Health Canada Santé Canada

Options Analysis Paper Feedback Analysis Report

Health Canada

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The information contained in this report represents the views of respondents who submitted comments on the Options Analysis Paper and in no way represents the views of Health Canada or Environment Canada.

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Introduction

The Options Analysis Paper Feedback Analysis Report attempts to analyse and summarize the feedback received from stakeholders regarding the “Options Analysis Paper - An Environmental Assessment Regime for New Substances in Products Regulated under the *Food and Drugs Act*” (OAP). Feedback on the OAP was requested from stakeholders to obtain their views on three possible regulatory options presented in the OAP and to determine if there were any other issues of concern to stakeholders.

In September 2001, Health Canada announced its intention to develop Environmental Assessment Regulations for new substances in products regulated under the *Food and Drugs Act* (F&DA). The development of the regulations is in response to the *Canadian Environmental Protection Act 1999* (CEPA 1999) requirement to assess both the direct impacts on the environment and indirect impacts on human health resulting from the release of new F&DA substances into the environment.

The OAP Feedback Analysis Report is one step in the process towards the development of the Environmental Assessment Regulations for F&DA substances. Since the beginning of this initiative stakeholder involvement has been, and continues to be, crucial to the successful development of the regulations. Throughout 2002 and 2003, stakeholders were consulted on the context, scope, and factors that needed to be considered by Health Canada in developing regulatory options for F&DA substances. Stakeholder feedback from these consultations was incorporated into the Final Issue Identification Paper which was released in July 2003.

In June 2005, the OAP was released for review and comment by stakeholders. The OAP identifies several critical issues of a proposed new regulatory regime for the environmental assessment for *F&DA* substances and discusses developing the regime under each of three possible regulatory options.

The OAP Feedback Analysis Report provides an analysis and summary of the comments from stakeholders on the regulatory options, the critical issues and their components, and other issues of concern. The stakeholder feedback has been used in developing a recommended legislative authority for the proposed Environmental Assessment Regulations for F&DA substances.

Executive Summary

Stakeholders were invited to submit comments on the regulatory options presented in the "Options Analysis Paper - An Environmental Assessment Regime for New Substances in Products Regulated under the *Food and Drugs Act"* (OAP) by September 30, 2005. They were given the choice of submitting their feedback via the electronic questionnaire (E-Questionnaire) designed to reflect the issues covered in the OAP, or via written submissions. The 71 submissions received by Health Canada represent a stakeholder response rate of 12 percent. A more detailed description of the methodology used to collect the feedback is presented in the Methodology section of this report.

The majority (71.8 percent) of submissions received were from the industry sector and most of these indicated they operate nationally. Approximately two thirds of the organizations were Canadian owned and operated. Eleven commodity groups were represented, with the highest representation from associations, manufacturers or producers of foods (including novel foods and food additives), personal care products, natural health products, and prescription and non-prescription drugs. (See Table 2 in the Choice of Option section of this report.)

Respondents submitted comments on the three critical issues and their 12 components as outlined in the OAP. A summary of these comments can be found in Table 1 in the Critical Issues section of this report.

In addition, respondents identified several other issues of concern. One of them was the requirement for a regulatory framework that would govern new substances within a product context due to the many differences (use patterns, risk levels, etc.) in products regulated under the F&DA. Respondents raised concerns about how the current review of CEPA 1999 could affect the new regulations. Respondents also highlighted the need to take into consideration other existing government and agency authorities, international approaches, Mutual Recognition Agreements (MRAs) and the principals of Smart Regulation when developing the Environmental Assessment Regulations. A streamlined single window approach under one federal department for product approval was identified as a very important issue. Concern was also raised that Health Canada might not have the resources, both financial and human, needed to implement and enforce new Environmental Assessment Regulations as well as concern about the financial implications new regulations might have on industry. These issues are discussed in more detail in the Other Issues section of this report.

Respondents were asked to comment on three possible regulatory options for the Environmental Assessment Regulations (EAR) for F&DA substances outlined in the OAP as follows:

- Option A: Applying the current New Substances Notification Regulations (NSNR) under the *Canadian Environmental Protection Act* (CEPA 1999)
- Option B: A new regime under CEPA 1999

- Option C: A new regime under the *Food and Drugs Act* (F&DA)

In addition to providing comments on these options, respondents also suggested the following regulatory options:

- NSNR with modifications to data schedules and trigger volumes
- NSNR for lower-risk substances and NSNR with modifications for higher-risk substances
- proposed Health Protection Act (i.e., new regulations under a revised F&DA).

Overall, 72 percent of respondents supported some kind of regulatory change. The choice of option, broken down by sector and commodity groups, has been included in the Detailed Analysis section of this report.

Overall, there was general support from all commodity groups for the goal of preventing and reducing risks to both the environment and human health.

Detailed Analysis

Data was compiled and analysed from all submissions, both written and those received via the electronic questionnaire (E-Questionnaire). This section provides analysis of who submitted feedback on the OAP, details on the comments received on the three critical issues and their components as outlined in the OAP, other issues of concern identified by respondents, choice of regulatory option, regulatory experience, and evaluation of the 'tools' used in obtaining feedback on the OAP.

Profiles of Respondents

Almost three quarters of submissions came from the industry sector most of which operate nationally. Other sectors represented were government (17 percent), environmental or consumer advocacy (5.6 percent), environmental (2.8 percent) and research or academic organization (2.8 percent). Over half of responses were from members of industry coalitions or associations.

The highest representation came from associations, manufacturers or producers of foods including novel foods and food additives, prescription and over the counter drugs, designed for human use, personal care products and natural health products. Most submissions were made on behalf of organizations as opposed to by individuals.

More than half (57.7 percent) of the respondents operated nationally, while 18.3 percent also operated internationally. Canadian regional operations were represented in the following order: Ontario (22.5 percent), Quebec (18.3 percent), Western Canada (14.1 percent), Prairies (9.9 percent), Eastern Canada (9.9 percent), and Northern Canada (2.8 percent). Approximately two thirds of the organizations were Canadian owned and operated.

A little more than half of respondents who submitted comments via the E-Questionnaire indicated they did more than 50 percent of all their business in Canada, and 18.2 percent did less than 50 percent of all business in Canada. In terms of the size of their Canadian operations, 23.8 percent of the respondents indicated that the number of employees was greater than 1,000, 21.4 percent had operations with between 101 and 500, and 19.1 percent had operations with between 11 and 100 employees. Operations with one to ten employees and those with between 501 and 1000 employees tied at 14.3 per cent. A small percentage indicated volunteers and no employees.

Respondents who submitted comments via the E-Questionnaire indicated that 45.5 percent of their Canadian operations was in distribution. Marketing/sales and research tied at 38.6 percent, production/manufacturing was 29.5 percent and exporting was 22.7 percent. Other types of operation were regulatory, government, environmental, associations, advocacy in public interest, public health, inspection, professional and publications.

Critical Issues

The Options Analysis Paper presented three possible regulatory options for the Environmental Assessment Regulations (EAR):

- Option A: Applying the current New Substances Notification Regulations (NSNR) under the *Canadian Environmental Protection Act* (CEPA 1999)
- Option B: A new regime under CEPA 1999
- Option C: A new regime under the *Food and Drugs Act* (F&DA)

These options were discussed in terms of how they addressed the following three critical issues and their 12 components:

Critical Issue	Components
#1 Substances covered by the Regime:	Definition of "new" substance Substances in F&DA products already in commerce Life-cycle point of application Exemptions Trigger quantities
#2 Notification Requirements:	Type of information How much information Timelines
#3 Risk Management Measures:	Authority to prohibit Point of manufacture Point of disposal Supplementary measures (e.g., best practices)

Table 1: Critical Issues and Components

Rating of each Critical Issue

Respondents who chose to comment via the E-Questionnaire were asked to rate each component within each of the three critical issues regarding its importance as part of a framework in which to evaluate and choose a regulatory option. The results from the E-Questionnaire submissions are as follows:

Critical Issue #1, Substances Covered by the Regime: "Exemptions" was rated as the most important issue by 50 percent of the respondents, followed closely by "definition of 'new' substance" (47.8 percent), "substances in F&DA products already in commerce" (36.4 percent), "trigger quantities" (36.4 percent) and "life-cycle point of application" (34.0 percent).

Critical Issue #2, Notification Requirements: "Timelines" was rated as the most important issue by 50 percent of the respondents, followed closely by "how much information" (45 percent) and "type of information" (43.2 percent).

Critical Issue #3, Risk Management Measures: "Authority to prohibit" was rated as the

most important issue by 54.5 percent of the respondents, followed by “supplementary measures” (43.3 percent), “point of manufacture” (36.4 percent) and “point of disposal” (29.5 percent).

Detailed Analysis of each Critical Issue

The following is a summary of feedback received on each critical issue and its components. The comments from all respondents have been taken into consideration.

Critical Issue#1: Substances Covered by the Regime

1.1 *Definition of* “new”

> Special Consideration for F&DA Regulated Products: Health Canada will need to define what constitutes a new substance and is proposing that the use pattern of the substance should be one of the criterions. (OAP, Summary: Options A, B & C Table)

While there was support by some low-risk commodity groups to keep the current definition of “new”, there was general agreement on the need to redefine what constitutes a “new” substance. The pharmaceutical groups wanted the definition to be more specific and comprehensive for pharmaceutical products, and be consistent with that of international regulatory regimes as well as the F&DA definition of “new”.

There was agreement among the prescription pharmaceutical commodity group that the definition of “new” should apply to new active ingredients. However, there were differing opinions on whether “new” should apply to non-active ingredients that are considered novel excipients or to new uses for existing drug substances resulting in a significant increase in volume, such as product-line extensions and export activities. The lower-risk commodity groups suggested that “new” should not apply to personal care products and cosmetics. There was agreement among both the higher- and lower-risk commodity groups that the definition should also not apply to the 530 substances that are eligible to be added to the Domestic Substance List (DSL) and the 9,000 In Commerce List (ICL) F&DA substances. Their reasoning was that, although these substances are currently designated as “new”, some of these substances have been in commerce up to eighteen years and it would be difficult for them to be assessed in a reasonable length of time. They also suggested that companies producing generic products should not be required to notify of a new substance if the substance were the same as the innovator’s that has been on the market for years.

With respect to the suggestion that the use pattern of a substance could be one of the criteria in defining “new”, the low-risk commodity groups suggested that the Significant New Activity[1] (SNAc) notices amendment to the NSNR, though not frequently used,

[1]Note concerning the SNAc: The SNAc provision was intended to be used on an infrequent basis. Under the NSNR, there is a set of notification tiers which enable a substance to be used up to a set volume. Although additional data should be submitted at any time until the next notification trigger volume is reached the uses cannot

could be applied to F&DA products. The SNAc provision requires that additional information be required for a significant new activity if there is insufficient information in the current notification to determine the risk from other proposed use patterns.

1.2*Substances in F&DA products already In Commerce*

> Special Consideration for F&DA Regulated Products: There is a need for a specially designed environmental assessment period and process for these 9000 substances. (OAP, Summary: Options A, B & C Table)

Some lower-risk commodity groups were critical of the lack of progress made on the In Commerce List (ICL) to date.

There was a general support among all the commodity groups to manage the 9,000 substances on the ICL as “existing” substances since the substances have been in commerce for up to 18 years.

There was also general support among both low- and high-risk commodity groups for a transitional regulatory framework for ICL substances to facilitate the post-market assessment of some products within a risk-based approach, similar to the Categorization and Screening of the Domestic Substance List (DSL). This framework would allow for the establishment of a priority-setting process for these substances and determine if a Screening Level Risk Assessment is warranted. The pharmaceutical commodity groups suggested that a consultative process would be needed prior to any mandatory call-in for additional data or mitigation through implementation of risk management practices. They also suggested that additional information requests should be focussed on new active ingredients and novel excipients. It was pointed out that excipients that have been in use for many years have well-established safety profiles and can generally be regarded as safe.

1.3 *Life-cycle point of application*

> Special Consideration for F&DA Regulated Products: Regulations should cover the life cycle of a substance. (OAP, Summary: Options A, B & C Table)

There was general agreement among all commodity groups that a life-cycle approach would be ideal to address the potential interaction of new F&DA substances with other food and drugs already in use, as well as any effects these substances may have once released into the environment. However, it was also recognized that it would be unrealistic to expect any regulatory framework to provide cradle-to-grave management throughout a substance’s life cycle.

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be controlled, unless there is a SNAc which is unusual at the lower schedules. The issue is with regard to flexibility in requesting additonal data. SNACs can be also applied to substances on the Domestic Substance List.

The pharmaceutical commodity groups proposed that the focus should be more on the environmental aspects as they relate to the stages where release into the environment may occur, such as use and disposal of substances by consumers. They also suggested that the import of active pharmaceutical ingredients (APIs) and excipients into Canada, as well as their manufacturing and marketing in Canada, should be covered by the environmental assessment regulations. Lower-risk commodity groups suggested that regulations already in place through other federal acts, such as the Feeds Act and Seeds Act, or provincial/territorial and municipal regulations that adequately address certain stages of a products life-cycle, such as the release of chemicals into the environment through manufacturing, should not be duplicated. Environmental groups further suggested that scientific data be provided on all stages of the life cycle and it would be governments' responsibility to verify this data.

1.4 *Exemptions*

> Special Consideration for F&DA Regulated Products: Regulations require exemptions for special classes, such as new drugs for emergency treatment, clinical trials, or new veterinary drugs for experimental studies. (OAP, Summary: Options A, B & C Table)

While some environmental groups did not support exemptions, there appeared to be general agreement among all commodity groups for the need to consider exemptions for certain products in special circumstances:

Special Access Programs drug products: There was an overall support across all commodity groups for exemptions of substances in products where it is believed that the individual health benefits of the product outweigh the risks. This exemption would include substances used in the context of unapproved prescription drugs released under Special Access Programs for emergency treatment, clinical trial usage, and for treatment or prevention of life threatening or severely debilitating illnesses or conditions. It was also suggested that where the product is used and by whom should also be taken into consideration. For example, injectable drugs used only in hospitals by trained professionals may be less of a risk than drugs used in the community by consumers.

Exported products: Higher-risk commodity groups suggested that drug substances in products manufactured in Canada exclusively for export should be exempted.

Enzymes: Lower-risk commodity groups suggested that enzymes should be exempted because of their favourable biodegradability properties, low toxicity, low probability of exposure to the environment, long history of safe use, and their many benefits to society and the environment

Licensed animal drug products: Higher-risk commodity groups suggested that substances used in animal drug products that are licensed under the Emergency Drug Release, Investigational New Drug and Experimental Study Certification programs be exempted. This would be consistent with the International Cooperation on

Harmonization of Technical Requirements for Registration of Veterinary Medical Product (VICH).

Natural health products and food additives: Lower-risk commodity groups would like to see natural health products (including homeopathic medicines) and food additives that use traditional extraction solvents be included in the "Substances occurring in nature" provision. This would result in these substances being considered as included on the DSL and therefore exempted from environmental assessment regulations. This group stated that many of the source or active ingredients in homeopathic medicines are herbal and botanical substances that meet the definition of substances occurring in nature. As well, some natural health products have little environmental toxicity data available to support a New Substance Notification (NSN) submission. They pointed out that virtually all of these ingredients, with the exception of minerals and elemental substances, can be completely metabolized by humans and animals and as such, are not persistent or bio-accumulative.

This commodity group also pointed out that one of the deciding factors in having a substance defined as "natural" is the method used to extract or prepare a substance. However, the definition of a "traditional method of preparation" is not the same in the DSL Guidelines as it is in the Natural Health Products Directorate's (NHPD) guidelines. For example the NHPD definition includes ethanol extractions, among others, as a "traditional method of preparation" while the DSL Guideline does not. This lower-risk commodity groups suggested that the NHPD definition is more appropriate for natural health products that use extraction solvents and should be included in the DSL Guidelines.

Internationally exempted substances: Higher-risk commodity groups suggested that in order to be consistent with Environmental Assessment Regulation exemptions of other jurisdictions, exempted substances should include the following:

- Non Genetically Modified Organism (GMO) vaccines both bacterial and viral,
- Vitamins, electrolytes, amino acids, peptides, and proteins, and
- Active ingredients used in orphan drugs.

It was also mentioned by this group that flexibility to include and exclude substances from the list of exemptions as the science develops should be an important consideration in the development of the environmental assessment regulations.

1.5 *Trigger quantities*

> Special Consideration for F&DA Regulated Products: Setting any trigger quantities for notification may allow potential environmental impacts to go undetected. (OAP, Summary: Options A, B & C Table)

Two different approaches were supported: volume-based triggers and risk-based triggers.

The lower-risk commodity groups supported the current NSNR volume-based trigger approach and suggested that the existing trigger volumes were appropriate for lower-risk substances. However, this group also recognized that the current trigger volumes may not be appropriate for some F&DA products and suggested the addition of trigger volumes so that all substances in F&DA products would be captured.

There was a general agreement among all commodity groups that the current high threshold levels of the NSNR imply that many substances that are toxic at very low concentrations (e.g., certain drugs) would not trigger a full CEPA 1999 assessment. Conversely, some substances that are not toxic at very high concentrations (e.g., novel foods produced in mass quantities) may be required to undergo full assessments that may not be warranted from either a safety or scientific standpoint.

As a reflection of this reasoning, the majority of respondents supported a risk-based approach in which trigger volumes would be directly related to risk level. Trigger volumes could be decreased for higher-risk F&DA substances, such as active ingredients found in cytotoxic drugs. Conversely, trigger volumes could be increased for lower-risk F&DA substances, such as active ingredients found in non-prescription or non-medicinal products, for example those used in self-care health products including over the counter drugs, cosmetics and natural health products. One of the risk factors could be the potential toxicity of a substance. This approach is more consistent internationally for prescription drugs designed for human use and with the VICH for drugs designed for veterinary use.

The pharmaceutical commodity groups suggested that there should be triggers and minimum quantities below which most pharmaceuticals would be exempted from the need to prepare an environmental risk assessment. For example, products in which the average aquatic concentration is less than one part per billion should be exempted unless special circumstances, such as the presence of hormones and cytotoxic substances, require assessment. This group also suggested that the environmental assessment should demonstrate the environmental fate and effects of a drug substance and be based on the expected environmental concentrations corresponding to the maximum projected use and volume for the drug.

It was pointed out by lower-risk commodity groups that the type of approval will be influenced by the trigger. Novel foods, for example, receive an approval for the product itself regardless of the quantity. However, food additives are approved for a specified use and maximum limit of addition. This raised some questions among this group such as what would be the trigger for a notification if the triggers differed for each commodity group (e.g., exposure versus quantity versus use). There was also the question of whether the risk should be defined at the commodity level or some other level.

Critical Issue #2: Notification Requirements

2.1 *Type of Information*

> Special Consideration for F&DA Regulated Products: Regulations should have provision for data on chronic effects and impacts on terrestrial environment. (OAP, Summary: Options A, B & C Table)

High-risk commodity groups and academia agreed that data on chronic effects and impacts on other types of environments such as terrestrial are essential for substances with chronic, low-level effects, such as are found in pharmaceuticals. It was pointed out that the NSNR fails to provide this data because only acute duration ecotoxicity data is used for Schedule III substances.

The pharmaceutical commodity group suggested that requirements for chronic effects should be driven by factors determined to be problematic such as class of compound (e.g., hormones), the absence of a removal mechanism, or having an acute toxicity $L(E)C_{50}$<1.0mg/L. However, many products such as pharmaceuticals may not have chronic impacts data readily available in the format required under the proposed legislation. This commodity group also suggested that pharmaceutical manufacturers should be responsible for providing information on only the drug substance they manufacture and not for all the excipients. Terrestrial testing should apply only when it can be demonstrated that active pharmaceutical ingredients (APIs) will reach the terrestrial compartment above a certain trigger concentration.

Lower-risk commodity groups consider the three aquatic species studies required in the NSNR data package sufficient for substances in products regulated by the F&DA since Health Canada is responsible for determining the toxicity and exposure of substances to only humans. This group also suggested that Environment Canada should work with industry to determine whether information provided by data packages is adequate for determining ecotoxicity of substances. They also recommended that additional schedules for various product classes could be added to the existing NSNR if there were evidence to suggest that they were necessary.

2.2 *How much information*

> Special Consideration for F&DA Regulated Products: Regulations require a tiered approach with minimum notification and increasing requirements based on level of risk (predicted environmental concentration). (OAP, Summary: Options A, B & C Table)

Lower-risk commodity groups suggested that the current data schedules in the NSNR were appropriate for substances used in self-care health products.

There was a general agreement that a tiered approach for notification requirements would be the most appropriate, as well as align with other international regimes. Since there are so many different F&DA products, appropriate information and schedules

should be developed based upon each product's risk profiles. A potentially more hazardous product should have a more rigorous data requirement and vice versa. Pharmaceutical commodity groups suggested that at the very least, minimal data requirements must be comprehensive enough to determine environmental fate and safety. Products in which the average aquatic concentration is less than one part per billion should not require a submission unless there are special circumstances requiring an environmental assessment such as the presence of hormones and cytotoxic substances. Once sufficient data are available to indicate that the drug substance is unlikely to pose a risk to the environment, additional data requirements could be terminated. This group also suggested that consideration should be given to what is required under other federal acts, for example the Feeds Act and Seeds Act, in order to reduce duplication and to impose more stringent requirements than those already existing for similar products within the same product line.

Industry raised some questions concerning the submission process for imported products such as how the graduated review process would be implemented, and would the process be based on a single importer or all importers of a substance (i.e., what the tracking mechanisms would be).

2.3 *Timelines*

> Special Consideration for F&DA Regulated Products: Regulations require that timelines offer flexibility so that they are compatible with safety and efficacy timelines. (OAP, Summary: Options A, B & C Table)

The lower-risk commodity groups supported adherence to well-defined, clear, realistic and predictable timelines as defined under the NSNR. They suggested that well-defined timelines contribute to the competitiveness of Canadian business and to the ability of regulatory agencies to secure the financial and human resources demanded of these timelines.

However, the pharmaceutical commodity groups suggested that flexible timelines for pre-market Environmental Assessment is needed. The timelines should reflect the degree of risk and be consistent with other legislation, including international, at similar risk levels. They also stressed that the timing of the reviews under CEPA 1999 and F&DA must be coordinated (i.e., the environmental assessment should occur at the time of the New Drug Submission) to ensure an efficient pre-market review and product-approval process. The pharmaceutical industry emphasized the importance of ensuring that access to beneficial new pharmaceutical products, both human and veterinary, is not delayed.

Critical Issue #3: Risk Management Measures

Overall, there was general support among all commodity groups for risk management measures that integrate the assessment of environmental risks with the benefit to improved human and animal health, and quality of life.

3.1 *Authority to Prohibit*

> Special Consideration for F&DA Regulated Products: Regulations require innovative approach that takes into account risk/benefit analysis made as part of the safety and efficacy analysis. (OAP, Summary: Options A, B & C Table)

There was concern among the government sector, academia, and higher-risk commodity groups that beneficial products, such as life-saving pharmaceuticals, could be approved or prohibited based exclusively on the results of its environmental risk assessment. They suggested that both the risk a product poses to the environment and its benefits for human or animal health must be weighed together. Rather than prohibit a substance, a product could be handled with restrictions imposed through appropriate risk management practices as part of the drug approval process. They also pointed out that in other jurisdictions review of the environmental impacts of pharmaceuticals is a component of the complete drug review process.

Other high-risk commodity groups suggested that the benefits to human and animal health should be the determining factor for approval of a new drug and that risk/benefit analysis should not be part of the safety/environmental fate analysis at all. It was suggested that Therapeutic Products and Biologics and Genetic Therapies directorates would be in the best position to evaluate all types of risks related to new drugs.

3.2 *Point of Manufacture*

> Special Consideration for F&DA Regulated Products: Regulations should be able to cover life cycle of substance. (OAP, Summary: Options A, B & C Table)

Though there was some support by the government sector for the authority to regulate manufacturing sites, there was a general agreement among respondents that environmental effects resulting from product use, not manufacturing, should be the point of focus. Manufacturing activities, such as manufacturing, distribution, storage, transportation and environmental releases, were understood to be already subjected to existing federal, provincial/territorial, and municipal regulations controlling the release of substances into the environment. They pointed out that this approach would be in line with other international regimes. Adding another regulatory layer would duplicate the environmental regulatory process.

3.3 *Point of Disposal*

> Special Consideration for F&DA Regulated Products: Regulations should be able to cover life cycle of substance. (OAP, Summary: Options A, B & C Table)

Though there was some support by the government sector for the authority to regulate disposal, there was a general agreement among respondents that having the federal government involved in waste management would duplicate responsibility. It was agreed that the authority for legislating the collection and disposal of consumer waste lies at the provincial/territorial and municipal levels.

However, there was general support for Health Canada to play an educational and promotional role by applying measures to engage the public on the issue of disposal. One suggestion was to build a strong federal/provincial/territorial framework for safe disposal policy initiatives and awareness programs. It was suggested that public communication strategies could make consumers more aware of potential environmental issues of unsafe disposal and help to clarify the public's role in ensuring safe disposal of a product. One of the suggested disposal options for expired or excess drug products would be to place the responsibility for disposal of any residual drug products with the drug manufacturer. An example of appropriate labelling with disposal directions would be information on labels directing users of a drug product to dispose of unused drug products in accordance with local provincial/territorial and municipal requirements.

The lower-risk commodity groups voiced concern with government having the legislative authority to require product labels to include disposal information since this would duplicate the provincial/territorial responsibility for waste management.

3.4 *Supplementary Measures (e.g., best practice)*

> Special Consideration for F&DA Regulated Products: Regulations require an innovative approach that takes into account the many uses of F&DA substances. (OAP, Summary: Options A, B & C Table)

The pharmaceutical groups suggested that public education, the adoption of best management practices, and the creation of guidelines were important supplementary measures. Suggested risk management measures included restricting the use of high-risk prescription drugs to a controlled setting, such as a hospital, or limiting the use of a product for emergency treatment or prevention of life threatening or significantly debilitating conditions. It was also suggested that products should be required to provide information on proper and safe use.

Other Issues

In addition to issues addressed in the OAP, several other issues were identified by respondents.

Unique approach for specific commodity groups

Both lower- and higher-risk commodity groups pointed out that there are two divergent groups of products regulated under the F&DA - lower-risk and higher-risk - and suggested that a regulatory framework governing new substances within a product context is needed. The lower-risk commodity groups pointed out that an umbrella approach where all products are assessed using regulations intended for toxic substances would impose an unnecessary regulatory burden on producers and manufacturers of nontoxic *F&DA*-regulated products. Higher-risk commodity groups suggested that specific commodity groups, such as pharmaceuticals, prescription drugs, biologics, such as vaccines, and veterinary drugs, each merit a unique approach that takes into account their product differences with respect to use pattern, distribution, potency, composition and existing regulations. For example, a system that is designed to handle mixtures, not just individual substances, is needed.

Concerns with the Legislative Authorities:

New Substance Notification Regulations (NSNR) under *Canadian Environmental Protection Act* (CEPA 1999): Food commodity groups voiced concern that, since the NSNR under CEPA 1999 was originally designed for chemicals and polymers, most requirements under these regulations are not applicable to substances in foods. The NSNR would place an extra burden on this commodity group that may not be warranted from a safety or scientific point of view. They pointed out that some foods, such as novel foods, produced in large quantities may require a full assessment even though they are not toxic to the environment or indirectly to human health. Other products, such as some pharmaceuticals, produced in small quantities may not require a full CEPA assessment even though they are toxic.

CEPA 1999: There was concern from advocacy groups about how the current review of CEPA 1999 will affect the review process and the new regulations. There was also concern raised by the pharmaceutical commodity group that a new regime under CEPA 1999 would put drug approval under two regulatory agencies with different timelines and different mandates for allocating resources. There would then be the possibility that a new chemical drug could be prevented from entering the Canadian market solely for environmental factors.

Relationships between Legislative Authorities: Lower-risk commodity groups suggested that relationships between the proposed authorities and existing authorities of other government departments and agencies, such as Canadian Food Inspection Agency, Department of Fisheries and Oceans, and Agriculture and Agri-Food Canada, must be taken into consideration when developing the Environmental Assessment Regulations to avoid duplication of regulatory oversight.

International Harmonization

There appeared to be a consensus among all commodity groups for the need to develop Environmental Assessment Regulations harmonized with those in other international jurisdictions, in particular the United States and Europe, to ensure Canadian industry stays competitive. Introducing requirements unique to Canada would greatly increase cost and regulatory delays. They suggested that existing global environmental assessment methodologies and product review processes should be used to ensure testing requirements and data interpretations in Canada are consistent with that in the international community. It was pointed out that this would also enable manufacturers to submit the same Environmental Assessment data to any international regime, something that is increasingly important in the rapidly expanding global market.

Mutual Recognition Agreements

Pharmaceutical commodity groups suggested that Mutual Recognition Agreements (MRAs), similar to those in place for Good Manufacturing Practices (GMP) requirements, should be kept in mind when developing the regulations. It was pointed out that MRAs increase communications between regulatory authorities and enable a better understanding of respective regulatory systems.

Smart Regulation

There appeared to be a consensus among all commodity groups for the need to adhere to the principles of Smart Regulation[2] to minimize the possibility of developing duplicate environmental assessment regulations for F&DA substances.

Single Window Approach

There was overwhelming support from all commodity groups for the need to have product approval driven by one agency that has access to the information contained in the entire application. The dual authority approach, as currently managed by Environment Canada and Health Canada, was not viewed as desirable due to potential duplication and conflict with other existing legislation and the possibility of preventing a new chemical drug from entering the Canadian market solely for environmental factors. However, there were conflicting views on which federal department, Environment Canada or Health Canada, should manage the environmental assessment submissions.

Lower-risk commodity groups preferred that Environment Canada receive all submissions. They suggested that a health review be done by Health Canada and an environmental review be done by Environment Canada using the NSNR to minimize duplicate regulations.

[2]Smart Regulation is a government-wide initiative aimed at improving the Government of Canada's regulatory system so that it can keep pace with today's realities and our evolving needs. It strives for a better coordinated, more transparent system that remains forward-thinking and accountable to citizens. http://www.regulation.gc.ca

There was agreement among the prescription pharmaceutical commodity group for centralizing the authority with Health Canada under the F&DA, since the F&DA is the principal governing legislation. There was the suggestion that the Environmental Assessment Regulations should be integrated into the New Drug Submission process.

Implementation and Enforcement

There was some concern within the natural health product and food commodity groups with how Health Canada might manage the financial and human resources to implement and enforce Environmental Assessment Regulations with respect to the growing number of imported products already approved in other jurisdictions. This may cause serious enforcement issues for the Canadian Food Inspection Agency (CFIA).

Financial Implications to Industry

Government advocacy groups raised the issue of the negative impact (cost, time and effort) on the financial aspects of industry imposed by implementing new Environmental Assessment Regulations. They suggested that cost recovery analysis and program implementation would be needed.

Choice of Option

Respondents were asked to comment on three possible regulatory options that were presented in the Options Analysis Paper:

- Option A: Applying the current New Substances Notification Regulations (NSNR) under CEPA 1999
- Option B: A new regime under CEPA 1999
- Option C: A new regime under the *Food and Drugs Act* (F&DA)

In addition to the original three regulatory options presented in the OAP, respondents suggested three other options:

- the current NSNR under CEPA 1999 with modifications to the data schedules and trigger volumes for potentially higher-risk classes of substances in F&DA products
- a combination of the current NSNR under CEPA 1999 for self-care health products (including non-prescription drugs, natural health products, cosmetics and personal care products) and the current NSNR with modification to the data schedules and trigger volumes for potentially higher-risk classes of substances
- proposed Health Protection Act (i.e., new regulations under a revised F&DA).

Overall, 72 percent of respondents supported some kind of regulatory change. Option C was supported by a third of the respondents, followed by Option B (18.3 percent), Option A (17 percent), and NSNR with modifications (17 percent). NSNR for lower-risk classes of substances and NSNR with modifications for higher-risk classes, and the proposed Health Protection Act accounted for the balance of support. Respondents who did not support any regulatory option accounted for 11.2 percent of the responses.

Choice of Option - By Commodity Group

Option A: Current NSNR under CEPA 1999 - 17 percent (12 of 71 responses)

- all respondents who supported this option were from industry
- industry was represented by organizations which regulate or are producers and manufacturers of over-the-counter drugs, natural health care products, and food, including novel foods, food ingredients and additives, and fresh produce.

Option B: A new regime under CEPA 1999 - 18.3 percent (13 of 71 responses)

- respondents who supported this option were mainly from industry and the government sector, along with some support from the environment and academia sectors
- industry was represented by organizations, associations and large manufacturers or producers of primarily human prescription drugs and foods, including novel food and food additives.

Option C: A new regime under F&DA - 32.3 percent (23 of 71 responses)

- respondents who supported this option were primarily from industry, along with some support from the government, environment and academia sectors
- industry was represented by organizations, associations and large manufacturers or producers of primarily prescription drugs and biologics.

Current NSNR with modifications - 17.0 percent (12 of 71 responses)

- respondents who supported this option were from industry
- industry was represented by organizations, associations and large manufacturers or producers of primarily personal care products and foods, including novel food and food additives.

Current NSNR and NSNR with modifications - 2.8 percent (2 of 71 responses)

- respondents who supported this option were from industry
- industry was represented by an association and large manufacturer of over the counter drugs, natural health and personal care products.

Proposed Health Protection Act - 1.4 percent (1 of 71 responses)

- respondents who supported this option were from the food sector.

In summary, the preferred option of each commodity group was as follows:

Commodity Group	Preferred Legislative Authority
Prescription drugs, human	Option C
Over the counter drugs, human	Options C & A
Natural health products	Option A
Veterinary drugs	Options C & B
Biologics	Options C & B
Genetic therapies	Options C & B
Radio-pharmaceuticals	Options C & B
Medical devices	split among Options A, B & C
Cosmetic products	NSNR with modifications
Personal care products	NSNR with modifications
Foods, including novel foods and food additives	NSNR with modifications & C

Table 2. Preferred Option by Commodity Group

Analysis of Choice of Option - by Sector

Industry - 71.8 percent (51 of 71 responses):

- represented by umbrella organizations, coalitions and associations and their member associations and companies
- split fairly evenly among support for Option A, Option C and the current

NSNR with modifications to data schedules and trigger quantities.

Government - 17 percent (12 of 71 responses):

- represented by environment, agriculture, health, conservation and sustainable development government groups, regulatory authorites
- split fairly evenly between support for Option B and Option C, with some preference for the proposed Health Protection Act.

Environmental or Consumer Advocacy Groups - 5.6 percent (4 of 71 responses):

- represented by a variety of advocacy groups
- split between support for Option B and Option C, leaning slightly more towards Option C.

Research or Academic Organizations - 2.8 percent (2 of 71 responses):

- represented by academia
- split between support for Option B and Option C.

Environmental Groups - 2.8 percent (2 of 71 responses):

- represented by a variety of environmental groups
- Option B was supported by this sector.

Regulatory Experience

Respondents who submitted comments via the electronic questionnaire (E-Questionnaire) were asked to indicate their level of experience with three different acts. Their responses indicated that there were a higher percentage with moderate to extensive experience with the *Food & Drugs Act* (F&DA) (88.7) compared to the same level of experience with the *Canadian Environmental Protection Act* (CEPA 1999) (62.3 percent) and the *Pest Control Products Act* (27.3 percent).

Respondents who submitted comments via the E-Questionnaire indicated that the greatest number (36.4 percent) of environmental assessments had been prepared for Health Canada. A further 27.3 percent had been prepared for Environment Canada, 11.4 percent for other federal departments, 18.2 percent for provinces/territories, 4.6 percent for municipalities, and 4.6 percent for other regulatory authorities. Other federal departments included Canadian Food Inspection Agency. Municipalities included the City of Montreal, Quebec, the municipality of Big Lakes, Alberta, and the municipality of Lesser Slave River, Alberta, and the town of Slave Lake, Alberta. Other regulatory authorities included the Canadian Nuclear Safety Commission, the U.S. Food and Drug Administration, and the European Medicines Agency (EMEA).

Approximately half of respondents who submitted comments via the E-Questionnaire had no experience with the New Substance Notification Regulations (NSNR) while a little more than a third had experience with the NSNR. Out of those with experience, only a small percentage had prepared more than 20 submissions while a little more than half had prepared only five to 10 submissions.

Over half of the respondents who submitted comments via the E-Questionnaire were aware of the planned amendments to the NSNR.

Evaluation of 'Tools'

Respondents who submitted comments through the E-Questionnaire were asked to rate each of the following analytical tools used to obtain their feedback on the OAP. A rating scale of '1' for Very Dissatisfied and '5' for Very Satisfied was provided.

Options Analysis Paper (OAP)

Overall, respondents gave the OAP a neutral rating as an analytical tool. Slightly less than three quarters of respondents gave the OAP either a satisfied rating (36 percent) or neutral rating (38 percent) for the comprehensiveness of the OAP. A slight majority (52 percent) gave the OAP a neutral rating for clarity and slightly less than half (47 percent) gave it a neutral rating for its length. Some respondents found the OAP confusing and the options not presented in a manner that was easy to follow. Others found the paper to be leading and biased toward Option B. Some responded that the OAP was a high-level overview with not enough details to envision how each option would work in practice, especially Option A and Option B. They stated that since there were pros and cons to each option, it was difficult to choose one option. Some found the paper complex but found the background information helpful. There were a few comments that were critical of the length of time between the last consultation and the release of the OAP. They also stated that regardless of which option is selected, further discussion between stakeholders would be needed as the details on the regulations are developed and the new regime implemented.

Summary: Options A, B & C Table

More than three quarters of respondents gave the Summary: Options A, B & C Table provided in the OAP a neutral rating for comprehensiveness (44 percent) and clarity (40 percent). Respondents were divided in their rating of the table for ease of use, giving it a rating of neutral (32 percent) and very satisfied (30 percent). Some commented that they found the table extremely helpful and useful and one respondent indicated that similar summary tables in future documents would be very helpful.

Regulatory Goals and Regulatory Options Table

Respondents gave the Regulatory Goals and Regulatory Options Table provided in the OAP an overall neutral rating as an analytical tool. A little less than half of respondents gave neutral ratings for comprehensiveness (45 percent), clarity (43 percent) and ease of use (48.8). Some stated that the goals were rather narrowly defined in terms of bureaucratic activities and biassed toward Option B.

Electronic Questionnaire

Overall, respondents who used the E-Questionnaire were generally satisfied with its use to submit feedback on the OAP. Slightly less than a third (32 percent) of respondents were satisfied with it as an effective method to provide feedback. A little more than a third (34 percent) gave the E-Questionnaire a neutral rating on its clarity and 6.8 percent were very dissatisfied with its clarity. A third (33 percent) of respondents were very satisfied with its ease of use. Some found the narrative comment boxes useful for

providing additional comments on issues.

A few negative comments from those who submitted via the E-Questionnaire centred mainly on software and design limitations. Respondents would have liked to have live links to the electronic version of the OAP, the ability to skip to the next appropriate section, to print the questionnaire in its entirety, to have less multiple choice questions and rating of issues, and more opportunity to elaborate or provide additional comments on some sections.

Some respondents stated that the E-Questionnaire was not an appropriate consultation tool for complex issues such as the OAP and suggested that it should not be the basis for Health Canada to determine the path forward on environmental assessments of F&DA products. Some found the E-Questionnaire confusing and general while others said that they did not have the expertise to answer some of the more complex and technical questions. Others stated that some of the questions were not flexible enough to address their comments.

NOTE: All comments with respect to the E-Questionnaire will be used to improve the questionnaire in the event that this type of feedback tool is used again by the Environmental Impact Initiative.

Methodology

Feedback Options

Respondents were invited to submit feedback on the Options Analysis Paper (OAP) via written submission or via the electronic questionnaire (E-Questionnaire).

Design of the Electronic Questionnaire

The E-Questionnaire was based on a questionnaire and work book that was originally intended to accompany the OAP. It was developed to facilitate stakeholder feedback on the OAP and ease the collection and compilation of stakeholder comments. The E-Questionnaire was made available in both official languages.

Sample Design

Approximately 600 stakeholders from the Environmental Assessment Regulations (EAR) stakeholder database were invited to provide feedback on the Options Analysis Paper (OAP). The EAR stakeholder database included stakeholders belonging to each of Health Canada's directorates in the Health Products Food Branch (HPFB) and the Cosmetics Directorate in Healthy Environments and Consumer Safety Branch (HECSB). International stakeholders, including those from the United States, were able to provide comment through their respective subsidiaries operating in Canada. Additionally, each directorate within HPFB, the Cosmetics Directorate in HECSB, and Environment Canada was asked to provide feedback on the OAP. An invitation to provide feedback was also extended to provincial and territorial governments and members of the *Canadian Environmental Protection Act* National Advisory Committee (CEPA NAC) and Committee on Health and the Environment (CHE).

Feedback Administration

Stakeholder feedback was solicited via two means. In June 2005, Health Canada mailed the OAP to approximately 150 stakeholders with an invitation to provide written comment. In addition, an e-mail announcing the availability of the OAP and providing a link to the electronic version of the report on the EII Web site was sent to approximately 460 stakeholders. In July 2005, the Environmental Impact Initiative within Health Canada sent an e-mail to all stakeholders providing a link to the E-Questionnaire and inviting feedback on the OAP, via either the E-Questionnaire or written comment. To prompt a response, a reminder e-mail was sent weekly to stakeholders throughout September 2005.

Completion Results

Health Canada received a total of 71 submissions, representing a response rate of 12 percent. Of the 71 submissions received, 27 were written submissions and 44 were received via the E-Questionnaire. Although 51 submissions were received via the E-Questionnaire, seven were not included in the total submission count because they were either incomplete or submission duplicates.

Appendix A: Electronic Questionnaire

Health Canada's E-Questionnaire for Options Analysis Paper: An Environmental Assessment Regime for New Substances in Products Regulated under the *Food and Drugs Act*

Welcome to Health Canada's Options Analysis Questionnaire. The main purpose of this questionnaire is to solicit feedback on the three possible environmental assessment regulatory options presented in the Options Analysis Paper: An Environmental Assessment Regime for New Substances in Products Regulated under the *Food and Drugs Act* (F&DA).

We will also be asking for basic information on your organization.

All of your answers will remain strictly confidential, and will not be linked with your organization's name.

This questionnaire should take approximately 20 minutes to complete. Should you wish to have a paper copy of your responses, we recommend that you print out each page of the survey ***prior*** to clicking the 'next' or 'submit' button. **NOTE**: this questionnaire is available until **September 30, 2005.**

If you have any difficulties regarding the questionnaire please contact the Environmental Impact Initiative, Office of Regulatory and International Affairs, Health Products and Food Branch, Health Canada at **1-888-492-1104** or by email at **ear-ree@hc-sc.gc.ca**

I. General Organizational Information
The information being requested in this section will be used for background and statistical purposes only to help us obtain a profile of our stakeholders. Your responses are confidential.

1. Please indicate the sector you or your organization represent:

- Industry
- Government
- Consumer
- Environmental
- Environmental or consumer advocacy group
- A research or academic organization
- Other (please specify below)

If you selected 'Other' please specify here:

Text Box

2. If you or your organization are a member of an association please indicate which one(s).

Text Box

3. If applicable, please indicate the commodity group(s) with which you or your organization work. Select all that apply:

_ Prescription drugs, human
_ Over the counter drugs, human
_ Natural health products
_ Veterinary drugs
_ Biologics
_ Genetic therapies
_ Radio-pharmaceuticals
_ Medical devices
_ Cosmetic products
_ Personal care products
_ Foods, including novel foods and food additives
_ N/A
_ Other (please specify below)

If you selected 'Other' please specify here:

Text Box

4. Please indicate if you are completing this questionnaire as:

- an individual
- on behalf of an organization

5. If you wish, enter your name or the name of the organization you represent (optional):

TEXT BOX

II. Evaluation of Regulatory Options

In this section we are seeking feedback on the three regulatory options presented in the Options Analysis Paper.

Rating the Importance of each Component:

This section deals with the three critical issues identified as the foundation for reviewing the regulatory options. Each option is outlined in detail in the Options Analysis Paper at: http://www.hc-sc.gc.ca/ewh-semt/contaminants/person/impact/consultation/options/pres_options_e.html These are: *Substances Covered by the Regime*, *Notification Requirements* and *Risk Management Measures.* Each critical issue has several components to be considered when evaluating each option.

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6. Critical Issue #1: *Substances Covered by the Regime*

Rate each component regarding its importance as part of a framework in which to evaluate and choose a regulatory option. Use the scale provided where '1' is Least Important and '5' is Most Important. If you are not sure how to respond please indicate and elaborate in the comment box at the end of this question.

Component and Special Consideration	1 Least Important	2	3	4	5 Most Important	Not Sure
1. Definition of New: Health Canada will need to define what constitutes a new substance, and is proposing that the use pattern of the substance should be one of the criterion.						
2. Substances in F&DA products already in commerce: There is a need for a specially designed environmental assessment period and process for these 9000 substances.						
3. Life Cycle point of application: Should cover life cycle of the substance.						
4. Exemptions: Requires exemptions for special classes, such as new drugs for emergency treatment, clinical trials or new veterinary drugs for experimental studies.						
5. Trigger quantities: Setting any trigger quantities for notification may allow potential environmental impacts to go undetected.						

7. If you have any additional comments on Critical Issue #1: *Substances Covered by the Regime* please provide them here (ie. critical issues, components, special considerations):

TEXT BOX

8. Critical Issue #2: *Notification Requirements*
Rate each component regarding its importance as part of a framework in which to evaluate and choose a regulatory option. Use the scale provided where '1' is Least Important and '5' is Most Important. If you are not sure how to respond please indicate and elaborate in the comment box at the end of this question.

Component and Special Consideration	1 Least Important	2	3	4	5 Most Important	Not Sure
1. Type of information: Should have provision for data on chronic effects and impacts on terrestrial environment.						
2. How much information: requires a tiered approach with minimum notification and increasing requirements based on level of risk (predicted environmental concentration).						
3. Timelines: Requires that timelines offer flexibility so that they are compatible with safety and efficacy timelines.						

9. If you have any additional comments on Critical Issue #2: *Notification Requirements* please provide them here (ie. critical issues, components, special considerations):

TEXT BOX

10. Critical Issue # 3: *Risk Management Measures*
Rate each component regarding its importance as part of a framework in which to evaluate and choose a regulatory option. Use the scale provided where '1' is Least Important and '5' is Most Important. If you are not sure how to respond please indicate and elaborate in the comment box at the end of this question.

Special Considerations for Risk Management	1 Least Important	2	3	4	5 Most Important	Not Sure

1. Authority to prohibit: Requires innovative approach that takes into account risk/benefit analysis made as part of the safety and efficacy analysis.						
2. Point of manufacture: Should be able to cover life cycle of substance.						
3. Point of disposal: Should be able to cover the life cycle of substance.						
4. Supplementary Measures (e.g. best practice): Requires innovative approach that takes into account the many uses of F&DA substances.						

11. If you have any additional comments on Critical Issue # 3: *Risk Management Measures* please provide them here (ie. critical issues, components, special considerations):

TEXT BOX

12. If you have any critical issues, components or special considerations that could be added to the above tables please list them here:

TEXT BOX

Evaluating Each Option:

This section builds on the feedback provided in the previous section and gives you the opportunity to evaluate each of the three regulatory options regarding their appropriateness in addressing each of the critical issues. Each option is outlined in detail in the Options Analysis Paper at http://www.hc-sc.gc.ca/ewh-semt/contaminants/person/impact/consultation/options/pres_options_e.html

Option A

13. For each of the 3 critical issues below rate how appropriate you believe *Option A: Applying the Current New Substances Notification Regulations (NSNR)* would be in addressing each critical issue. Use the scale provided where '1' is Least Appropriate and '5' is Most Appropriate. If you are not sure how to respond please indicate and elaborate in

the comment box at the end of this question.

Critical Issue	1 Least Appropriate	2	3	4	5 Most Appropriate	Not Sure
Substances Covered by the Regime						
Notification Requirements						
Risk Management Measures						

14. If you have any additional comments on *Option A: Applying the Current New Substances Notification Regulations (NSNR)* please provide them here:

TEXT BOX

Option B

15. For each of the 3 critical issues below rate how appropriate you believe *Option B: A New Regime under the Canadian Environmental Protection Act, 1999 (CEPA 1999)* would be in addressing each critical issue. Use the scale provided where '1' is Least Appropriate and '5' is Most Appropriate. If you are not sure how to respond please indicate and elaborate in the comment box at the end of this question.

Critical Issue	1 Least Appropriate	2	3	4	5 Most Appropriate	Not Sure
Substances Covered by the Regime						
Notification Requirements						
Risk Management Measures						

16. If you have any additional comments on *Option B: A New Regime under the Canadian Environmental Protection Act, 1999 (CEPA 1999)* please provide them here:

TEXT BOX

Option C

17. For each of the 3 critical issues below rate how appropriate you believe *Option C: A New Regime under the Food and Drug Act (F&DA)* would be in addressing each critical issue. Use the scale provided where '1' is Least Appropriate and '5' is Most Appropriate. If you are not sure how to respond please indicate and elaborate in the comment box at the

end of this question.

Critical Issue	1 Least Appropriate	2	3	4	5 Most Appropriate	Not Sure
Substances Covered by the Regime						
Notification Requirements						
Risk Management Measures						

18. If you have any additional comments on *Option C: A New Regime under the Food and Drugs Act (F&DA)* please provide them here:

TEXT BOX

Summary: Options A, B & C

19. If you or your organization *do not* agree with any of the information presented in the Summary: Options A, B & C table in the Options Analysis Paper please explain why and provide supporting arguments for this position:

TEXT BOX

III. Preferred Regulatory Option

20. In this question we are asking you to rate each of the three options for its appropriateness as a regulatory regime for the environmental assessment of new substances in products regulated under the *Food and Drugs Act* (F&DA).

When rating the regulatory options please take into consideration:

- **the problem definition as stated in the Final Issue Identification Paper (*The NSNR under CEPA 1999 were not specifically designed to deal with substances in products regulated under the Food and Drugs Act and, as such, may or may not be appropriate for some substances*).**
- **the Regulatory Goals and Regulatory Options (Options Analysis Paper)**
- **the Summary: Options A, B & C table (Options Analysis Paper)**
- **how you or your organization rated each option overall according to its appropriateness in addressing each of the critical issues**

Use the scale provided where '1' is Least Appropriate and '5' is Most Appropriate. If you are not sure how to respond please indicate and elaborate in the comment box at the end of

this question.

Regulatory Option	1 Least Appropriate	2	3	4	5 Most Appropriate	Not Sure
Option A: Applying the current NSNR						
Option B: A new regime under CEPA 1999						
Option C: A new regime under the F&DA						

21. If you have any additional comments on question 20 please provide them here:

TEXT BOX

22. If you believe there are other options that should be considered for assessing new substances in products regulated under the *Food and Drugs Act* (F&DA) please indicate and explain:

TEXT BOX

23. Do you believe there are any other issues or considerations, e.g. for a particular *Food & Drugs Act* product or commodity group, that should be considered? If so, please indicate and explain:

TEXT BOX

24. Do you believe there are any other issues, in particular, that should be considered to support coherence and consistency of approach with other Acts already listed under the *Canadian Environmental Protection Act*, 1999 (CEPA 1999)? If so, please indicate and explain:

TEXT BOX

IV. Regulatory Experience

This section is for background information and is OPTIONAL. However, completing it will not affect how your comments on the regulatory options are considered.

<u>Experience with Federal Acts and Environmental Assessments</u>

This section deals with the experience you or your organization may have with Federal Acts and with preparing/providing information for environmental assessments.

25. Please indicate your or your organization's level of experience with the following

Federal Acts:

Federal Act	None	Limited	Moderate	Extensive
Food & Drugs Act				
Canadian Environmental Protection Act				
Pest Control Products Act				

26. If you or your organization is currently involved in preparing/providing information for environmental assessments, please indicate for which government, or level of government, they are prepared. Select all that apply:

_ Federal (Health Canada)
_ Federal (Environment Canada)
_ Other Federal Departments
_ Province of Newfoundland
_ Province of Nova Scotia
_ Province of Prince Edward Island
_ Province of New Brunswick
_ Province of Quebec
_ Province of Ontario
_ Province of Manitoba
_ Province of Saskatchewan
_ Province of Alberta
_ Province of British Columbia
_ Yukon
_ Northwest Territories
_ Nunavut
_ Municipalities
_ Another Regulatory Authority

27. If you or your organization are preparing/providing information for environmental assessments for a Federal Department other than Health Canada please specify which Department(s):

Text Box

28. If you or your organization are preparing/providing information for environmental assessments for Municipal government(s) please specify which municipality(ies):

Text Box

29. If you or your organization are preparing/providing information for environmental assessments for another regulatory authority(ies) please specify which authority(ies):

Text Box

Experience with the New Substance Notification Regulations (NSNR) under the *Canadian Environmental Protection Act*, 1999 (CEPA 1999)

This section deals specifically with the experience you or your organization may have with the current regulatory regime (New Substances Notification Regulations (NSNR)) under the *Canadian Environmental Protection Act*, 1999 (CEPA 1999).

30. Do you or your organization have any experience with the New Substance Notification Regulations (NSNR) under the *Canadian Environmental Protection Act*, 1999 (CEPA 1999)?

- No If No, SKIP TO QUESTION 32
- Yes

31. If yes, indicate how many submissions you or your organization have prepared/provided under the New Substances Notification Regulations (NSNR) under the *Canadian Environmental Protection Act*, 1999 (CEPA 1999):

- 5
- 10
- 20
- greater than 20

32. Are you aware of the planned amendments to the New Substances Notification Regulations (NSNR)?

- Yes
- No

V. Analytical Tools Used in this Consultation Process

In this section we would like to know how satisfied you were with each of the analytical tools used in this process. Use the scale provided where '1' is Very Dissatisfied and '5' is Very Satisfied.

33. Options Analysis Paper: An Environmental Assessment Regime for New Substances in Products regulated under the *Food and Drugs Act:*

	1 Very Dissatisfied	2	3	4	5 Very Satisfied
Comprehensiveness					
Clarity					
Length					

34. If you wish, you may provide additional comments, below, on the Options Analysis Paper:

TEXT BOX

35. Summary: Options A, B & C table in the Options Analysis Paper:

	1 Very Dissatisfied	2	3	4	5 Very Satisfied
Comprehensiveness					
Clarity					
Ease of Use					

36. If you wish, you may provide additional comments, below, on the Summary: Options A, B & C table:

TEXT BOX

37. Regulatory Goals and Regulatory Options table in the Options Analysis Paper:

	1 Very Dissatisfied	2	3	4	5 Very Satisfied
Comprehensiveness					
Clarity					
Ease of Use					

38. If you wish, you may provide additional comments, below, on the Regulatory Goals and Regulatory Options table:

TEXT BOX

39. Electronic Questionnaire:

	1 Very Dissatisfied	2	3	4	5 Very Satisfied
Effective Method to Provide Feedback					
Clarity					

Ease of Use					

40. If you wish, you may provide additional comments, below, on the Electronic Questionnaire:

TEXT BOX

VI. Specific Organizational Information

The information being requested in this section will be used for background and statistical purposes only. Your responses will remain confidential.

41. Please indicate in which region(s) you or your organization operates. Select all that apply:

_ Western Canada (BC, AB)
_ Prairies (SK, MB)
_ Ontario
_ Quebec
_ Eastern Canada (NB, NS, NL, PE)
_ Northern Canada (YK, NT, NU)
_ National
_ International (Please specify below)
_ Other (please specify below)

If you selected 'Other' please specify here:

Text Box

42. The organization I work for is:

- Canadian owned and operated
- Other (please specify below)

If you selected 'Other' please specify here:

Text Box

43. Please indicate the size of your Canadian operations in terms of employees:

- 1 - 10
- 11- 50
- 51 - 100
- 101 - 500
- 501 - 1,000
- Other (please specify below)

If you selected 'Other' please specify here:

Text Box

44. Our Canadian operations fall into (select all that apply):

__ Production/manufacturing
__ Distribution
__ Marketing/sales
__ Research
__ Exporting
__ Other (please specify below)

If you selected 'Other' please specify here:

Text Box

45. Please indicate if the total business you or your organization does in Canada is:

- less than 50 % of all business
- greater than 50% of all business
- N/A

VII. Next Steps

The next step in the consultation process will be a Stakeholder Workshop to discuss the results of this 'feedback' process and to begin developmental work regarding the appropriate environmental assessment regime for new substances in products regulated under the *Food and Drugs Act.*

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46. Please indicate the name of the person we should contact concerning participation in the Stakeholder Workshop:

Name:

Text box

Title:

Text box

Organization:

Text box

Phone:

Text box

Format: 999-999-9999

Fax Number:

Text box

Format: 999-999-9999

Email address:

Text box

Thank you for your input and your participation in completing this questionnaire. Once the results have been compiled, a report will be made available to stakeholders.

For further information on next steps, you may visit our website at: http://www.hc-sc.gc.ca/ewh-semt/contaminants/person/impact/consultation/comment/com_e.html

Environmental Impact Initiative
Office of Regulatory and International Affairs
Health Products and Food Branch
Health Canada
Phone: 1-888-492-1104
Email: ear-ree@hc-sc.gc.ca

Appendix B: Acronyms and Glossary

Acute toxicity - Adverse effects, particularly mortality, that are observed over a short period of time, typically 1 to 5 days, following single or multiple dose administration of a test substance.

API - Active Pharmaceutical Ingredient.

CEPA 1999 - *Canadian Environmental Protection Act,* 1999.

CEPA NAC - *Canadian Environmental Protection Act* National Advisory Committee.

CHE - Committee on Health and the Environment.

Chronic toxicity - Adverse effects that are observed over a prolonged period of time resulting from continuous exposure to the test substance, generally by an oral route, e.g., tumorgenesis, reproductive effects.

Commodities - The commodity groups to be regulated are pharmaceuticals, veterinary drugs, biologics, genetic therapies and radiopharmaceuticals, natural health products, cosmetics and personal care products, medical devices, and novel foods and food additives.

Critical Issue - An issue that must be considered in the development of a suitable regulatory regime for substances in products regulated under the *Food and Drugs Act*.

DSL - Domestic Substance List under CEPA 1999.

EAR - Environmental Assessment Regulations.

EII - Environmental Impact Initiative.

EU - European Union.

Excipients - inactive substances that serve as the vehicle or medium for a drug or other active substance.

F&DA - *Food and Drugs Act*.

GMO - Genetically Modified Organism.

HECSB - Healthy Environments and Consumer Safety Branch in Health Canada.

HPFB - Health Products and Food Branch in Health Canada.

ICL - In Commerce List.

NHPD - Natural Health Products Directorate of HPFB in Health Canada.

NSNR - New Substance Notification Regulations under CEPA 1999.

New substance - Any chemical, polymer or living organism that is not on the DSL.

OAP - "Options Analysis Paper - An Environmental Assessment Regime for New Substances in Products Regulated under the *Food and Drugs Act*".

Product - Products are considered any food, drug, cosmetic or medical device that are subject to notification under the F&DA. A product may consist of one or more substances. For example, a food additive may be a single substance, whereas a drug may contain one substance that is the active ingredient and others that are excipients.

Smart Regulation - Smart Regulation is a government-wide initiative aimed at improving the Government of Canada's regulatory system so that it can keep pace with today's realities and our evolving needs. It strives for a better coordinated, more transparent system that remains forward-thinking and accountable to citizens. http://www.regulation.gc.ca

SNAc - Significant New Activity.

Sub-chronic toxicity - Adverse effects observed over a period of time greater than that used in acute toxicity test (but not exceeding ten percent of the life span of the test species) from repeated daily exposure.

Substance - Any distinguishable kind of organic or inorganic matter, whether animate or inanimate and includes:

- any matter that is capable of being dispersed in the environment or of being transformed in the environment into matter that can be dispersed or that is capable of causing such transformations.
- Any element or free radical.
- any combination of elements of a particular molecular identity that occurs in nature or as the result of a chemical reaction.
- complex combinations of different molecules that originate in nature or are the result of chemical reactions but that could not be formed by simply combining individual constituents.

Note: Environmental Assessments are conducted on substances in F&DA products, not on the products themselves.

Trigger quantity - The quantity of a substance to be imported into or manufactured in Canada that requires the notifier to provide a NSN notification (prior to that quantity being exceeded). Sometimes referred to as a threshold.

VICH - International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medical Product.