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INSTITUTE FOR SCIENCE, SOCIETY AND POLICY

PRIMER
REGULATION
2011

A Primer on Nanomaterials Regulation

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Acknowledgments

We wish to thank Health Canada for financial support and all respondents of our survey and all our interviewees (from seven regulatory departments and agencies of the Government of Canada) for their valuable input – all errors in this text remain our own.

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Preamble

This Primer describes the existing federal regulatory framework for nanomaterials in Canada and provides a starting point for a successful debate on nanomaterials regulation. To do this, it is necessary to explain what nanomaterials are, and select some examples. However, as soon as such examples are named, stakeholders legitimately wonder if the examples represent an emerging "black list" or if those materials that were not selected will be ignored. The approach we chose for this Primer is to use the least controversial list of nanomaterials available to identify the most important Canadian federal regulations and regulators.

This Primer is directed at anyone with a serious interest in the effective and appropriate governance of nanotechnologies and nanomaterials in Canada – policymakers, regulators, innovators and the interested public. We preface this inquiry with a detailed explanation of why one would pay attention to nanomaterials in a regulatory context.

Key concepts are highlighted throughout the Primer in **boldface**. The focus of the Primer is federal regulation, but we should note that other levels of jurisdiction may play a major role in regulating, and that regulation is just one instrument when it comes to the governance of emerging technologies (voluntary measures are another instrument, for example).

Regulation in an Age of Rapid Innovation

Regulating an emerging technology is rarely straightforward because little is known about the potential risks and benefits of brand-new innovations. Yet, the protection of human health and the environment demands policy-makers think ahead. They will typically find the following situation. On one hand, it is unknown if the new technology will lead to serious damage to human health or the environment, especially over the longer term, but it seems quite clear that burdensome regulations will hamper innovative start-ups. On the other hand, a potential human health or environmental crisis represents a larger public policy issue than the damage that could be caused by burdensome regulations. It does not help that innovators rather than regulators initially hold risk-relevant information, resulting in practical challenges to information sharing and trust. Because discussions on emerging technologies are laden with jargon and uncertainties, it is not rare that policymakers and communicators struggle to engage in the debate or to form a clear opinion.

Among emerging technologies, nanotechnology is not a simple case. Together with its ingredients and products, nanomaterials, nanotechnology touches on all sectors in a very significant way because the potential combined world market is in the trillion-dollar

range. Regulatory decisions are risk-based and are informed by the best available scientific evidence.

The challenge of regulating nanomaterials raises the following question: *How does one regulate **in many sectors** based on only **emerging** knowledge; knowledge that may be incomplete, may not be fully understood, or may not be fully trusted?*

This question needs to be answered in a step-wise fashion and priority setting is key. Regulations can be applied to any conceivable context along the innovation life cycle (more on this below), and decisions need to be made regarding where to focus attention, which jurisdiction should act and which policy instrument should be chosen. Regulation is only one instrument within a toolkit that is available to craft a desired policy outcome. In a nutshell, a regulation is a legal instrument that is subordinate to an existing law. Although regulations are developed by the public service rather than elected officials, they remain under political oversight and need to pass a political approval process. Regulations, thus, are often called "delegated law." Non-legal or paralegal policy instruments that function like regulations are other important components of regulatory activity; in Canada they have been highlighted within the so-called "SMART Regulation" concept (the acronym for **S**pecific, **M**easurable, **A**ttainable, **R**ealistic, and **T**imely), which is a foundation for the Cabinet Directive on Streamlining Regulation.

The concept of **regulatory attention** sheds some light on how policy makers and regulators approach priority setting. Regulatory attention comes in two kinds: (1) attention to a specific material or product that triggers a **routine** regulatory reaction or (2) attention to a new technology, a group of products or a single new product that triggers a **non-routine** reaction: a reaction that could culminate in an adjustment of regulatory processes, the legal text of the regulation itself or even in the creation of a new legal instrument. In analogy with Thomas Kuhn's analysis of the progress of science, one could call the former "**normal regulation**" and the latter "**paradigm-shifting regulation**." During times of normal regulation, the process is efficient and routine, whereas paradigm shifts are the results of serious stresses on the regulatory system.

We need to discuss the concept of '**novelty**', which is integral to any implementation of a regulation, whether routine or non-routine. A non-novel product such as a substance that is already considered safe or ready for sale in the market place (white-listed or registered) will not trigger a regulation. However, if the product is different in a risk-relevant way, then it should trigger a regulation. We must remember, that risk not only is a function of the nature of the material itself (its hazard) but also a function of the amount released, the place and nature of the release and its transportation and transformation in the environment (the exposure). Therefore, a change to the quantity released, for example, can also represent a novelty in regulatory context. Such changes could occur anywhere on the life cycle from importation or manufacturing to disposal.

The risk and novelty contexts can be taken further and also be applied to regulatory capacity, administrative capacity, public perception and so forth. Here is a list of some key concepts of novelty that matter in the context of nanomaterials – all these can be causes for regulatory attention:

- A completely novel material
- A known material with novel properties (regarding fate or effect or both)
- A new level of exposure predicted because of intense research activities
- A significant recent increase in use or release, or a novel use
- A new indication of hazard
- New public attention

To judge if nanomaterials should be considered novel in such fashion – and, thus, trigger regulatory attention – we will use the **thirteen representative nanomaterials** identified by the international community, under the lead of the Organization for Economic Co-operation and Development (OECD) amended by a "catch-all" category to cover the many complex nanomaterials that have already arrived or are anticipated in the marketplace and regulatory system. At this stage, the set of materials simply serves to evaluate if nanomaterials have features that are worthy of regulatory attention. We will explain the nature of the materials and expound on the utility of this list later in the text.

Table 1, below, judges the OECD representative materials (plus a category for complex nanomaterials) in the light of these six kinds of novelty based on the best current knowledge of the authors – this can be no more than an illustration at this point and is also bound to change over time. We assigned the thirteen nanomaterials into four groups ("carbon," "dendrimers and clays," "metal nanoparticles" and "metal-oxide nanoparticles") to improve the visual legibility of the list.

Table 1: Six Kinds of Regulatory Novelty and the Example of OECD Representative Materials (amended by a "Complex Nano-based Constructs" category and based on the best current knowledge of the authors).

NOVELTY / MATERIAL	Basic Properties		Public Risk			Other
	Completely Novel Material	Known Material with Novel Properties	Significant Recent Increase in Research Activity	Significant Recent Increase in Use or Release	New Indication of Potential Hazard	New Public Attention
Carbon						
Single-walled Carbon Nanotubes	*		*	*	*	*
Multi-walled Carbon Nanotubes	*		*	*	*	*
Fullerenes	*		*			
Dendrimers and Clays						
Dendrimers	*					
Aluminosilicate Nanoclays		*	*			
Metal Nanoparticles						
Silver nanoparticles		*	*	*	*	*
Iron nanoparticles		*	*	*	*	
Gold nanoparticles		*	*			
Metaloxide Nanoparticles						
Titanium dioxide nanoparticles		*	*	*	*	*
Aluminum oxide nanoparticles		*	*			
Cerium oxide nanoparticles		*	*		*	
Zinc oxide nanoparticles		*	*	*		
Silicon dioxide nanoparticles		*	*	*		
Complex Nano-based Constructs						
Composites, formulants, assemblies	*		*	*		*
Regulatory Attention Due To:	Truly novel risk or benefit	"Small is different"	Future scale of exposure	Novel scale of exposure	Novel effect, hazard	Novel public trust issue

One certainly may quibble with how representative the list is and how to assign the stars in **Table 1** (particularly in the "new indication of potential hazard" column) but the overall picture shows that even this short list triggers regulatory attention of all kinds. We have thus established that a regulatory discussion is meaningful at this stage.

Once a novelty event occurs, in particular when it is a potential cause for regulatory paradigm shifts, then the potential gaps, duplications, weaknesses and strengths of the current regulatory framework need to be evaluated. In the case of nanomaterials, the list of potential **regulatory stresses** is as follows:

- *Lack of information* about what is being produced and how it is being used, for example, caused by legislative exemptions such as the volume triggers in the *Canadian Environmental Assessment Act*.
- *Lack of appropriate administrative and scientific terminology*, for example, when there is no nomenclature to name the difference between a white-listed or registered material and a new nano-form with novel properties.
- *Lack of agreement (or understanding) over the fundamental assumptions and value judgments in scientific assessment,* for example when the scope of an assessment needs to be adjusted or when standards of quality need to be aligned internationally.
- *Gaps in the scientific assessment*, for example, when parts of the life cycle of a product are not considered or when pre-market assessment appears important but is not legally mandated. Note that regulatory issues may arise throughout the life cycle from research and manufacture (workplace safety and containment issues), through regular use (consumer health and environmental pollution issues), to product failure and disposal.
- *Gaps in the detection toolkit*, for example, when the presence or absence of a novel substance simply cannot be ascertained.
- *Gaps in the coverage of all relevant types*, for example, when incidental releases could cause harm or when a product type is unknown to regulators.
- *Insufficient capacity to evaluate*, for example, when new product submissions or notifications arrive faster than experts can be found and hired.
- *Insufficient foresight*, for example, when a new hazard is first reported in the media rather than by regulatory scientists.
- *Insufficient international cooperation*, for example, if a key player, such as China, does not participate in the international efforts to harmonize regulations (e.g., via the OECD).

A basic need for the anticipation and identification of regulatory novelty, and the potentially ensuing regulatory stresses, is an understanding of the innovation pipeline and, in some cases, a tailoring of the **notification triggers** (the circumstances under which companies must notify regulators that they are importing or producing nanomaterials). To discuss the issue better we need to turn now to some basic definitions and concepts used in nanomaterials regulation.

Talking About "Nano"

Nanotechnology, literally "dwarf-technology", deals with very small things. There are many definitions in use for key terms such as the nanoscale, nanotechnology, and nanomaterials. This section will provide a selected definition for each of these words.

In the world of physics, definitions are relatively straightforward. The **nanoscale** ranges from 1 to 999 nanometers (nm). When you add 1nm to the top of that scale, you have a micrometer (µm), still very small at one thousandths of a millimeter. At the bottom of the scale we arrive at the world of molecules and atoms. For example, the size of a single carbon atom is about 1/10 of a nanometer (0.1nm) while a gold atom is about 1/3 (0.3nm) of a nanometer. Human DNA is about 3nm wide, while a virus may be 100nm in diameter. At the lower end of the nanoscale, quantum mechanics become a dominant force.

A key definition is used by the world-leading U.S. National Nanotechnology Initiative (NNI): "**Nanotechnology** is the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications."

Due to the early leadership position of the NNI, its definition is often used and it has become common to restrict the nanoscale (see above) to 1-100nm. However, the justification of a sharp upper limit is contested on scientific grounds, for example by the Scientific Committee on Emerging and Newly Identified Health Risks of the European Commission. The International Organization for Standardization (ISO) is another important player in the conception of nano terminologies and the discussion shows no signs of abating.

Health Canada has been an international leader in defining the third term, **nanomaterials**. The *Policy Statement on Health Canada's Working Definition for Nanomaterials* states:

> "Health Canada considers any manufactured substance or product and any component material, ingredient, device, or structure to be nanomaterial if:
>
> (a) It is at or within the nanoscale in at least one external dimension, or has internal or surface structure at the nanoscale, or;
>
> (b) It is smaller or larger than the nanoscale in all dimensions and exhibits one or more nanoscale properties or phenomena."

Talking about nanomaterials would be easier if we would only be dealing with freely moving **particles**. Nanomaterials, however, can be many things. Nanomaterials can also be **membranes** or **clays** where we are not dealing with particles but the inverse: pores or cavities. While the **scaling down** of materials to the nanoscale is a current interest,

we must not forget that nanotechnology is also about the **building up** of materials. For example, the enwrapping of a substance inside a membrane to alter a property, such as water-solubility, results in a nanomaterial. Nanomaterials may also be scaffolds or polymers. It can be anticipated that some future nanomaterials will represent highly complex **engineered assemblies.**

From a regulatory perspective it matters whether the release of a nanomaterial is **natural**, **incidental**, or **intentional**. Natural nanomaterials (such as parts of volcanic ash) and incidental nanomaterials (such as parts of diesel exhaust) are not rare. However, since regulations are a body of legally binding rules that are designed to influence human actions, the primary target is intentional releases of manufactured nanomaterials. Finally, nanomaterials may be used during the **production process** and no longer be present in a commercial product, or they may be present but entirely **absorbed** into a matrix, or they may **aggregate** beyond the nanoscale. These features do matter in a risk assessment, of course.

Given the number of interwoven concepts and similar-sounding definitions, a discussion on the regulation of nanomaterials takes much precision and care. Many of us discussing this file simply use the word “nano” to save some time but it does not always help to speak of dwarfs… we are well advised to watch our tongues when it comes to mythical creatures.

Toward a Starting Point: Representative Nanomaterials

In the first section of this Primer, we used a list published by the OECD without much justification. In this section we will explain this choice.

A review of the nanomaterials regulation would ideally begin with a complete list of nanomaterials – a challenging prospect considering the controversy surrounding current definitions. The best-known comprehensive list is published by the *Project on Emerging Nanotechnologies* (supported by the U.S. Pew Charitable Trusts and the Woodrow Wilson Centre for International Scholars), which reports approximately 1300 products in the Nanotechnology Consumer Products Inventory. While this inventory is a very useful tool, nanotechnology experts have contested many of its entries and no formal assessment of products prior to inclusion in the inventory is required. Furthermore, it is not arranged in categories that matter to regulators. Regulators are interested in issues such as label claims, quantities produced and basic features like biological activity, environmental persistence, water solubility and so forth. However, the inventory lists products according to commercial categories such as “appliances” or “home and garden.”

On the upside, many regulations apply to fully formulated, commercial products such as the ones listed in the Nanotechnology Consumer Products Inventory. These products, if they **trigger** a regulation (for example, if a therapeutic claim is made) will be, or have been reviewed under routine regulatory procedures. In addition, regulators can ask the

question: what changes if these products contain nano-sized materials? Indeed, some of the existing regulatory procedures may need to be discussed, improved, or even replaced, because detection methods, bioassays and models commonly used may not be appropriate for the nano-sized ingredients of formulated products.

Despite these issues, the attention of the international regulatory community is elsewhere. The biggest worry lies in the unknown; for example, the nanomaterials that are unknown to be produced (if they do not trigger the regulatory requirement for notification; then they are silently present, so-to-speak) or those that are contained in products with limited pre-market regulations, such as cosmetics. Of particular interest are nanomaterials that are completely novel or those that are well known in their bulk form but that exhibit new properties at the nanoscale.

In Canada, the *Canadian Environmental Protection Act* (CEPA) is designed to deal with substances with new properties. CEPA requirements are triggered when the production or import of a new substance hits a certain **quantity-threshold**. The issue that CEPA administrators and jurisdictions internationally grapple with is that the current thresholds may no longer be appropriate in all cases, as nanomaterials may exhibit far greater activity per weight-unit than their macro-sized counterpart.

The 13 OECD representative materials introduced in **Table 1**, above, cover many of these issues. Furthermore, many, if not most, of the products in the Consumer Products Inventory are based on the OECD representative materials. We should note that the OECD admits that their list of priorities is a snapshot in time; it has changed in the past and it will change in the future. However, it provides a starting point for discussion because commercial substances with new properties are currently and internationally a key issue in nanomaterials regulation. Last but not least, while the list may be controversial, it is by far the least controversial list in existence and it has the benefit of international standing.

The *OECD Working Party on Manufactured Nanomaterials* (WPMN) explains its selection of representative manufactured nanomaterial in its December 2010 paper, as follows:

> "The list of representative manufactured nanomaterial has been selected by the WPMN for use in its work. The word "representative" refers to those manufactured nanomaterials now, or soon to enter into commerce, for inclusion in a set of reference materials to support measurement, toxicology and risk assessment of nanomaterials. Therefore, the list was mainly selected taking into account those materials which are in commerce (or close to commercial use), but other criteria were also considered: for example, production volume, the likely availability of such materials for testing and the existing information that is likely to be available on such materials.
>
> It was also emphasised that certain nanomaterials not included in the list may become important in the future and certain nanomaterials currently on the list may have (over time) reduced production and/ or use. Accordingly,

> the list should be considered as a "snapshot in time" of those nanomaterials in commerce or likely to enter into commerce in the near term. At the same time, some nanomaterials on the list may have variants that the WPMN may wish to consider in detail in the future."

By relating the thirteen OECD representative materials to their current uses (**Table 2**, below), plus a catch-all category for complex constructs, we gain a starting point, the ability to identify the key regulations that should be considered at this point in time (ultimately, however, all sectors are likely to have nanomaterial components and a larger number of regulations will have to deal with the "nano-file").

Table 2: A Description of OECD Representative Materials (Plus Complex Constructs). Common to these materials is that significant size reduction causes a change in the fundamental properties or phenomena. Descriptions and potential uses are based on the best current knowledge of the authors – some potential uses may not become realized.

Material	Description	Potential Uses
Carbon		
Single-walled Carbon Nanotubes	Carbon nanotubes are essentially rolled up graphene sheets - graphene is a one-atom thick sheet of carbon atoms - which are arranged in a honeycomb structure. Multi-walled nanotubes are comprised of thinner tubes nested inside larger ones. Single-walled nanotubes are hollow inside. Carbon nanotubes are only one to few nanometers in diameter, but may be synthesized to be up to several centimeters in length.	Polymer composites, medical applications (including potential cancer treatments), atomic force microscopy, solar cells, materials, electrical circuits, flame retardants
Multi-walled Carbon Nanotubes		
Fullerenes	Fullerenes are spherical and hollow carbon structures, which roughly resemble soccer balls. The most common fullerene, the Buckminster fullerene, is composed of 60 carbon atoms (diameter ~ 1nm). Fullerene structures can, however, be synthesized in various sizes and also can be nested in one another like the many layers of an onion.	Superconductors, fuel cells (photovoltaics), transport, drug carriers, polymer additives, electronics
Dendrimers and Clays		
Dendrimers	Dendrimers are repeatedly branching and roughly spherical organic structures, which are typically symmetrical around the core. The properties of dendrimers are dominated by the functional groups incorporated in the structure as well as their size.	Drug delivery, sensors
Alumino-silicate nanoclays	Nanoclays are aluminosilicate (similar to glass) structures containing nano-sized pores. They can be thought of as an inert, rigid and porous material.	Flame retardants
Metal Nanoparticles		
Silver nanoparticles	Metal nanoparticles are very small particles of metal - approximately 10,000 to 100,000 metal atoms come together to form nanoparticles on the order of 1 to 10nm in diameter. Metal nanoparticles have increased surface area relative to bulk metals.	Antibacterial applications, including wound dressings, clothes, and appliances
Iron nanoparticles		Treat ground contamination
Gold nanoparticles		Combined with light therapy to treat cancer, imaging, catalysis

Material	Description	Potential Uses
Metaloxide Nanoparticles		
Titanium dioxide nanoparticles	Oxidized metal nanoparticles are smaller version of bulk materials that may exhibit, for example, greater translucency (in the case of sunscreens) or greater ability to form composites (in the case of bone and dental implants).	Sunscreen, white pigment, catalysis, self cleaning surfaces, water treatment
Aluminum oxide nanoparticles		Polymer composite – strong and light materials (bone and dental implants)
Cerium oxide nanoparticles		Sunscreen, diesel fuel additive
Zinc oxide nanoparticles		Sunscreen, electronics and photonics applications
Silicon dioxide nanoparticles		Nano silica composite fuel cells, scratch resistance, gold coated nanosilica in tumour targeting, agro-products, pesticides
Complex Nano-based Constructs		
Composites, formulants, assemblies	Liposomes, micelles, nano-emulsions, polymer materials, nano-scaffolds, quantum dots (etc.)	Formulations of drugs and vaccines, targeted drug delivery, medical devices, bone tissue engineering, cosmetics, imaging, industrial applications.

In **Table 3**, below, we map the OECD representative nanomaterials onto five broad industrial sectors to help in the identification of key regulations (the precise allocation of stars in **Table 3** is not very important, what matters is the big picture of identifying the broad regulatory space):

- **Medical:** Products defined as drugs, medical devices, certain cosmetics, supplements and natural health products. These products are used in the diagnosis, treatment, mitigation or prevention of diseases, disorders, abnormal physical states, or its symptoms, either in animals or in humans as well as those products that restore, correct or modify bodily functions or body structures.
- **Food and Food Packaging:** This sector includes those products that are ingested by humans like foods, novel foods and food additives, as well as products that are used to package and store food.
- **Agriculture (other than food):** Products used in the agricultural sector such as fertilizers, feeds, and pesticides.
- **Consumer products:** This broad sector encompasses products obtained by an individual to be used for non-commercial purposes, such as household products, cosmetics, clothing and electronics.

- **Industrial and commercial products:** These products are often purchased, acquired or manufactured on a large scale by parties in the course of their business. They include products in the field of research and development, military and security, environmental remediation, waste management, manufacturing as well as construction and building materials.

Table 3: Industrial Sectors and OECD Representative Materials (Plus Complex Constructs) – Based on the best current knowledge of the authors.

	Industrial Sector				
	Medical	**Food & Food Packaging**	**Agriculture**	**Consumer Products**	**Industrial & Commercial Products**
Carbon					
Single-walled Carbon Nanotubes	*			*	*
Multi-walled Carbon Nanotubes	*		*	*	*
Fullerenes	*			*	*
Dendrimers and Clays					
Dendrimers	**			*	
Aluminosilicate Nanoclays	*		*	*	
Metal Nanoparticles					
Silver nanoparticles	*	*	*	*	*
Iron nanoparticles					*
Gold nanoparticles	*				*
Metaloxide Nanoparticles					
Titanium dioxide nanoparticles	*	*		*	*
Aluminum oxide nanoparticles	*	*			
Cerium oxide nanoparticles					*
Zinc oxide nanoparticles		*		*	*
Silicon dioxide nanoparticles	*	*	*	*	*
Complex Nano-based Constructs					
Composites, formulants, assemblies	***	*	*	**	**
Overall Relative Importance	***	*	*	**	***

The Canadian Regulatory Landscape for Nanomaterials

While Canada currently relies on existing legislation and their associated regulations to mitigate potential risks of nanomaterials and to help realise their benefits, it is recognised that new approaches may be necessary in the future, as it is an emergent field.

Manufactured nanomaterials can fall under the regulatory umbrella of not only several federal agencies, but also multiple acts and regulations. This pervasiveness makes the regulatory landscape of manufactured nanomaterials a complex one. Based on **Tables 2** and **3**, above, key regulatory instruments are summarized below in an attempt to shed light on this topography. These regulations are listed in **Table 4**, below. They have been selected for their potential of becoming key regulations for nanomaterials (in the broadest sense) in the short to medium term.

Table 4: Key Canadian Federal Regulations in the Context of Nanomaterials

Scope Of Regulation	Legislation And Regulations	Federal Agency
Consumer Products	Hazardous Products Act; Canada Consumer Product Safety Act	Health Canada
Pest Control Products	Pest Control Products Act	Health Canada
Fertilizers	Fertilizers Act	Agriculture and Agri-food Canada, Canadian Food Inspection Agency
Feeds	Feeds Act	Health Canada, Canadian Food Inspection Agency
Drugs Cosmetics Medical devices Foods	Food and Drugs Act: • Cosmetics Regulations • Natural Health Product Regulations • Medical Devices Regulations • Food and Drug Regulations (drugs, novel foods, food packaging, food labeling, and food additives)	Health Canada, Canadian Food Inspection Agency
Natural Environment and Human Health	Canadian Environmental Protection Act: • New Substances Regulations	Environment Canada, Health Canada
	Canadian Environmental Assessment Act	Environment Canada
	Canada Water Act	Environment Canada
Fisheries	Fisheries Act	Environment Canada, Fisheries and Oceans
Animal Health	Health of Animals Act	Agriculture and Agri-food Canada, Canadian Food Inspection Agency
Handling or Transportation of Dangerous Goods	Transportation of Dangerous Goods Act	Transport Canada
Occupational Health and Safety	Canada Labour Code, Part II and Occupational Health and Safety Regulations; Part II of the Hazardous Products Act Workplace Hazardous Materials Information System (WHMIS)	Labour Program of Human Resources and Skills Development Canada; National WHMIS Office (and provincial and territorial agencies)

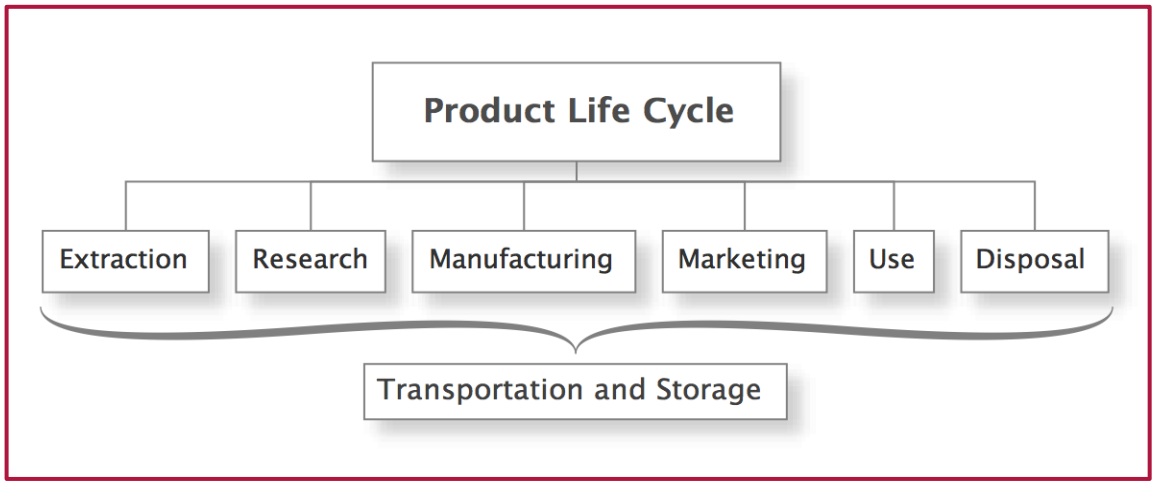
Note that regulations of trade and commerce, for example the *Consumer Packaging and Labeling Act,* the *Patent Act* and the *Canada Agricultural Products Act*, were not included in this Primer. Moreover, the regulation of high-risk products such as explosives and

tobacco were omitted, as the potential incremental risk of nanomaterials would be negligible in this context.

We are now ready to move to a summary of nanomaterials regulation in Canada. **Table 5** (next page) correlates the five industrial sectors from **Table 3** with the key regulations from **Table 4**.

It is meaningful to use the concept of the Product Life Cycle at this stage – see **Figure 1** for an illustration. In **Table 5** we distinguish the most basic steps in the innovation life cycle (pre-market and post-market, in particular) and this helps highlight the respective responsibilities of various federal agencies involved.

Figure 1: Components of a Product Life Cycle



"Entire Life Cycle" in **Table 5** addresses all steps, including Transportation and Storage.

"Pre-market" in **Table 5** addresses the steps *before* Marketing.

"Post-market" in **Table 5** addresses the steps *after* Marketing.

Table 5: Life Cycle Perspective of Federal Regulations Currently Relevant to Nanomaterials

	Industrial Sector				
	Medical	**Food and Food Packaging**	**Agriculture**	**Consumer Products**	**Industrial & Commercial Products**
Entire Life Cycle	**Importation/Production – Use – Disposal (or Release Into Environment):** *Canadian Environmental Protection Act* (HC, EC) *Canadian Environmental Assessment Act* (EC) *Canada Water Act* (EC) *Fisheries Act* (EC, DFO) *Health of Animals Act* (AAFC, CFIA) **Handling - Transportation:** *Canada Labour Code* (Labour Program of HRSDC) *Hazardous Products Act* Part II (HC) *Transportation of Dangerous Goods Act* (TC) **Consumer Products:** *Canada Consumer Product Safety Act* (HC) ***Legend:*** ***AAFC:*** *Agriculture and Agri-Food Canada* ***CFIA:*** *Canadian Food Inspection Agency* ***DFO:*** *Fisheries and Oceans Canada* ***EC:*** *Environment Canada* ***HC:*** *Health Canada* ***TC:*** *Transport Canada* ***HRSDC:*** *Human Resources and Skills Development Canada*				
Pre-market	**Medical devices (Classes II, III, IV):** *Food and Drugs Act* (HC) **Drugs:** *Food and Drugs Act* (HC) **Supplements and Natural Health Products:** *Food and Drugs Act* (HC)	**Novel Foods:** *Food and Drugs Act* (HC) **Food Additives:** *Food and Drugs Act* (HC) **Food packaging and storage in registered establishment:** *Meat Inspection*, *Fish Inspection and Egg Regulations* (CFIA)	**Pest Control Products**: *Pest Control Products Act* (HC) **Feeds:** *Feeds Act* (HC, CFIA) **Fertilizers:** *Fertilizers Act* (AAFC, CFIA)	**Pest Control Products**: *Pest Control Products Act* (HC) **New Substances**: *Canadian Environmental Protection Act New Substances Notification Regulations* (EC, HC)	
Post-market	**Medical devices:** *Food and Drugs Act* (HC) **Drugs:** *Food and Drugs Act* (HC) **Supplements and Natural Health Products:** *Food and Drugs Act* (HC)	**Food Labeling:** *Food and Drugs Act* (HC)	**Pest Control Products**: *Pest Control Products Act* (HC) **Fertilizers:** Fertilizers Act (AAFC, CFIA)	**Pest Control Products**: *Pest Control Products Act* (HC) **Cosmetics:** *Food and Drugs Act* (HC)	**Pest Control Products**: *Pest Control Products Act* (HC)

Based on **Table 5**, when looking at regulations that cover the **entire life cycle**, Environment Canada plays an important role along with the Department of Fisheries and Oceans, the Canadian Food Inspection Agency, and Transport Canada; and the Labour Program of Human Resources and Skills Development Canada is responsible for the maintenance and enforcement of the Canada Labour Code Part II and its pursuant Regulations.

Under **pre-market** regulation, we find acts and regulations under the authorities of Health Canada (in particular) and Environment Canada. The Canadian Food Inspection Agency is also significantly involved, although the OECD representative nanomaterials are not immediately expected to show up in food.

Health Canada is the department mostly responsible for **post-market** regulations in the context of OECD nanomaterials. A focus on formulated products will not change this picture.

Table 5 and the additional comment above provide a succinct map of the existing federal regulatory framework for nanomaterials in Canada. As a tool, **Table 5** is intended to help not only those stakeholders who require a quick introduction to the regulatory mechanisms that can be triggered by nanomaterials, but also those stakeholders who are part of the regulatory system and are tasked with optimizing coordination of their activities with other regulatory agencies and departments.

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