Health Canada Santé Canada

Final Audit Report

Audit of
New Substances Assessment and Control Bureau

September 2009

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Executive Summary

The New Substances Program (NSP) was established to ensure, as per the *Canadian Environmental Protection Act* (CEPA), that no new substances are introduced into the Canadian market place before they have been assessed and where necessary conditions to manage risks to the environment and/or human health have been applied.

The objective of this audit was to assess the management control framework within the New Substances Assessment and Control Bureau (the Bureau) in relation to operational plans and objectives; the identification, assessment and response to risks; and the monitoring of performance. The audit was conducted in accordance with the Internal Auditing Standards for the Government of Canada, and has examined sufficient, relevant evidence and obtained sufficient information and explanations to provide a reasonable level of assurance in support of the audit conclusion.

The Bureau's operational plans clearly define its strategic direction, objectives and results. In turn, these activities were aligned with the Branch Strategic Plan and mandate. The Bureau's management team also identified and assessed the key risks that could compromise the Bureau's ability to achieve its objectives.

While the Bureau has profiled its risks it has been difficult to put in place mitigating strategies. As required by legislation, the Bureau should respond to submissions from companies or individuals (notifiers) who want to import or manufacture substances that are new to Canada within a legislated timeframe. Historically these timelines have been exceeded and when timelines are exceeded the notifier may proceed with the planned use of the substance.

A second area noted in the audit relates to they way the Bureau "risk manages" newly received assessments. The audit notes, and the Bureau agrees, that a more formal risk management process is needed for prioritizing the assessment of new substances.

One factor that determines the extent of documentation required for a new substance that is under consideration is the volume being assessed. However, volume may not be the best indicator of risk given that a small volume may present a substantial health and/or environmental risk (such as in the area of nanotechnology where the material is 100 to 1000 times smaller than a microscopic particle). Moreover, the Bureau notes that the graduated, quantity-based process for submissions *may* be bypassed.

Lastly, actions to measure whether the Bureau is meeting its legislative requirements for new submissions is not routinely documented or reported to senior management.

The program reports that it has consulted with its other government department partner in the development of the management action plan and there is a commitment to joint action where required to respond to the four recommendations of this audit.

Introduction

Background

The New Substances Program (NSP) was established to ensure, as per the *Canadian Environmental Protection Act* (CEPA), that no new substances are introduced into the Canadian market place before they have been assessed and where necessary conditions to manage risks to the environment and/or human health have been applied. These substances include chemicals, polymers, inanimate and animate (microorganisms and higher organisms) products of biotechnology, nanomaterials, as well as new substances present in products subject to the *Food and Drugs Act* (F&DA).

Since 1994, Health Canada has received more than 15,000 notifications and currently receives approximately 500 notifications per year, although volumes vary over time according to business decisions of the companies involved. With an annual budget for 2008-09 of $5.6 million, it represented 23 percent of the budget for the Product Safety Program.

Health Canada shares the responsibility for assessing whether a new substance meets the CEPA criteria for a toxic substance with another government department. Under CEPA "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."

Under the Government of Canada's New Substances Notification Program, companies or individuals who want to import or manufacture substances that are new to Canada must first notify the government so that the substances can be assessed. The key issues are the immediate and long term harmful effects of the substance on the environment and human health.

The New Substances Assessment and Control Bureau (the Bureau) comes into the assessment process to conduct a pre-market/pre-manufacture risk assessment for the new chemical substance (such as fabric dyes and fuel additives). The Department also looks at biotechnology products such as micro-organisms used in reclaiming land after an oil spill.

In addition, they assess new substances covered by the Food and Drugs Act (F&DA). For assessment of the F&DA substances, the Bureau works with Health Products and Foods Branch (HPFB). These substances include human drugs, biologics, veterinary

drugs, cosmetics, and genetically modified foods For F&DA substances, the Environmental Assessment Unit (EAU) of the Bureau is responsible for tracking, screening and assessing notifications, both from an environmental and health perspective.

For the remaining new substances, the work under CEPA is done collaboratively with another government department who receives the notifications and does the environmental assessment while Health Canada does the health assessment.

The Bureau also has the leading role in the categorization and eventual assessment of the In Commerce List (ICL) of over 9000 substances in F&DA products. This is a list of substances which entered commerce between 1987 and September 2001 and thus were not eligible for inclusion in the Domestic Substances List (DSL) of CEPA (substances in commerce between 1984 and 1986). Lastly, the Bureau has prioritized and is carrying out screening risk assessments of all microorganisms on the DSL in collaboration with another government department.

If a substance is found to pose an unacceptable risk to the health of Canadians or the environment, then conditions may be imposed to ensure that the substance is handled in ways that will adequately manage the risk or the chemical may be disallowed if its release to the environment cannot be controlled. However, even if a substance is controlled or banned, it still may be able to enter the country through other means such as being part of an existing manufactured product.

New substance notifications are submitted against specific legislated “schedules” based on the type of substance that is imported or manufactured. Currently, under the CEPA there are nine notification schedules for chemicals and polymers and five for living organisms. The schedules are differentiated based on the type and amount of the substance the notifier is seeking to bring into Canada. For example there are separate schedules for chemicals, polymers and organisms. In addition there is an increasing weight scale associated with the application which involves getting permission to import 100kg., 1,000 kg., or 50,0000 kg. of a given substance. The documentation required to support the application, and the time required to complete the assessment, will vary depending on the individual substance and the quantity involved.

Objective

The objective of this audit was to assess the management control framework within the New Substances Assessment and Control Bureau in relation to operational plans and objectives; the identification, assessment and response to risks; and the monitoring of performance.

Scope and approach

The audit was undertaken by the Audit and Accountability Bureau in accordance with the Health Canada Risk-Based Audit Plan 2008-2009, which was approved by the Departmental Audit Committee at its April 3, 2008 meeting and was conducted in accordance with the Internal Auditing Standards for the Government of Canada, and has examined sufficient, relevant evidence and obtained sufficient information and explanations to provide a reasonable level of assurance in support of the audit conclusion.

The audit focused on key aspects of the control framework for ensuring that the environmental impact and risks to human health through environmental exposure to new substances are assessed before these substances can enter the country and be used for their intended purpose. The core management controls focused on during the audit included: strategic direction and planning, risk management, and results and performance.

The audit covered the Bureau's assessment activities for new substances during fiscal 2007-08 and 2008-09 and audit criteria were drawn from Treasury Board of Canada Secretariat document: *"Core Management Controls: A Guide for Internal Auditors"*. The audit was conducted in the National Capital Region.

Findings, Recommendations and Management Responses

Strategic Direction and Planning

Audit criterion

The organization has in place operational plans and objectives aimed at achieving its strategic objectives.

Strategic direction

Operational plans and objectives provide clear direction on how resources should be allocated to achieve identified objectives. The New Substance Assessment and Control Bureau (the Bureau) reports through the Healthy Environments and Consumer Safety Branch (HECSB). A review of planning documentation, for the period under

examination, showed that the Branch has established and communicated its strategic direction and strategic objectives and aligned them with the Branch Strategic Plan and its mandate. A Branch Strategic Framework was also developed, circulated, and used in producing the operational plans within the Bureau.

In addition, a draft Integrated Management Accountability Framework (IMAF) Charter has been developed for the Bureau. It addresses the following management practices: strategic planning, operational planning, budgeting, stewardship, variance reporting, resource allocation, human resource management, performance management and reporting, risk management and evaluation.

Planning

Planning involves articulating strategic choices in light of past performance and indicates how an organization intends to deliver on its priorities and achieve its results. Planning and other documentation were examined to determine whether essential elements were in place to set strategic direction in order to fulfil the mandate of the New Substances Assessment and Control Bureau.

The documentation relating to the Bureau's operational planning clearly defined the Bureau's strategic directions, objectives and results. The Bureau had operational plans and objectives aimed at achieving its strategic objectives. In addition, operating objectives and priorities exist for all key activities, and they were documented and linked to strategic objectives and priorities. The Bureau carries out periodic environmental scans internally and externally to gather information from key resources on risk areas in order to identify potential changes. Lastly, lines of communication existed between the organization, notifiers and other external stakeholders.

Risk Identification and Assessment

Audit Criterion

Management identifies and assesses the risks that may preclude the achievement of its objectives.

Identification and assessment of risks

Risk management, as defined by Health Canada, is a systematic process that includes the practices and procedures that the Department uses to identify and manage the risks it faces. The process includes identifying, assessing, understanding, acting on and communicating risk issues.

The Bureau's management team had identified and assessed the key risks that could compromise the Bureau's ability to achieve its objectives and responses to the risks that

had been identified. The risk assessment process was rigorous, and considered both internal and external sources.

Responding to Identified Risks

Audit criterion

Management responds to the risks that may preclude the achievement of its objectives.

Legislated deadlines

CEPA legislation and regulations requires the Bureau to respond to new substance submissions within set deadlines. The mandatory response timelines range from 5-75 days for chemicals and polymers, and 30 to 120 days for organisms.

Historically, the Bureau has had problems meeting its legislated deadlines for assessing submissions from notifiers. If the Bureau fails to meet a deadline the notifier may proceed with the planned use of the substance. If the submission is for one of the lower quantities (such as 100 kg. or 1,000 kg. a year) of a substance, the Bureau may have another opportunity to review the substance if it receives a second submission for a higher quantity. However, at a certain point, if the Bureau has not placed any restrictions on the substance, it can eventually become part of the Domestic Substances List. At this point, the Bureau cannot place further controls over the substance. As a result, a substance could enter into common use in Canada without ever having been assessed. The Bureau was unable to identify the extent to which this had occurred. As a result, any failure to meet legislated timelines for completing its assessments constitutes a risk that is currently not being tracked and used for decision making. (see Performance Monitoring)

Triage

In 2007 a “Capacity Assessment” was completed for the Bureau which noted that a formal risk management process was needed for prioritizing new substance assessments and that a risk management framework should be developed including targets for completing assessments. A key part of a risk management process for better managing the submission process is “triage”. Triage is a medical term for selecting patients who should receive treatment first based on need and probability of success. Using the triage system within the submission process could potentially help with prioritization by first assigning resources to those submissions that may potentially pose the highest risk to human health and the environment.

The 2007 Capacity Assessment noted that the Bureau was piloting a formalized approach to risk management in one section and was to extend this approach to the remaining sections by mid-November 2007. While individual sections within the Bureau were

practicing risk management to set priorities for dealing with submissions, the process is informal, varies from unit to unit, and has not been documented.

A more formal and consistent approach to triage would enable the Bureau to better allocate its resources to those substances that pose the greatest risks to human health and the environment.

Recommendation 1

It is recommended that the Assistant Deputy Minister of Healthy Environments and Consumer Safety Branch formalize and document a framework for prioritizing new substance assessments.

Management Response

Management accepts the recommendation and plans to take the following actions:

- In cooperation with other government department partner, formalized criteria for prioritization based on risk and legislative timelines will be developed and implemented, including a mechanism to document decisions on level of priority.

Effective Legislative and Regulatory Authority

Given that the program is the front line for screening a large variety of substances, it is critical to keep the notification regulations up-to-date. This is necessary to meet needs associated with assessment of such items as genetically modified animals and substances in *Food and Drugs Act* products and to develop new regulations to address manufactured nanomaterials.

The Bureau reports that the "In Commerce List" is being revised to enable the List to be used as a statutory instrument for conducting environmental assessments of these substances to determine their risk to human health and the environment. These substances will be managed more like "existing substances" under CEPA, and to accomplish this, amendments to CEPA or to the F&DA will be required to give the ICL legislative standing. On-going stakeholder consultations and development of criteria for listing, categorization and prioritization are being carried out.

According to the legislation, when a new substance is submitted for assessment, the notifier must provide appropriate documentation to support the submission. The factors that generally determine the extent of the documentation required by the Bureau are: the nature of the substance; the volume/quantity that the notifier wants to manufacture or import, or the level of containment required for living organisms.

Regulations have set up pre-determined quantities which "trigger" assessments. As the trigger quantity (i.e. 100 kg., 1000 kg., 10,000 kg. or 50,000 kg./year) increases, the level

of scrutiny and documentation requirements also increases. However trigger quantities are not always the best indicator of risk as they do not adequately take into account issues such as how the substance is going to be used. For example, the risks associated with substances that are going to be used by humans, (i.e. for pharmaceuticals, cosmetics) may be greater than if they are to be used in a chemical production process with safeguards to prevent them from moving into the environment.

In addition, trigger amounts for substances related to nanotechnology (1,000, 10,000 or 50,000 kg. /year) may not be appropriate given the potential for significantly higher risks to human health and the environment.

The Bureau's staff also has concerns that the intent of the graduated, quantity-based process for submissions may be bypassed. For example, companies may "volume split" (i.e. make numerous submissions for lower quantities of a substance) in order to "work around" the documentation demands associated with submissions for higher quantities. This practice could lead to both higher usages of the specific substances without appropriate scrutiny intended by the regulations, and an increased risk to human health and the environment.

Recommendation 2

It is recommended that the Assistant Deputy Minister of Healthy Environments and Consumer Safety Branch develop measures to address issues involving legislative and regulatory needs, including those related to volume splitting.

Management Response

Management accepts the recommendation and plans to take the following actions:

- Revision of notification regulations for living organisms: Develop and implement amendments for "higher organisms" portion of the regulations with partner.

- Regulatory framework for environmental assessment of new substances in products subject to the Food and Drugs Act: Preparation of drafting instructions for notification regulations that deal with all 9 commodity groups.

- Volume Splitting: Monitor each notification and advise partner department of any potential volume splitting and continue to work with partner department on compliance and promotion activities including informing and educating new and existing notifiers on the subject.

- Regulatory framework for manufactured nanomaterials: Work in collaboration with other department partner and other parts of HC (HPFB, PSP, SPB and PMRA) on definition, stakeholder consultations and development of regulatory framework, based on legislative authority in a two phased approach

- Legislative changes: Propose changes to clarify/expand authority in CEPA and/or the F&DA required to allow regulatory changes above

Horizontal Risk Management

The analysis of submissions for new substances deals with one facet of protecting human health and the environment by identifying risks associated with a new substance and by placing restrictions on how a notifier can use that substance. However, if the Bureau identifies a risk with a substance that could affect other organizations within or outside the Department, no formal mechanisms exist for sharing this information. For example, when a new substance has a restricted use this does not prevent the substance from entering Canada as a component of an existing imported product. In this particular example, the Existing Substance Division could benefit from this information.

More and more, the approaches and control mechanisms between "new" and "existing" substances are evolving towards merging at a number of levels. For example, tools similar to Significant New Activity controls traditionally used to manage risk for new substances are increasingly being applied to existing substances under the Chemicals Management Plan (CMP). Should industry want to introduce those existing chemicals back into the marketplace in Canada, these chemicals would be assessed as if they were new chemicals. In addition, given that it is expected that assessment of the medium priority existing substances under CMP in coming years will be a challenge due to lack of data, these assessments will rely increasingly on the methods, tools and processes used for new substances. Similarly for categorizing substances on the In Commerce List, some methods and lessons learned from existing substances are being applied.

Recognizing there was a need for more in-house horizontal management within the Healthy Environments and Consumer Safety Branch; in June 2008 they announced the creation of a Chemicals Management Directorate (subsequently reorganized and renamed Safe Environments Directorate).

One of the new Directorate's focuses is to provide a focal point for the *Canadian Environmental Protection Act* (CEPA), and the Government's Chemical Management Action Plan activities in the Department. While the role of the Bureau within the reorganization had not been finalized under the new structure the Bureau would become part of the new Safe Environments Directorate.

The role of the new Directorate is to bring together staff from a variety of areas including the New Substance Assessment Control Bureau, the Existing Substances Division, the Water, Air and Climate Change Bureau, the Environmental Assessment Division,

Contaminated Sites Division and the Risk Management Bureau. In addition, there will be a new management committee structure within the new Directorate.

Collaboration on risk assessment and risk management of chemicals is done not only across programs within Health Canada and its partner but also with other countries (e.g., United States and Europe) and international organizations such as the OECD. This collaboration, coupled with the evolution of two programs into one, will bring about changes in requirements for greater transparency with respect to decision making and new governance which addresses common priorities and shared objectives internationally to meet domestic goals.

Recommendation 3

It is recommended that the Assistant Deputy Minister of Healthy Environments and Consumer Safety Branch ensure that the new Directorate has a process in place for the identification and communication of risks associated with new substances that cross both organizational and departmental boundaries.

Management Response

Management accepts the recommendation and plans to take the following actions:

- Recognizing the inevitable need for further integration of the work on new and existing substances and the need to reach out to new partners including those in the occupational health area, and to work to ensure that information obtained through new substance assessments is available to other program partners.

- In cooperation with legal services and directorates within HECS, HPFB and PMRA, implement new mechanisms on information sharing:

    - Negotiate with other CEPA programs and provide access to databases that contain Confidential Business Information by other risk assessment groups in SED
    - Develop an Alert System for unanticipated hazards
    - Identify legal barriers that may exist with respect to the sharing of scientific information collected under different Health Canada Acts (e.g. CEPA, F&DA, and PCP Act). If legal barriers exist, identify methods and procedures to overcome these barriers. Negotiate roles and responsibilities for the handling of Confidential Business Information and implement sharing agreements

Monitoring Performance

Audit criterion

Management monitors actual performance against planned results and adjusts course as needed.

Performance measurement

Ongoing performance measurement is a key tool for determining what is or is not working and the extent to which objectives are met. The results of performance measurement provide opportunities for making any changes necessary to help ensure that an organization can achieve its objectives and produce the desired results.

Planning and performance measures

A review of the Bureau's documentation showed that the management team had identified performance measures and had linked them to planned results through the departmental operational planning process. Management had also linked the planned results to organizational objectives.

Tracking and monitoring performance

Having the ability to effectively collect and analyse information on notifications and their assessment is critical to ensuring that the Bureau can not only set priorities and track performance, but strengthen its role in sharing information on new substances within the Department. Since these substances can be in consumer products, cosmetics, drugs, etc., this would support a more coherent and integrated action amongst programs.

At the time of the audit the Bureau was not measuring its performance to demonstrate the extent to which it meets regulated timelines nor was there information on the extent to which the Bureau had improved its performance in this area since the 2007 Capacity Assessment. The Bureau's management team acknowledges that it needs to improve the way in which it measures and reports on performance and recognizes that monitoring performance would allow them to identify any delays within the assessment process.

The Bureau does have a plan to develop management and monitoring software, in the meantime individual managers have developed their own computerized spreadsheets to track the assessment of substances under their control. Typically, they identify the submission by number, staff assignment, and assessment completion date. Recently, managers made improvements to their spreadsheets in order to better determine where the various substances were in the assessment process.

Despite these efforts to track submissions the Bureau does not track those substances that were not assessed within the legislated timeframe. As previously noted, in the audit report those substances can eventually become part of the Domestic Substances List which allows them to be freely used. As such, there is a need to develop and implement a tracking system to identify those substances that have not been assessed by the Bureau and to communicate this information to appropriate stakeholders. In addition, this information would also assist the Bureau in assessing the impact of the risk associated with missed timelines and should be reported to senior management.

The Bureau reports that the longer term goal is to have a system that would allow the information to be shared through a common IT system between Health Canada and its partners. This one window would encompass information from both existing substances and the Bureau. Until this system is implemented the Bureau needs to find a means to monitor their performance against planned results and report to management.

Recommendation 4

It is recommended that the Assistant Deputy Minister of Healthy Environments and Consumer Safety Branch, in the interim, enhance their spreadsheet to automate query routines for monitoring and measuring performance.

Management Response

Management accepts the recommendation and plans to take the following actions:

- Enhance the current Excel spreadsheet to automate query routines for monitoring and measuring performance.

- Continue to work with partner department and HC IMSD to find a longer term solution to link to partner department's One Window solution for new and existing substances.

- Establish baselines for performance based on risk, define service standards and review performance on a regular basis.

Conclusion

Overall, the New Substance and Assessment Control Bureau have suitable controls in place at the strategic level in order to manage the new substance assessment process. In particular, the Bureau's operational plans clearly define their strategic direction, objectives and results. In turn, these were aligned with the Branch Strategic Plan and its mandate. As well, the Bureau's management had identified and assessed the key risks that could compromise the Bureau's ability to achieve its objectives.

At the operational level, the Bureau has historically had difficulties meeting legislated deadlines for assessing submissions. They need to implement a triage system in order to prioritize assessment work. Issues related to volume splitting need to be addressed to ensure that new substances receive the appropriate scrutiny. Lastly, the Bureau needs to better measure its performance to demonstrate the extent to which it meets regulated timelines and to demonstrate performance improvements.

The program reports that it has consulted with its other government department partner in the development of the management action plan and there is a commitment to joint action where required to respond to the recommendations of this audit.

Appendix 1: Lines of Enquiry and Audit Criteria

Line of enquiry (The Bureau should)	Audit Criteria
1. Set strategic direction.	1. The organization has in place operational plans and objectives aimed at achieving its strategic objectives. 2. Management identifies and assesses the risks that may preclude the achievement of its objectives.
2. Monitor performance for reporting and decision making.	3. Management responds to the risks that may preclude the achievement of its objectives. 4. Management monitors actual performance against planned results and adjusts course as needed.