Health Canada Santé Canada

Interim Policy Statement on Health Canada's Working Definition for Nanomaterials

1. Introduction

Nanomaterials are being used in the marketplace in a wide range of products and substances, a trend which is expected to increase in the future. Health Canada helps protect and promote health by using existing legislative and regulatory frameworks to mitigate the potential health risks of nanomaterials and to help realize their health benefits. However, it is recognized that new approaches may be necessary in the future to keep pace with advances in this area as there is inadequate information on risks associated with nanomaterials at this time. A working definition is a useful tool which can help the Department gather safety information about products containing nanomaterials.

2. Objectives

The key objectives of this policy statement are to:

(1) Establish a working means of identifying nanomaterials;

(2) Assist Health Canada to collect information and establish internal inventories regarding products, materials, substances, ingredients, devices, systems or structures that are, contain, or make use of nanomaterials;

(3) Support communications about nanomaterials with the broader community of interested stakeholders; and,

(4) Support the administration of the legislative and regulatory frameworks under the authority of Health Canada and to help further the development of policy, guidance and programs applicable to nanomaterials.

3. Policy statement

Health Canada's Working Definition of Nanomaterials

Health Canada considers any manufactured product, material, substance, ingredient, device, system or structure to be nanomaterial if:

a) It is at or within the nanoscale in at least one spatial dimension, or;

b) It is smaller or larger than the nanoscale in all spatial dimensions and exhibits one or more nanoscale phenomena.

For the purposes of this definition:

i) The term "nanoscale" means 1 to 100 nanometres, inclusive;

ii) The term "nanoscale phenomena" means properties of the product, material, substance, ingredient, device, system or structure which are attributable to its size and distinguishable from the chemical or physical properties of individual atoms, individual molecules and bulk material; and,

iii) The term "manufactured" includes engineering processes and control of matter and processes at the nanoscale.

4. Scope and application

The state of science around nanomaterials is evolving. A flexible approach is warranted to capture important changes which will occur as our knowledge about real and perceived risks and benefits related to nanomaterials continues to develop. This working definition of nanomaterials intentionally casts a wide net so that diverse program areas and legislative and regulatory authorities across Health Canada can request and collect necessary information for nanomaterial characterization and nanoscale measurement, as described in the general guidance section. It will be updated as the body of scientific evidence increases and international norms progress.

Other sources of definition provide context for the application of this statement, including the sources listed in Appendix A.

The working definition will be applied in specific regulatory contexts across the Department to support the assessment of nanomaterials and to provide assistance to manufacturers and other stakeholders in meeting their respective statutory obligations for the health and safety of Canadians, pursuant to applicable Acts and Regulations including, but not limited to, those stated in Appendix B. Guidance documents specific to products, substances or commodity groups will be developed over time.

The Department will apply the appropriate precautionary approaches[1] as may be warranted, according to the best available information.

Furthermore, Health Canada encourages manufacturers and other stakeholders to communicate with the Department early in the development process, especially for combination products that are, contain or make use of nanomaterials.

[1] *A Framework for the Application of Precaution in Science-based Decision Making about Risk* (2003), Privy Council Office.

5. Authority

Health Canada has authorities within existing legislative and regulatory frameworks, including those listed in Appendix B, to require the submission of information that is essential to the assessment of potential risks to the health and safety of Canadians.

6. General guidance

In order to identify and assess potential risks (and benefits where applicable) of nanomaterials, the Department may require the following types of information:

1) Intended use of the nanomaterial, including any end product in which it will be used;
2) Characterization of the nanomaterial, including manufacturing methods, identity and purity;
3) Physico-chemical properties, toxicological, eco-toxicological, metabolism and environmental fate data that may be both generic and specific to the nanomaterial if applicable; and,
4) Risk assessment and risk management strategies, if considered or implemented.

Future guidance specific to program areas and legislative and regulatory authorities will be developed in a manner that promotes a consistent set of approaches.

7. Date of senior management approval: November 23, 2009

Appendix A – Other Sources of Definitions

(1) Standards, particularly the standards for nanotechnology established by the International Organization for Standardization Technical Committee 229[2] (ISO TC 229)

(2) *Intellectual property*, as described in the International Patent Classification or in the United States Patent Classification

(3) *Canadian governmental guidance or regulatory definitions*, as developed by Federal Departments and Agencies, *and international regulatory guidance or regulatory definitions*, as developed by peer regulators and/or competent national authorities in other nations and jurisdictions

[2] http://www.iso.org/iso/standards_development/technical_committees/other_bodies/iso_technical_committee.htm?commid=381983

(4) *Descriptive lists and examples* based on Health Canada's experience and precedent, gathered through operations of applicable Canadian legislative and regulatory frameworks

Appendix B – Acts and Regulations

This draft interim policy statement will be applied under Acts and Regulations which are relevant to nanomaterials at Health Canada, which include but are not limited to:

(1) Food and Drugs Act
- Cosmetic Regulations
- Food Additive Regulations
- Food and Drug Regulations
- Medical Devices Regulations
- Natural Health Products Regulations
- Novel Food Regulation
- Safety of Human Cells, Tissues and Organs for Transplantation Regulations

(2) Canadian Environmental Protection Act 1999
- New Substances Notification Regulations (Chemicals and Polymers)
- New Substances Notification Regulations (Organisms)

(3) Hazardous Products Act

(4) Pest Control Products Act
- List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern
- Pest Control Products Regulations

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