to efficiently manage applications of agricultural chemicals and water resources, and water quality improvements. In addition, NIFA investments will support the discovery and characterisation of nanoscale phenomena and processes important to agricultural production species.

## ANNEX 4b. MEDICAL PRODUCT GOVERNMENT-SPONSORED REGULATORY SCIENCE RESEARCH AND OTHER RESEARCH ACTIVITY DESCRIPTIONS FROM DELEGATIONS

This section provides delegation statements on nanotechnology activities relevant to medical products.

**Statement from Canada**
**General statement:** Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health.
**Implementation:** Research focuses on the bio/nano interface and investigates the biophysical interactions between nanoparticles and proteins. These proteins can either be endogenous to the body (circulatory proteins), administered therapeutics (separately or associated with the nanoparticles), or vaccine components (separately or associated with the nanoparticles). It is critical to quantify and understand these interactions as many nanoparticles have unique properties that do not exist in their bulk form. When in close contact with proteins, the unique properties of nanoparticles can result in biophysical changes to a protein. This may lead to a reduction or elimination of function and/or exposure of antigenic epitopes and recognition of the protein as foreign.

**Statement from the Netherlands**
**General statement:** The Netherlands government supports nanomedicine research via three strands: NanoLabNL, NanoNextNL, and some projects at the National Institute for Public Health and the Environment (RIVM).
**Implementation:** First, NanoLabNL provides a coherent and accessible infrastructure for nanotechnology research and innovation for parties from the Netherlands and abroad. In the field of bionanotechnology and nanomedicine access to the following expertise facilities is available: 1) nanofabrication; 2) surface analysis and characterization; 3) cellular and biomolecular analysis; and 4) cellular and biomolecular manipulation.
Second, NanoNextNL is the large nanotechnology research programme of the Netherlands. It covers many topics, e.g. nano-electronics, nanomaterials, food, nanomedicine and risk analysis and technology assessment. The nanomedicine theme focuses on targeted drug delivery (nanomedicine), specifically the development of nanocarrier systems for controlled and targeted delivery of medicine. In addition, use of nanotechnology for the development of diagnostics tools and improvement of molecular imaging techniques, cellular and biomolecular manipulation, toxicokinetic studies on the behavior of nanomaterials, effective management of potential risks posed by (manufactured) nanomaterials and nanoparticles, and improving pathogen detection by micro- and nanotechnology are additional objectives within this programme.
Third, RIVM works to evaluate the applicability of various safety assays for testing of nanomaterials both *in vitro* and *in vivo*, toxicokinetic studies on the behaviour of nanomaterials, and risk assessment of nanomaterials. Evaluation of the use of current methodology for risk assessment applied to nanomaterials is also studied by RIVM.

**Statement from the United States**
**General statement:** Two government agencies work in the medical products area, including medical products that may contain nanomaterials or otherwise involve the application of nanotechnology.
**Implementation:** Within the FDA, regulatory science research investments include studies evaluating the application of nanotechnology in medical products. Regulatory science research activities focus on the promotion of, and participation in, research and other efforts to increase scientific understanding and to facilitate assessment of data needs for FDA-regulated products, including data needs for FDA-regulated products that may contain nanomaterials or otherwise involve the application of nanotechnology. Regulatory science research activities include: 1) developing improved methods and tools to detect and measure the physical structure, chemical properties, and safety of nanomaterials in FDA-regulated medical products; 2)

developing and evaluating *in vitro* and *in vivo* assays and models to assess safety and/or efficacy of nanomaterials in FDA-regulated products; 3) targeting research in FDA-regulated product areas of potential applications of nanotechnology where risk characterisation information would help to enhance the understanding of hazard identification, exposure science, and risk modeling; 4) enhancing the state of knowledge and scientific evidence to support potential development of generalised class-based approaches to risk assessment of FDA-regulated products containing nanomaterials; and 5) improving risk communication about FDA regulated products that contain nanomaterials or otherwise involve the application of nanotechnology.

Within the NIH, research investments also supports nanotechnology-related projects and programmes focusing on utilising the unique properties of materials at the nanoscale to develop new diagnostics, therapeutics, biological interfaces, drug delivery systems, and other medical product applications.