

FACTSHEET

REGULATORY ROADMAP FOR NEW SUBSTANCES IN CANADA

Anyone (person or company) who wants to import, manufacture or sell any new substance is required to notify the appropriate Canadian regulatory authority so the new substance can be evaluated for potential effects on human health and the environment prior to the importation, manufacturing or sale (as the case may be).

The Canadian Environmental Protection Act, 1999 (CEPA) is the key authority for the government to ensure that all new substances are assessed for their potential to harm human health or the environment. Recognizing that other Acts provide for such an assessment process, CEPA includes a provision whereby substances regulated by other Acts are exempt from the new substance notification requirements of CEPA. This avoids regulatory duplication, while ensuring that standards for protection of the environment and human health are met, and applied to all substances.

Under CEPA, the Government determines, by order, which Acts and Regulations meet the above criteria for providing appropriate notification and assessment and lists them in published Schedules (or 'annexes') to CEPA. Acts and Regulations relating to new substances that are chemicals or polymers are listed in Schedule 2 and those that are animate products of biotechnology are listed in Schedule 4. To date, it has been determined that the following Acts and Regulations meet the CEPA criteria:

TABLE 1

CEPA SCHEDULES OF ACTS AND REGULATIONS (SEPT 13, 2001)

Schedule 2 (chemicals and polymers)	Schedule 4 (animate products of biotechnology)
Pest Control Products Act & Pest Control Products Regulations	Pest Control Products Act & Pest Control Products Regulations
Feeds Act & Feeds Regulations	Feeds Act & Feeds Regulations
Fertilizers Act & Fertilizers Regulations	Fertilizers Act & Fertilizers Regulations
	Seeds Act & Seeds Regulations
	Health of Animals Act & Health of Animals Regulations (veterinary biologics)

Other Acts, such as the *Food and Drugs Act*, the *Plant Protection Act* and the *Fisheries Act*, may be added to these Schedules at a later date as they are amended or created, and when they meet the CEPA criteria for listing. At this time, new substances subject to these “non-listed” Acts are also subject to the CEPA *New Substances Notification Regulations*. Proponents are encouraged to contact the appropriate agency to obtain clarification. For more information on the CEPA New Substances program, please call 1 800 567-1999 or visit the New Substances website at <http://www.ec.gc.ca/substances>.

Tables 2 and 3 relate the regulatory responsibilities for new substances to various Acts and Regulations as of September 13, 2001. Table 2 is organized by regulatory authority, and Table 3 is organized by substance type and use.

TABLE 2

**ACTS AND REGULATIONS APPLICABLE TO THE ENVIRONMENTAL
AND HUMAN HEALTH ASSESSMENT OF NEW SUBSTANCES**

APPLICABLE LEGISLATION AND REGULATIONS	RESPONSIBLE DEPARTMENT OR AGENCY	NEW SUBSTANCE (whether imported, made or sold in Canada)
<i>Seeds Act and Seeds Regulations</i> www.inspection.gc.ca/english/reg/rege.shtml	Canadian Food Inspection Agency www.inspection.gc.ca	All plants with novel (new) traits (PNT) including food crops, trees, horticultural, and marine plants, intended for planting in the environment
<i>Feeds Act and Feeds Regulations</i> www.inspection.gc.ca/english/reg/rege.shtml	Canadian Food Inspection Agency www.inspection.gc.ca	All new livestock feeds, including new feed ingredients
<i>Health of Animals Act and Health of Animals Regulations (Veterinary Biologics)</i> www.inspection.gc.ca/english/reg/rege.shtml	Canadian Food Inspection Agency www.inspection.gc.ca	All novel veterinary biologics (i.e. live veterinary product like certain animals vaccines and test kits)
<i>Fertilizers Act and Fertilizers Regulations</i> www.inspection.gc.ca/english/reg/rege.shtml	Canadian Food Inspection Agency www.inspection.gc.ca	All new fertilizers (i.e. chemicals) and new novel supplements (i.e. organisms)
<i>Pest Control Products Act and Pest Control Products Regulations</i> http://laws.justice.gc.ca/en/P-9/index.html	Health Canada, Pest Management Regulatory Agency www.hc-sc.gc.ca/pmra-arla	All new substances in pest control products

APPLICABLE LEGISLATION AND REGULATIONS	RESPONSIBLE DEPARTMENT OR AGENCY	NEW SUBSTANCE (whether imported, made or sold in Canada)
<p><i>Canadian Environmental Protection Act, 1999, and New Substances Notification Regulations</i> www.ec.gc.ca/cceb1/nsd/eng/reg_e.htm</p>	<p>Environment Canada and Health Canada www.ec.gc.ca/substances</p>	<ul style="list-style-type: none"> - All remaining new substances including: - New industrial chemicals, biochemicals, polymers and biopolymers, (e.g. pigments, plasticizers, additives, etc.) and organisms (e.g. used in bioremediation, industrial enzyme production, etc.) - Imports of plant material with novel (new) traits (PNT) intended for direct use as food, non-livestock feed, or for processing into food or industrial products and not covered by either the <i>Seeds Act</i> or the <i>Feeds Act</i> and Regulations. - Genetically modified microorganisms not covered by a CEPA listed Act and Regulation - Novel feeds for non-livestock animals (e.g. new substances in pet foods) - Transgenic animals and fish - New substances in fertilizers and novel supplements manufactured for export only - New substances used as intermediates to manufacture pest control products - New substances in drugs (human and veterinary), human biologics, cosmetics, medical devices

TABLE 3

REGULATORY AUTHORITY ORGANIZED BY NEW SUBSTANCE TYPE AND USE

New Substance	Regulatory Authority	
Microorganism in:		
livestock feed	<i>Feeds Act and Feeds Regulations</i>	
fertilizer	<i>Fertilizers Act and Fertilizers Regulations</i>	
animal biologic	<i>Health of Animals Act and Health of Animals Regulations (Veterinary Biologics)</i>	
human biologic	<i>Food and Drugs Act (human safety and efficacy) Notification Regulations</i>	<i>Canadian Environmental Protection Act, 1999: New Substances Notification Regulations</i>
a pest control product	<i>Pest Control Products Act and Pest Control Products Regulations</i>	
any other use (e.g. bioremediation, industrial enzyme production, waster water, etc.)	<i>Canadian Environmental Protection Act, 1999: New Substances Notification Regulations</i>	

New Substance	Regulatory Authority	
Plant:		
grown in the environment	<i>Seeds Act and Seeds Regulations</i>	
imported plants used for food (directly)	<i>Plant Protection Act (plant pest risk ass.) and Food and Drugs Act (food safety)</i>	<i>Canadian Environmental Protection Act, 1999: New Substances Notification Regulations</i>
plant material to be used as livestock feed (directly)	<i>Feeds Act and Feeds Regulations</i>	
any other use	<i>Canadian Environmental Protection Act, 1999: New Substances Notification Regulations</i>	
Animal or Fish:		
released into the environment	<i>Fisheries Act (fish health permit) or Health of Animals Act (animal health permit)</i>	<i>Canadian Environmental Protection Act, 1999: New Substances Notification Regulations</i>
used as food	<i>Food and Drugs Act (food safety)</i>	<i>Canadian Environmental Protection Act, 1999: New Substances Notification Regulations</i>

Chemical or Polymer in:		
a pest control product	<i>Pest Control Products Act and Pest Control Products Regulations</i>	
a livestock feed	<i>Feeds Act and Feeds Regulations</i>	
a fertilizer	<i>Fertilizers Act and Fertilizers Regulations</i>	
veterinary drug	<i>Health of Animals Act</i>	<i>Canadian Environmental Protection Act, 1999: New Substances Notification Regulations</i>
a drug, cosmetic, food or medical device	<i>Food and Drugs Act (human or food safety, drug efficacy)</i>	<i>Canadian Environmental Protection Act, 1999: New Substances Notification Regulations</i>
any other use	<i>Canadian Environmental Protection Act, 1999: New Substances Notification Regulations</i>	