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Report of the
**Auditor General
of Canada**
to the House of Commons

NOVEMBER

Chapter 8
Allocating Funds to Regulatory Programs—
Health Canada



Office of the Auditor General of Canada

The November 2006 Report of the Auditor General of Canada comprises Matters of Special Importance—2006, Main Points—Chapters 1 to 12, Appendices, An Overview of the Federal Government's Expenditure Management System, and 12 chapters. The main table of contents is found at the end of this publication.

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Chapter

8

Allocating Funds to Regulatory Programs
Health Canada

All of the audit work in this chapter was conducted in accordance with the standards for assurance engagements set by the Canadian Institute of Chartered Accountants. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

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Allocating Funds to Regulatory Programs

Health Canada

Main Points

What we examined

Health Canada is responsible for regulating the safety and use of a wide range of items that Canadians commonly use. We examined both the process by which Health Canada decides what resources to allocate to each of its branches and the information used as the basis for resource allocation. We looked in particular at how branches allocate resources to three regulatory programs: product safety, drug products, and medical devices. We examined the impact of the Department's resource allocation process on its ability to carry out its regulatory responsibilities in these areas. The audit focused on fiscal years 2003–04 and 2004–05.

Why it's important

When Canadians use products regulated by Health Canada—whether household products such as cribs, medical devices such as blood test kits, or prescription drugs—they expect that as long as they follow directions, the product will be safe to use. Programs that regulate these products need enough resources to ensure that Canadians are adequately protected from risks to their health and safety. Health Canada, as a regulator, needs to be able to demonstrate that it is fully meeting its regulatory responsibilities.

What we found

- Program managers have indicated to branch management that some core compliance and enforcement activities are insufficient to protect Canadians' health and safety. While the total funding allocated to two of the three audited programs has remained constant, all three programs audited received less funding for core activities in 2005–06 than in 2003–04. Meanwhile, the complexity of programs and the growing demands on programs could significantly affect Health Canada's ability to meet its regulatory responsibilities.
- Health Canada has not set performance targets for all of the compliance and enforcement activities of the programs we audited. It has not determined the level of activities the programs must carry out to meet the Department's regulatory responsibilities, or the level of resources they would need to do so. Therefore, it does not know if it is fully meeting its responsibilities as the regulator of drug products, medical devices, and product safety.

- Program managers do not always have complete information to decide on how best to allocate their resources. There is limited information on the required level of program performance and the funding needed for the programs to meet its legislative requirements. There is also limited information on the results achieved for the funding received by the programs. This makes it difficult for program managers to determine the level of funding each activity needs if it is to provide Canadians with the appropriate level of protection.
- In the absence of a baseline, program managers use their experience and knowledge of their programs to report to branch management on funding shortfalls and unfulfilled regulatory responsibilities. Furthermore, the Departmental Executive Committee does not routinely receive information on how well Health Canada is fulfilling its core role as regulator, even though the Committee is the only group in Health Canada that can address cross-branch funding issues.
- Health Canada is taking steps to improve its resource allocation process. The Department has redesigned the operational planning process that will be implemented in 2006–07. This is intended to standardize the process, document decisions, and communicate to senior management the expected results based on the funding approved.

Health Canada has responded. Health Canada agrees with our recommendations. Its detailed responses follow the recommendations throughout the chapter.

Introduction

Importance of regulatory programs in Health Canada

8.1 One of Health Canada's core roles is that of regulator, according to the *Department of Health Act*. As such, the Department carries out legislative and statutory activities to protect Canadians' health and safety and ensure that products vital to their health and well-being are provided.

8.2 The Department has regulatory responsibilities for thousands of products. These include pesticides, toxic substances, pharmaceuticals, biologics, medical devices, natural health products, consumer goods, and foods. Health Canada delivers a range of programs and services in environmental health protection, and has responsibilities in the areas of substance abuse, tobacco policy, workplace health, and the use of consumer products.

8.3 Regulatory programs for which Health Canada has primary responsibility play an important part in furthering public health and safety. Accordingly, it is critical that the Department adequately fund these programs to fulfill its responsibilities. In essence, Health Canada, as a regulator, needs to have adequate resources to fulfill its obligations, which include monitoring compliance with the regulations and enforcing them as necessary.

Need for a sound financial resource allocation process

8.4 For Health Canada, to make responsible spending decisions related to the delivery of programs and services, the Department needs an effective resource allocation process. As part of this process, the Department needs to decide what it is trying to achieve, what its priorities are, and direct resources toward programs and services that help Canadians. It then needs to monitor its programs to ensure that they are achieving the intended results. Therefore, to make these important decisions, Health Canada requires sound financial and performance information that must include the cost to achieve the stated objectives. It also needs to be able to link financial and performance information to determine results achieved with the funding received.

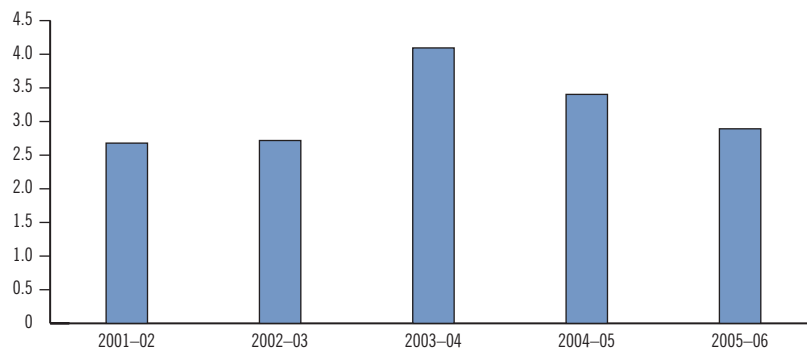
8.5 Health Canada spent \$3 billion in 2005–06 on helping Canadians maintain and improve their health. The Department needs to have a sound resource allocation process to ensure that funds are spent where they will do the most good. Exhibit 8.1 shows the

Department’s total spending over five years. The increased spending in 2003–04 was due to payments of large grants to organizations and to address the emergence of bovine spongiform encephalopathy (BSE), severe acute respiratory syndrome (SARS), and West Nile virus. The decreased spending in 2005–06 was due in part to Health Canada transferring some of its resources to the newly created Public Health Agency of Canada as of 1 April 2005, and to the Department’s contribution to government-wide cost reductions.

8.6 The primary source of funding for the regulatory programs is core funding, which represents funds that are provided to Health Canada to support ongoing programs. The Minister of Health may also seek approval from Cabinet and the Treasury Board to carry out a special initiative that the Department would otherwise be unable to undertake. Additional funding may be required to carry out such initiatives. This report refers to this secondary source of funding as funding for special initiatives. Both core funding and funding for special initiatives require parliamentary approval through the Estimates.

8.7 A third source of funding is revenue, which consists of fees that Health Canada collects from industry for services provided to it such as reviews of submissions for new drugs. Health Canada has the authority to use its revenue from fees to finance the service from which they are generated. A regulatory program can also receive funds through internal reallocations, which refers to taking funds from one program or activity and reallocating them to another program or activity (see 8.48 to 8.51).

Exhibit 8.1 Health Canada’s spending from 2001–02 to 2005–06 (\$ billions)



Source: Public Accounts of Canada

Focus of the audit

8.8 Our audit focused on whether Health Canada allocates financial resources according to plans based on sound financial and performance information. We also wanted to determine whether program managers regularly report relevant information on sources of funding, program costs, and results at all levels of the organization and whether this information is used to allocate resources. Finally, we wanted to know whether Health Canada can demonstrate that it allocates adequate funds to regulatory programs to ensure that they can meet the Department's regulatory responsibilities.

8.9 Since most of the regulatory programs at Health Canada are found in two branches, we focused our work in these units: the Healthy Environments and Consumer Safety Branch (HECSB) and the Health Products and Food Branch (HPFB), which had a budget of \$226.5 million and \$239 million respectively in 2004–05. Within these two units, we examined three regulatory programs. In HECSB, we selected the Product Safety program because it had the most acts and regulations under its responsibility. In HPFB, we selected the Drug Products and Medical Devices programs because of the importance of their budgets, their large cost-recovery component, and the increased funding the programs received through special initiatives. Exhibit 8.2 describes the three regulatory programs audited.

8.10 We examined how resources are allocated to programs and directorates within each branch. Specifically, we examined their plans, budgets, resource allocation, and decision making. We also looked at reporting by the programs and directorates to senior management on program costs and results.

8.11 Exhibit 8.3 shows the three programs audited within the two branches.

8.12 Our audit focused on the process by which Health Canada decides what resources to allocate to each of its branches and programs and the information on which it bases those decisions. We have not audited the efficiency of the three selected programs.

8.13 More details on the audit objectives, scope, approach, and criteria are in **About the Audit** at the end of this chapter.

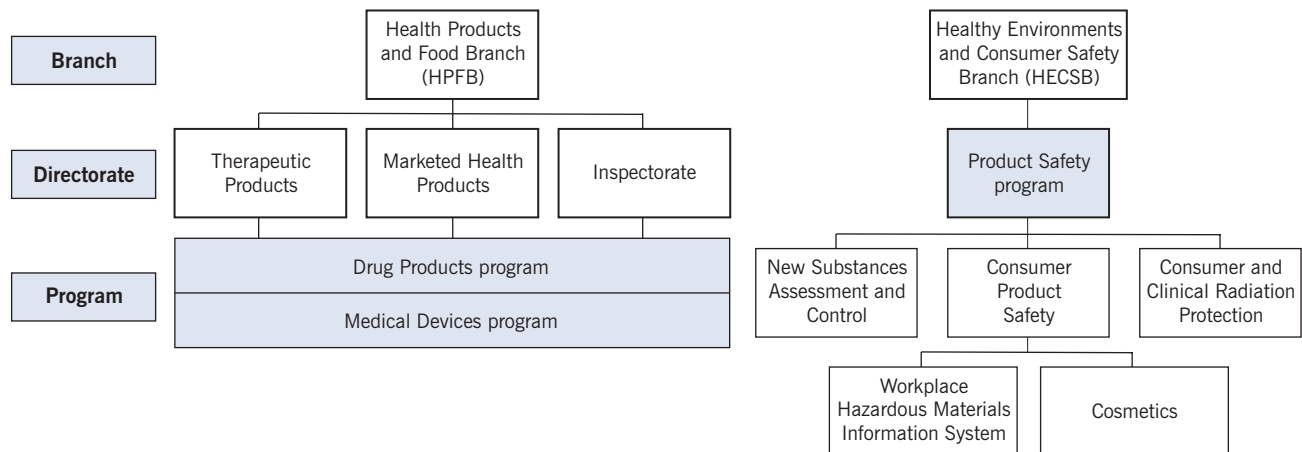
Examples of drug products—Prescription drugs and non-prescription products such as sunscreens.

Examples of medical devices—Pacemaker, scalpel, contact lenses, orthopaedic implants, and diagnostic ultrasound systems.

Exhibit 8.2 Regulatory programs audited

<p>Product Safety. The mandate of the Product Safety program is to identify, assess, and manage the health and safety risks to Canadians associated with</p> <ul style="list-style-type: none"> • consumer products, • hazardous workplace materials, • cosmetics, • new chemical substances, • products of biotechnology, • radiation produced by radiation-emitting devices, • environmental noise, and • solar UV radiation. <p>The program has responsibilities under several acts and regulations, including the <i>Hazardous Products Act</i>, and had a budget of \$17.8 million in 2003–04 and \$18.7 million in 2004–05.</p>	<p>Drug Products. According to Health Canada, the Drug Products program maximizes the safety of marketed human drug products through its regulations. The program is delivered by three directorates in the HPFB (Exhibit 8.3).</p> <ul style="list-style-type: none"> • The Therapeutic Products Directorate provides pre-market approval of pharmaceutical drugs offered for sale in Canada, ensuring that they are safe, effective, and of high quality. • The Marketed Health Products Directorate conducts post-market surveillance of prescription and over-the-counter drugs and other health products for their safety and therapeutic effectiveness. • The HPFB Inspectorate delivers a national compliance and enforcement program such as inspections of manufacturers and product investigations for all health products under the Branch's 	<p>mandate, including drugs for humans.</p> <p>The Drug Products program had a budget of \$51.8 million in 2003–04 and \$50.6 million in 2004–05.</p> <p>Medical Devices. The goal of the Medical Devices program is to ensure, to the extent possible, that the public has timely access to safe, effective, and quality devices. It also contributes to the continued protection of the public by informing health professionals and the public of any safety concerns on a timely basis. Like the Drug Products program, the Medical Devices program is delivered jointly by the Therapeutic Products Directorate, the Marketed Health Products Directorate, and the HPFB Inspectorate, which apply the <i>Medical Devices Regulations</i>. The program budget was \$8.8 million in 2003–04 and \$11.4 million in 2004–05.</p>
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Exhibit 8.3 The three audited programs within the Health Products and Food Branch and the Healthy Environments and Consumer Safety Branch



Source: Health Canada

Observations and Recommendations

Meeting regulatory responsibilities

8.14 For drug products, medical devices, and product safety, Health Canada has a legislated responsibility that is outlined in the *Food and Drugs Act*, *Hazardous Products Act*, *Radiation Emitting Devices Act*, *Canadian Environmental Protection Act*, and related regulations. As a regulator, Health Canada carries out activities to ensure that regulations are complied with and, if not, that enforcement actions are taken. In delivering on these responsibilities, Health Canada helps ensure that the public has access to safe and effective drugs, medical devices, and consumer products. It also helps ensure the public's continued protection by informing health care professionals and the public of any safety concerns on a timely basis and ensuring that products on the market are safe.

8.15 The Department carries out pre-market and post-market regulatory activities. Pre-market activities are conducted before authorizing a company to market a product. These activities include authorizing clinical trials for drug products, authorizing investigational testing (clinical trials) for medical devices, and reviewing submissions of scientific evidence by manufacturers to determine a product's safety, quality, and efficacy before authorizing it for market. Surveillance and post-market activities are conducted after manufacturers are authorized to market drugs and medical devices. Activities focus on product safety and effectiveness, and regulatory compliance. For unapproved products, other compliance and enforcement activities are carried out, such as stopping sales and making recalls.

Health Canada does not know whether regulatory responsibilities are fully met

8.16 According to the government's *Regulatory Policy*, departments must ensure that enough resources have been approved to effectively discharge enforcement responsibilities and to ensure compliance with the regulations. We therefore expected Health Canada program managers to know the required level of funding needed to carry out their regulatory responsibilities.

8.17 We examined a number of documents, such as program policies, operational plans, mid-year reports, programs' Results-based Management and Accountability Frameworks where they existed, and documents providing the rationale for proposing and amending the regulations, for evidence of **program baselines**. We found that some directorates have components of a program baseline. For example, performance targets have been developed for some of their activities

Program baseline—The required level of activities that a program must carry out in order to meet its regulatory responsibilities of protecting the health and safety of Canadians, the targeted performance for these activities, and the resources needed to do this work.

(such as review times for drug products and medical devices submissions, and the frequency of inspections). However, none of the directorates had all of the elements of a baseline that could have been used for planning, resource allocation, and accountability.

8.18 Without defining the program baseline, Health Canada cannot demonstrate that it has allocated enough resources to the three programs audited to meet its regulatory responsibilities.

Program managers are concerned that some regulatory activities are insufficient

8.19 Program managers indicated to their branch management that insufficient compliance and enforcement activities were carried out. Without a program baseline, they used their experience and knowledge of the program to arrive at this conclusion. Program managers have also indicated that they use a risk-based approach to minimize the health risks to Canadians.

8.20 The Product Safety program is responsible for five commodity areas:

- consumer product safety (for example, cribs, tents, carpets);
- cosmetics (for example, deodorants, soaps);
- workplace hazardous materials information systems (for example, communication of information on corrosive material);
- consumer and clinical radiation protection (for example, x-rays, lasers, sunlamps); and
- new substances (for example, fabric dyes, fuel additives).

8.21 Product Safety program managers considered many of their regulatory activities to be insufficient to meet their regulatory responsibilities. We found these opinions were confirmed in an internal study of the program's resource needs, documents relating to resource allocation, and in interviews conducted as part of our audit (Exhibit 8.4).

8.22 The Product Safety program has requested additional funding, but it received very little funds for special initiatives in 2005–06 to address the shortfalls presented above. Program managers indicated that their inability to carry out these responsibilities could have consequences for the health and safety of Canadians, such as exposure by consumers to non-compliant hazardous products. There is also a risk of liability to the Crown.

8.23 Program managers for Drug Products and Medical Devices also indicated in an internal study and in interviews that they consider the level of some post-market compliance and enforcement activities to be insufficient to meet their regulatory responsibilities (Exhibit 8.5).

8.24 Drug Products and Medical Devices programs were successful in getting some additional funding for special initiatives. According to program managers, this allowed them to eliminate the backlog of submissions made by manufacturers seeking review and authorization to market a product. However, they considered the additional funding to be insufficient to address all the shortfalls identified in Exhibit 8.5.

8.25 According to program managers, failure to carry out these responsibilities could have consequences for the health and safety of Canadians, such as exposure to unsafe, ineffective, or dangerous therapeutic products. There is also an increased risk of liability to the Crown.

Exhibit 8.4 Examples of regulatory activities considered by Product Safety program managers to be insufficient

Regulatory activities	Product Safety				
	Consumer Product Safety	Cosmetics	Workplace Hazardous Materials Information Systems	Consumer and Clinical Radiation Protection	New Substances Assessment and Control
Protecting public from hazardous products and substances	○	○	○	○	○
Enforcing and ensuring compliance with acts and regulations	○	○	n/a	○	n/a
Conducting regular surveys, research, and surveillance	○	○	○	○	–
Responding to emergencies or product complaints	–	○	n/a	○	n/a
Issuing timely and accurate health warnings to the general public	○	–	n/a	○	n/a
Conducting appropriate risk assessments (for example, new products)	–	○	n/a	○	○

- Insufficient level of activity
- Not raised as a concern by Health Canada
- n/a Not applicable

Sources: Health Canada's internal study, resource allocation documents, and interviews

Exhibit 8.5 Examples of post-market compliance and enforcement activities considered by Drug Products and Medical Devices program managers to be insufficient

Compliance and enforcement activities	Drug Products	Medical Devices
Conducting inspections of manufacturers of drug ingredients	○	n/a
Reviewing trends, surveillance, market surveys, and complaints on non-compliant products	○	○
Sharing and coordinating information and expertise with other regulatory organizations (for example, Canada Border Services Agency)	○	○
Inspecting the manufacturing practices of foreign sites and accompanying foreign inspectors at Canadian sites	○	–
Conducting investigations of clinical trials	○	○
Conducting investigations of Internet pharmacies	○	n/a
Inspecting manufacturing practices and issuing licences	○	n/a
Investigating reports, complaints, and recalls of medical devices	n/a	○

- Insufficient level of activity
- Not raised as a concern by Health Canada
- n/a Not applicable

Sources: Health Canada’s internal study, resource allocation documents, and interviews

8.26 Without a program baseline, it is difficult to properly determine the level of funding needed to adequately carry out regulatory responsibilities. We are therefore concluding that Health Canada cannot demonstrate that it allocates adequate financial resources to regulatory programs in order to fulfill its regulatory responsibilities.

8.27 Recommendation. Health Canada should establish program baselines for Product Safety, Drug Products, and Medical Devices programs by defining the required level of activities that the programs must carry out in order to meet their regulatory responsibilities of protecting the health and safety of Canadians. It should also identify the targeted performance for these activities, and the resources needed to do this work.

Health Canada’s response. Agreed. A review of the funding allocated to the three regulatory programs is currently underway, as well as activities to establish program baselines. The goal is to complete these by 31 March 2008.

Demands on regulatory programs are increasing while funding remains constant

8.28 We examined the funding allocated to the three regulatory programs audited, by sources of funding. Exhibit 8.6 shows the trends in funding from 2003–04 to 2005–06.

8.29 The demands on the three programs are increasing. According to program managers, the number of consumer and therapeutic products in the marketplace is increasing every year due to globalization of the

Exhibit 8.6 Funding trends for the three programs audited (\$ millions)

Product Safety	2003–04	2004–05	2005–06
Core funding	8.1	9.9	7.3
Revenue authorized to be respent (fees for services)	0	0	0
Special initiatives	10.3	10.3	10.4
Reallocations (funds taken from or given to a program)	(0.6)	(1.5)	0.5
Total	17.8	18.7	18.2

Drug Products Program	2003–04	2004–05	2005–06
Core funding	7.1	7.1	4.8
Revenue authorized to be respent (fees for services)	28.6	28.6	28.6
Special initiatives	17.1	18.3	21.3
Reallocations (funds taken from or given to a program)	(1.0)	(3.4)	(3.9)
Total	51.8	50.6	50.8

Medical Devices Program	2003–04	2004–05	2005–06
Core funding	2.0	1.1	1.0
Revenue authorized to be respent (fees for services)	7.6	7.6	7.6
Special initiatives	3.4	4.0	4.7
Reallocations (funds taken from or given to a program)	(4.2)	(1.3)	0.4
Total	8.8	11.4	13.7

Source: Health Canada (unaudited)

Canadian market. New technologies and their application are increasing the level of knowledge that Health Canada must acquire, interpret, and maintain to address public concern, provide the oversight functions, and manage the associated risks.

8.30 Since the program funding level is constant but demand on the programs is increasing, it is more difficult for program managers to fully meet the regulatory responsibilities of protecting the health and safety of Canadians.

Using plans in resource allocation decisions

Plans have limited impact on resource allocation decisions

8.31 According to Health Canada's *Financial Management and Control Framework*, plans and budgets are developed based on objectives and expected results to be achieved. The Health Products and Food Branch's guiding principles for resource allocation states, "The business planning process is the overarching framework on which resource allocation decisions should be based." We expected the plans to be developed based on a program's objectives and expected results. We also expected the plans to include the budget necessary to carry out the program and to ensure that the expected results would be achieved.

8.32 We examined the strategic plans that were prepared at the corporate and branch levels. We also examined operational plans developed at the directorate level where they existed and the documents used to make decisions on resource allocation.

8.33 Of the three programs audited, we found that only Product Safety had operational plans for 2003–04 and 2004–05. We found that these plans included objectives and priorities that were consistent with the strategic direction set out in plans developed at the branch and corporate levels. We also found that plans included the program budget. The plans also noted activities that would not be carried out because of insufficient funding, as well as what might happen if those activities were not carried out.

8.34 The operational plans for Product Safety included performance measures without any measurable targets for expected results. In 2003–04, program managers developed a performance measurement framework to monitor the program's performance with respect to outcomes, levels of compliance with acts and regulations, service standards, client satisfaction, and operational and financial performance. In 2004–05 and 2005–06, program managers developed indicators and an approach to collect the necessary data. Program

managers have indicated that they are currently setting measurable targets.

8.35 In 2003–04, only one of the directorates responsible for the delivery of Drug Products and Medical Devices programs prepared an operational plan. It included objectives, priorities, and the funding allocated to the directorate. However, the plan did not include performance measures with targets for expected results.

8.36 The situation improved in 2004–05. We found that all three directorates prepared plans for that fiscal year. Templates were used to standardize the process. The plans included objectives, key indicators, a few measurable targets, and the budget. However, they did not include priorities.

8.37 We found that, when operational plans were prepared, they were used as input to the resource allocation process but resulted in marginal funding changes. The budget each branch and directorate received was based on historical funding levels rather than on plans. Because resource allocation is not based on program objectives and expected results, regulatory programs may not receive the funding they need to achieve their objectives.

8.38 Recommendation. Health Canada should ensure that the operational plans for its regulatory programs include comprehensive information on program objectives and measurable targets for expected results. Health Canada should use these operational plans to make resource allocation decisions.

Health Canada's response. Agreed. Health Canada will continue to improve the operational planning process. In 2006–07, the Department is strengthening the process through the launching of a combined strategic and operational planning process that includes performance measures, indicators and measurable targets, as well as decisions on resource allocations. The completion date for implementing the new process is fiscal year 2007–08.

Using financial and performance information in resource allocation decisions

8.39 According to Treasury Board Secretariat's *Results for Canadians*, "departments and agencies need to produce information on program costs and results required for sound decision making." We therefore expected Health Canada to have financial and performance information to support decisions regarding resource allocation. We also expected Health Canada to produce relevant information on sources of funding, program costs, and program results.

Sources of funding need to be taken into account in resource allocation

8.40 Knowing the sources of funding is important to program managers to guide the resource allocation process because funding may come with conditions. Core funding needs to be allocated to ongoing activities, such as compliance and enforcement activities. When Treasury Board approves funding for special initiatives, it may include financial and/or non-financial conditions that must be respected, and the funds must be spent for the intended purposes. Revenue from industry is used to pay for the costs of running the program and to provide specified service levels and may not be reallocated to other programs.

8.41 We found that program managers for the Product Safety program do not track sources of funding. In HPFB, information on sources of funding was produced at the directorate level in 2003–04, but not in 2004–05. Furthermore, this information, when produced, was not reported to branch management and was not used to allocate resources to the Medical Devices and Drug Products programs.

8.42 Core funding. As presented in Exhibit 8.6, the budget for core funding for the three programs audited has significantly decreased over three years: 10 percent for the Product Safety program, 32 percent for the Drug Products program, and 50 percent for Medical Devices program. The Department needs to ensure that its regulatory programs receive sufficient core funding to fulfill its mandate.

8.43 Recommendation. Health Canada should review the core funding allocated to regulatory programs to ensure that all programs receive sufficient funding to meet regulatory responsibilities and to adequately protect the health and safety of Canadians.

Health Canada's response. Agreed. A review of funding allocated to regulatory programs, including core funding, is currently underway and the goal is to complete it by 31 March 2008.

8.44 Revenue. According to the *Financial Administration Act* and the *Department of Health Act*, fees charged for a federal service may not exceed the cost of providing the service. We therefore expected Health Canada to know the full program costs for Drug Products and Medical Devices programs, which recover part of their costs through fees. We also expected the Department to have service standards that have been agreed upon by industry. We expected the user fees charged to industry to be based on agreed upon service standards and that revenues would not exceed full program costs.

8.45 We found that Health Canada presents the full program costs for both Drug Products and Medical Devices in the *Departmental Performance Report 2004–2005*. We also found that the costs recovered are less than the full program costs as required by the *Financial Administration Act*. For example, the full program cost for Medical Devices is \$21.8 million and Health Canada recovered \$7.4 million or 34 percent. Treasury Board policy requires user fees to be tied to performance standards for the services provided. However, we found that service standards have not been fully established for all fees.

8.46 Recommendation. Health Canada should, in consultation with clients, set user fees for Drug Products and Medical Devices program services that are based on clear and measurable service standards.

Health Canada's response. Agreed. Health Canada recently approved a new cost recovery strategy and framework for all its user fees programs, including drugs and medical devices, to align it to the Treasury Board Policy on *Service Standards for External Fees* and to develop a full costing model. The work on the cost recovery strategy and framework is expected to be completed by 31 March 2008.

Building on stakeholder consultations in 2005, Health Canada is renewing its cost-recovery regime for drugs and medical devices in accordance with the Treasury Board policy and the *User Fees Act*. Health Canada has launched consultations with stakeholders in 2006–07 with a goal to complete the work over the next two fiscal years (2007–08 and 2008–09).

8.47 Special initiatives. We found that funds were not always spent for the purposes approved by the Treasury Board. In 2003–04, 12 percent of the \$20.5 million that the Drug Products and Medical Devices programs received for special initiatives was transferred to other programs within HPFB. We also found that in 2004–05, 6 percent of the \$10.3 million that the Product Safety program received for special initiatives was transferred to other programs within HECSB. Additional funds provided by the Cabinet and the Treasury Board are for specific initiatives. Health Canada must ensure that funds for special initiatives are spent for the purposes intended.

8.48 Reallocations. Funds are reallocated at the corporate and branch levels to address

- emerging priorities, such as government-wide cost-cutting exercises and public health emergencies, such as the emergence of severe acute respiratory syndrome;

- the indirect cost of services to the program such as information technology, human resources, legal services, planning and policy, telecommunications, postage, and accommodations; and
- insufficient funding allocated to regulatory programs.

To fund these costs, branches and programs are asked to contribute part of their budgets.

8.49 At the branch level, funds collected from each program go into a reserve. Program managers redirect money from core funding, revenues (user fees), and special initiatives to pay for the reallocations. From that point on, any conditions attached to the funds can no longer be tracked and monitored. When the funds are reallocated, they may no longer support the program for which the money was intended.

8.50 Reallocations can have a significant impact on program funding. The Drug Products program has seen its contribution to reallocations increase drastically over the three-year period (Exhibit 8.6). Even though Parliament approved additional funds for special initiatives for this program in recent years, we found that the total funding for the program has not increased because the funding taken out of the Drug Products program through reallocations has risen. This means that the program has no additional money to deliver on its regulatory responsibilities, which continue to increase.

8.51 Health Canada needs to monitor the sources of program funding used to pay for reallocations to ensure that the conditions attached to the funding are respected and that it allocates the resources to the intended purposes. The Department also needs to monitor the impact of reallocations on program funding to ensure that the ability to meet the program's objectives is not compromised.

8.52 We conclude that information on sources of funding was not produced and reported on a regular basis for both HECSB and HPFB. Therefore, the branches do not have complete information to allocate resources to the intended purposes.

8.53 Recommendation. Health Canada should ensure that it complies with the conditions of Treasury Board decisions when allocating and reallocating funds internally.

Health Canada's response. Agreed. As part of its Financial Management and Control Framework, the Department is introducing a Budget Management Framework with guidelines on resource allocation and monitoring of Treasury Board decisions.

The Framework will be developed by 1 April 2007, and implementation will begin in fiscal year 2007–08.

Full costs of programs are not considered in decision making

8.54 The Treasury Board Secretariat’s *Manager’s Guide to Operating Budgets* states, “To make the best decisions managers will need to know the full costs of all aspects of delivering their programs, including the full cost of other delivery options. Full cost means all costs to the government, not just those of the program manager.”

8.55 As stated in 8.45, the *Departmental Performance Report 2004–2005* presents the full program costs of the Medical Devices and Drug Products programs. We found that only the direct cost of the Product Safety program is known, not the full program cost.

8.56 We also found that the information on full program costs is not used for resource allocation decisions. It is important to have information on the full costs of delivering a program, including the administration and overhead costs of program activities. Without that, it is difficult for the Department to make realistic requests for special initiatives funding and to ensure the integrity of regulatory programs that are critical to the health and safety of Canadians.

8.57 Recommendation. Health Canada should determine the full cost of delivering its regulatory programs and use this information in its decisions on resource allocation.

Health Canada’s response. Agreed. In addition to the review of funding allocated to regulatory programs and the current exercise to establish program baselines, the Department is also implementing its new cost recovery strategy and framework, including the establishment of a full costing model. The implementation of the full costing model is scheduled for fiscal year 2007–08.

Information on results is not used in decision making

8.58 Information on program results shows how well a program is doing and what it has achieved compared with what it intended to achieve (that is, the expected results). According to the federal government’s Expenditure Management System, performance information is needed to make informed decisions on the allocation and reallocation of resources and to enhance accountability.

8.59 We found that for the Product Safety program, several performance indicators have been developed, but none have

measurable targets. Without measurable targets, it may be difficult for program managers to know and demonstrate how well the program is doing.

8.60 We found that the three directorates responsible for delivering the Drug Products and Medical Devices programs have made progress in measuring performance. Since 2004–05, all three directorates have performance indicators for most of their activities—a few with measurable targets. Results achieved compared with the few targets that exist are reported at mid-year and at year-end for accountability purposes. However, the information was not used to allocate resources.

8.61 We also found that, for the three programs audited, Health Canada does not measure program efficiency. This would allow the Department to identify where program dollars could be better spent and thus reallocate the funds saved to these activities.

8.62 We conclude that program managers report limited information on results. Furthermore, that information is not used to allocate resources.

8.63 Recommendation. Health Canada should develop meaningful indicators with targets to measure efficiency and results. The Department should use this information in making resource allocation decisions.

Health Canada's response. Agreed. Improvements to the existing performance measurement frameworks are currently underway and will include expected results, indicators, and targets where feasible. Initiatives related to performance measurement will be implemented by 31 March 2008 and performance will be measured on an ongoing basis.

Rationale for resource allocation decisions is not documented

8.64 Health Canada's Financial Management and Control Framework requires that "budget assumptions, risks, estimates, and constraints are documented and monitored" to maintain transparency and accountability.

8.65 At both the corporate and branch levels, we found that the rationale for showing how funding decisions were made had not been documented. There were no detailed minutes of discussions showing the options, priorities, trade-offs for reallocation decisions, and risks that were considered in arriving at funding decisions. Nor were we

provided with any documentation showing the impact of funding decisions on program delivery.

8.66 We found that, when the funding level allocated to a program was lower than what was requested by program managers, there was no documentation explaining which activity would not be carried out and how this decision was reached. For example, the initial budget for one directorate in 2003–04 was \$21.5 million. However, the directorate was allocated a budget of only \$17.1 million. There was no clear explanation for the reduced amount, the changes required to program delivery, or how the increased risk will be managed in light of this funding decision.

8.67 The Department is taking steps to improve resource allocation (see 8.85 to 8.89).

8.68 Recommendation. Health Canada should document the rationale for any allocation and reallocation decisions on its programs, including the long-term consequences of the funding decisions that affect the program's outcome and its ability to adequately achieve its objectives.

Health Canada's response. Agreed. Improvements have been made since 2004–05 in the areas of operational planning, corporate risk profiling, performance measurement, and the resource allocation process. Health Canada will build on the departmental strategic and operational planning process to strengthen documentation on the rationale for resource allocation decisions. Initiatives related to the documentation of rationale for resource allocation and reallocation decisions will be implemented in the 2007–08 operational planning process.

Principles guiding planning and resource allocation are not standardized

8.69 We found that there is no common resource allocation or planning framework in Health Canada. Although the Corporate Services Branch has a *Budget Management Directive* and a *Decision Making Framework*, we found that the two branches we examined (the Healthy Environments and Consumer Safety Branch and the Health Products and Food Branch) also have their own documented resource allocation process, principles, and decision-making framework. We observed that resource allocation was carried out differently from branch to branch, resulting in varied plans based on different allocation assumptions.

8.70 A standardized resource allocation process and practice in Health Canada is necessary for senior management to interpret adequately the cross-branch information given to them and to make informed decisions on the impact of resource allocation on the health and safety of Canadians.

8.71 Health Canada is taking steps to standardize the operational planning process (see 8.85 to 8.89).

8.72 Recommendation. Health Canada should standardize its resource allocation process to ensure that the information given to senior management is consistent from branch to branch.

Health Canada's response. Agreed. Health Canada will continue to build on the strategic and operational planning process to ensure the standardization of the resource allocation process. The 2007–08 operational planning process will be standardized.

Reporting program results

There is limited reporting on results achieved with funding received

8.73 According to Treasury Board Secretariat's *Results for Canadians*, "[departments and agencies] must bring together financial and non-financial performance information to link costs with actual or expected results." The Treasury Board Secretariat's *Manager's Guide to Operating Budgets* states that managers are accountable for the results obtained with the resources provided. This is important to ensure good stewardship of resources and effective program delivery. We therefore expected program managers to report to senior management the results achieved in their programs with the funding they received.

8.74 To report results achieved based on funding received, resources have to be linked to results. This means that, at the planning stage, expected results need to be linked to the budget. At year-end, actual results need to be linked to the actual total costs.

8.75 We found that an attempt was made to link resources to results at the planning stage for the Drug Products and Medical Devices programs in 2004–05. However, we found that there was no link between costs and results for any of the programs at year-end. Because of the limited information on results (see 8.58 to 8.62), program managers have incomplete performance information that they can link to financial information. This reduces their ability to report to senior management the results achieved with funding received.

8.76 As mentioned at 8.60, the three directorates responsible for delivering the Drug Products and Medical Devices programs report to

branch management at mid-year the results achieved compared with the few measurable targets that exist. However, there is no reporting of results achieved with funding received to branch management at year-end.

Unfulfilled regulatory responsibilities are not systematically reported to the Departmental Executive Committee

8.77 We expected that shortfalls in funding for the Department's regulatory responsibilities would be reported, along with the reasons for them, to a level where decisions could be made on how to redress the shortfalls. According to the Treasury Board Secretariat's *Manager's Guide to Operating Budgets*,

...in the health or safety inspection field, it is often argued that all activities are important and, therefore, must not be constrained by funding limitations. It is the manager's responsibility to review his or her program and allocate resources to the most important activities. Once the manager has exhausted all avenues for reallocation and if serious program deficiencies remain, it is the responsibility of management to bring these to the attention of ministers.

8.78 We also expected program managers to report to Health Canada's senior management on a regular and timely basis on how their programs have met the Department's regulatory responsibilities according to the government's *Regulatory Policy*.

8.79 We found that program managers report regularly to branch management on the funding shortfalls and the activities that they cannot carry out because of insufficient funding (Exhibits 8.4 and 8.5). This information is submitted to the Branch Executive Committee or the Assistant Deputy Minister (ADM), who make the funding decisions.

8.80 The information on funding shortfalls in regulatory programs and the activities that are not carried out because of insufficient funding is not systematically reported to the Departmental Executive Committee. Branches are asked to submit funding requests, based on certain criteria, to the Departmental Executive Committee, for immediate reallocation of internal funds. Branches are asked to try to limit the number of requests to a maximum of three. This exercise is not designed to address ongoing funding shortfalls in regulatory programs but to address emerging issues that require short-term funding.

8.81 Other than the funding requests by branches, and information on actual and forecasted spending compared with the budget, the Departmental Executive Committee does not systematically receive information related to programs' funding shortfalls and their consequences. At the time of the audit, there was no formal process in place to report this information to the Departmental Executive Committee.

8.82 One of the Department's core roles is that of regulator. In our view, the extent to which the Department is fulfilling this role needs to be communicated to the Departmental Executive Committee, which is ultimately accountable for setting the Department's high-level strategic direction. The Departmental Executive Committee is also the only group in Health Canada that can address cross-branch funding issues.

8.83 The Department is taking steps to further involve the Departmental Executive Committee in resource allocation decisions (see 8.85 to 8.89).

8.84 Recommendation. Health Canada should develop a reporting mechanism that would require program managers to inform the Departmental Executive Committee systematically about the

- level of financial resources allocated to each program,
- results achieved with the funds, and
- extent to which each program has met its regulatory responsibilities, including significant gaps and their consequences.

Health Canada's response. Agreed. Directorates are now reporting program results and their regulatory responsibilities to their Branch Executive Committee. With the strategic and operational planning process, results will be reported to the Departmental Executive Sub-committee on Finance, Evaluation and Accountability and to the Senior Management Board for final decision. The new operational planning process will be implemented in fiscal year 2007–08. Program results are also reported in the Departmental Performance Report.

Improving resource allocation

Steps are being taken to improve resource allocation

8.85 Health Canada has recognized the weaknesses with the current resource allocation process. To address some of these weaknesses, the Department has redesigned the operational planning process, which is being implemented in fiscal year 2006–07.

8.86 According to Health Canada, the new operational planning process is a significant improvement over the existing one. It is intended to address many of the issues raised in this report. For example, the new process aims to standardize the way in which decisions are documented and ensure that there is a link between departmental priorities and corporate, branch, program, and regional priorities. To achieve these objectives, program managers will be asked to describe the program activities under their responsibility, key priorities, performance measures, funding levels, funding pressures, and lowest priorities. This information will be challenged by a newly created subcommittee to the Departmental Executive Committee. Ultimately, the Departmental Executive Committee will approve the operational plans, which include the level of funding for the program activity.

8.87 As part of the new operational planning process, decisions would be documented, the planning process would be integrated with the resource allocation process, every activity would receive a budget, and senior management (Departmental Executive Committee) would be clear on the expected results based on the funding approved.

8.88 The new process does not address weaknesses in producing information on full program costs and listing sources of funding by programs. Also, the Departmental Executive Committee needs to be informed of results achieved based on funding received.

8.89 Health Canada is still implementing the new process. We are pleased to see that the process is intended to address many of the issues we raised and we encourage the Department to continue with its full implementation.

Conclusion

8.90 One of Health Canada's core roles is that of regulator. The Department needs to know if it is fully meeting its regulatory responsibilities. However, Health Canada has not established, for the three programs audited, the required level of activities that it must carry out to protect the health and safety of Canadians, the targeted performance for these activities, and the resources needed to do this work. Without this information, Health Canada cannot demonstrate to what extent it is meeting its regulatory responsibilities and whether adequate financial resources are allocated to regulatory programs.

8.91 While the total funding allocated to two of the three audited programs has remained constant, all three programs audited received

less funding for core activities in 2005–06 than in 2003–04. Meanwhile, the complexity of and the growing demands on programs could significantly affect Health Canada’s ability to meet its regulatory responsibilities.

8.92 To have an effective resource allocation process, Health Canada needs to allocate funds based on plans, risks, and priorities; sources of funding and program costs; and program results. The Department reports full program costs for two of the three regulatory programs audited. Program managers report limited information on results but do not report sources of funding. Even when reported, the information is not used for resource allocation decisions. Rather, Health Canada’s system of allocating its resources among its various branches and programs is based on the previous year’s funding rather than on plans and sound financial and performance information.

8.93 Program managers report funding shortfalls to branch management. They also report what activities that they cannot carry out because of insufficient funding. This information does not routinely reach the Departmental Executive Committee, which is the only group in Health Canada that can address cross-branch funding issues.

8.94 The Department needs to document its rationale for resource allocation decisions, and hold managers accountable for the results achieved with the funding received. This would ensure that limited resources are allocated to where they would do the most good and program objectives would be met.

8.95 The Department is making progress in resolving some of the issues with its current resource allocation process. Health Canada has redesigned the operational planning process, which is scheduled to be in place in 2006–07. We are pleased to see that the new process is intended to address many of the issues raised in this report and we encourage the Department to continue with its full implementation.

About the Audit

Objectives

The audit objectives are to determine whether Health Canada

- allocates financial resources at all levels according to a plan and with consideration for financial/performance information;
- regularly reports relevant information on sources of funding, program costs, and results at all levels of the organization and uses this information to allocate resources; and
- can demonstrate it allocates adequate financial resources to regulatory programs in order to fulfill its regulatory responsibilities.

Scope and approach

This audit focused on fiscal years 2003–04 and 2004–05, but it also took previous years and 2005–06 into account to study trends in resource allocation. We examined how financial resources are allocated to each branch and how the branches report to senior management on program costs and results.

Since most of the regulatory programs at Health Canada are found in two branches—Healthy Environments and Consumer Safety Branch (HECSB) and Health Products and Food Branch (HPFB)—the audit focused on these two units. We examined how resources are allocated to directorates within each branch. Specifically, we examined their plans, budgets, resource allocation, and decision making. We also looked at reporting by the directorates to senior management on program costs and results.

We selected three programs within HECSB and HPFB: Product Safety, Drug Products, and Medical Devices. We examined the programs' sources of funding (including cost recovery), program costs, results, and budget. We interviewed the program managers reporting to the directorate and branch level to determine how the reports are used in resource allocation decisions.

We have not audited the efficiency or the effectiveness of the three selected programs. We are not commenting on whether the activities that are being carried out to protect the health and safety of Canadians are efficient. Our audit focused on the process by which Health Canada decides what resources to allocate to each of its branches and programs and the information on which it bases those decisions.

Evidence was collected mainly from interviews with key personnel and a documentation review of budgets, plans, resource allocation exercises, and any other relevant information used for decision making on resource allocation.

Criteria

We expected Health Canada would

- have plans that are developed based on objectives, priorities, and expected results to be achieved;
- have budgets related to these plans and allocate financial resources according to plans;
- ensure that relevant information is produced at all levels of the Department regarding sources of funding, program costs, and program results;
- have financial and performance information to support decisions regarding resource allocation;
- ensure funding shortfalls and the reasons for shortfalls are reported to a departmental level where decisions can be made about redressing the situation;
- ensure that managers report results achieved at the program level based on funding received;
- ensure that managers of regulatory programs report to senior management on how the Department's regulatory responsibilities have been met; and
- ensure that financial resources are adequate to carry out regulatory responsibilities effectively.

Audit work completed

Audit work for this chapter was substantially completed on 1 September 2006.

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Appendix List of recommendations

The following is a list of recommendations found in Chapter 8. The number in front of the recommendation indicates the paragraph where it appears in the chapter. The numbers in parentheses indicate the paragraphs where the topic is discussed.

Recommendation	Department's response
Meeting regulatory responsibilities	
<p>8.27 Health Canada should establish program baselines for Product Safety, Drug Products, and Medical Devices programs by defining the required level of activities that the programs must carry out in order to meet their regulatory responsibilities of protecting the health and safety of Canadians. It should also identify the targeted performance for these activities, and the resources needed to do this work. (8.14–8.26)</p>	<p>Agreed. A review of the funding allocated to the three regulatory programs is currently underway, as well as activities to establish program baselines. The goal is to complete these by 31 March 2008.</p>
Using plans in resource allocation decisions	
<p>8.38 Health Canada should ensure that the operational plans for its regulatory programs include comprehensive information on program objectives and measurable targets for expected results. Health Canada should use these operational plans to make resource allocation decisions. (8.31–8.37)</p>	<p>Agreed. Health Canada will continue to improve the operational planning process. In 2006–07, the Department is strengthening the process through the launching of a combined strategic and operational planning process that includes performance measures, indicators and measurable targets, as well as decisions on resource allocations. The completion date for implementing the new process is fiscal year 2007–08.</p>

Recommendation	Department's response
Using financial and performance information in resource allocation decisions	
<p>8.43 Health Canada should review the core funding allocated to regulatory programs to ensure that all programs receive sufficient funding to meet regulatory responsibilities and to adequately protect the health and safety of Canadians. (8.40–8.42)</p>	<p>Agreed. A review of funding allocated to regulatory programs, including core funding, is currently underway and the goal is to complete it by 31 March 2008.</p>
<p>8.46 Health Canada should, in consultation with clients, set user fees for Drug Products and Medical Devices program services that are based on clear and measurable service standards. (8.44–8.45)</p>	<p>Agreed. Health Canada recently approved a new cost recovery strategy and framework for all its user fees programs, including drugs and medical devices, to align it to the Treasury Board Policy on <i>Service Standards for External Fees</i> and to develop a full costing model. The work on the cost recovery strategy and framework is expected to be completed by 31 March 2008.</p>
<p>8.53 Health Canada should ensure that it complies with the conditions of Treasury Board decisions when allocating and reallocating funds internally. (8.47–8.52)</p>	<p>Building on stakeholder consultations in 2005, Health Canada is renewing its cost-recovery regime for drugs and medical devices in accordance with the Treasury Board policy and the <i>User Fees Act</i>. Health Canada has launched consultations with stakeholders in 2006–07 with a goal to complete the work over the next two fiscal years (2007–08 and 2008–09).</p>
<p>8.57 Health Canada should ensure that it complies with the conditions of Treasury Board decisions when allocating and reallocating funds internally. (8.47–8.52)</p>	<p>Agreed. As part of its Financial Management and Control Framework, the Department is introducing a Budget Management Framework with guidelines on resource allocation and monitoring of Treasury Board decisions. The Framework will be developed by 1 April 2007, and implementation will begin in fiscal year 2007–08.</p>
<p>8.57 Health Canada should determine the full cost of delivering its regulatory programs and use this information in its decisions on resource allocation. (8.54–8.56)</p>	<p>Agreed. In addition to the review of funding allocated to regulatory programs and the current exercise to establish program baselines, the Department is also implementing its new cost recovery strategy and framework, including the establishment of a full costing model. The implementation of the full costing model is scheduled for fiscal year 2007–08.</p>

Recommendation	Department's response
<p>8.63 Health Canada should develop meaningful indicators with targets to measure efficiency and results. The Department should use this information in making resource allocation decisions. (8.58–8.62)</p>	<p>Agreed. Improvements to the existing performance measurement frameworks are currently underway and will include expected results, indicators, and targets where feasible. Initiatives related to performance measurement will be implemented by 31 March 2008 and performance will be measured on an ongoing basis.</p>
<p>8.68 Health Canada should document the rationale for any allocation and reallocation decisions on its programs, including the long-term consequences of the funding decisions that affect the program's outcome and its ability to adequately achieve its objectives. (8.64–8.67)</p>	<p>Agreed. Improvements have been made since 2004–05 in the areas of operational planning, corporate risk profiling, performance measurement, and the resource allocation process. Health Canada will build on the departmental strategic and operational planning process to strengthen documentation on the rationale for resource allocation decisions. Initiatives related to the documentation of rationale for resource allocation and reallocation decisions will be implemented in the 2007–08 operational planning process.</p>
<p>8.72 Health Canada should standardize its resource allocation process to ensure that the information given to senior management is consistent from branch to branch. (8.69–8.71)</p>	<p>Agreed. Health Canada will continue to build on the strategic and operational planning process to ensure the standardization of the resource allocation process. The 2007–08 operational planning process will be standardized.</p>
<p>Reporting program results</p>	
<p>8.84 Health Canada should develop a reporting mechanism that would require program managers to inform the Departmental Executive Committee systematically about the</p> <ul style="list-style-type: none"> • level of financial resources allocated to each program, • results achieved with the funds, and • extent to which each program has met its regulatory responsibilities, including significant gaps and their consequences. <p>(8.73–8.83)</p>	<p>Agreed. Directorates are now reporting program results and their regulatory responsibilities to their Branch Executive Committee. With the strategic and operational planning process, results will be reported to the Departmental Executive Sub-committee on Finance, Evaluation and Accountability and to the Senior Management Board for final decision. The new operational planning process will be implemented in fiscal year 2007–08. Program results are also reported in the Departmental Performance Report.</p>

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