Health Canada Santé Canada

The Development of Environmental Assessment Regulations for New Substances Contained in Products Regulated under the *Food & Drugs Act*

Discussion Document for the March 29 & 30, 2006 Stakeholder Consultation

March 13, 2006

Canada

Note: This document has been created by the Environmental Impact Initiative Division of the Office of Regulatory and International Affairs of Health Canada for discussion and consultation purposes only.

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LIST OF ACRONYMS

CAS	Chemical Abstract Service
CEPA 1999	Canadian Environmental Protection Act 1999
CFIA	Canadian Food Inspection Agency
DSL	Domestic Substances List
EAU	Environmental Assessment Unit
EII	Environmental Impact Initiative
HECSB	Healthy Environments and Consumer Safety Branch
ICL	In Commerce List
ICSU	In Commerce Substances Unit
MOU	Memorandum of Understanding
NSNR	New Substances Notification Regulations
OAP	Options Analysis Paper: An Environmental Assessment Regime for New Substances in Products Regulated under the *Food & Drugs Act*
ORIA	Office of Regulatory and International Affairs
SNAc	Significant New Activity
SNAN	Significant New Activity Notification
UVCBs	Unknown and Variable Composition complex reaction products and Biological materials

EXECUTIVE SUMMARY

Recent scientific reports from Canada, the United States and the European Union have shown that certain substances contained in products regulated under the *Food & Drugs Act* have been detected at low levels in the environment. The presence of these substances in the environment is an important national and international issue, with potential implications for the health and safety of Canadians and the Canadian environment.

As such, the Environmental Impact Initiative (EII) Division of the Office of Regulatory and International Affairs (ORIA) in Health Canada is mandated to develop appropriate Environmental Assessment Regulations for new substances contained in products regulated under the *Food & Drugs Act*.

In June 2005, Health Canada released an *Options Analysis Paper - An Environmental Assessment Regime for New Substances in Products Regulated under the Food & Drugs Act* (OAP) to obtain feedback on the legislative authority under which the Environmental Assessment Regulations should be placed. The OAP can be found at the following address: www.healthcanada.gc.ca/eii

Stakeholder feedback was received by September 30, 2005 on the OAP. An analysis of the feedback was undertaken and an OAP Feedback Analysis Report has been developed and will be posted on the Health Canada website.

An analysis of the legislative authority was then undertaken by Health Canada and Environment Canada. Health Canada and Environment Canada recommend that the Environmental Assessment Regulations for new substances contained in products regulated under the *Food & Drugs Act* be developed under the *Canadian Environmental Protection Act, 1999* at this point in time.

The next step in developing appropriate Environmental Assessment Regulations is to analyse several key elements of the regulatory framework. These key elements will fit into the overall framework of the Environmental Assessment Regulations. An initial analysis of these key elements has been conducted by Health Canada and Environment Canada and is presented in this discussion document for consideration by stakeholders.

Objectives of the Consultation

Health Canada is hosting a stakeholder consultation on March 29 & 30, 2006 to address specific issues associated with the development of appropriate Environmental Assessment Regulations for new substances contained in products regulated under the *Food & Drugs Act*. The objectives of the stakeholder consultation are to present the Health Canada/Environment Canada recommended legal framework, to seek feedback on the key elements of the Environmental Assessment Regulations for new substances contained in products regulated under the *Food & Drugs Act* and the path forward for developing appropriate regulations.

Purpose of the Discussion Document

The following document is intended to provide participants with background information on the development of the Environmental Assessment Regulations in order to initiate discussion at the March 29 & 30, 2006 consultation.

Guiding Principles

Health Canada and Environment Canada will continue to apply the following guiding principles in developing the Environmental Assessment Regulations:

1. To safeguard the health of Canadians and the Canadian environment;
2. To ensure Canadians have continued access to products they need;
3. To participate in an open and transparent process with all stakeholders throughout the development of new regulations; and
4. To meet the legal and policy requirements of the *Canadian Environmental Protection Act, 1999*

BACKGROUND

The *Canadian Environmental Protection Act, 1999,* (CEPA 1999) is a major legislative framework for pollution prevention and the protection of the environment and human health in Canada. The Minister of the Environment and the Minister of Health are jointly responsible for administering certain provisions of CEPA 1999. CEPA 1999 requires that all substances new to Canada be evaluated for their potential risks to the Canadian environment and to human health. The Act also allows for a derogation regime to the notification regime (addition to schedules 2 or 4 of the Act), but currently, the *Food & Drugs Act* does not meet the legislative and policy criteria for that regime to be used (this does not prevent the scheduling of the *Food & Drugs Act* at a later date if the criteria are met). Therefore, all new substances contained in products regulated under the *Food & Drugs Act* that are in commerce after September 14, 2001 are subject to notification and assessment requirements under the *New Substances Notification Regulations* (NSNR) of CEPA 1999.

A decision was also made at that time to place substances that were in commerce between January 1, 1987 and September 13, 2001 on the In Commerce List (ICL) and substances that were in commerce before January 1, 1987 on the Domestic Substances List (DSL).

The NSNR were designed specifically for industrial chemicals rather than for new substances contained in products regulated under the *Food & Drugs Act*, which have different characteristics and applications of use (e.g., substances contained in pharmaceuticals, veterinary drugs, biologics, radiopharmaceuticals, natural health products, cosmetics, medical devices, novel foods and food additives). Consequently, in 2001, the Minister of Health notified the public that it is Health Canada's intention to undertake the development of environmental assessment regulations for new substances in products regulated under the *Food & Drugs Act* pursuant to subsection 30(1) of the *Food & Drugs Act* and/or pursuant to sections 89 and 114 of CEPA 1999 (Notice of Intent published in Canada Gazette I on September 1, 2001). The proposed regulations mentioned in the Notice of Intent would define the process for notification and assessment for new substances contained in products regulated under the *Food & Drugs Act.*

Several divisions/units within Health Canada are responsible for specific aspects related to the regulation of substances contained in products regulated under the *Food & Drugs Act.* The EII Division in ORIA is currently leading the development of the Environmental Assessment Regulations. The Environmental Assessment Unit (EAU) in the Healthy Environments and Consumer Safety Branch (HECSB) was created to receive notifications and conduct environmental risk assessments for impacts on both human health and the environment for new substances contained in products regulated under the *Food & Drugs Act*. The In Commerce Substance Unit (ICSU) in HECSB is responsible for the management of the ICL. Environment Canada is responsible for signing correspondence to notifiers who submit assessment packages, for imposing risk management measures when necessary and for enforcing the NSNR under CEPA 1999.

An Issues Identification Paper was developed in 2003 in consultation with stakeholders to identify key issues associated with regulations for new substances contained in products regulated under the *Food & Drugs Act.* Two international scientific workshops were held, one in February 2002 and one in March 2004. For further information, please see: www.healthcanada.gc.ca/eii

An analysis was undertaken on the legislative authority for the proposed Environmental Assessment Regulations for new substances contained in products regulated under the *Food & Drugs Act*. In June 2005, a report entitled, *Options Analysis Paper: An Environmental Assessment Regime for New Substances in Products Regulated under the Food and Drugs Act* (OAP), was released to stakeholders, with a 90 day comment period which ended September 30, 2005.

As analysis of the stakeholder feedback was undertaken and the OAP Feedback Analysis Report has been developed. This report will be posted on the Health Canada website at: www.healthcanada.gc.ca/eii

It is the intent of Health Canada and Environment Canada to develop an appropriate regulatory framework for new substances contained in products regulated under the *Food & Drugs Act* with minimal disruption to affected stakeholders.

LEGISLATIVE AUTHORITY

The legislative authority options that were presented in the OAP were:

Option A: The current NSNR under CEPA 1999 - status quo
Option B: Develop new regulations under CEPA 1999
Option C: Develop new regulations under the *Food & Drugs Act*

Stakeholders also proposed the following options:

Option D: The NSNR under CEPA 1999 with modifications to the data schedules and trigger volumes; and
Option E: Develop new regulations under a renewed *Food & Drugs Act*

In order to select an appropriate legal framework, an analysis of each option was undertaken. The detailed analysis can be found in Annex I.

The analysis led Health Canada and Environment Canada to recommend that, at this time, the Environmental Assessment Regulations for new substances contained in products regulated under the *Food & Drugs Act* will be developed under CEPA 1999.

The Health Canada/Environment Canada recommendation is based on the following key issues:

- HC is committed to developing environmental assessment regulations that are appropriate for new substances contained in products regulated under the *Food & Drugs Act*;
- The NSNR were developed for industrial chemicals and not for new substances contained in products regulated under the *Food & Drugs Act*;
- There is a need to proceed with the development of the Environmental Assessment Regulations with specific information requirements respecting the risks to the environment and human health associated with exposure to new substances contained in products regulated under the *Food & Drugs Act*; and
- The current *Food & Drugs Act* does not meet the criteria for addition to either Schedules 2 or 4 of CEPA 1999 because it does not contain the legislative authority to (i) require notification from a manufacturer and/or importer prior to the manufacture or import of a new substance and (ii) allow the Minister of Health to develop and implement risk management measures.

It is important to note that the specific requirements (e.g., notification requirements, etc.) of the Environmental Assessment Regulations for new substances contained in products regulated under the *Food & Drugs Act* can be established, irrespective of the legislative authority under which the regulations are developed.

KEY ELEMENTS OF THE REGULATORY FRAMEWORK

The following sections provide information on the key elements of the regulatory framework for the Environmental Assessment Regulations. As it is the recommendation of Health Canada and Environment Canada that Environmental Assessment Regulations be developed under CEPA 1999, specific requirements outlined in CEPA 1999 must be reflected in the regulations. The following sections of this discussion document are intended to stimulate discussion at the consultation.

1. New substances contained in products regulated under the *Food & Drugs Act* that will be subject to the Environmental Assessment Regulations

For the purposes of CEPA 1999, a new substance[1] is any substance that does not appear on the Domestic Substances List (DSL)[2] of CEPA 1999. Therefore, all substances that are not listed on the DSL are subject to the notification requirements of the Environmental Assessment Regulations unless they are exempt from the notification requirements (see section 8).

It is understood that different substances pose different risks and thus, the same type of environmental assessment should not apply to all substances. Risk is not commodity[3] based and as such, the regulatory framework cannot be strictly based on the risk of a specific commodity group. The Environmental Assessment Regulations will require notification for all new substances contained in products regulated under the *Food & Drugs Act*, including substances in cosmetics, natural health products, veterinary drugs, pharmaceuticals, biologics, radiopharmaceuticals, medical devices, novel foods and food additives. Notification of excipients is required if they are not listed on the DSL.

If a new *Food & Drugs Act* substance is a product of biotechnology, a notification of that substance will be required under the Environmental Assessment Regulations.

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[1] A substance is any matter, whether organic or inorganic, animate or inanimate.

[2] The DSL is an inventory of approximately 26,500 substances manufactured in, imported into or used in Canada on a commercial scale. It is based on substances present in Canada, under certain conditions, between January 1, 1984 and December 31, 1986. All substances not on this list are considered new and must be notified prior to importation or manufacture in order that they can be assessed to determine if they meet the criteria of toxic to the environment or human health as established under section 64 of CEPA 1999. Substances can be nominated to the DSL if there is proof of being in commerce between January 1, 1984 and December 31, 1986 and the appropriate information requirements are satisfied. If the assessment of a new substance has been completed and no controls have been placed on the substance, it is eligible for addition to the DSL.

[3] Commodity: specific groups of products regulated under the Food & Drugs Act, e.g., pharmaceuticals, natural health products, etc.

2. Special Category Substances

Health Canada and Environment Canada propose that consideration be made for Special Category Substances in the Environmental Assessment Regulations for new substances contained in products regulated under the *Food & Drugs Act*. These Special Category Substances are subject to reduced notification requirements. In the NSNR, a Special Category Substance is defined as any substance that is manufactured or imported as:

(a) a research and development substance
(b) a contained site-limited intermediate substance; or
(c) a contained export-only substance

Research and Development Substance
A research and development substance is defined in the NSNR as one that is undergoing systematic investigation or research, by means of experimentation or analysis other than test marketing, whose primary objective is any of the following:

(a) to create or improve a product or process;
(b) to determine the technical viability or performance characteristics of a product or process; or
(c) to evaluate a substance prior to its commercialization, by pilot plant trials, production trials (including scale-up) or customer plant trials, so that technical specifications can be modified in response to the performance requirements of potential customers.

The NSNR also define "test marketing," in respect of a product as referred to above, as "the exploration of its market capability in a competitive situation where the creation or improvement of the product is not the primary objective".

Contained Site-limited Intermediate Substance
A contained site-limited intermediate substance is defined in the NSNR as a substance that is consumed in a chemical reaction used for the manufacture of another substance and that is:

(a) manufactured and consumed at the site of manufacture;
(b) manufactured at one site and transported to a second site where it is consumed; or
(c) imported and transported directly to the site where it is consumed.

The NSNR also define "contained" as "an absolute release limit of the substance of 1 kg per day per site to the aquatic environment after wastewater treatment"; and "consumed" as "destroyed or completely converted to another substance." If a substance is classified as a site-limited intermediate, it must, at all times during its existence (manufacture, importation, storage, transport, handling, use and disposal), be contained, as defined above, to prevent any significant environmental release. A substance that is a direct precursor in the manufacture of an item defined above is not considered a site-limited intermediate and would be subject to the regular notification requirements. However, if the direct precursor of the item meets the criteria of a "transient reaction intermediate", it would not be subject to notification.

Contained Export-Only Substance
Contained export-only substances are limited to new substances manufactured in or imported into Canada that are destined solely for foreign markets and that are contained. Contained is defined as an absolute release limit of the substance of 1 kg/day per site to the aquatic environment after wastewater treatment.

Health Canada and Environment Canada propose that consideration be given to create special categories for the following substances:
- Substances that are used in an emergency treatment;
- Substances used in clinical trials; and
- Substances used in new veterinary drugs for experimental studies.

Notification of "special category" new substances will be required. **In your view, are the above noted definitions for (i) a research and development substance, (ii) a contained site-limited intermediate substance, and (iii) a contained export-only substance appropriate for new substances contained in products regulated under the *Food & Drugs Act*? Why/why not?**

Are there other special categories of new substances contained in products regulated under the *Food & Drugs Act* that should be considered in the Environmental Assessment Regulations and why?

The notification requirements for special category substances would likely be reduced compared to regular notification requirements. **As such, what information should be required for special category substances?**

3. Timing of Notification of new substances contained in products regulated under the *Food & Drugs Act*

The intent of the Environmental Assessment Regulations is to ensure that new substances contained in products regulated under the *Food & Drugs Act* do not pose a threat to the environment and human health. Notification prior to manufacture and/or import is a requirement of CEPA 1999. Therefore, notification of a new *Food & Drugs Act* substance will be required prior to its manufacture and/or import.

A submission under the *Food & Drugs Act* (i.e., *Food & Drugs Regulations, Natural Health Product Regulations*, *Medical Device Regulations*, etc.) is required prior to the sale of the product. The notification under the new Environmental Assessment Regulations will not be linked to the submission for product approval by Health Canada. It will be the responsibility of the notifier to ensure that the notification requirements are met on all non-exempted new substances contained in products regulated under the *Food & Drugs Act* prior to manufacture and import of the product that contains that substance.

The notifier may choose to submit information packages for the *Food & Drugs Act* regulations and for Environmental Assessment Regulations under CEPA 1999 either simultaneously or at different times. It should be noted, however, that manufacture or import of the new substance cannot commence until the regulatory requirements have been satisfied.

4. Product authorization and Environmental Assessment Regulations for new substances contained in products regulated under the *Food & Drugs Act*

The notification and environmental risk assessment of a new *Food & Drugs Act* substance will be undertaken independently of the product authorization assessment. However, if an environmental risk assessment reveals that the new substance poses a threat to human health and/or the environment, it will be subject to risk management measures, such as conditions or manufacturing and import prohibition. To date, there have only been a few substances that have been prohibited under CEPA 1999. If a substance is prohibited, the substance cannot be used in the *Food & Drugs Act* product.

A request may be made for information on the status of the Environmental Risk Assessment for all new substances contained in products regulated under the *Food & Drugs Act* when a submission is sent to Health Canada for product approval. Information supplied voluntarily by the notifier regarding the status of the new substance, whether the substance is on the DSL, ICL or has been assessed under the Environmental Assessment Regulations, may facilitate the product approval process.

5. Processing notifications of new substances contained in products regulated under the *Food & Drugs Act*

The notification requirements (i.e., the required information to determine if a new substance contained in products regulated under the *Food & Drugs Act* meet any of the criteria set out in section 64 of CEPA 1999[4]), are yet to be developed. These notification requirements will be developed in consultation with stakeholders. The new Environmental Assessment Regulations will prescribe the notification requirements for new substances contained in products regulated under the *Food & Drugs Act* with consideration for specific uses and exposure scenarios. This prescribed information will be used to complete an environmental assessment on the new substance. It is proposed that the amount and type of information required to do an environmental assessment reflect the potential risks of the new substance.

As outlined in CEPA 1999, the environmental assessment of a new *Food & Drugs Act* substance

[4]Section 64 of CEPA 1999: For the purposes of Part 5 and Part 6, except where the expression "inherently toxic" appears, a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that
(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
(b) constitute or may constitute a danger to the environment on which life depends; or
(c) constitute or may constitute a danger in Canada to human life or health.

will take into consideration the entire life-cycle of that substance. The use pattern and disposal of a new substance will be addressed in the environmental risk assessment.

The prescribed notification and data requirements are yet to be determined. The next steps in developing the notification and data requirements will be addressed during the path forward session of the consultation.

The risk management strategy, including any conditions imposed, will be developed by Health Canada and Environment Canada in consultation with the notifier. Environment Canada will have final authority over the risk management conditions. Risk management proposals can be supplied by the notifier for consideration by Health Canada and Environment Canada in determining the risk management strategy. The conditions placed on new substances contained in products regulated under the *Food & Drugs Act* can be imposed at any point in the life-cycle of the substance (i.e. manufacture, storage, distribution, use, waste treatment, disposal).

If there is no indication of a substance meeting any of the criteria in section 64 of CEPA 1999 for a specific use pattern, the substance may be eligible for addition to the DSL. However, a Significant New Activity (SNAc) can be placed on the new substance that is listed on the DSL where there is insufficient information to determine whether this new activity (i.e., an activity/use that is different from the one identified in the original notification) poses risks to the environment and human health. The SNAc notice identifies which activities trigger the need for a Significant New Activity Notification (SNAN). The SNAc will also specify what information is required in the SNAN.

If a new substance has dual applications (e.g., a surfactant used in both an industrial cleaner and a hand soap) a notification and risk assessment may only be required under either the NSNR or the Environmental Assessment Regulations. The risk assessment conducted under either set of regulations must consider all possible uses of the new substance. A SNAc may be placed on the substance if there are concerns regarding other applications/uses.

6. Timelines after Notification of new substances contained in products regulated under the *Food & Drugs Act*

Most, but not all, products subject to the *Food & Drugs Act* are currently subject to approval timelines for safety and efficacy. Each commodity group has its own specific set of timelines for these approvals. It should be noted that the timelines for environmental assessment will not be linked to those that have been set for product approval.

CEPA 1999 requires that a prescribed assessment period to do a risk assessment be defined within regulations. Therefore, the Environmental Assessment Regulations will determine the prescribed time for the environmental risk assessment to be completed. The time will start upon notification of a new *Food & Drugs Act* substance.

Timelines will need to be established for the assessment of the notification data and for the assessment of the environmental assessment data. The prescribed timelines for assessment will be developed in conjunction with the development of the notification requirements.

7. New substances contained in products regulated under the *Food & Drugs Act* that are exempt from the notification requirements

Under CEPA 1999, the following substances are exempt from the notification requirements as outlined in CEPA 1999 Paragraph 81(6):

- A substance that is manufactured or imported for a use that is regulated under any other Act of Parliament that provides for notice to be given before the manufacture, import or sale of the substance and for an assessment of whether it is toxic or capable of becoming toxic;
- Transient reaction intermediates that are not isolated and are not likely to be released into the environment;
- Impurities, contaminants and partially unreacted materials the formation of which is related to the preparation of a substance;
- Substances produced when a substance undergoes a chemical reaction that is incidental to the use to which the substance is put or that results from storage or from environmental factors; or
- A substance that is manufactured, used or imported in a quantity that does not exceed the maximum quantity prescribed as exempt from this section.

Health Canada and Environment Canada will examine the need to apply the regulations to substances occurring in nature[5] and substances that are in transit through Canada.

8. Waivers of Prescribed Data Requirements for new substances contained in products regulated under the *Food & Drugs Act*

CEPA 1999 Section 81(8) states that the Minister [of Environment] may waive any of the requirements for prescribed information if:

(a) in the opinion of the Ministers [of Health and Environment], the information is not needed in order to determine whether the substance is toxic or capable of becoming toxic;

(b) the substances is to be used for a prescribed purpose or manufactured at a location where, in the opinion of the Ministers, the person requesting the waiver is able to contain the substances so as to satisfactorily protect the environment and human health; or

(c) it is not, in the opinion of the Ministers, practicable or feasible to obtain the test data

[5]Substances occurring in nature are defined as naturally occurring and are: unprocessed; processed only by manual, gravitational, or mechanical means, by dissolution in water, by flotation, or by heating solely to remove whether; or extracted from air by any means.

necessary to generate the information.

Therefore, CEPA 1999 contains the provision for the Minister of the Environment to waive any of the prescribed information requirements at the request of the notifier. As such, it is the responsibility of the proponent to develop a scientific rationale as to why specific information requirements regarding a new substance should be waived. The Minister of Environment will ultimately make a decision regarding the request to waive the information requirements. The Minister of Environment may at any time require the information that has been previously waived if "corrections" are provided to the original information used in the rationale for the waiver request.

9. Assessment of substances in commerce between January 1, 1987 and September 13, 2001 (ICL)

Health Canada identified approximately 9,000 substances in products regulated under the *Food and Drugs Act* that were in commerce between January 1, 1987 and September 13, 2001. These substances were placed on the In Commerce List (ICL). Requests have been received from industry for the addition of approximately 275 substances to this list. The information provided in support of adding these substances to the ICL is being assessed by the In Commerce Substances Unit (ICSU) at Health Canada. The work being done on the requests for the additions to the ICL is providing valuable information and experience that will be utilized in the revision of the list. It is recommended that the ICL be finalized (i.e. no further additions) at the time the regulations are implemented.

A framework has been developed for the revision of the ICL. The goal is to produce a single, readily searchable list with each substance accurately identified. Duplications and substances that are already on the DSL will be removed. Industry stakeholders will be consulted on this process and for gathering the information required to complete the revision of the ICL.

To ensure that the ICL can be used as a statutory instrument, the revised ICL will contain an unambiguous name or process description, Chemical Abstract Service (CAS) Number (or ATCC number for micro-organisms), and notifier(s). Additional information on the use pattern(s) and estimated annual use quantities for each substance would be useful. The project will involve collaboration between Health Canada, Environment Canada and industry stakeholders. Based on the experience in creating the DSL, it is estimated that approximately two years will be required to prepare the revised ICL.

There is a need to prioritize substances on the ICL which will initially undergo an assessment. The approach taken to prioritization must take into account the diversity of these substances, in particular those substances which are not discrete chemical entities. The use of predictive models cannot be applied to these complex substances. Consequently, a "one-size fits all" approach cannot be adopted.

In order to proceed with the prioritization of the substances on the ICL, a revised ICL needs to be developed. **What approaches and tools can be used to minimize the time it will take to**

complete the revision of the ICL?

10. Conclusion

As this document is intended to provoke discussion at the Consultation on the Development of Environmental Assessment Regulations, the purpose of this final question is to obtain feedback on any issues that have not been addressed in the key elements section of the discussion document. As such, **are there other key considerations for Health Canada/Environment Canada in developing the regulatory framework model?**

ANNEX I

Option A: The NSNR under CEPA 1999 (Status Quo)

All new substances contained in products regulated under the *Food & Drugs Act* are currently subject to notification and assessment under the NSNR of CEPA 1999. Under this option, all new substances would continue to be subject to the NSNR.

Advantages	Disadvantages
• Appropriate risk management measures exist for industrial chemicals, polymers and animate products of biotechnology. • Regulations and program structure currently exist	• Specific for industrial chemicals and polymers and animate products of biotechnology. Some new substances contained in products regulated under the *Food & Drugs Act* (e.g., human and veterinary drugs) are designed to be biologically active, posing an entirely new set of questions on the direct impact on the environment and impact on human health and any type of control measures needed. • Approval of one substance is subject to two Acts. There is no legislative joint decision making mechanism between Environment Canada and Health Canada for one substance. • Data requirements only include acute toxicity studies, whereas most of the anticipated risks for new substances contained in products regulated under the *Food & Drugs Act* will be chronic. • Ecotoxicity data are only requested for the highest level of notification under the NSNR, for some new substances contained in products regulated under the *Food & Drugs Act* this level would not be reached. • Terrestrial organisms need to be considered in some instances (e.g., veterinary drugs) during the risk assessment which is not currently in the data requirements in the NSNR. • Environmental consideration for antimicrobial resistance is not addressed under the NSNR. • The triggers for notification are based on annual import and/or manufacture volumes for chemicals and polymers. These volumes are not appropriate for some new substances contained in products regulated under the *Food & Drugs Act* (e.g., pharmaceuticals) which, in some cases will likely never reach the minimum trigger volume for notification. • The assessment approach based on volumes may not be suitable for new substances contained in products regulated under the *Food & Drugs Act* as this approach assumes that low volumes equate to low risk.

Option B: Develop New Regulations under the CEPA 1999

New regulations that are appropriate/specific to new substances contained in products regulated under the *Food & Drugs Act* would be developed under CEPA 1999.

Advantages	Disadvantages
• The regulations could accommodate the special nature of new substances contained in products regulated under the *Food & Drugs Act* and their potential risk. The characteristics and use patterns of the new substances can be taken into consideration when determining the type and amount of information that is required. • Risk management measures/authorities are currently in place. • Harmonization, where possible, with other international regimes can be taken into account when developing new regulations. • The regulations would be developed specifically for new substances contained in products regulated under the *Food & Drugs Act* and therefore be easier to understand.	• The meaning of "new" in CEPA is not the same as the one used in the *Food & Drugs Act* regulations (e.g., "new active substance" for biologics). • Approval of one substance is subject to two Acts. There is no legislative joint decision making mechanism between Environment Canada and Health Canada for one substance.

Option C: Develop New Regulations under the *Food & Drugs Act*

In order to schedule an Act (i.e., *Food & Drugs Act*) under CEPA 1999, the criteria for notification and risk assessment under Schedules 2 and 4 of CEPA 1999 have to be met. The two legislative requirements are:

- Notice, containing prescribed information, to be given prior to manufacture, import or sale of a substance; and
- Determination of whether the notified substance meets any of the criteria in section 64 of CEPA 1999.

There are also two policy tests that are applied to ascertain CEPA 1999-equivalency:

- whether the entire life-cycle of the substance is covered in risk assessment/management; and
- whether there is authority to impose risk management measures.

The current *Food & Drugs Act* does not fully meet the criteria for listing in either Schedules 2 or 4 of CEPA 1999 because it does not provide for notice to be given before manufacture or import of a new substance for an assessment of whether it poses risks to the environment and/or human health. Furthermore, the *Food & Drugs Act* does not meet scheduling policy requirements of life-cycle assessment and management.

As such, using the legislative authority of the current *Food & Drugs Act* is not an option at this

point in time. However, there are advantages to using the *Food & Drugs Act* as the legislative authority if the necessary scope and control measures are incorporated into a renewed Act.

Option D: The NSNR under CEPA 1999 with Modifications to Trigger Volumes and Data Schedules specific for new substances contained in products regulated under the *Food & Drugs Act*

Some stakeholders proposed that modifications be made to the trigger volumes and data schedules of the NSNR so they are more appropriate for new substances contained in products regulated under the *Food & Drugs Act*.

The current trigger volumes of the NSNR are appropriate for industrial chemicals and the data requirements are based on volumes of the substance imported or manufactured in Canada. However, the basic tiered structure of the NSNR poses challenges for the notification and assessment of new substances contained in products regulated under the *Food & Drugs Act* even if the trigger volumes and data schedules were amended. The NSNR were developed for industrial chemicals based on the assumption that the increases in volume lead to increases in risk. As such, without an increase in annual volume the next level of assessment (schedule) is not triggered. However, continuous exposure to an annual low level of a biologically active substance could pose a threat to the environment and human health. Additionally, low levels of a new substance could pose a threat as they accumulate over years at a continuously low exposure levels (bioaccumulation and bioconcentration issues).

Advantages	**Disadvantages**
• The characteristics and use patterns of new *Food & Drugs Act* substances can be taken into consideration when determining the type and amount of information that is required.	• Volume triggers may not be suitable for new *Food & Drugs Act* substances as this approach assumes that low volume equate to low risk.
• The program structure already exists.	• Approval of one substance is subject to two Acts. There is no legislative joint decision making mechanism on the approval of substances.

It should be noted that amending the NSNR would be a lengthy process and could potentially take as long as developing new regulations.

Option E: Develop New Regulations under a Renewed *Food & Drugs Act*

New regulations appropriate/specific to new substances contained in products regulated under the *Food & Drugs Act* would be developed under a renewed *Food & Drugs Act*. The renewed Act would contain the appropriate legislative authorities to enable the Act to be listed under schedules Schedules 2 and 4 of CEPA 1999.

Advantages	**Disadvantages**
• The renewed *Food & Drugs Act* would have the legislative authority to fully meet the CEPA 1999 scheduling requirements. • Approval of one substance is subject to one Act. • Harmonization, where possible, with other international regimes can be taken into account when developing new regulations.	• The timeline for the renewed *Food & Drugs Act* to be completed is uncertain.