Description of Proposed Amendments

It is proposed that the *Controlled Products Regulations* (CPR) be repealed and replaced with new regulations to be titled the *Hazardous Products Regulations* (HPR). These new regulations would implement the GHS hazard classification criteria and hazard communication elements - labels and safety data sheets (SDS) - as per the third revision of the GHS published by the United Nations in 2009 and, to the maximum extent possible, in alignment with the United States Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (HCS) as amended on March 26, 2012 (HCS 2012). Consequential amendments would also need to be made to related regulations.

The GHS elements are proposed for adoption in a manner that is consistent with the GHS 'building block' approach. The GHS may be considered as a collection of 'building blocks', such as hazard classes or divisions within a hazard class, that are available for adoption by a jurisdiction. Additionally, the proposal ensures that workers would continue to be provided with health and safety information related to hazardous products to the same, or to a greater extent, than is currently the case under the CPR. Lastly, the proposal maximizes alignment between the proposed HPR and the OSHA HCS 2012 with the exception of areas where a variance is necessary to maintain the current level of protections afforded to Canadian workers or to respect the framework of the Canadian legislation and regulations.

The proposed HPR would implement changes in five broad areas: 1) the manner of establishing the classification of hazardous products; 2) classification of physical hazards; 3) classification of health hazards; 4) hazard communication and other requirements; and, 5) exemptions. The following provides a brief description of the key regulatory changes proposed in each of these areas.

In addition, consequential amendments to the *Hazardous Materials Information Review Regulations* and *Hazardous Materials Information Review Act Appeal Board Procedures Regulations* would be required in relation to the proposed HPR, as well as amendments that were made to the *Hazardous Materials Information Review Act* that came into force on April 1, 2013.

1) Manner of Establishing the Classification of Hazardous Products

A new approach to establishing the classification of hazardous products would be set out in the HPR by integrating the relevant provisions of the GHS, as adopted by US OSHA, with the current manner of establishing classification under the CPR. The CPR principle that classification should be based on existing data and no testing should have to be undertaken for the purposes of classification would be retained and is harmonized with the HCS 2012. However, the proposed approach to the classification of mixtures is more structured than the current CPR, as it provides a stepwise approach to the consideration of different types of data available for the mixture or its ingredients. The classification of substances would be based on the evaluation of the substance, using all available data, against the criteria for each hazard class.

In addition, a new provision in the proposed regulations would allow the classification of substances to be prescribed in regulation. This is a targeted means of ensuring that substances currently classified under the CPR would remain classified under the HPR. Where a classification is prescribed for a substance, the substance would still need to be evaluated against the classification criteria of other hazard classes.

Two types of GHS hazard classes are proposed for adoption in alignment with HCS 2012: physical hazard classes, which represent hazards relating to chemical properties, such as flammability or compressed gases; and health hazard classes, which represent hazards to health arising from exposure to a substance or mixture. With respect to the physical hazard classes, the same manner of establishing

classification would be used for both substances and mixtures. With respect to the health hazard classes, the manner of establishing classification of mixtures would follow the GHS procedures for each hazard class. These include the application of bridging principles that allow a classification to be determined for an untested mixture on the basis of a similar tested mixture, as well as the classification of the mixture on the basis of its ingredients subject to consideration of the concentrations of the ingredients and their interactions in the mixture.

The proposed regulations would clarify that a product would need to be classified in the division of the hazard class that represents the greatest hazard for which it meets the classification criteria. However, the Acute Toxicity, Respiratory or Skin Sensitization, Reproductive Toxicity and Specific Target Organ Toxicity – Single Exposure hazard classes would permit classification in multiple divisions within the hazard class, where appropriate, in accordance with the GHS building blocks and in alignment with the HCS 2012.

For the purposes of classification, mixtures or products sold together in one outer container but packaged individually (commonly called a "kit") would each be treated as an individual product or mixture. Two or more discrete mixtures, materials or substances that are contained in common packaging not designed for individual access would be treated as a single mixture or product.

The proposed HPR is aligned with the HCS 2012 on all requirements relating to the manner of establishing the classification of a product.

2) Classification - Physical Hazards

The GHS physical hazard classes and their classification criteria are proposed to be adopted in the HPR in alignment with the HCS 2012. While the GHS hazard classes subdivide physical hazards in a manner that differs from the current CPR, these classes address all of the physical hazards that are currently covered in the CPR, and introduce some additional types of hazards that are not currently covered but that would enhance protections for workers.

The GHS physical hazard classes proposed in the HPR that are currently covered in the CPR are: Flammable Gases; Flammable Aerosols; Oxidizing Gases; Gases under Pressure; Flammable Liquids; Flammable Solids; Self-Reactive Substances and Mixtures; Pyrophoric Liquids; Pyrophoric Solids; Self-Heating Substances and Mixtures; Substances and Mixtures that, in Contact with Water, Emit Flammable Gases; Oxidizing Liquids; Oxidizing Solids; Organic Peroxides; and Corrosive to Metals.

In addition, a Physical Hazards Not Otherwise Classified (PHNOC) hazard class is proposed to capture some products that are currently covered under the CPR but are not addressed by the GHS, such as products that undergo vigorous polymerization.

The proposed HPR also introduces the following new hazard classes: Pyrophoric Gases, Simple Asphyxiants and Combustible Dusts. The proposed Pyrophoric Gases, Simple Asphyxiants and Combustible Dusts hazard classes are not addressed by the GHS but are proposed for adoption in the HPR in alignment with the HCS 2012 and to ensure that these hazards would also be communicated to workers. Notably, the proposed HPR would not regulate products that are shipped in a non-dust form but which, when processed, would present the hazard of combustible dust. However, the HCS 2012 will require such products to be accompanied by a label and SDS. This difference is not an impediment to harmonization because the voluntary provision of a label or SDS for such products in Canada would be acceptable.

The proposed HPR is aligned with the HCS 2012 on all of the physical hazard classes, with the exception of Combustible Dusts and PHNOC. While the manner in which these hazards would be addressed by the HPR and the HCS 2012 would be different, Health Canada would continue to work with US OSHA to ensure that there would be alignment in these areas wherever possible. The HCS 2012 neither defines nor provides classification criteria in respect of combustible dusts. It also does not define a hazard class for physical hazards not otherwise classified, but instead, defines the general term "hazards not otherwise classified". In both cases, the proposed HPR sets out a hazard class that includes a definition and classification criteria. The criminal law framework of Canadian legislation and regulations for workplace hazardous chemicals does not provide the latitude to require the classification of a substance without specifying the criteria by which a supplier must determine whether the substance is classified.

3) Classification - Health Hazards

The GHS health hazard classes and their classification criteria are proposed to be adopted in the HPR in alignment with the HCS 2012. While the GHS hazard classes subdivide health hazards in a manner that differs from the current CPR, these classes address all of the health hazards that are currently covered in the CPR, and introduce some additional types of hazards that are not currently covered but would enhance protections for workers.

The GHS health hazard classes proposed in the HPR that are currently covered in the CPR are: Acute Toxicity (Categories 1 to 4); Skin Corrosion/Irritation (Categories 1A, 1B, 1C and 2); Serious Eye Damage/Eye Irritation (Categories 1, 2A and 2B); Respiratory or Skin Sensitization (Categories 1A and 1B for both respiratory and skin sensitization); Germ Cell Mutagenicity (Categories 1A, 1B and 2); Carcinogenicity (Categories 1A, 1B and 2); Reproductive Toxicity (Categories 1A, 1B, 2 and an additional category for effects on or via lactation); and Specific Target Organ Toxicity - Repeated Exposure (Categories 1 and 2). Notably, substances which react vigorously with water to release a toxic gas (currently classified as a Dangerously Reactive Material under the CPR) would be classified in the Acute Toxicity hazard class of the proposed HPR in alignment with the HCS 2012. The category building blocks proposed for adoption within each hazard class are aligned with the HCS 2012.

The proposed HPR introduces the following new GHS hazard classes, in alignment with the HCS 2012: Specific Target Organ Toxicity - Single Exposure (Categories 1, 2 and 3); and Aspiration Hazard (Category 1). It also introduces a Health Hazards Not Otherwise Classified (HHNOC) hazard class that is not addressed by the GHS but proposed for adoption in the HPR. Lastly, the proposed HPR retains a separate hazard class for Biohazardous Infectious Materials in order to maintain the current level of worker protection in Canada. The classification criteria of this class would have the same scope as the CPR but would be amended to align with the *Human Pathogens and Toxins Act* and the *Health of Animals Act* and *Regulations* in order to ensure consistency in Canadian legislation and regulations.

The proposed HPR is aligned with the HCS 2012 on all of the health hazard classes, with the exception of the Biohazardous Infectious Materials and HHNOC hazard classes. The HCS 2012 does not regulate biohazardous infectious materials, however the class is proposed to be retained to maintain the current level of worker protection in Canada. It is expected that this variance would have a limited impact as biohazardous infectious materials are often specialized products that are distinct from most chemical products and the market for such products is limited. With respect to the HHNOC hazard class, the HCS 2012 does not define a hazard class, but instead, defines the general term "hazards not otherwise classified." The proposed HPR divides these into physical and health hazards in order to ensure the appropriate disclosure of substances or ingredients in a mixture that present a health hazard. The proposed HPR hazard class includes a definition and classification criteria due to the framework of the Canadian legislation and regulations, as described above. It is expected that a very small number of

products would be classified in this hazard class and therefore the different requirements would be expected to impact very few products.

4) Hazard Communication and Other Requirements

The HPA requires a label and SDS for each hazardous product (i.e. each product that meets classification criteria set out in the HPR). The current CPR requirements for labels and SDSs would be amended to respect the content and format specifications of the GHS in alignment with the HCS 2012. This includes a proposal that the term *"safety data sheet"* (SDS) replace the term *"material safety data sheet."* However, the general approach to communicating the hazards of a product on a label and SDS through pictures and statements that convey messages about hazards, precautions and first aid measures would remain the same.

Labelling

A label under the HPR is proposed to be comprised of a product identifier and supplier identifier, as well as standardized pictograms, a signal word, hazards statements, precautionary statements and supplemental label elements that are required based on the classification of the hazardous product. The GHS pictogram format of a black symbol on a white background with a red frame in the shape of a square set on a point would be adopted for all GHS pictograms. The current CPR symbol for biohazards, in a black circle, would be retained as the biohazard symbol as there is no equivalent symbol under the GHS. For all other hazards, the GHS pictograms would be adopted. The hazard pictogram(s), the signal word, the hazard statement(s) would be required to be grouped together on the label. The label would need to be durable and legible without the aid of any devices other than corrective lenses. The CPR requires similar label elements (hazard symbols, risk phrases and first aid measures) to convey the hazard to workers. However, the only standardized CPR label element is the hazard symbol, whereas the GHS, HCS 2012 and proposed HPR require standardized hazard statements, signal words and precautionary statements.

The supplier identifier would consist of the contact information for the Canadian manufacturer or importer. However, a distributor could provide its contact information in lieu of the supplier and an importer could retain the name of the foreign supplier if the product was imported for the importer's own use (e.g., in their workplace). This approach is aligned with the HCS 2012, which requires the disclosure of the identity of a U.S. manufacturer, importer or other responsible person. Each jurisdiction requires the identification of a supplier within its jurisdiction for the purposes of compliance and enforcement.

For each hazard class adopted from the GHS in which the hazardous product is classified, the corresponding pictogram, signal word, hazard statement and precautionary statements set out in Section 3 of Annex 3 of the GHS would be required to appear on the label. For all other hazard classes in which the hazardous product is classified, those elements as set out in the HPR for the hazard class would be required. The GHS supplemental label element warning that ingredients in the mixture are of unknown acute toxicity would also be adopted and required to appear on the label of such mixtures. The HPR would contain rules of precedence to ensure no duplication of information on the label. In addition, hazard statements could be combined as appropriate, as could precautionary statements. Inapplicable precautionary statements could be omitted. Unlike the proposed HPR, the HCS 2012 additionally allows the omission of non-applicable hazard statements. The impact of this variance is, however, expected to be small, because the number of cases in which it would be appropriate to classify a product but not apply the associated hazard statement is expected to be limited.

With the exceptions noted above, the proposed HPR is aligned with the HCS 2012 on all label requirements, with the exception of the Carcinogenicity, PHNOC, HHNOC and Biohazardous Infectious Materials hazard classes, as described below.

- Carcinogenicity – The proposed HPR requires, as does the CPR, a label on all mixtures containing a carcinogenic ingredient at a concentration of 0.1% or more. The HCS 2012 makes a label optional for mixtures containing a Category 2 carcinogen at a concentration between 0.1% and 1%. However, this option would not maintain the current level of worker protection in Canada and is therefore not proposed to be adopted.
- PHNOC and HHNOC – The proposed HPR requires a label on all products classified in these classes whereas the HCS 2012 does not. Because the nature of these hazards, as defined by the proposed HPR, is such that they may cause death, labelling elements were deemed to be necessary. The label elements proposed are a pictogram and a hazard statement appropriate to the hazard, as well as the signal word "Danger".
- Biohazardous Infectious Materials - Products meeting the criteria in the proposed HPR would be required to be labelled with the biohazard pictogram, the signal word "Danger" and an appropriate hazard statement and precautionary statements. Biohazardous infectious materials are not regulated by the HCS 2012. It is expected that this variance would have a limited impact as biohazardous infectious materials are often specialized products that are distinct from most chemical products and the market for such products is limited.

Safety Data Sheets (SDS)

The SDS under the proposed HPR would have a format of 16 standardized GHS headings in alignment with the HCS 2012. Available information with respect to each header/topic would have to appear in the SDS, with the exception that the information in sections 12 – 15 would be optional, in alignment with the HCS 2012.

Comparison of Suggested MSDS Headings in the CPR and Required (GHS) SDS Headings in the Proposed HPR

Existing CPR		**Proposed HPR**	
Item	**Suggested Heading**	**Section**	**Required (GHS) Heading**
1	Hazardous Ingredients	1	Identification
2	Preparation Information	2	Hazard Identification
3	Product Information	3	Composition/Information on Ingredients
4	Physical Data	4	First Aid Measures
5	Fire or Explosion Hazard	5	Fire Fighting Measures
6	Reactivity Data	6	Accidental Release Measures
7	Toxicological Properties	7	Handling and Storage
8	Preventive Measures	8	Exposure Controls/Personal Protection
9	First Aid Measures	9	Physical and Chemical Properties

		10	Stability and Reactivity
		11	Toxicological Information
		12	Ecological Information
		13	Disposal Considerations
		14	Transport Information
		15	Regulatory Information
		16	Other Information

For products classified as Biohazardous Infectious Materials, a new nine-heading appendix to the SDS based on the information sheets made publically available by the Public Health Agency of Canada is proposed to be required. As infectious materials are not regulated by the HCS 2012, this requirement would not be harmonized.

The SDS would be required to provide, in the case of a substance, its chemical identity. In the case of a mixture, the chemical identity and concentration or concentration range of all ingredients in the mixture that present a health hazard would be required to be disclosed on the SDS.

In order to harmonize with the GHS and HCS 2012, the following elements would differ from current CPR requirements. The SDS would be required to provide the classification of the hazardous product as well as information about any reaction product produced as a result of having followed instructions for use provided with the product. In addition, the supplier and product identifiers appearing on the SDS would be required to be the same as those appearing on the label. These small changes would harmonize with the GHS and HCS 2012 and increase the protections available to workers.

The requirements that the SDS disclose any other hazard information that is available to the supplier with respect to the hazardous product or a product or material that has similar properties would be retained. While this requirement is not explicit in the HCS 2012, its removal would constitute a reduction in the level of protections available to workers. In addition, the units of a ratio represented by a percentage would be required to be disclosed on the SDS. This is currently required under the CPR, but will not be required by the HCS 2012. Its removal may constitute a reduction in the level of protections available to workers.

The proposed HPR is aligned with the HCS 2012 in respect of all the SDS requirements, with the exception of the PHNOC, HHNOC and the Biohazardous Infectious Materials hazard classes. Products classified in the PHNOC or HHNOC hazard classes would need to have that classification disclosed in section 2 of the SDS under the proposed HPR, whereas under the HCS 2012, only a description of the hazard would be required. In addition, the chemical identity of an ingredient classified in the HHNOC hazard class would be required to be disclosed in section 3 of the SDS in order to maintain the current level of protection. As described above, an appendix to the SDS providing information that is specifically relevant to the biohazard would be required for products classified in the Biohazardous Infectious Materials hazard class under the proposed HPR in order to maintain protections available to workers.

Other requirements

Information on the label and SDS would continue to be required to be provided in both English and French in conformity with the requirements of the *Official Languages Act*, and despite the unilingual HCS 2012 requirements. The information could appear on a single SDS or two separate SDSs.

The requirement to provide information to a health professional in the case of an emergency would be retained. However, the requirement that the health professional retain the information in confidence would be subject to the requirement that the health professional be informed as to the confidentiality of the information they are being provided.

The requirement to revise the SDS every three (3) years in the absence of new information in respect of the hazardous product would no longer be required as it is duplicative of the requirement that an SDS and label be accurate at the time of sale or import.

5) Exemptions

The current regulations include a number of provisions that allow, under specified conditions: (i) an exemption from the requirement of the HPA to provide, obtain or prepare an SDS; (ii) an exemption from the requirement of the HPA to have a label on the hazardous product or its container; or (iii) reduced information on a label and/or an SDS. In the proposed HPR, some of the current exemptions would be removed, some would be retained without modification (other than amendments required as a consequence of other amendments), some would be retained with modification, and a few new exemptions would be created, as described below.

The exemption for flavours and fragrances would not be retained in order to harmonize with HCS 2012. The exemption for a generic SDS would not be retained in the regulations, but it would be allowed by policy. The exemptions for complex mixtures, confidential business information as per the proposed amended *Hazardous Materials Information Review Act* and for SDSs with the same product identifier would be retained largely as they are set out in the CPR.

The CPR bulk shipment exemption would be extended to products sold without packaging of any sort regardless of whether they are shipped. This is harmonized with the HCS 2012. In addition, these products would be exempted from the requirement for a label as all label information would be provided within sections 1 and 2 of the SDS required by the proposed HPR.

Products packaged in small volume containers with a capacity of less than 100mL are proposed to be exempted only from the requirement to bear precautionary statements on the label. The HCS 2012 does not have such an exemption, but OSHA addresses provisions for small package labelling on a case-by-case basis.

Only two of the existing exemptions from the labelling of the outer container of a hazardous product would be retained: 1) when the inner container label is visible and legible through the outer container; and 2) when the outer container has a label in accordance with the *Transportation of Dangerous Goods Regulations*. The HCS 2012 only requires the immediate (innermost) container of a product to be labelled, and therefore requires no exemption for the labelling of outer containers. However, the requirement to label each container of a hazardous product, with exemptions as proposed, would be retained in order to maintain the current level of protection in Canada.

Three of the existing exemptions for radioactive nuclide mixtures are proposed to be retained: 1) non-radioactive carriers present in small quantities (< 1 ml or < 1 g) and not classified specified hazard classes need no label or SDS requirements; 2) non-radioactive carriers need no label on the inner container if the

outer container bears the required label; and 3) non-radioactive carrier labels do not require a supplier identifier and precautionary statements. The exemption for carrier materials that are vehicles, radioactive drugs or diagnostic devices is not proposed to be retained. The exclusion for radioactive nuclides in quantities greater than the quantity specified for that nuclide in the *Transport Packaging of Radioactive Materials Regulations* is not retained as those regulations no longer exist. The HCS 2012 does not provide exemptions for radioactive nuclide mixtures.

It is proposed that bailed[1] lab samples in quantities of less than 10 kg be excluded from all requirements if the sample is only classified as a Biohazardous Infectious Material. The same sample would not require an SDS if sold or imported, nor would a lab sample of a non-commercialized product that is bailed and for which the chemical identity or concentration of the substance or ingredients is unknown. In both the previous cases, reduced labelling requirements would also apply. OSHA regulates some lab samples under 29 CFR 1910.1450, *Occupational exposure to hazardous chemicals in laboratories*, but provides no exemptions for other lab samples.

In addition, the following new exemptions are proposed:

- When bailing a product for the purpose of transportation, the supplier would not need to provide an SDS to the bailee (i.e. the person transporting the product). The provision of hazard information during transportation is covered under the *Transportation of Dangerous Goods Regulations*.
- Products packaged in a container with a capacity of 3 mL or less where the label interferes with the normal use of the product would be required to have a label that remains durable and legible only while in transport and storage, but that could be removed for use. The HCS 2012 does not have such an exemption, but OSHA addresses provisions for small package labelling on a case-by-case basis.
- A single outer container that contains two or more different hazardous products (commonly referred to as a "kit") would be allowed to bear a reduced label. The HCS 2012 does not currently have such an exemption.
- Products that bear a *UN Model Regulations on the Transport of Dangerous Goods* pictogram on the label would not require a GHS pictogram for the same hazard. This is a GHS specification and is aligned with the HCS 2012.
- Substances that are not biologically available would not need to be classified. This is a GHS specification and is aligned with the HCS 2012.
- An SDS and label would be exempt from the requirement to reflect significant new information for a period of 90 and 180 days, respectively, from the date upon which the information became available, so long as the new information and date upon which it became available are transmitted by the seller, or obtained or prepared by the importer, in written form. This exemption is proposed in order to maintain the current level of protection for workers, respect the nature of the HPA as a criminal statute, and align to the extent possible with the HCS 2012. This variance would have no impact on labels or SDSs; however, Canadian suppliers would need to convey new information in written format in a more timely manner than would be required in the U.S.

Many of the exemptions proposed in the HPR cannot be aligned with the HCS 2012 because of the different ways in which the two jurisdictions regulate. While OSHA has the authority to exempt products on a case-by-case basis, the HPR must specify exemptions that can be applied as a rule, rather than on an individual basis.

6) Consequential Amendments

[1] A bailed product is a product in relation to which there is a transfer of possession but not ownership; for example a laboratory sample sent for analysis or a product provided to a third party for processing.

In relation to the proposed *Hazardous Products Regulations* outlined above, consequential amendments are being proposed to: the *Hazardous Materials Information Review Regulations*; the *Hazardous Materials Information Review Act Appeal Board Procedures Regulations*; the *Food and Drug Regulations*; the *Consumer Chemicals and Containers Regulations, 2001*; the *Export of Substances Under the Rotterdam Convention Regulations*; the *New Substances Regulations (Chemicals and Polymers)*; and the *Safety of Cells, Tissues and Organs for Transplantation Regulations*. These proposed amendments are consequential in nature and reflect the proposed terminology, definitions and structure of the proposed *Hazardous Products Regulations*. Despite the proposed consequential amendments, the mechanism to protect confidential business information through the *Hazardous Materials Information Review Regulations* and *Hazardous Materials Information Review Act Appeal Board Procedures Regulations* would continue to function as it does currently.

In addition, further amendments to the *Hazardous Materials Information Review Regulations* and *Hazardous Materials Information Review Act Appeal Board Procedures Regulations* are being proposed to reflect the amendments to the *Hazardous Materials Information Review Act* that came into force on April 1, 2013, as a result of the enactment of the *Jobs and Growth Act, 2012*. These proposed amendments would reflect the transfer of the powers and functions under the HMIRA from the Hazardous Materials Information Review Commission to Health Canada.

In summary, it is proposed that the current *Controlled Products Regulations* be repealed and new regulations under the title, the *Hazardous Products Regulations*, be established to enable Canada to apply the new globally recognized standard for classifying and communicating hazards to its workplace chemicals system and to do so in alignment with the approach adopted in the U.S. in its Hazard Communications Standard as amended on March 26, 2012.