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REPORT 3

Chemicals in Consumer Products and Cosmetics



Office of the Auditor General of Canada
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OAG

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Introduction

Background

Chemicals in consumer products and cosmetics



Chemistry testing for chemicals of concern

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3.1 The number and variety of consumer products and cosmetics available in Canada are growing. Products with more complex chemistries and new materials are entering the Canadian marketplace. While these products provide benefits, effective oversight is important to address or prevent dangers to consumers.

3.2 Substances used in some **consumer products** and **cosmetics** pose risks to human health. Exposure to some chemicals may lead to reproductive, developmental, and cognitive disorders, depending on the level of exposure and the stage of life. Of particular concern are chemicals that are considered **endocrine disruptors**. Even at low doses, these can present dangers to human health and safety.

3.3 Since 2006, Health Canada has been implementing the government's Chemicals Management Plan. It aims to examine approximately 4,300 chemical substances used commercially in Canada by 2020, and to assess new substances entering the Canadian market, to determine whether risk management measures are needed to control their use. When chemicals are determined to have harmful effects, the government may introduce risk management controls such as regulations to protect Canadians and their environment.

3.4 For example, the Chemicals Management Plan process identified phthalates (mainly used to make vinyl plastic soft and flexible) as harmful to human health, which led to *Phthalates Regulations* under the *Canada Consumer Product Safety Act* setting limits for phthalates in toys and child care articles. The Chemicals Management Plan process also added chemicals such as bisphenol A (used to make hard, clear plastics and protective linings for food and beverage cans) and TCEP (a flame retardant) to Schedule 2 of the Act, which prohibits certain products

Consumer product—A product, including its components, accessories, and packaging, that may be used for personal, domestic, and recreational purposes. According to the *Canada Consumer Product Safety Act*, consumer products do not include natural health products, tobacco products, drugs, controlled substances, food, medical devices, firearms, ammunition, explosives, pest control products, plants, animals, or vehicles.

Cosmetic—Any substance or mixture of substances manufactured, sold, and used as a personal product to clean, improve, or alter the complexion, skin, hair, scent, or teeth.

Endocrine disruptors—Chemicals that may interfere with the body's endocrine system and produce negative developmental, reproductive, neurological, and immunological effects in humans. Endocrine disruptors may be found in many everyday products, including plastic bottles, metal food cans, detergents, flame retardants, food, toys, cosmetics, and pesticides.

containing these chemicals from being manufactured, imported, or sold. The Chemicals Management Plan process also identified chemicals of concern to be added to the prohibited or restricted categories in the **Cosmetic Ingredient Hotlist**.

Consumer Product Safety Program

3.5 While the Chemicals Management Plan assesses chemical substances to determine what risk management measures may be warranted, the role of Health Canada's Consumer Product Safety Program is to ensure that risk management measures, including regulatory controls, are being respected and enforced in the Canadian marketplace.

3.6 As is the case in other jurisdictions, including the United States and the European Union, the federal government has established a post-market program to oversee the safety of consumer products and cosmetics. This means that Health Canada does not conduct pretesting of product safety, nor does it preapprove products before they are available on store shelves. While legislation prohibits industry from selling non-compliant products, companies are not required to demonstrate compliance with safety regulations before selling a product in Canada. In a post-market regulatory environment, industry is responsible for ensuring that products are safe, the regulator is responsible for oversight of industry to ensure that regulations are respected, and consumers are expected to make informed choices and use products appropriately. In this context, reliable and specific information on product attributes and ingredients is critical to protect consumers.

3.7 Through its Consumer Product Safety Program, Health Canada administers the *Canada Consumer Product Safety Act*, which is intended to protect the public by addressing or preventing dangers to human health and safety posed by consumer products, including imported products. Health Canada also administers the *Cosmetic Regulations* under the *Food and Drugs Act*, which states, "no person shall sell any cosmetic that has in or on it any substance that may cause injury to the health of the user when the cosmetic is used."

3.8 The mission of the Consumer Product Safety Program is to identify, assess, manage, and communicate to Canadians health or safety risks associated with consumer products and cosmetics. The Program's long-term objective is to reduce adverse health incidents related to consumer products and cosmetics in Canada.

Cosmetic Ingredient Hotlist—A tool that helps industry meet the requirements to sell a cosmetic by providing a list of substances that are restricted or prohibited in cosmetics.

3.9 The Program's strategic focus is prevention, detection, and rapid response:

- Prevention—Promote compliance through industry and consumer outreach, and work with industry to develop safety standards.
- Detection (targeted oversight)—Take a risk-based approach to the timely and accurate detection of consumer product and cosmetic hazards.
- Rapid response—Use the Program's full range of abilities and authorities, such as ordering product recalls, to effectively respond to risks in the marketplace and hold industry accountable for non-compliance.

Focus of the audit

3.10 This audit examined the extent to which Health Canada's Consumer Product Safety Program was working to protect the public by addressing or preventing dangers to human health and safety posed by chemicals of concern in household consumer products and cosmetics. Specifically, we examined the Program's detection and rapid response activities.

3.11 This audit is important because effective oversight of products containing chemicals of concern is essential to protect the health and safety of Canadians.

3.12 We did not examine the Program's activities related to consumer outreach or promoting industry compliance, and we did not examine the Chemicals Management Plan process.

3.13 More details about the audit objective, scope, approach, and criteria are in **About the Audit** at the end of this report (see pages 26–29).

Findings, Recommendations, and Responses

Detection of risks to human health

Overall finding



3.14 Overall, although we found that Health Canada made progress in improving its oversight approach, we found a number of information gaps that limited the Consumer Product Safety Program's ability to detect and assess risks to human health and safety posed by chemicals of concern in consumer products and cosmetics:

- The Department had not assessed the scope and magnitude of risks associated with international e-commerce, and its oversight of the growing e-commerce market was very limited.
- The Department had not assessed the scope and magnitude of the health and safety risks posed by counterfeit consumer products and cosmetics, despite concerns raised in Canada and internationally.
- The Department does not regularly test cosmetic products to verify the accuracy of product labels or to check for the presence of prohibited substances, microbial contaminants, and heavy metals.
- The chemical components of cosmetic ingredients characterized as "parfum," "aroma," "fragrance," or "flavour," which might contain chemicals of concern, are not required to be disclosed to Health Canada or consumers.
- In contrast to consumer products, where industry is required to report health and safety incidents to Health Canada, there is no legal requirement to report such incidents related to cosmetic products.

3.15 These findings are important because the information gaps we identified limited Health Canada's ability to prevent, detect, assess, and respond to potentially important threats to human health and safety posed by consumer products and cosmetics. They also mean that consumers have less information upon which to make informed choices to protect their health and safety.

Context

3.16 In response to a growing number of product recalls, the government initiated a five-year Food and Consumer Safety Action Plan in 2007 to strengthen Canada's approach to consumer product safety. In part, the plan was also meant to address issues identified in the 2006 November Report of the Auditor General of Canada, Chapter 8—Allocating Funds to Regulatory Programs—Health Canada.

3.17 Subsequently, under the *Canada Consumer Product Safety Act*, which came into force in 2011, Health Canada was given additional powers to order product recalls, levy penalties, and establish mandatory

incident reporting for manufacturers, importers, and retailers of consumer products. By contrast, Health Canada has no powers under the *Food and Drugs Act* to order recalls of cosmetic products, and there is no mandatory reporting of incidents involving adverse reactions to cosmetics.

Health Canada improved its oversight approach

What we found

3.18 We found that, since the *Canada Consumer Product Safety Act* came into force in 2011, Health Canada had made progress in developing policies and procedures to guide risk management and compliance and enforcement activities. Its approach included tools to identify higher-risk consumer products and companies, such as those with poor compliance history.

3.19 Our analysis supporting this finding presents what we examined and discusses

- the Program's risk-based approach.

Why this finding matters

3.20 This finding matters because a methodical approach for managing risks associated with chemicals of concern in consumer products and cosmetics is needed to ensure consistent and effective implementation of the acts and regulations intended to protect Canadians from dangers to their health and safety.

Recommendations

3.21 We made no recommendations in this area of examination.

Analysis to support this finding



Children's toys

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3.22 **What we examined.** We examined the frameworks, policies, procedures, and guidance documents relevant to the Consumer Product Safety Program, to determine whether there was a methodical approach in place to detect, assess, and manage human health and safety risks from chemicals of concern in consumer products and cosmetics.

3.23 **The Program's risk-based approach.** We found that the Program's approach incorporated risk-based processes to prioritize higher-risk incidents, products, and companies for oversight and action. For example, processes were in place to prioritize incoming health and safety incident reports for response, on the basis of a range of risk factors, including injury severity, victim age, and past incidents.

3.24 The approach also includes inspection cycles of six years or less, depending on risk, for oversight of regulated products. Higher-risk product categories, such as cosmetics or products for children, are to be inspected more frequently, on annual cycles. Reports on each cyclical enforcement project might include recommendations on whether the frequency of the inspection cycle should be changed.

3.25 After the *Canada Consumer Product Safety Act* came into force, the Consumer Product Safety Program enhanced its policies, procedures, and guidance to implement the Act. The Program developed or further improved

- a surveillance and intelligence-gathering strategy, including a partnership with the Canada Border Services Agency to monitor imports;
- a process to triage and prioritize safety **incidents** reported by industry, as well as complaints by consumers and referrals by border officials;
- procedures and timelines for assessing risks of specific products and substances;
- a process and criteria for selecting compliance and enforcement instruments to manage risks;
- an updated approach to conducting inspections and ensuring consistent compliance and enforcement action, such as ordering recalls; and
- a more formalized and streamlined process for dealing with **cosmetic notifications**.

Information gaps limit Health Canada's ability to detect and assess risks to human health and safety

What we found

3.26 Although Health Canada made progress in improving its oversight approach, we found a number of areas where the Department can improve its ability to detect and assess risks in order to target its compliance and enforcement resources and provide important health and safety information to consumers.

3.27 Our analysis supporting this finding presents what we examined and discusses

- e-commerce,
- counterfeit products,
- validating cosmetic safety through product testing,
- disclosure of ingredients in cosmetics, and
- oversight for cosmetic safety.

Incident—Occurrence, defect, or characteristic that resulted or may be expected to result in an individual's death or in serious adverse effects on his or her health, including a serious injury. It may also include incorrect or insufficient information on a label or in instructions, or a recall or a measure initiated for human health or safety reasons by other jurisdictions.

Cosmetic notification—Notification from manufacturers and importers provided to Health Canada, at the latest, 10 days after they first sell a cosmetic in Canada. Notifications include information such as product name, function, form, and a list of ingredients and their concentrations.

Why this finding matters

3.28 This finding matters because the deficiencies we identified limited Health Canada's ability to detect, assess, and manage risks in the marketplace. They also limited Canadian consumers' ability to make informed choices. Addressing these deficiencies would improve Health Canada's ability to target its oversight activities and to assure consumers that the Department is addressing or preventing dangers to health and safety from chemicals of concern in consumer products and cosmetics.

Recommendations

3.29 Our recommendations in this area of examination appear at paragraphs 3.34, 3.38, 3.41, and 3.45.

Analysis to support this finding



Cross-border transactions through e-commerce

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3.30 **What we examined.** We examined the Department's frameworks, policies, procedures, guidance documents, commitments, plans, and projects, as well as information on existing and emerging risks relevant to the Consumer Product Safety Program. Our aim was to determine the extent to which the Program was working to detect, assess, and manage risks to human health and safety from chemicals of concern in consumer products and cosmetics.

3.31 **E-commerce.** It is common for consumers and small retailers to have products shipped directly to them from abroad through e-commerce. Health Canada officials acknowledged that cross-border transactions can bypass the Department's detection and response mechanisms. The Department has also noted that its ability to protect Canadians from product risks may be weakened due to the increasing complexity of global supply chains and the pace of innovation.

3.32 We found that the Department had few controls to address or prevent dangers associated with imported products shipped directly to consumers through e-commerce. It also lacked sufficient information to assess the scope and magnitude of the risks.

3.33 At the time of the audit, the Department was part of a collaborative international project with the Organisation for Economic Co-operation and Development (OECD) to test the availability of non-compliant products via online sellers. It was in the early stages of efforts to better understand the risks to consumers from e-commerce.

3.34 **Recommendation.** Health Canada should

- assess the scope and magnitude of risks posed by e-commerce products, and
- inform consumers and retailers about the risks and the limitations of regulatory oversight and recourse in these areas.

***The Department's response.** Agreed. Health Canada will continue to participate in international collaborations to review and assess the risks associated with the e-commerce market, such as the Organisation for*

Economic Co-operation and Development's Working Party on Consumer Product Safety, which has completed an online sweep and is currently considering the possibility of online market surveillance guidelines and a consumer awareness campaign in 2017.

As part of Health Canada's ongoing outreach plan for consumer products and cosmetics, an outreach campaign will inform consumers and retailers of regulatory oversight and recourse for products purchased through e-commerce channels. Planned consumer outreach activities include social media, web page updates, and stakeholder outreach.



Counterfeit products can have an impact on health and safety

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3.35 Counterfeit products. A House of Commons committee identified the growing issue of counterfeit products as a serious health risk in 2007. The Royal Canadian Mounted Police website states that counterfeiting is a serious problem because, among other reasons, counterfeits are untested and often manufactured in unsanitary conditions, and that these products have been found to contain dangerous toxins and contaminants that are harmful to health. A 2007 OECD report found that

- the magnitude and effects of counterfeiting and piracy are of such significance that they require strong and sustained action from governments, business, and consumers;
- the types of counterfeit products are growing at an alarming rate, and they include products that have an impact on health and safety, such as personal care items and toys; and
- the Internet has provided counterfeiters with a new and powerful way to sell their products to larger numbers of consumers worldwide.

3.36 Health Canada told us that the Department works with its federal partners to address risks to human health or safety caused by counterfeit products when issues are identified and that it had taken action on a few cases. However, we found that Health Canada had not assessed the scope and magnitude of health and safety risks posed by counterfeit consumer products and cosmetics in Canada.

3.37 Health Canada told us that historical evidence of reported incidents showed that this is not an area of relatively high risk. While we agree that the number of incident reports is an input to risk assessment, a low number of incident reports on its own is not sufficient evidence to conclude that the issue poses low risk. It is our view that the Department's reactive approach to addressing reported product safety incidents did not provide an acceptable substitute for a more strategic assessment of risk to determine whether further attention to this issue may be warranted.

3.38 Recommendation. Health Canada should

- assess the scope and magnitude of health and safety risks posed by counterfeit products, and
- inform consumers and retailers about any significant risks identified.

The Department's response. Agreed. The Government of Canada responded to concerns raised over counterfeit products, including health and safety concerns, with its Combating Counterfeit Products Act in 2015. Health Canada, working with its regulatory partners, plays a role within the Act in addressing human health or safety concerns related to counterfeit products. The Department will continue to work with regulatory partners to assess the health and safety risks of counterfeit products found on the Canadian marketplace, or entering the country.

The Department, working with its regulatory partners, will assess available data on counterfeit products to understand the scope and magnitude of any health or safety risks they pose. Results from this evaluation may inform future decision making by identifying high-risk areas associated with counterfeit products.

As part of Health Canada's ongoing outreach plan for consumer products and cosmetics, an outreach campaign will inform consumers and retailers of the risks associated with counterfeit products. Planned consumer outreach activities include social media, web page updates, and stakeholder outreach.

3.39 Validating cosmetic safety through product testing. We found that Health Canada did not regularly test cosmetics to

- verify the accuracy of the cosmetic notifications submitted by industry,
- check for the presence of substances that are prohibited and to verify the concentrations of restricted ingredients listed in the Cosmetic Ingredient Hotlist, and
- check for the presence of microbial contaminants and heavy metals.

3.40 We found that, during the nine-year period covered by our analysis, Health Canada conducted two projects on microbial contamination, one in 2009–10 and the other in 2010–11, and two on heavy metals in cosmetics, which took place in 2008–09 and 2012–13. The Department recognizes that the work carried out in these projects is insufficient to draw general conclusions about market compliance or product safety.

3.41 Recommendation. Health Canada should inform consumers that it does not regularly test cosmetic products for prohibited and restricted substances, microbial contamination, and heavy metals.

The Department's response. Agreed. As part of Health Canada's ongoing outreach plan for cosmetics, an outreach campaign will inform consumers of the Department's risk-based post-market regulatory regime, including information on how product testing is undertaken through a risk-based sample selection process.

Messaging about the product testing cycle used by the Department will also be communicated publicly.



Labelling and disclosure of ingredients allow consumers to make informed choices

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3.42 Disclosure of ingredients in cosmetics. The *Cosmetic Regulations* do not require industry to disclose the chemical components of cosmetic ingredients characterized as “parfum,” “aroma,” “fragrance,” or “flavour” to Health Canada or to consumers on product labels. This is also the case in other jurisdictions, including the United States and the European Union. The rationale is that these mixtures are considered trade secrets.

3.43 Many chemicals commonly found in fragrance can trigger allergies and asthma, and have been linked to cancer. Given that industry does not disclose the specific chemical composition and concentration in “parfum,” “aroma,” “fragrance,” or “flavour,” and that the Department does not regularly test for prohibited or restricted ingredients in cosmetics, Health Canada cannot assure consumers that these products comply with the *Food and Drugs Act* and are safe.

3.44 In addition, Health Canada told us that marketing terms such as “hypoallergenic,” “preservative-free,” “fragrance-free,” and “unscented” fall outside its mandate unless a product makes a claim that affects health and safety, in which case the Department has the ability to take action. However, in our view, these terms suggest health and safety benefits and may be misleading. For example, a product labelled “fragrance-free” or “unscented” may contain chemicals to mask the scent.

3.45 Recommendation. To improve Health Canada’s ability to detect and assess risks, and to provide information to consumers so that they can make informed choices, the Department should

- do product testing to determine the extent to which cosmetics include prohibited and/or unsafe concentrations of substances under the labels “fragrance,” “parfum,” “aroma,” or “flavour”;
- consider options to encourage manufacturers to provide the Department, on a confidential basis, with the complete list and concentrations of substances that comprise ingredients listed under these terms; and
- inform consumers that marketing terms such as “hypoallergenic,” “preservative-free,” “fragrance-free,” and “unscented” should not be confused with health and safety claims.

The Department’s response. Agreed. The Department’s Cyclical Enforcement (CE) plan for the testing of cosmetics is being reviewed and will include the testing of products that use the terms “fragrance,” “parfum,” “aroma,” or “flavour,” to determine the presence of prohibited or restricted substances that may be included as an ingredient in the product formulation.

Health Canada will consider options to encourage manufacturers to disclose, on a confidential basis, the complete list and concentrations of substances that comprise ingredients listed under the umbrella terms referenced in the recommendation. The results of testing under the aforementioned CE plan will inform options for analysis.

As part of Health Canada's ongoing outreach plan for consumer products and cosmetics, consumers and retailers will be informed that marketing terms such as those referenced are not necessarily an indicator that a product has improved health benefits, and that it is up to the consumer to make informed choices about the purchase and use of products. Planned consumer outreach activities include social media, web page updates, and stakeholder outreach.

3.46 Oversight for cosmetic safety. In 2007, the government launched an initiative to improve the oversight of cosmetic safety and, in 2008, provided funds to Health Canada to implement the identified areas of improvement. The Department's analyses indicated that the changes would

- improve protection of consumer health and safety,
- increase information to support consumer decision making, and
- align Health Canada's requirements with those of its international counterparts.

3.47 Three of the proposed improvements to Health Canada's oversight of cosmetic safety were as follows:

- Industry would be required to undertake mandatory incident reporting of consumers' adverse reactions to cosmetics. Health Canada noted that this would enable it to rapidly identify and respond to cosmetic product safety problems in the marketplace. It would also facilitate cooperation with other regulatory authorities to identify unsafe products regardless of their origins. Mandatory incident reporting by industry was instituted in 2011 for consumer products, but not for cosmetics.
- Industry would be required to notify Health Canada of ingredients prior to the sale of a cosmetic in Canada. Health Canada noted that this would allow for improved monitoring and oversight, enable a preventative approach to potential product and ingredient risks, and reduce the likelihood of adverse incidents for consumers. At the time of this audit, industry was required to notify Health Canada, at the latest, 10 days after the first retail sale of a product in Canada.
- Disclosure on product labelling of 26 known fragrance allergens would be mandatory. Health Canada noted that this would provide useful information to Canadians who have sensitivities to specific fragrance ingredients, so that they could avoid products that might cause an allergic reaction. This change would also align with requirements in place since 2003 in the European Union to disclose fragrance allergens on product labels. There is currently no requirement in Canada to disclose fragrance allergens on product labels.

3.48 Health Canada told us that it had decided in 2012 not to pursue the identified improvements and that it was looking at other ways to achieve the goal of improving the oversight of cosmetics. In our view, the shortcomings that the Department identified in 2007 remain, and consumers lack important information to make informed product choices. However, given the Department's 2012 decision, we made no recommendation in this area of examination.

Response to incidents and regulatory violations

Overall finding



3.49 Overall, we found that Health Canada could not demonstrate rapid response in some critical areas. While we found that prioritization and assessment of incident reports were well managed and generally timely, the Department did not know whether industry was respecting the legislated timelines to ensure rapid reporting of potential health and safety incidents, and for submitting cosmetic notifications. It was also slow to respond to cosmetic notifications that included prohibited substances, and slow to follow up on product recalls to confirm that non-compliant products were no longer available to Canadians.

3.50 It is important that Health Canada fulfill its commitment to ensure rapid response to incidents and regulatory violations, to minimize the time that Canadians are exposed to dangerous products, and to hold industry accountable for non-compliance.

Context

3.51 The *Canada Consumer Product Safety Act* and the *Cosmetic Regulations* under the *Food and Drugs Act* set out the framework for rapid response and Health Canada's enforcement powers. The Consumer Product Safety Program established a system of procedures and service standards to process and assess cases, and to correct violations.

Health Canada managed the initial assessment and prioritization of safety incident reports efficiently

What we found

3.52 We found that Health Canada's initial assessment and prioritization of incident reports were well managed and generally timely. We were able to track how the Department managed individual incident reports.

3.53 Our analysis supporting this finding presents what we examined and discusses

- screening reported incidents,
- prioritizing and assessing reported incidents, and
- timeliness of the initial decision on reported incidents.

Why this finding matters

3.54 This finding matters because the ability to efficiently assess, prioritize, and route incident reports is important to effectively target enforcement resources and facilitate rapid response to significant incidents. This can help minimize the time that Canadians are exposed to dangers from cosmetics and consumer products.

Recommendations

3.55 We made no recommendations in this area of examination.

Analysis to support this finding

3.56 **What we examined.** Industry has an obligation to report health- and safety-related incidents for consumer products to Health Canada. There is no obligation for industry to report health- and safety-related incidents for cosmetic products. The Department may also receive voluntary reports from industry or directly from consumers about any product. Each incident report received by Health Canada is screened to determine whether the case falls within the Consumer Product Safety Program's mandate and whether there is sufficient information to act on. Qualifying cases may be routed to the Program's Risk Assessment Bureau or Risk Management Bureau for more in-depth analysis, or the Department may take immediate compliance and enforcement action.

3.57 We examined key steps in Health Canada's preliminary screening and prioritization of reported health and safety incidents to determine whether established procedures had been followed. The steps included screening, prioritizing, and assessing reports received from consumers and industry. In addition, we examined the timeliness of the Department's initial decisions on how to handle incoming cases.

3.58 **Screening reported incidents.** We examined 890 incident reports received by Health Canada between 1 July 2011 and 30 June 2015. We found that the Department's decisions on how to route incident reports had been clearly documented.

3.59 **Prioritizing and assessing reported incidents.** We found that the Program consistently implemented its standard procedures for prioritizing incidents for further action. We also found that, when more in-depth risk assessments were needed, the Program carried out the required assessments.

3.60 **Timeliness of the initial decision on reported incidents.** Health Canada had established a three-day service standard for deciding how to proceed with incident reports. We found that the Department met its service standard in over 95 percent of the cases examined between April 2012 and June 2015.



Reporting of health and safety incidents

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Health Canada did not ensure industry compliance with reporting requirements for health and safety incidents and cosmetic notifications

What we found

3.61 We found that Health Canada did not routinely confirm whether industry was complying with two key legislated requirements for reporting potential health and safety incidents and for submitting cosmetic notifications.

3.62 Our analysis supporting this finding presents what we examined and discusses

- reporting on consumer product safety incidents, and
- submission of cosmetic notifications.

Why this finding matters

3.63 This finding matters because health and safety incidents and cosmetic notifications must be reported to the regulator in a timely manner for the regulator to respond rapidly to dangers to human health and safety. When Health Canada fails to systematically verify that industry is reporting incidents and submitting cosmetic notifications, health and safety issues may go unnoticed for extended periods. Furthermore, the Department cannot assure Canadians that it has acted promptly to address risks or that it has been effective in holding industry accountable for non-compliance.

Recommendation

3.64 Our recommendation in this area of examination appears at paragraph 3.71.

Analysis to support this finding

3.65 **What we examined.** We examined whether Health Canada was able to demonstrate the extent to which industry was adhering to statutory reporting requirements for health and safety incidents related to consumer products (excluding cosmetics) and whether it was submitting cosmetic notifications in conformance with legislated timelines.



Household cleaning products

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3.66 **Reporting on consumer product safety incidents.** The *Canada Consumer Product Safety Act* requires industry to provide Health Canada with a report within two days of becoming aware of a consumer product health and safety incident, not including cosmetics. It is industry's responsibility to then follow up with a second report, including any measures it proposes be taken. This second report is due within 10 days after the date the company becomes aware of the incident.

3.67 We found that Health Canada did not verify industry compliance with legislated incident reporting timelines. In addition, Health Canada told us that it believed industry was under-reporting incidents.

3.68 We found that the Department undertook a series of initiatives to inform industry of its reporting obligations. These included recent projects to examine whether companies had sufficient mechanisms in place to comply with statutory reporting requirements. This approach could help the Department target its resources at higher-risk companies that lack reliable mechanisms to comply.

3.69 **Submission of cosmetic notifications.** Canada's *Cosmetic Regulations* require that a cosmetic notification be submitted to Health Canada "at the latest 10 days after the manufacturer or importer first sells a cosmetic" in Canada.

3.70 When we asked Health Canada for a report of all cosmetic notifications in our audit period and the dates of first sale, we found that the Department could not provide the dates of first sale. Officials stated that the *Cosmetic Regulations* do not require industry to provide this date. However, the Department noted that the cosmetic notification form could be amended to request the actual or expected date of first sale on a voluntary basis. In our view, this change could help the Program to better track compliance and prioritize its oversight activities.

3.71 **Recommendation.** To assist the Department in tracking compliance and prioritizing its oversight and response activities, Health Canada should

- verify the extent of industry compliance with incident reporting requirements for consumer products, and
- update its cosmetic notification form to request voluntary disclosure of the actual or expected date of first sale in Canada.

The Department's response. Agreed. Over the first five years of the Canada Consumer Product Safety Act, Health Canada has focused its efforts on promotion of compliance with the new requirements for incident reporting set out in the Act. The Department is now moving to a stronger enforcement stance, including reviewing documents of individual companies to verify compliance with the mandatory incident reporting requirements.

The Cosmetic Notification form will be updated with the addition of the voluntary disclosure of the actual or expected date of first sale in Canada.

Health Canada was slow to respond when cosmetic notifications included prohibited substances

What we found



Cosmetic products for women

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3.72 We found that Health Canada was slow to respond to notifications of cosmetics containing substances prohibited by the Cosmetic Ingredient Hotlist. While the Department did not have a service standard for responding to these notifications, in our view, its response time was slow. Health Canada took an average of nine months from receiving a notification to confirming that cosmetics containing prohibited substances had been removed from, or prevented from entering, the Canadian market. However, in the cases we reviewed since the introduction of online notifications in 2013, we noted a marked improvement in response time.

3.73 We found Health Canada's follow-up on enforcement actions, such as requesting a product recall or sales stoppage, was frequently insufficient to confirm that cosmetics containing prohibited substances had actually been removed from, or prevented from entering, the Canadian market.

3.74 Our analysis supporting this finding presents what we examined and discusses

- response time to notifications with prohibited substances, and
- compliance verification.

Why this finding matters

3.75 This finding matters because delays in responding to cosmetic notifications that include a prohibited substance mean that consumers may be exposed to dangerous products for prolonged periods. Failure to follow up to confirm compliance means that Canadians cannot be certain that cosmetic products with prohibited substances have been removed from store shelves or prevented from entering the market. It also means that industry might not be held to account for violations, which in turn can reduce the deterrent effect of regulations.

Recommendation

3.76 Our recommendation in this area of examination appears at paragraph 3.80.

Analysis to support this finding

3.77 **What we examined.** According to data provided by Health Canada, the Department received 50 cosmetic notifications from April 2013 to June 2015 that included prohibited substances in the cosmetics' formulation. Using representative sampling, we measured how long it took the Department to determine the need for action, and how long it took to complete enforcement actions and follow up to confirm that non-compliant products had been prevented from entering Canada or had been removed from the market. We also examined whether there was sufficient information on file to make this determination.



Cosmetic products for men

Photo: © Volkova Vera/
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3.78 Response time to notifications with prohibited substances. Over the period we examined, we found that it took the Department six months on average to determine whether enforcement action was required. When we added the time Health Canada took to confirm that its enforcement actions resulted in compliance, we found that the average elapsed time was about nine months from the time it had received the notification. However, for the cases we examined since the introduction of online notifications in 2013, we noted a marked improvement in response time.

3.79 Compliance verification. In 48 percent of the cases we examined, we found that there was insufficient evidence on file to confirm that products containing prohibited substances had been removed from, or prevented from entering, the Canadian market. In some cases, the Department did not completely verify that a company had implemented the corrective actions it had agreed to take. In other cases, the Department notified the company of its non-compliant status, but did not request or receive information on how or when the company would correct the non-compliance.

3.80 Recommendation. Health Canada should improve its follow-up on cosmetic notifications with prohibited substances by verifying that companies have implemented corrective actions and that non-compliant products are no longer available to Canadians.

***The Department's response.** Agreed. With the introduction of online cosmetic notifications, Health Canada has been able to substantially reduce its processing time of incoming notifications. Our improvements in processing time have had a significant impact on the ability of the Department to identify prohibited substances in cosmetics and respond accordingly. Moving forward, Health Canada will continue to explore improvements to the cosmetic notification process and follow-up actions with the intention to reduce overall response time for verifying that companies have implemented corrective actions and that non-compliant products are no longer available to Canadians.*

Health Canada was slow to confirm compliance after requesting product recalls

What we found

3.81 We found that Health Canada was slow to verify the effectiveness of its product recalls. The Department met its service standard for verifying the effectiveness of recalls in just over half of the recall cases since it revised its standard in 2012.

3.82 In addition, we found that the case documentation for product recalls normally did not include clear conclusions about the overall recall effectiveness.

3.83 Our analysis supporting this finding presents what we examined and discusses

- timeliness of follow-up on product recalls, and
- verification that non-compliant products were no longer available to Canadians.

Why this finding matters

3.84 This finding matters because follow-up after initiating recalls is important to assure consumers that non-compliant products have been removed from the market. Incomplete follow-up, lack of follow-up, or lack of consequences for violations can reduce the deterrent effect of enforcement and the incentive for industry to comply with regulations. They can also mean that non-compliant products that pose health and safety dangers may remain on store shelves.

Recommendation

3.85 Our recommendation in this area of examination appears at paragraph 3.90.

Analysis to support this finding

3.86 **What we examined.** We examined 30 cases from July 2011 to June 2015 where Health Canada had requested that companies implement product recalls. We measured how long it took Health Canada to follow up on the recalls to confirm that non-compliant products were no longer available to Canadians. For example, we looked for evidence that inspectors checked to ensure that recalled products had been removed from store shelves, and that the Department verified companies' reports of progress in implementing the recalls.

3.87 **Timeliness of follow-up on product recalls.** Over the period we examined, Health Canada implemented a series of service standards for completing its follow-up of product recalls, and we found that its success in meeting those standards varied:

- July 2011 to April 2012: During this period, the Department set a maximum of six months after posting a recall notice on its website to complete its enforcement work. We found that the Department met this standard in 90 percent of cases.
- May 2012 to October 2013: The time allowed was reduced to 60 working days. We found that the Department met the new standard in 60 percent of cases.
- October 2013 to June 2015: The standard was further reduced to 60 calendar days. We found that the Department met the standard in 50 percent of cases.

3.88 **Verification that non-compliant products were no longer available to Canadians.** As of May 2012, the Department's service standards required it to include in case files a roll-up of comments on the effectiveness of each recall. During the period we examined, we found that Health Canada normally did not record its conclusions about the overall effectiveness of a recall. Without such a roll-up to confirm that the recall had worked, there was insufficient evidence to conclude that the non-compliant products had been removed from the market.

3.89 One of the methods that Health Canada often used to check whether recalled products were no longer being sold to Canadians was to follow up with the vendors by telephone to ask whether they had received a recall notice and whether products had been removed from store shelves. In our view, this approach and reliance on the verbal representations of vendors would provide minimal assurance about whether the recall was effective.

3.90 **Recommendation.** Health Canada should improve the verification of product recalls and the documentation of overall recall effectiveness.

***The Department's response.** Agreed. As noted in the audit report, the Department has continually introduced more stringent time frames into its service standards for recall monitoring since the coming into force of the Canada Consumer Product Safety Act in 2011. Moving forward, the Department will continue with process improvements to recall monitoring, such as improving standard operating procedures, industry education, and performance monitoring.*

Verifying effectiveness by measuring results

Health Canada had not measured whether its Consumer Product Safety Program was achieving expected results

Overall finding



3.91 Overall, we found that the mechanisms Health Canada had in place to measure results were not sufficient to verify the effectiveness of the Consumer Product Safety Program. Specifically, the Program could not demonstrate that it was achieving expected results in

- addressing or preventing dangers to human health and safety,
- reducing adverse health incidents, and
- ensuring industry compliance with regulatory reporting and product safety requirements.

3.92 This finding is important because it is through measuring results that Health Canada can demonstrate the success of its Consumer Product Safety Program in protecting Canadians from chemicals of concern in household consumer products and cosmetics. This is essential to enable the Department to

- understand which oversight activities are working and which are not;
- verify where there may be opportunities to improve the Program's economy, efficiency, or effectiveness; and
- provide assurance to parliamentarians and Canadians that expected outcomes are being achieved.

3.93 Our analysis supporting this finding presents what we examined and discusses

- monitoring industry compliance with reporting requirements,
- cyclical enforcement results,
- biomonitoring results, and
- performance measurement.

Context

3.94 The purpose of the 2011 *Canada Consumer Product Safety Act* is to protect the public by addressing or preventing dangers to human health or safety that are posed by consumer products. Under the *Food and Drugs Act*, no person shall sell a cosmetic that contains any substance that may cause injury to the health of the user.

3.95 The Government of Canada's 2007 Food and Consumer Safety Action Plan and the Consumer Product Safety Program's 2015 performance measurement strategy set out the Program's expected long-term outcome, which is reduced adverse health incidents related to consumer products, including cosmetics.

3.96 To assure parliamentarians and Canadians that the Program is working as intended, Health Canada needs to measure its performance against these regulatory objectives and expected results.

Recommendation

3.97 Our recommendation in this area of examination appears at paragraph 3.107.

Analysis to support this finding

3.98 What we examined. We examined whether Health Canada's Consumer Product Safety Program could demonstrate that its post-market oversight approach to chemicals of concern in consumer products and cosmetics was working to achieve expected results. In addition to the other aspects of Program operations reported in previous sections, we examined whether the Program

- monitored industry compliance with legislated reporting obligations,
- assessed the effectiveness of its regulations through cyclical enforcement projects and biomonitoring, and
- measured its performance against expected results.

3.99 Monitoring industry compliance with reporting requirements. Health Canada did not routinely confirm whether industry was complying with two key legislated reporting requirements as described in paragraphs 3.61 to 3.71. As a consequence, the Department did not have the information needed to assure that industry was fulfilling its legislated reporting obligations, or that the Program had been effective in reducing the number of health and safety incidents.



Cyclical enforcement projects test children's jewellery for chemicals of concern








































Photo: © Dinoman/Shutterstock.com

3.100 Cyclical enforcement results. Health Canada conducts cyclical enforcement projects to monitor compliance of regulated products. The Program generally conducted its cyclical enforcement projects in accordance with its established schedules (Exhibit 3.1). However, the Department has acknowledged that sample sizes within cyclical enforcement projects are very small and that the results are not intended to reflect overall market compliance. This means that the results cannot be used to draw conclusions about overall industry compliance and trends, or Program effectiveness.

3.101 Biomonitoring results. Health Canada's biomonitoring program is intended to measure and track concentrations of chemicals of concern in people and help to determine the effectiveness of regulatory and other actions in reducing exposures over time. However, Health Canada told us that it was too early to measure trends for most chemicals of concern. Therefore, the Department could not yet use the data to assess and report on the effectiveness of the Consumer Product Safety Program.

3.102 Performance measurement. The Cabinet Directive on Regulatory Management directs federal departments to assess the outcomes of their regulatory programs and the extent to which the programs contributed to achieving results.

Exhibit 3.1 Health Canada's cyclical enforcement projects were conducted according to established schedules, but results cannot be used to assess overall market compliance




























Selected regulations	Enforcement cycle	Year and number of products examined								
		2014–15	2013–14	2012–13	2011–12	2010–11	2009–10	2008–09	2007–08	2006–07
Children's Jewellery Regulations	1-year cycle (but 2-year cycle for 2009–11 only)	 20 products	 13 products	 186 products	 61 products		 103 products	 78 products	 67 products	 83 products
Proposed cadmium Guidelines (2011) ¹	1-year cycle									
Toys Regulations	2-year cycle	 31 toys	Project postponed		 58 toys		 80 toys	 92 toys	 84 toys	
Hazardous Products (Pacifiers) Regulations	6-year cycle		 9 pacifiers						 9 pacifiers	
Hazardous Products (Infant Feeding Bottle Nipples) Regulations	6-year cycle		 3 bottle nipples						 2 bottle nipples	
Phthalates Regulations ²	3-year cycle	Project postponed	 32 products	 12 products	 81 products					
Consumer Products Containing Lead (Contact with Mouth) Regulations ³	3-year cycle	 31 toys	 27 pacifiers		 58 toys					
Children's Sleepwear Regulations	2-year cycle	 6 products		 9 products		 8 products		No project done		 9 products
Consumer Chemicals and Containers Regulations, 2001	1-year cycle	 51 products	 19 products	 70 products	 107 products  25 products	 21 products	 107 products	 65 products	 50 products	 32 products
Hazardous Products (Kettles) Regulations	6-year cycle			 23 products						 18 products

¹ Health Canada tests cadmium limits as part of cyclical enforcement projects for the *Children's Jewellery Regulations*. These limits are not found in the regulations but are set out in the proposed cadmium guidelines (2011).

² The *Phthalates Regulations* came into force in June 2011.

³ The *Consumer Products Containing Lead (Contact with Mouth) Regulations* came into force in November 2010.

Exhibit 3.1 Health Canada's cyclical enforcement projects were conducted according to established schedules, but results cannot be used to assess overall market compliance (continued)

Selected regulations	Enforcement cycle	Year and number of products examined								
		2014-15	2013-14	2012-13	2011-12	2010-11	2009-10	2008-09	2007-08	2006-07
Glazed Ceramics and Glassware Regulations	4-year cycle		 22 products				 121 products		 31 products	
Science Education Sets Regulations	6-year cycle		 19 products						 27 products	
Cosmetic Regulations	1-year cycle	 41 products	 32 products	 29 products	 31 products	 97 products	 110 products	 60 products	 217 products	 1,973 products
Surface Coating Materials Regulations	4-year cycle				No project done				 54 products	
Surface Coating Materials Regulations	2-year cycle since 2007-08 for furniture and articles for children			 29 products			 31 products		 29 products	
	6-year cycle for pencils and artists' brushes			 27 products					 31 products	
Canada Consumer Product Safety Act, Schedule 2 ⁴	No cycle; ad hoc projects	 TCEP 21 products	 Bisphenol A (BPA) 3 products			 BPA 26 products				
 Laboratory testing was done to check for compliance with requirements for chemicals of concern.  Laboratory testing for microbial contamination was done.  No laboratory testing was done to check for compliance with requirements for chemicals of concern; instead, activities such as audits of companies' documents were done.  No laboratory testing was done to check for compliance with requirements for chemicals of concern; instead, visual inspections of product labels, for example, were done.										

⁴ BPA was added to Schedule 2 of the Act in March 2010, and TCEP was added in May 2013. While Health Canada has not established enforcement cycles to test for these substances, the Department has conducted ad hoc projects.

3.103 We found that the Department had not assessed the outcomes prescribed for the Consumer Product Safety Program. It could not demonstrate the extent to which the Program was achieving the objectives of the *Canada Consumer Product Safety Act* and the *Food and Drugs Act*. We also found that the Program was not tracking critical performance information such as the extent to which regulations were working to reduce health and safety incidents.

3.104 The Department's 2013 internal evaluation also found that there was not enough data to support a definitive conclusion about the Program achieving its expected outcomes. The evaluation noted that many of the Program's performance indicators were activity-based, and some critical indicators were not being tracked.

3.105 Our review of past departmental performance reports found that the Program did not consistently report on performance indicators in the period from the 2009–10 fiscal year to the 2014–15 fiscal year. Health Canada told us that this was due to a change in overall Program structure and implementation of the *Canada Consumer Product Safety Act*.

3.106 In May 2015, Health Canada approved a new performance measurement strategy. At the time of the audit, the Department had yet to establish baselines for its new performance indicators.

3.107 **Recommendation.** Health Canada should ensure that it collects the data needed to answer fundamental questions about Consumer Product Safety Program effectiveness, including whether

- industry compliance with key regulatory requirements is improving, declining, or staying the same;
- the Program's oversight approach is working to reduce adverse health incidents; and
- the Program's oversight approach is working to address or prevent dangers to health and safety from chemicals of concern in consumer products and cosmetics.

The Department's response. Agreed. In 2015, Health Canada's new Performance Measurement Strategy for the Consumer Product Safety Program was approved. The Strategy was developed in line with the Treasury Board's direction on performance measurement plans and in 2015 it was presented to the Community of Federal Regulators as a good practice example. The Strategy will ensure that relevant performance data is collected and reported in a timely manner. Performance indicators in the Strategy include measurements that speak to program effectiveness, including those areas highlighted in the audit recommendation. Fiscal year 2015–16 was used to establish baselines for the majority of performance indicators, with reporting expected to begin in 2016–17.

Conclusion

3.108 We concluded that Health Canada's Consumer Product Safety Program could not fully assure Canadians that its post-market oversight activities were working to protect the public by addressing or preventing dangers to human health or safety posed by chemicals of concern in household consumer products and cosmetics.

3.109 Given the size of the Canadian marketplace, it would be challenging for Health Canada to provide Canadians with a high level of assurance about the health and safety of consumer products and cosmetics. However, we have identified improvements that could be made within a post-market environment that would help the Program to detect, assess, and respond to risks and help consumers to make fully informed choices in the interests of their own health and safety.

About the Audit

The Office of the Auditor General's responsibility was to conduct an independent examination of Health Canada's Consumer Product Safety Program, to provide objective information, advice, and assurance to assist Parliament in its scrutiny of the government's management of resources and programs.

All of the audit work in this report was conducted in accordance with the standards for assurance engagements set out by the Chartered Professional Accountants of Canada (CPA) in the CPA Canada Handbook—Assurance. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

As part of our regular audit process, we obtained management's confirmation that the findings in this report are factually based.

Objective

The objective of the audit was to determine the extent to which Health Canada's post-market oversight activities were working as designed to protect the public by addressing or preventing dangers to human health or safety posed by chemicals of concern in household consumer products and cosmetics.

Scope and approach

To conclude against our audit objective, we carried out our examination work under two broad lines of enquiry. The first line of enquiry examined the Consumer Product Safety Program's management of risks through detection (targeted oversight) and rapid response. The second line of enquiry examined the extent to which the Program has assessed whether its post-market oversight activities were working as intended to improve industry compliance and to protect Canadians. We did not examine Health Canada's pre-market risk assessment of chemical substances used in Canada, which is carried out under the Chemicals Management Plan process, nor did we examine the Department's activities related to consumer and industry outreach or industry compliance promotion.

The audit scope focused on Health Canada's Consumer Product Safety Program within the Consumer Product Safety Directorate of the Healthy Environments and Consumer Safety Branch. The scope also included Health Canada's Regions and Programs Bureau.

The audit focused on risks from chemicals of concern to which Canadians could be exposed in consumer products or cosmetics. We did not examine the mechanical, electrical, or flammability risks of products.

The audit approach included an examination of Health Canada's documentation related to the management of consumer product and cosmetic safety, such as policies, frameworks, standard operating procedures, and other materials to guide the work of departmental staff.

It also included a review of files from Health Canada's case management database system that is used to manage consumer product and cosmetic safety incident reports, as well as to record the Program's compliance and enforcement activities. Where representative sampling was used, sample sizes were

sufficient to conclude on the sampled population with a confidence level of 90 percent and a margin of error of no more than 10 percent.

We interviewed Health Canada officials in Ottawa who were involved in the oversight and management of consumer product and cosmetic safety. We also met with managers and product safety inspectors in three of the Department's regions: Ontario, Quebec, and British Columbia.

Criteria

Criteria	Sources
To determine the extent to which Health Canada's post-market oversight activities were working as designed to protect the public by addressing or preventing dangers to human health or safety posed by chemicals of concern in household consumer products and cosmetics, we used the following criteria:	
Health Canada's Consumer Product Safety Program has determined the required level of oversight activities and associated human and financial resources necessary to effectively carry out its regulatory responsibilities.	<ul style="list-style-type: none"> • Cabinet Directive on Regulatory Management • 2006 November Report of the Auditor General of Canada, Chapter 8—Allocating Funds to Regulatory Programs—Health Canada, responses to recommendations 8.27 and 8.43
Health Canada's Consumer Product Safety Program has collected, assessed, prioritized, and managed hazard and risk information in order to focus its resources on addressing the greatest threats to human health and safety.	<ul style="list-style-type: none"> • Risk Assessment Framework (final), Consumer Product Safety Program, Health Canada, December 2014 • Risk Management Framework (draft), Consumer Product Safety Program, Health Canada, 17 June 2014 • Regional Market Intelligence-Gathering Standard Operating Procedure (C&E-SOP-100-02), v0.06, Consumer Product Safety Program, Health Canada, 11 September 2014 • Book 9—Risk Assessment Operational Procedures: Risk Assessments Following Assignment to Risk Assessment Division, draft v22, Consumer Product Safety Program, Health Canada, 8 April 2013
Health Canada's Consumer Product Safety Program can demonstrate that it has implemented its targeted oversight and rapid response activities as planned.	<ul style="list-style-type: none"> • Book 6—Compliance and Enforcement Policy Guidelines: Introduction and Compliance and Enforcement Strategy (C&E-POL-001), v0.10, Consumer Product Safety Program, Health Canada, 31 July 2015 • Book 6—Compliance and Enforcement: Planned Compliance Verification Projects (C&E-POL-100), draft v0.11, Consumer Product Safety Program, Health Canada, 15 July 2015 • Cyclical Enforcement Policy, Consumer Product Safety Program, Health Canada, 1 June 1999 • Book 6—Compliance and Enforcement: Cyclical Enforcement (C&E-SOP-100-01), draft v0.03, Consumer Product Safety Program, Health Canada, 17 February 2015

Criteria	Sources
To determine the extent to which Health Canada's post-market oversight activities were working as designed to protect the public by addressing or preventing dangers to human health or safety posed by chemicals of concern in household consumer products and cosmetics, we used the following criteria: (continued)	
	<ul style="list-style-type: none"> • Book 7—Operational Procedures: Cyclical Enforcement Standard Operating Procedures (final), Consumer Product Safety Program, Health Canada, 7 April 2009 • Food and Consumer Safety Action Plan, Government of Canada, 2007 • <i>Food and Drugs Act</i> • <i>Cosmetic Regulations</i> • <i>Canada Consumer Product Safety Act</i>, and selected regulations • Evaluation of the Consumer Products Activities, Health Canada and Public Health Agency of Canada, September 2013
Health Canada's Consumer Product Safety Program can demonstrate that its post-market oversight approach is working as intended to protect Canadians by addressing or preventing dangers to human health or safety posed by chemicals of concern in household consumer products and cosmetics.	<ul style="list-style-type: none"> • Framework for the Management of Risk, Treasury Board of Canada Secretariat • Evaluation of the Consumer Products Activities, Health Canada and Public Health Agency of Canada, September 2013 • Food and Consumer Safety Action Plan, Government of Canada, 2007 • Framework for Cyclical Enforcement (C&E-POL-100), draft v0.04, Consumer Product Safety Program, Health Canada, October 2014 • Annual Cyclical Enforcement Summary Reports from 2006–07 to 2014–15, Consumer Product Safety Program, Health Canada, recommendations
Health Canada's Consumer Product Safety Program uses its performance data to inform its risk management strategies and oversight plans.	<ul style="list-style-type: none"> • Strategic Plan 2013–2016, Consumer Product Safety Program, Health Canada • Guide to Integrated Risk Management, Treasury Board of Canada Secretariat • Risk Management Framework (draft), Consumer Product Safety Program, Health Canada, 17 June 2014

Management reviewed and accepted the suitability of the criteria used in the audit.

Period covered by the audit

The audit covered the period from 1 April 2006 to 31 March 2016. Audit work for this report was completed on 31 March 2016.

Audit team

Principal: Andrew Ferguson

Director: James Reinhart

Anne Benaroya

Marie Duchaine

Mark Kepkay

Johanne Sanschagrin

Raniya Shams

Crystal St-Denis

List of Recommendations

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

Recommendation	Response
Detection of risks to human health	
<p>3.34 Health Canada should</p> <ul style="list-style-type: none"> • assess the scope and magnitude of risks posed by e-commerce products, and • inform consumers and retailers about the risks and the limitations of regulatory oversight and recourse in these areas. <p>(3.31–3.33)</p>	<p>The Department's response. Agreed. Health Canada will continue to participate in international collaborations to review and assess the risks associated with the e-commerce market, such as the Organisation for Economic Co-operation and Development's Working Party on Consumer Product Safety, which has completed an online sweep and is currently considering the possibility of online market surveillance guidelines and a consumer awareness campaign in 2017.</p> <p>As part of Health Canada's ongoing outreach plan for consumer products and cosmetics, an outreach campaign will inform consumers and retailers of regulatory oversight and recourse for products purchased through e-commerce channels. Planned consumer outreach activities include social media, web page updates, and stakeholder outreach.</p>
<p>3.38 Health Canada should</p> <ul style="list-style-type: none"> • assess the scope and magnitude of health and safety risks posed by counterfeit products, and • inform consumers and retailers about any significant risks identified. <p>(3.35–3.37)</p>	<p>The Department's response. Agreed. The Government of Canada responded to concerns raised over counterfeit products, including health and safety concerns, with its <i>Combating Counterfeit Products Act</i> in 2015. Health Canada, working with its regulatory partners, plays a role within the Act in addressing human health or safety concerns related to counterfeit products. The Department will continue to work with regulatory partners to assess the health and safety risks of counterfeit products found on the Canadian marketplace, or entering the country.</p> <p>The Department, working with its regulatory partners, will assess available data on counterfeit products to understand the scope and magnitude of any health or safety risks they pose. Results from this evaluation may inform future decision making by identifying high-risk areas associated with counterfeit products.</p> <p>As part of Health Canada's ongoing outreach plan for consumer products and cosmetics, an outreach campaign will inform consumers and retailers of the risks associated with counterfeit products. Planned consumer outreach activities include social media, web page updates, and stakeholder outreach.</p>

Recommendation	Response
<p>3.41 Health Canada should inform consumers that it does not regularly test cosmetic products for prohibited and restricted substances, microbial contamination, and heavy metals. (3.39–3.40)</p> <p>3.45 To improve Health Canada's ability to detect and assess risks, and to provide information to consumers so that they can make informed choices, the Department should</p> <ul style="list-style-type: none"> do product testing to determine the extent to which cosmetics include prohibited and/or unsafe concentrations of substances under the labels "fragrance," "parfum," "aroma," or "flavour"; consider options to encourage manufacturers to provide the Department, on a confidential basis, with the complete list and concentrations of substances that comprise ingredients listed under these terms; and inform consumers that marketing terms such as "hypoallergenic," "preservative-free," "fragrance-free," and "unscented" should not be confused with health and safety claims. (3.42–3.44) 	<p>The Department's response. Agreed. As part of Health Canada's ongoing outreach plan for cosmetics, an outreach campaign will inform consumers of the Department's risk-based post-market regulatory regime, including information on how product testing is undertaken through a risk-based sample selection process.</p> <p>Messaging about the product testing cycle used by the Department will also be communicated publicly.</p> <p>The Department's response. Agreed. The Department's Cyclical Enforcement (CE) plan for the testing of cosmetics is being reviewed and will include the testing of products that use the terms "fragrance," "parfum," "aroma," or "flavour," to determine the presence of prohibited or restricted substances that may be included as an ingredient in the product formulation.</p> <p>Health Canada will consider options to encourage manufacturers to disclose, on a confidential basis, the complete list and concentrations of substances that comprise ingredients listed under the umbrella terms referenced in the recommendation. The results of testing under the aforementioned CE plan will inform options for analysis.</p> <p>As part of Health Canada's ongoing outreach plan for consumer products and cosmetics, consumers and retailers will be informed that marketing terms such as those referenced are not necessarily an indicator that a product has improved health benefits, and that it is up to the consumer to make informed choices about the purchase and use of products. Planned consumer outreach activities include social media, web page updates, and stakeholder outreach.</p>
<p>Response to incidents and regulatory violations</p> <p>3.71 To assist the Department in tracking compliance and prioritizing its oversight and response activities, Health Canada should</p> <ul style="list-style-type: none"> verify the extent of industry compliance with incident reporting requirements for consumer products, and update its cosmetic notification form to request voluntary disclosure of the actual or expected date of first sale in Canada. (3.61–3.70) 	
	<p>The Department's response. Agreed. Over the first five years of the <i>Canada Consumer Product Safety Act</i>, Health Canada has focused its efforts on promotion of compliance with the new requirements for incident reporting set out in the Act. The Department is now moving to a stronger enforcement stance, including reviewing documents of individual companies to verify compliance with the mandatory incident reporting requirements.</p> <p>The Cosmetic Notification form will be updated with the addition of the voluntary disclosure of the actual or expected date of first sale in Canada.</p>

Recommendation	Response
<p>3.80 Health Canada should improve its follow-up on cosmetic notifications with prohibited substances by verifying that companies have implemented corrective actions and that non-compliant products are no longer available to Canadians. (3.72–3.79)</p>	<p>The Department's response. Agreed. With the introduction of online cosmetic notifications, Health Canada has been able to substantially reduce its processing time of incoming notifications. Our improvements in processing time have had a significant impact on the ability of the Department to identify prohibited substances in cosmetics and respond accordingly. Moving forward, Health Canada will continue to explore improvements to the cosmetic notification process and follow-up actions with the intention to reduce overall response time for verifying that companies have implemented corrective actions and that non-compliant products are no longer available to Canadians.</p>
<p>3.90 Health Canada should improve the verification of product recalls and the documentation of overall recall effectiveness. (3.81–3.89)</p>	<p>The Department's response. Agreed. As noted in the audit report, the Department has continually introduced more stringent time frames into its service standards for recall monitoring since the coming into force of the <i>Canada Consumer Product Safety Act</i> in 2011. Moving forward, the Department will continue with process improvements to recall monitoring, such as improving standard operating procedures, industry education, and performance monitoring.</p>
<p>Verifying effectiveness by measuring results</p> <p>3.107 Health Canada should ensure that it collects the data needed to answer fundamental questions about Consumer Product Safety Program effectiveness, including whether</p> <ul style="list-style-type: none"> • industry compliance with key regulatory requirements is improving, declining, or staying the same; • the Program's oversight approach is working to reduce adverse health incidents; and • the Program's oversight approach is working to address or prevent dangers to health and safety from chemicals of concern in consumer products and cosmetics. (3.99–3.106) 	
	<p>The Department's response. Agreed. In 2015, Health Canada's new Performance Measurement Strategy for the Consumer Product Safety Program was approved. The Strategy was developed in line with the Treasury Board's direction on performance measurement plans and in 2015 it was presented to the Community of Federal Regulators as a good practice example. The Strategy will ensure that relevant performance data is collected and reported in a timely manner. Performance indicators in the Strategy include measurements that speak to program effectiveness, including those areas highlighted in the audit recommendation. Fiscal year 2015–16 was used to establish baselines for the majority of performance indicators, with reporting expected to begin in 2016–17.</p>