Regulations Amending the Hazardous Products Regulations

Statutory authority
Hazardous Products Act

Sponsoring department
Department of Health

REGULATORY IMPACT ANALYSIS STATEMENT

(*This statement is not part of the Regulations.*)

Issues

Health Canada is responsible for the administration and enforcement of the *Hazardous Products Act* (HPA) and its regulations. The purpose of the HPA is to protect the health and safety of Canadians by regulating the sale and import of hazardous products for use in the workplace.

Safety data sheets (SDSs), which accompany hazardous products sold or imported for use in Canadian workplaces, must disclose the concentrations or concentration ranges of the ingredients in a product that present health hazards in accordance with the *Hazardous Products Regulations* (HPR). This information could be considered confidential business information (CBI) to industry. CBI for workplace hazardous products can be protected by filing an application with Health Canada under the *Hazardous Materials Information Review Act* (HMIRA) and paying the associated fee.

Regulated parties proposed that they should have a means to protect the concentrations or concentration ranges of ingredients without having the burden and cost of the HMIRA application process.

Background

The Workplace Hazardous Materials Information System (WHMIS), Canada's national hazard communication standard, came into effect on October 31, 1988. It represents tripartite consensus between regulators, industry and organized labour. It is implemented through coordinated federal, provincial and territorial (FPT) legislation using an integrated approach that avoids duplication, inefficiency, and the potential for interprovincial trade barriers by allowing the application of a single consistent hazard communication system nationwide. WHMIS is supported by the Current Issues Committee (CIC), which includes representatives of FPT regulators, suppliers, employers and organized labour. The HPA requires consultation with these representatives prior to making or amending regulations under the HPA; therefore, the CIC is the mechanism by which discussions on industry's proposal to protect the concentrations or concentration ranges of ingredients without having the burden and cost of the HMIRA application process were undertaken. .

On February 11, 2015, the HPR came into force and the *Controlled Products Regulations* (CPR) were repealed. This fulfilled a commitment under the Canada–United States Regulatory Cooperation Council (RCC) to implement the Globally Harmonized System (GHS) of Classification and Labelling of Chemicals in Canada without reducing the level of safety or protection for workers. This modified WHMIS is referred to as WHMIS 2015.

Regulated parties are currently in transition from the old WHMIS to WHMIS 2015. The phases of transition were set up in such a way as to allow three steps to occur in sequence. Currently, all suppliers have the option of complying with the repealed CPR or the HPR. Manufacturers and importers (those responsible for bringing products to the Canadian market) must comply with the HPR by June 1, 2018, and

then distributors (those responsible for reselling products on the Canadian market) and importers who use the imported product only in their workplace must comply with the HPR by September 1, 2018. Following this, there was national agreement among all FPT jurisdictions that the final stage of transition, which allows for updating of existing information in the workplace by employers, would be completed by December 1, 2018. This final transition deadline is set by the FPT jurisdictions responsible for occupational health and safety, not by Health Canada.

Industry representatives informed Health Canada officials that under the old CPR, some companies protected their CBI ingredient concentrations by disclosing prescribed concentration ranges rather than using the CBI protection mechanism provided by the HMIRA. Prescribed concentration ranges were generic ranges set out in the repealed CPR that companies could use when the concentration of an ingredient varied from batch to batch in the manufacturing of a product. The concentration ranges prescribed in the CPR were not retained in the HPR. Instead, the HPR require the actual concentrations or concentration ranges of ingredients that present health hazards to be disclosed. In order to protect the concentrations or concentration ranges of ingredients, industry must use the CBI protection mechanism provided by the HMIRA. Therefore, the protection of actual concentrations of ingredients that used to be possible by using the prescribed ranges in the CPR is only possible by submitting an application and fee under the HMIRA. This means that the number of filings Health Canada receives is predicted to increase.

Absent any changes to these HPR requirements, industry representatives have estimated that thousands of claims will need to be filed under the HMIRA in order to protect the concentrations or concentration ranges of ingredients as CBI when they transition to HPR compliance, and that these filings will cost millions of dollars. They have stated that the HMIRA requirements for CBI protection in Canada will result in increased compliance costs compared to the United States.

Alignment of the mechanisms to protect CBI in Canada and the United States was outside the scope of the RCC commitment. In the United States, as in Canada, companies are required to identify on product labels and SDSs when information is withheld due to a CBI claim. However, unlike in Canada, the United States approach allows suppliers to self-declare information as CBI, with no application or verification process by the United States Occupational Health and Safety Administration. There is no fee related to verification of CBI claims in the United States. In Canada, there is a fee associated with the Health Canada review of CBI applications.

Currently, all suppliers have the option of complying with either the CPR or the HPR. However, in order to protect ingredient concentrations or concentration ranges as CBI once suppliers transition to compliance with the HPR, they have to use the mechanism provided by the HMIRA. Since manufacturers and importers who resell imported hazardous products are required to comply with the HPR by June 1, 2018, they would have to submit any CBI claims before that date.

In order to avoid the burden of protecting CBI under the HMIRA, industry stakeholders proposed that prescribed concentration ranges could be permitted in the HPR and used to replace the actual concentrations and concentration ranges of ingredients rather than having to use the HMIRA to protect CBI. Their proposal would allow the supplier to choose whether to disclose the actual concentration or concentration range of the ingredient or to make use of the prescribed concentration ranges. As under the old WHMIS, suppliers would continue to have the option to submit HMIRA claims to protect ingredient names or concentrations or concentration ranges, but given this option of using prescribed concentration ranges, it is not expected that the number of filings Health Canada receives under the HMIRA will increase.

Objectives

The objective of this amendment of the HPR is to provide industry with the option to use prescribed concentration ranges to protect the actual chemical ingredient concentrations or concentration ranges on SDSs for hazardous workplace products in Canada rather than submitting CBI applications under the HMIRA.

Description

The amendment allows the use of prescribed concentration ranges to protect ingredient concentrations and concentration ranges that are considered CBI without having to submit claims for exemption under the HMIRA. These prescribed concentration ranges are spelled out directly in the amended HPR. The concentrations and concentration ranges of ingredients in the product that present a health hazard must be disclosed on the SDS as either

- the actual concentration or actual concentration range of the material or substance (i.e. the ingredient) in the hazardous product; or
- one of the following prescribed concentration ranges within which the actual concentration or actual concentration range of the material or substance in the hazardous product falls:

  (a) from 0.1 to 1%;

  (b) from 0.5 to 1.5%;

  (c) from 1 to 5%;

  (d) from 3 to 7%;

  (e) from 5 to 10%;

  (f) from 7 to 13%;

  (g) from 10 to 30%;

  (h) from 15 to 40%;

  (i) from 30 to 60%;

  (j) from 45 to 70%;

  (k) from 60 to 80%;

  (l) from 65 to 85%; and

  (m) from 80 to 100%.

In addition, if the actual concentration range falls between 0.1 and 30% and does not fit entirely into one of the prescribed concentration ranges of (a) to (g), a single range created by the combination of two applicable consecutive ranges between (a) and (g) may be disclosed instead, provided that the combined concentration range does not include any range that falls entirely outside the actual concentration range in which the ingredient is present in the hazardous product.

The amendment also requires any supplier who uses a prescribed concentration range to protect from disclosure the actual concentration or concentration range to provide immediately following that prescribed range a statement to the effect that the actual concentration or concentration range is withheld as a trade secret.

"One-for-One" Rule

The "One-for-One" Rule does not apply, as the amendment does not contain requirements that would place an administrative burden on industry.

Small business lens

The small business lens does not apply, as there are no costs to small business.

Consultation

Consultations prior to publication in *Canada Gazette*, Part I, as required by s.19 of the HPA

The proposal to use prescribed concentration ranges was discussed by CIC representatives in late 2016 and early 2017. There was general agreement that the use of prescribed concentration ranges might be acceptable to all parties. However, additional issues raised by labour representatives relating to the protection of ingredients that are carcinogens, mutagens, reproductive toxins and respiratory sensitizers (CMRs) as CBI and to the protection of product sectors excluded from WHMIS (e.g. consumer products and manufactured articles) remain under discussion.

Specifically, labour representatives expressed concerns that CMRRs should not be eligible for CBI protection because the risks associated with these substances are too great to have their identities concealed. However, it is important to note that under WHMIS 2015, all health hazards will still be indicated on the label (and this includes CMRRs) and labels will also have updated pictograms, which are expected to improve hazard communication. With respect to the excluded product sectors, there are 12 product sectors that have always been excluded from WHMIS requirements in the HPA, the majority of which are already regulated under other acts. However, labour representatives are continuing to call for the removal of all exclusions in the HPA because of the risk that they potentially present to workers, who view these exclusions as undermining a perceived "right to know".

Given that both of these concerns are outside the scope of the issue addressed by this regulatory amendment, they are not discussed further in this document. Health Canada has, however, committed to working with stakeholders going forward to examine these additional concerns in more detail.

Labour representatives expressed concerns that if the use of prescribed concentration ranges is allowed, the level of worker protection may be reduced because, unlike the HMIRA application process, there would be no independent review by Health Canada of the SDSs and labels. Health Canada is of the opinion that the use of prescribed concentration ranges would offer the same level of protection as under the former CPR and that a risk-based compliance and enforcement program is a more strategic approach to identifying and correcting non-compliant SDSs and labels. Furthermore, actual concentrations or concentration ranges of ingredients are unlikely to have been provided on the SDSs of products where companies wanted to protect this information from disclosure, as either the companies did not make the change to the new requirement under the HPR or they filed applications under the HMIRA. Therefore, there is unlikely to be any change in precision of the information being provided with respect to concentrations or concentration ranges of ingredients for products for which the concentration or concentration range is protected under the HMIRA. It was also suggested that the use of prescribed concentration ranges for CBI purposes should be identified through a statement on the SDS; this was supported by all stakeholders, and is reflected in the amendment.

Industry stakeholders strongly supported the proposal, since implementing the use of prescribed concentration ranges offers significant cost savings. Industry actively sought support for the amendment from Health Canada, Innovation, Science and Economic Development Canada, and the Canada–United States RCC Secretariat.

Representatives from provincial and territorial governments responsible for the regulation of occupational health and safety, as well as the federal Labour Program at Employment and Social Development Canada, elected not to participate in the detailed discussions because they were all in agreement with the proposal. Employers also elected not to participate, as they are not directly subject to the requirements of the HPR and must instead meet the regulatory requirements set out by the provincial or territorial governments or by Employment and Social Development Canada in the case of federally regulated workplaces.

To provide sufficient time to work with stakeholders to address the issue of CBI protection identified by industry, while taking into consideration possible ways to address the concerns raised by labour representatives relating to excluded product sectors and CMRs, an order in council has granted an extended deadline of June 1, 2018, to manufacturers and importers who resell imported hazardous products to finalize their transition to the HPR.[1]

Canada Gazette, Part I, consultation

On October 21, 2017, the proposed amendment to the HPR was published in the *Canada Gazette*, Part I (CGI). Direct emails were sent to stakeholders on the WHMIS Current Issues Committee (CIC); the Intergovernmental WHMIS Coordinating Committee (IWCC); the Workplace Hazardous Materials Bureau listserve; the Society for Chemical Hazard Communication; the HMIRA Confidential Business Information list of active claimants; and the US Occupational Safety and Health Administrator. Interested parties were invited to provide comments on the proposal within 30 days.

Submissions were received from 55 stakeholders divided as follows: 12 from industry associations, 38 from suppliers (manufacturers and distributers), one from an independent researcher, and four from labour organizations. 48 stakeholders (12 industry associations**,** 35 suppliers, and one independent researcher) indicated support for the proposed amendment. Two suppliers did not state a position with respect to the regulatory changes, but rather posed questions on the text. One supplier was opposed to the amendment, as were all four labour organizations.

The comments and non-supportive responses fell under the following themes:

[1] *Order Amending the Order Fixing the Day for the Purposes of Sections 130, 133 and 135 of the Economic Action Plan 2014 Act, No. 1*: http://gazette.gc.ca/rp-pr/p2/2017/2017-05-31/html/sor-dors92-eng.php.

Combining ranges

Three stakeholders provided the suggestion to limit the number of possible combined consecutive concentration ranges to two (from three as listed in the proposed amendment). They suggested that there is no evidence to conclude that three combined concentration ranges would be necessary to cover batch variations due to industry's strict quality control measures. However, this suggestion was included in a broader submission that indicated they were not supportive of the overall amendment, and was presented as a proposal only if we decided to finalize the amendments despite their opposition. Health Canada informed stakeholders of this comment and requested any additional evidence to support the use of either two or three ranges, but received no such evidence. In considering this comment, Health Canada conducted an analysis of randomly selected WHMIS 2015 CBI claims to protect ingredient concentrations, consisting of over 250 products containing over 900 hazardous ingredients. The findings indicated that the vast majority of the claims (~88%) were for an exact concentration and not a concentrations range, and of the more than 900 ingredients assessed, only 5 required a combination of three ranges. This means that based on the evidence available, less than 1% of all potential concentration CBI claims would be impacted by the shift to two from three. In addition to the minimal impact anticipated by making this change, and given the stakeholders' general opposition to the amendment as a whole, Health Canada agreed that this was a reasonable compromise to make, and it is now reflected in the final regulatory amendment.

Refunds

Two stakeholders requested clarity on the plan to address and/or refund products for which HMIRA claims have already been submitted to seek exemption from the HPR requirements for concentration disclosure. Health Canada is currently exploring options for addressing CBI claims for ingredient concentration submitted under WHMIS 2015.

CBI Fees

One stakeholder asked if claims for exemption will still be required but at no cost. Claims will not be required to be filed to enable the use of prescribed ranges. As such, no fee will be associated with the use of prescribed ranges. However, if a supplier wishes to protect an ingredient concentration or concentration range without using a prescribed range, they would need to submit a claim for exemption under the HMIRA and pay the associated fee. Claims for exemption from the requirement to disclose ingredient identities would still be required to be filed under the HMIRA, along with the associated fee.

Impact on CAS registry numbers of CBI ingredients

One stakeholder asked how the amendment will impact the masking of Chemical Abstracts Service (CAS) registry numbers of confidential raw materials. They stated that relief from the HMIRA CBI exemption process and associated fees would be welcomed by them, but not if it results in disclosure of formulations. Health Canada clarified that the proposal is only for the masking of ingredient concentrations or concentration ranges. In the event that the identification of an ingredient, including the CAS registry number, is considered trade secret, a claim for exemption from disclosure on the SDS must still be made through the CBI process under the HMIRA. In instances where just the concentration or concentration range of the ingredient is considered trade secret, the CAS registry number will still need to be provided.

Impact on WHMIS 2015 compliant industries

One stakeholder did not support the proposed amendment on the basis that their company has already developed SDSs based on the requirements of WHMIS 2015, and is concerned that their ranges may not align with the new proposed ranges. They did not feel that companies who initially complied with the HPR should have to re-do SDSs and re-send to affected customers. They proposed adding a section with ranges

for trade secret protection and keeping s.4.5 as currently written. Health Canada is of the opinion that the amendment should not require the drafting of new SDSs. As no prescribed concentration ranges were permitted for CBI ingredients in the HPR without an application under the HMIRA, the only concentration ranges used on WHMIS 2015 compliant labels should be in the cases of (1) actual ranges for non-confidential ingredients or non-hazardous ingredients that are not always present at the same concentration (e.g. batch variation), or (2) ranges that have already been provided an HMIRA Registration Number (RN) protecting the actual concentration or actual concentration range of an ingredient as CBI. The former will not be impacted by the amendment, as non-confidential ingredient concentrations will not be permitted to use the prescribed ranges, and, as such, the concentration information on these ingredients should not require a change to the SDS. The disclosure of non-hazardous ingredient concentrations is not regulated by the HPR. Ranges that have already been provided an HMIRA RN will continue to be protected under the HMIRA.

Compliance and Enforcement

Two stakeholders agreed with the proposed amendment but asked how Health Canada intends on auditing companies to verify CBI claims when using prescribed ranges. Health Canada, in collaboration with its FPT Occupational Health and Safety (OHS) agencies have a WHMIS 2015 compliance and enforcement (C&E) program. Working together, Health Canada and its FPT partners coordinate and administer an inspection program to verify compliance or prevent non-compliance with the HPA and the HPR. Inspectors designated under the HPA may visit workplaces and/or suppliers of hazardous products to conduct inspections. During an inspection, inspectors may review SDSs and labels of hazardous products. Inspectors also have the authority to take samples of hazardous products for analysis in order to verify the information that is disclosed on a SDS. Health Canada also carries out other compliance and enforcement initiatives, such as the review of SDSs and labels independently from inspections, in addition to working closely with the Canada Border Services Agency (CBSA) on the importation of products that may potentially be classified as hazardous products under the HPA.

One stakeholder asked, in particular, how s.4.5(1)(c) will be monitored. Both the FPT inspection program and Health Canada's review of the SDSs can be used to audit the use of multiple prescribed ranges in addition to the statement required following the use of a prescribed concentration to hide CBI (s. 4.4.1(4) and s. 4.5(4)).

Four stakeholders recommended that Health Canada work to improve the accuracy of SDSs which are estimated to contain inaccuracies or omissions at a rate of 50%. Health Canada believes that a risk-based C&E program is a strategic approach to identifying and correcting non-compliant SDSs and labels. A component of the C&E program is compliance promotion of industry's regulatory requirements. Health Canada, in partnership with other FPT partners, uses education and information-sharing to help ensure that regulatory requirements are communicated and made readily accessible to industry. This includes both the direct sharing of compliance promotion packages, and outreach conducted by FPT inspectors during inspections and through other general communications.

Impact on non-CBI ingredients

One stakeholder agreed with the proposed amendment but asked if the prescribed ranges can be used for all ingredients, not just those that are trade secrets. The prescribed concentration ranges are to be used only when ingredient concentrations are considered trade secret, and as such, a statement must be included to indicate the prescribed concentration range(s) is (are) being used to protect a trade secret. For ingredients where the actual concentration varies from batch to batch, and it is not a trade secret, the actual concentration range must be provided.

Non-hazardous ingredients

One stakeholder asked if the clause regarding use of the prescribed ranges is necessary in the case of non-hazardous ingredients which are trade secret. As non-hazardous ingredients are not required to be disclosed on the SDS or label, this regulatory amendment will not impact how these ingredients are reported on an SDS or label.

Use of the prescribed ranges

One stakeholder agreed with the proposed amendment as it read in the context of the CGI publications, but asked for the following clarification: can smaller ranges be used if they (1) fall within an existing range, e.g. using 3.8-4.5% rather than 3-5% (as listed), or (2) when combining up to three prescribed ranges, e.g. combining ranges (e), (f), and (g) would be 5-30% but using 6-28% instead. Health Canada clarified that the prescribed concentration ranges are only to be used when the ingredient concentration or concentration range is considered to be a trade secret and must be followed by a statement indicating as such. In such cases, the only ranges permitted to be used are those listed in subsections 4.4.1(3) and 4.5 (3). However, when the ingredient concentration or concentration range is not a trade secret, the actual concentration or actual concentration range must be provided, and the prescribed concentration ranges are not permitted.

Statement required when using prescribed concentration ranges

One stakeholder asked if the provision indicating the use of the prescribed concentration ranges for the purposes of protecting a trade secret must, indeed, be stated immediately following each usage of a prescribed range, or in the case of a table in which multiple are used, if the clause can be listed once at the end of the table. Health Canada clarified that "immediately following" can be interpreted to mean placement at the end of a table of ingredients if an asterisk or footnote is included that clearly links each prescribed concentration range to the statement.

Worker safety

Four stakeholders did not agree with the statement in the Regulatory Impact Analysis Statement that there was "general agreement […] by all parties" on the proposal to allow for the use of prescribed concentrations during preliminary discussions; rather, they indicated that they only agreed to discuss the use of prescribed ranges as part of an overall discussion of HPA, HPR, and HMIRA amendments to "improve worker safety". Health Canada acknowledges that there were other issues impacting worker safety that the stakeholders felt should be addressed concurrently with the use of prescribed concentration ranges, and, as such, published a Notice of Intent (NoI) at the same time as the proposed HPR amendment in CGI. The NoI was to inform the public of Health Canada's intent to examine the issues and possible solutions to the exclusion of consumer products from the HPR and claiming of carcinogens, mutagens, reproductive toxins, and respiratory sensitizers (CMRRs) as CBI.

The same four stakeholders argued that removing the only mandated systematic review of SDSs and label accuracy, which occurs via the CBI claim for exemption review process, will lead to the degradation of the accuracy of the SDS system, and, thus, weaken worker protection. The stakeholders are correct that Health Canada will not be reviewing the SDSs using prescribed concentration ranges, as it does with a CBI claim for exemptions. However, Health Canada believes that a risk-based C&E program is a more strategic approach to identifying and correcting non-compliant SDSs and labels. In addition, such a review was not conducted prior to the coming-into-force of the HPR (i.e., under the former CPR) as there were previously prescribed concentration ranges that could be used to disclose ingredient concentrations or concentration ranges that, by their prescribed nature, protected exact ingredient concentrations or exact ingredient concentration ranges from disclosure. Given that industry is still transitioning to the HPR, and some

suppliers may still be in compliance with the CPR, this amendment is not a reduction in worker protection, but maintenance of the approach that existed under the CPR.

In the same light, the four stakeholders stated that the use of prescribed concentrations to mask CBI was not the original intent in the CPR, and thus is a continuation of a practice that compromises "workers' right to know" and for which the impact to workers was never monitored due to the prescribed concentrations, as permitted in the CPR, having been misused. Health Canada acknowledges that this was not the intended use of the prescribed concentrations under the CPR. However, the CPR prescribed concentration ranges, by their prescribed nature, protected actual ingredient concentrations or actual ingredient concentration ranges from disclosure. Further, with the amendment to allow prescribed concentrations only when protecting trade secret concentrations being written into the HPR, Health Canada is addressing this issue by ensuring that the use of prescribed concentrations will only be permitted in cases where the concentration is a trade secret. Under the CPR, Health Canada had no means of determining how and when the prescribed ranges were being used, as the trade secret requirement was not included in the regulations. Health Canada is, thus, of the opinion that the use of prescribed concentration ranges in the HPR does not decrease the level of protection as compared to what was provided under the former CPR.

One stakeholder expressed concern regarding the proposal under subsection 4.4.1(2), which states, "if the actual concentration of a material or substances in a hazardous product falls within more than one of the concentration ranges […], any one of those ranges may be provided on the SDS" as it could allow an ingredient with a range from 0.5% to 5% to be represented in the lowest concentration range (from 0.1-1%). Health Canada clarified that this is not the meaning of this provision. Subsection 4.4.1(2) refers only to ingredients that are always present at the same concentration. Therefore, the prescribed range in which the actual concentration falls must be used. This may allow the choice of more than one range. However, only a prescribed range in which the actual concentration falls may be selected. A prescribed range in which the actual concentration does not fall could not be used. For example, the concentration 1.2% falls into the prescribed concentration ranges (b) 0.5-1.5% and (c) 1-5%, so either (b) or (c) could be used. However, the prescribed concentration range (d) 3-7% could not be used. In subsection 4.5 (2), which refers to ingredients that may not always be present at the same concentration, the actual concentration range of that ingredient must fall fully within the prescribed range being used. Otherwise, pursuant to the final version of paragraph 4.5(1)(c), two consecutive ranges may be provided to cover the full range of the ingredient concentration. Such would be the case for the example provided by the stakeholder: for an ingredient with an actual concentration range of 0.5-5%, the SDS could indicate a prescribed concentration of the combination of (b) 0.5-1.5% and (c) 1-5% to give a combined range of 0.5-5%.

Health Canada's CBI process

Three stakeholders suggested that Health Canada adequately fund and fulfil regulatory requirements for protecting CBI. They were of the opinion that the claim of inadequate resources by Health Canada to process the potential influx of claims is unacceptable and appears to reward industry for a history of deliberate misuse of the CPR in the past. Health Canada is not in a position to comment on program funding. This falls outside the scope of the regulatory amendment.

These three stakeholders further suggested that regulatory burden to Health Canada be reduced by adopting a CBI process like the EU in which there is greater onus on industry to provide information with a claim to demonstrate both confidentiality and value. The HMIRA requires that the claimant provide information that demonstrates economic value and material financial loss with respect to the trade secret, as well as details of the measures implemented to restrict knowledge of the confidential information. The full list of requirements is set out in s.8.1 of the *Hazardous Materials Information Review Regulations* (HMIRR). As such, Health Canada already requires the information suggested by the stakeholder. Furthermore, any

changes to the overall CBI process are outside the scope of what is regulated under the HPR, and falls under the HMIRA. Changes to the HMIRA are outside the scope of this regulatory amendment.

Rationale

Regulated parties proposed that they should have a means to protect the concentration or concentration range of ingredients without having to carry the burden and cost of the application process under the HMIRA. Health Canada agrees that enabling the use of prescribed concentration ranges improves alignment with the United States and offers the same level of protection as under the former CPR while reducing the potential administrative burden on both industry and the Department.

Benefits

By combining reports from several industry associations, Health Canada estimated that thousands of new products would have required a trade secret exemption under the HMIRA prior to the transition to the HPR to protect ingredient concentrations and concentration ranges previously protected by prescribed concentration ranges under the CPR.

In Canada, the filing fee associated with applications for CBI exemption is between Can$200 and Can$1,800 depending on volume discounts. This fee schedule is detailed in sections 4, 5, and 7 to the HMIRR. The American Coatings Association and the Canadian Paint and Coatings Association reported that to comply with the concentration disclosure requirement of the HPR, their members projected application costs of between US$2 million and US$6 million. The American Chemistry Council (ACC) reported that, without the regulatory amendment, one of their members would have required 2 800 new claims, which would cost over US$5 million, while another member required 1 000 new claims totalling US$6 million. Based on estimates from 7 of their 35 member companies, the Canadian Consumer Specialty Products Association reported an impact exceeding Can$12 million for application fees for over 6 000 products alone. These estimates suggest that 10 000 new claims could have been submitted. Health Canada has no way of verifying this information, but assumes that there is the possibility for duplication among companies that are represented by multiple associations and that the estimate is likely high for this reason.

With the regulatory amendment companies will no longer have to dedicate work hours to prepare the submissions, as well as respond to the proposed and final decisions. Industry submissions did mention the burden that would have resulted from the increased work, but most did not quantify its impact. One ACC member who provided a cost impact of US$2.1 million reported that they would have required an additional six full-time employees to comply with the HMIRA requirements. If a majority of companies required additional hires to process the new claims by the transition deadline, this cost to industry would also have been significant.

Health Canada estimates that the CBI registration fees for industry to file the estimated 10 000 new claims prior to June 2018 could have ranged from Can$2 million to Can$18 million. The large span of this estimate is due to the potential for the application of volume discounts. The fees for claim registration include a high of $1,800 per claim for the first 15 filed, drop considerably to $400 for the next 10 claims filed in the same submission, and to $200 for each claim beyond the 25th that is filed in the same submission. The $2 million estimate is based on one company submitting all 10 000 claims in a single submission, in which case most of the claims (9 975) would be registered at the lowest discount rate. The $18 million estimate is calculated based on the assumption that each claim would be submitted separately at the highest rate of $1,800 per claim.

Further, based on the Statistics Canada average labour and overhead cost estimates for natural and applied science employees of $41.59/hour and the estimate that the preparation of a single claim application

requires 1 to 2 hours of work, multiplied by the industry estimate of 10 000 claims, the cost to prepare the applications was estimated to be between $400,000 and $800,000, depending on the time required for information gathering and form completion. This estimate assumes there would have been no additional reductions in resource requirements for submitting claim applications in batches as opposed to individually.

The total potential cost to industry ranged therefore from $2.4 million to $18.8 million. It is important to note, however, that considering the variability of claim estimates provided by industry, which represent only a sample of regulated companies, and with no way of predicting how many new claims would have needed to be filed, the total financial benefit to industry arising from the avoidance of the HMIRA registration application process is difficult to quantify. It is clear, however, that these costs are significant and that avoiding them will save industry millions of dollars with no anticipated impact on worker protection.

The majority of reported estimates were based solely on the cost of new applications to protect from disclosure a concentration or concentration range; however, some stakeholders also mentioned refiling costs without quantifying them. Claims for exemption under the HMIRA expire three years after they are granted, and applications must be refiled to maintain the CBI protection. Refiling costs are discounted relative to new filings and range from Can$160 to Can$1,400. The reoccurring refiling fee for thousands of new products therefore also represents a substantial avoided cost to industry when projected over a 10-year period.

In 2016–17, Health Canada received 1 302 claims, an almost fourfold increase over the average number of CBI registrations filed per year over each of the previous five fiscal years (average of 348 claims per year). This resulted in total revenues of $1.3 million in 2016–17. This increase in the number of claims was believed to be due to suppliers preparing for compliance with WHMIS 2015, including concentration disclosure requirements. This increase represents only part of a potential influx of thousands of new claims that could have occurred by the transition deadline without the amendment. Assuming an estimate of 10 000 anticipated new claims, the influx would have approximately equaled the total number of claims filed under the HMIRA since its inception in 1988, almost 30 years ago. Even setting aside the uncertainty in industry's estimate of 10 000 new claims, the fourfold increase that was witnessed in 2016–17 was an indication of a substantial increase in the number of claims that could have been expected under WHMIS 2015 prior to this amendment.

The average cost to Health Canada to process one claim has changed in recent years for two reasons. First, work output has increased as a result of improved technologies such as electronic submissions and a program restructuring. Second, claim processing times have increased due to the learning curve associated with new regulations; as staff become more familiar with the HPR, claim processing times will decrease. Nonetheless, the average cost to Health Canada to process a claim has ranged from Can$4,200 to Can$14,000[2] in recent years.

Multiplying the cost per claim by the number of anticipated new claims provides an estimate of cost savings to Health Canada that range between Can$4.2 million and Can$14 million. This estimate does not incorporate the substantial cost of reassessing these claims once refiled upon expiry, or any additional investments, such as overtime or additional staff that would have been required by Health Canada to address a backlog resulting from a large influx of claims by the HPR transition deadline. In conclusion, the cost to Health Canada to process these claims would have been significant and, with the amendment, will now be avoided, saving Health Canada millions of dollars.

[2] The average cost to process a claim is calculated by dividing the cost (salaries and operational costs) to run the operational program required by the HMIRA by the number of decisions on claims that were issued in one year.

Costs

The cost to industry of the amendment is expected to be zero, because this is a relieving amendment that adds an option to use a prescribed concentration range rather than imposing any new regulatory requirements.

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