About the Revised In Commerce List (R-ICL)

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Overview

The Revised In Commerce List (R-ICL) is comprised of substances which were in products that were regulated under the *Food and Drugs Act* (F&DA) and that were in Canadian commerce between January 1, 1987, and September 13, 2001.

The R-ICL was initially posted on May 3, 2013, and was periodically revised to reflect updates and corrections. The process for nomination of substances for addition to the R-ICL closed on November 3, 2019. Some substances have since been removed from the R-ICL for various reasons.

R-ICL tracking table can be used to identify the substances currently on the R-ICL and substances that have been removed from the R-ICL.

Manufacturers and importers who wish to market a new substance for use in a product regulated under the F&DA that is not already listed on the Domestic Substances List (DSL) must submit a notification under the *New Substances Notification Regulations* (NSNR) (Chemicals and Polymers) or NSNR (Organisms). For more information, contact Health Canada's Regulatory Affairs Unit.

Since substances on the R-ICL are not on the DSL, they are subject to the *New Substances Notification Regulations* of CEPA. Manufacturers and importers who wish to market a substance on the R-ICL for use other than in products regulated under the F&DA must submit a notification.

All substances on the R-ICL are subject to the *Canadian Environmental Protection Act, 1999* (CEPA) and appropriate action may be taken at any time under that Act in respect to substances on the R-ICL that pose a risk to human health or the environment.

Prior to 2019, Health Canada conducted an R-ICL prioritization exercise to prioritize the substances on the R-ICL using a risk-based approach. Information on hazard and exposure was considered together to identify substances that may warrant assessment. The results of this R-ICL prioritization exercise are available in the R-ICL tracking table. These results and available information on R-ICL substances have since been taken into consideration during the identification and selection of priorities for assessment under CEPA for the Plan of Priorities.

Addition of R-ICL substances to the Domestic Substances List

CEPA, as amended by the *Strengthening Environmental Protection for a Healthier Canada Act* in 2023, enables the Minister of the Environment to add R-ICL substances to the DSL, provided that they are not subject to any risk management and meet criteria in subsections 66.1 and 105.1 of

CEPA. Any addition of eligible R-ICL substances to the DSL in the context of this new authority will be subject to public consultation. Once added to the DSL, the substances will be removed from the R-ICL to avoid duplication. For information on the DSL, visit the Domestic Substances List web page.

Information gathering

CEPA section 71 notices were published in 2017 and 2022:

- *Notice with respect to substances included as part of the 2017 Inventory Update*
- *Notice with respect to certain substances on the Revised In Commerce List, including biopolymers, plant extracts, mineral extracts, proteins, fats, animal extracts, waxes, and carbohydrates*

The purpose was to collect information on the commercial status and use patterns of some R-ICL substances. These mandatory notices sought information pertaining to F&DA uses only, including Canadian manufacture or import quantities, and the identity of stakeholders who manufactured or imported the substances. The information collected was used to support decisions to remove substances from the R-ICL. It is also considered in the identification and selection of assessment priorities for CEPA's Plan of Priorities, and any future assessment of the substances.

For more information, please visit the information gathering initiatives web page.

Removal of substances from the R-ICL

Substances may be removed from the R-ICL for various reasons, such as:

1. substances with no commercial activity in Canada in products regulated under the F&DA or not supported by Canadian manufacturers or importers with information on commercial activity, and this was the basis for the removal of 602 substances from the R-ICL in 2022
2. duplication with a substance already on the DSL (that is, present on both the DSL and R-ICL)
3. substances which are subject to risk management actions, such as a ministerial condition, or listing on Schedule 1 to CEPA
4. any time that environmental or human health concerns are identified

Substances that are removed from the R-ICL can still enter into Canadian commerce subject to applicable statutes, including the NSNR (Chemicals and Polymers), or NSNR (Organisms). The R-ICL tracking table is the list of all substances added to the R-ICL, the results of prioritization, and also shows the status of substances, including the removal of substances when this occurs.

For more information on considerations for the removal of substances from the R-ICL, visit the Removal of substances from the Revised In Commerce web page.

Assessment of pharmaceutical substances on the R-ICL

Health Canada's Pharmaceutical Drugs Directorate is responsible for authorizing therapeutic drugs for sale in Canada, and verifying that they meet the safety, efficacy and quality requirements ofthe F&DA and its regulations.

The Government of Canada is also responsible for undertaking assessments of pharmaceutical substances as environmental contaminants under the authority of CEPA, extending risk assessment to the potential exposure of people in Canada through environmental media such as air, soil, sediments and water while also considering the potential for exposure and impacts on the environment and its biological diversity.

Additional information

1. The substance names for chemicals and polymers that appear on the R-ICL accord with either the Chemical Abstracts Service (CAS) nomenclature, or the International Union of Pure and Applied Chemistry (IUPAC) nomenclature, or in the case of a living organism, acceptable international codes of nomenclature and standard taxonomic sources
2. The term "substance identifier" can refer to:
    1. a CAS Registry Number (CAS RN) [1]
    2. an Enzyme Commission (EC) Number assigned by the International Union of Biochemistry and Molecular Biology (IUBMB)
    3. an International Numbering System for Food Additives Number (INS Number) or
    4. an acceptable identifier for living organisms

Where multiple substance identifiers (CAS RNs) are listed on the R-ICL for a substance, the bold font and an asterisk (*) indicates the substance identifier which has most recently been assigned by CAS.

Contact information

For information on the R-ICL, please contact:

By mail:
Environment and Climate Change Canada
Place Vincent Massey, 351 St. Joseph Blvd
Gatineau, QC K1A 0H3
Telephone: 1-800-567-1999 (in Canada) or 819-938-3232 (outside of Canada)
E-mail: substances@ec.gc.ca

For information on notification of new substances for use in F&DA regulated products under the NSNR, please contact:

By mail:
Regulatory Affairs Unit
Health Canada
Healthy Environments and Consumer Safety Branch
Mail stop PL 4905B
Ottawa, ON K1A 0K9
Telephone: 1-866-996-9913 (in Canada) or 613-948-3591
E-mail: eau-uee@hc-sc.gc.ca

Please include your full contact information: name, address, phone number and email address.

Footnote

1 The Chemical Abstracts Service Registry Number (CAS RN) is the property of the American Chemical Society, and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior written permission of the American Chemical Society.

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