Health Canada Santé Canada

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Canadian GHS Implementation Update

Consumer Product Safety Directorate

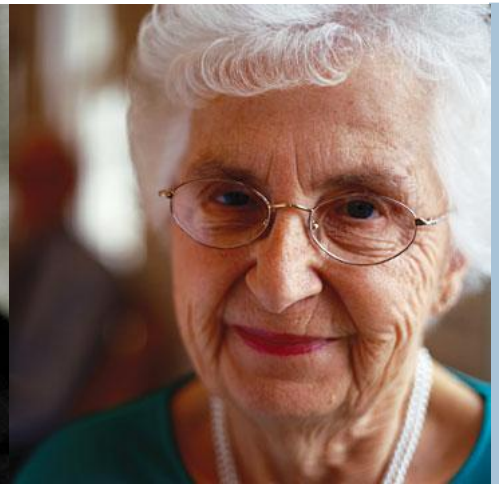
Healthy Environments and Consumer Safety Branch

Health Canada

Rosslynn Miller-Lee

Presentation to the

Society for Chemical Hazard Communication, September 29, 2015



Canada

Outline

- What is WHMIS?
- WHMIS Exclusions
- Guidance – What's New?
- CBI Mechanism in Canada
- Compliance and Enforcement
- Resources
- Next Steps

What is WHMIS?

WHMIS – An Overview

WHMIS is Canada's national hazard classification and hazard communication standard for workplace chemicals.

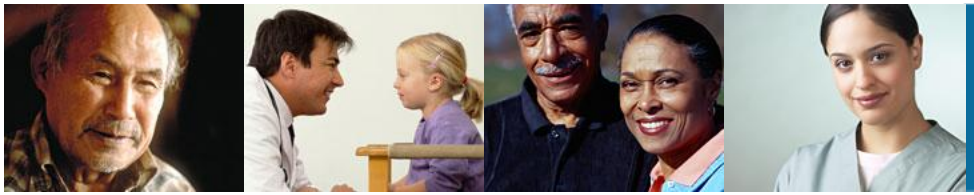
Key elements of WHMIS include:

- ü Classification criteria
- ü Labelling
- ü Safety Data Sheets (SDSs)
- ü Worker Education and Training Programs

WHMIS covers hazardous products from the point of manufacture to the point of use in a workplace.

Current WHMIS Legislation

- WHMIS is implemented through interlocking federal legislation administered by the Department of Health and federal, provincial and territorial (FPT) occupational health and safety (OHS) laws.
- *Supplier* requirements fall under the *Hazardous Products Act* (HPA), as amended in 2014, and the new *Hazardous Products Regulations* (HPR) administered by Health Canada.
  - Covers: Classification criteria; labelling; safety data sheets (SDSs)
- *Employer* requirements fall under FPT OHS laws administered by each of the FPT OHS Regulatory Agencies.
  - Covers: Workplace labelling; worker accessibility to SDSs; worker education and training programs
- A mechanism to protect confidential business information (CBI) is provided under the *Hazardous Materials Information Review Act* (HMIRA) administered by Health Canada.



Canada-U.S. Regulatory Cooperation Council

- The Regulatory Cooperation Council (RCC) was created in February 2011 to align Canadian and the U.S. regulatory approaches in various sectors.
- In December, 2011, the first Joint Action Plan was announced which identified initiatives across various sectors, including Classification and Labelling of Workplace Chemicals.
- The RCC commitment on Workplace Chemicals is to "*to align and synchronize implementation of common classification and labelling requirements for workplace hazardous chemicals …without reducing the level of safety or of protection to workers."*
- On August 29, 2014, the RCC *Joint Forward Plan* (Phase 2) was released. The plan sets the stage for fundamental changes in the way regulatory departments and agencies in both countries work together, making it easier for businesses to operate in both countries.

Canada-U.S. Regulatory Cooperation Council

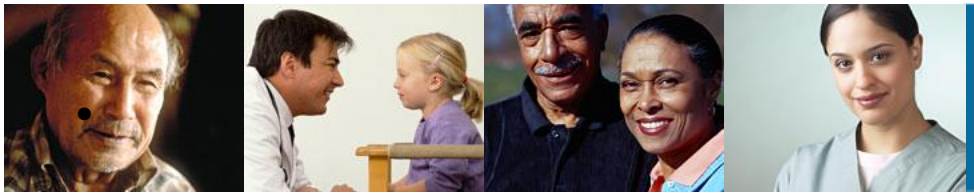
- As part of the RCC Phase 2 commitments, Health Canada and U.S. OSHA prepared a Regulatory Partnership Statement (RPS) and a Work Plan for Workplace Chemicals.

- Canada and the U.S. continue to collaborate on alignment of hazard classification and communication requirements for workplace chemicals, without reducing the level of safety or protection to workers.

- Elements of the work plan include:
  - Reducing and preventing variances through on-going collaboration of guidance materials
  - Mechanisms for developing common positions and for reporting out from international discussions
  - Developing an approach for synchronizing implementation of GHS updates

- Stakeholders will continue to be engaged in planning and priority-setting.

For further information on the RCC, Workplace Chemicals RPS and Work Plan:
http://actionplan.gc.ca/en/page/rcc-ccr/joint-action-plan-canada-united-states-regulatory



WHMIS 2015

Changes to WHMIS 1988 (now known as WHMIS 2015) were as a result of Health Canada's commitments to:

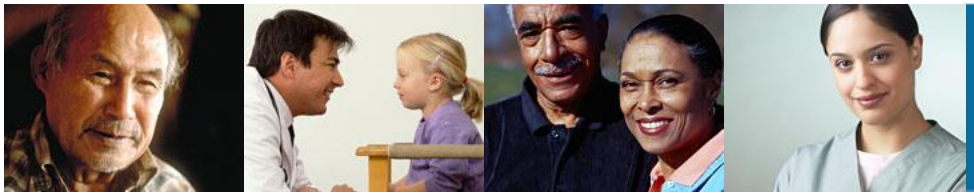
- Implement the GHS without loss of current protections;
- Harmonize the WHMIS requirements to the fullest extent possible with the U.S. Hazard Communication Standard 2012 (HCS 2012); and
- Update WHMIS regulations to include recommendations made by industry stakeholders (i.e., suppliers/importers/distributors and employers), organized labour stakeholders, and the FPT OSH regulatory agency partners.

While WHMIS 2015 includes new harmonized criteria for hazard classification and requirements for labels and SDS, roles and responsibilities for suppliers, employers and workers **have not been changed**.

WHMIS 2015

- Health Canada and U.S. OSHA continue to work collaboratively to keep the variances between the two countries to a minimum.
- Under WHMIS 2015, you must comply with the requirements under the HPR. It is not sufficient to only comply with the HCS.

Now possible under WHMIS 2015 to meet both Canadian and U.S. requirements using a single label and single SDS for each hazardous product.

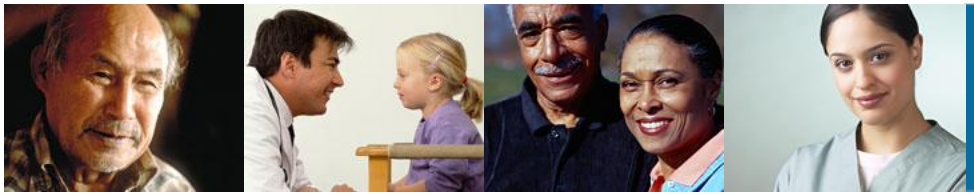


Some of the Key Canadian Requirements

Variances between the HPR and the U.S. HCS 2012 include:

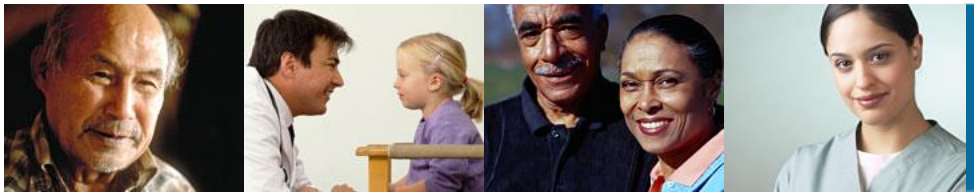
- Bilingual labels and SDSs
- Supplier Identifier
- Mixture containing a Category 2 carcinogen at a concentration between 0.1 - 1.0%
- Physical Hazards Not Otherwise Classified / Health Hazards Not Otherwise Classified vs. Hazards Not Otherwise Classified
- Biohazardous Infectious Materials
- Water-Activated Toxicants
- Updating of SDS and label information
- Labels on multi-container shipments
- Labels on kit outer containers

For additional information visit: http://www.hc-sc.gc.ca/ewh-semt/occup-travail/whmis-simdut/ghs-sgh/classification/hazardous-products-produits-dangereux/variances-ecarts-eng.php

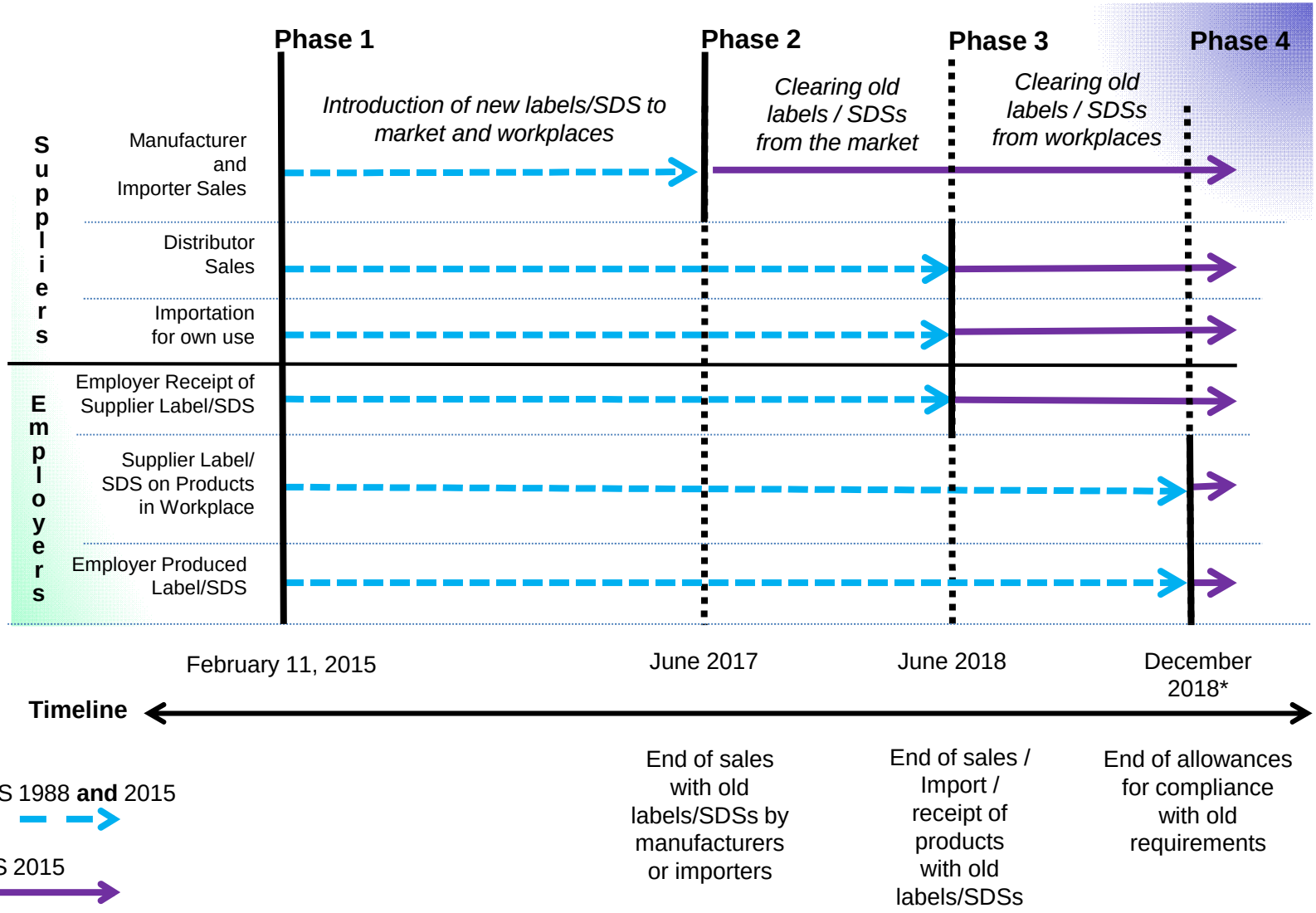


Purpose of Transition

- To allow suppliers, employers and workers time to adjust to WHMIS 2015, the implementation of the GHS will take place gradually, over a four-stage transition period.
- To move old labels and SDSs out of the supply chain and workplaces in a predictable and consistent manner across Canada.



Transition Approach to WHMIS 2015



***The final date for employers is dependant on Federal, Provincial and Territorial OSH legislation that have yet to be finalised.**

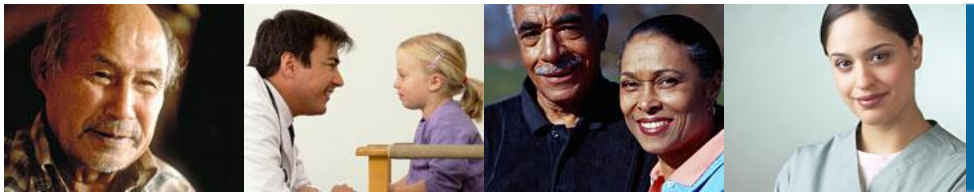
WHMIS Exclusions

WHMIS Exclusions

WHMIS covers hazardous materials in all Canadian workplaces with the following exceptions:

- **Explosive** as defined in section 2 of the *Explosives Act*
- **Cosmetic**, **device**, **drug** or **food** as defined in section 2 of the *Food and Drugs Act*
- **Pest control product** as defined in subsection 2(1) of the *Pest Control Products Act*
- **Nuclear substance**, within the meaning of the *Nuclear Safety and Control Act*, that is radioactive
- **Hazardous waste**, being a hazardous product that is sold for recycling or recovery or is intended for disposal
- **Consumer product** as defined in section 2 of the *Canada Consumer Product Safety Act*
- **Wood or product made of wood**
- **Tobacco or tobacco products** as defined in section 2 of *the Tobacco Act*
- **Manufactured articles** as defined in section 2 of the HPA

Consult appropriate OHS Regulator for requirements regarding worker training that may still be required in respect of a product type listed above.



WHMIS Exclusions: Consumer Products

"Consumer product" is defined in section 2 of the *Canada Consumer Product Safety Act* (CCPSA):

- means a product, including its components, parts or accessories, that may reasonably be expected to be obtained by an individual to be used for non-commercial purposes, including for domestic, recreational and sports purposes, and includes its packaging.

Consumer products are regulated by the CCPSA and its Regulations.

- For more information on consumer product requirements, please contact Consumer Product Safety Program at CPS-SPC@hc-sc.gc.ca.

For some hazardous products, application of the CCPSA and the HPA needs to be assessed on a case-by-case basis.

If you have questions regarding whether your product is a workplace or a consumer product, please contact Health Canada for guidance.

Guidance – What's New?

Technical Guidance

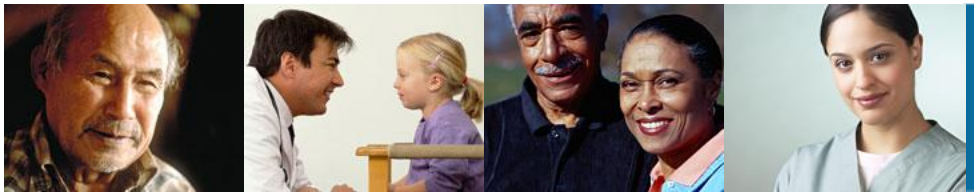
Technical guidance is a key component of the Canada-U.S. RCC Joint Forward Plan and is the main tool intended to communicate and facilitate Canada-U.S. alignment of the GHS for workplace chemicals, without reducing the level of safety or of protection to workers.

Intended as an “Evergreen” document with a phased release approach.

- Working with stakeholders to meet their needs.
- Informed by enquiries that Health Canada receives:
  - WHMIS exclusions
  - Bilingual labels and SDSs
  - Supplier identifier
  - Precautionary statements
- Reflecting future GHS revisions captured in the HPR.

Initial Phase
- SDSs
- Labels
- Exemptions
- Classification principles

Later Phases
- Physical hazard classes
- Health hazard classes



Guidance: Ingredient Disclosure

The purpose of the Guidance (developed in consultation with U.S. OSHA) is to provide suppliers with information on:

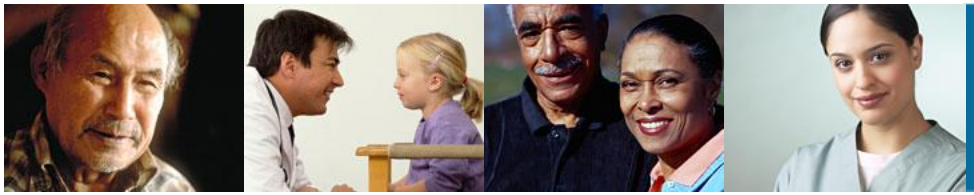
(1) WHMIS 2015 requirements related to ingredient disclosure;

(2) When and how to appropriately characterise a concentration range on SDSs; and

(3) The alignment with the U.S. on disclosure requirements.

In Summary

- Requirements in WHMIS 2015, related to ingredient disclosure, have been adjusted from WHMIS 1988 requirements.
- Canada and the U.S. are aligned with regard to ingredient concentration disclosure requirements, and these can be met with a single SDS.
- Confidential Business Information (CBI) related to concentrations of ingredients must be protected using the CBI protection mechanism prescribed by the *Hazardous Materials Information Review Act* (HMIRA).



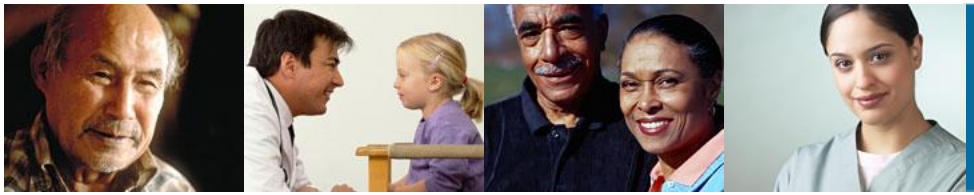
Guidance: Ingredient Disclosure

Disclosing a Concentration Range

When a range is disclosed, SDSs must be in compliance with requirements in the HPR:

1. The ingredient must be present in the mixture at a range of concentrations.
2. The range must accurately reflect the concentration variation.
3. The hazard classification must accurately reflect the hazards associated with the mixture. The hazard classification and the health and safety information provided on the SDS must be reflective of the highest degree of hazard that the mixture could present.
4. Maintaining documentation on the manufacturing process which demonstrates product composition variability is important to support the disclosure of any existing concentration range.

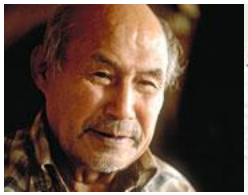
If the concentration range is a trade secret, then a CBI process must be followed.



Guidance: Ingredient Disclosure

Example

Example Ingredient Concentration		Regulatory System		
Chemical Name: Toluene; Volume %: 17%		**WHMIS 1988 (WHMIS before GHS)**	**WHMIS 2015 (GHS in Canada)**	**HCS 2012 (GHS in U.S.)**
Chemical Name: Acetone; Volume %: 32-41%				
Ingredient Concentration (No CBI)	**Concentration** (where concentration does not vary)	True Concentration Chemical Name: Toluene; Volume %: 17%	True Concentration Chemical Name: Toluene; Volume %: 17%	True Concentration Chemical Name: Toluene; Volume %: 17%
	Concentration Range (where concentration varies, e.g. batch-to-batch variability)	Standardized Concentration Range Chemical Name: Acetone; Volume %: 30-60%	True Concentration Range Chemical Name: Acetone; Volume %: 32-41%	True Concentration Range Chemical Name: Acetone; Volume %: 32-41%
Alignment of Canada / U.S. Requirements		Aligned	Not Aligned	Volume %: True Concentration / True Concentration Range Disclosed




Confidential Business Information (CBI) Mechanism in Canada

CBI: Requirements in Canada and the U.S.

The CBI protection mechanisms in Canada did not change with the GHS implementation.

In Canada

- CBI can be claimed for the name of an ingredient and/or either its concentration or concentration range.
- Industry must file a CBI claim with Health Canada.

Confidential Business Information

- If a supplier or employer does not want to disclose a trade secret on their SDS/label, they may file for a claim for disclosure exemption.

- Possible claims for exemption under the *Hazardous Materials Information Review Act* (HMIRA), and its Regulations:

Supplier or employer:

- The chemical name or concentration of an ingredient, substance or material
- The name of a toxicological study that identifies an ingredient, substance or material

Employer may also include:

- The chemical, common, generic, trade or brand name of the hazardous product, or
- Information that could be used to identify the supplier

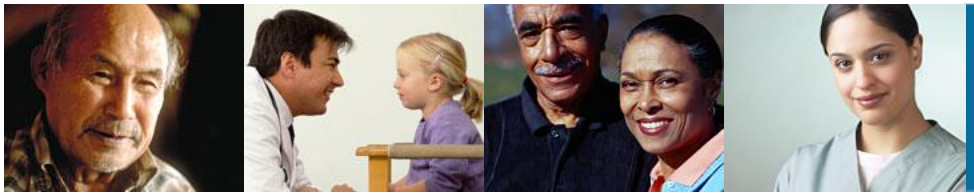
Process for CBI

Step (1) Supplier or employer (claimant) applies for an exemption and is issued a HMIRA Registry Number

Step (2) The claim is evaluated for validity and compliance

Step (3) Consultation with claimant may be initiated

Step (4) Health Canada issues a decision

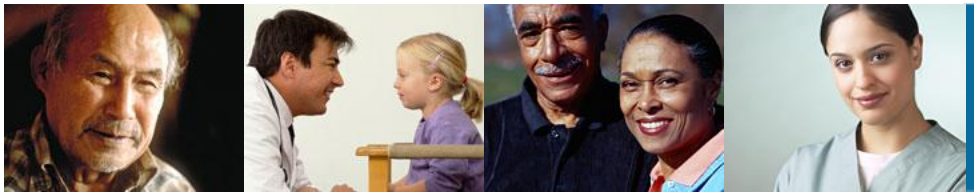


Step 1 of CBI Process

How the process works

1) Supplier or employer (claimant) must first apply for an exemption

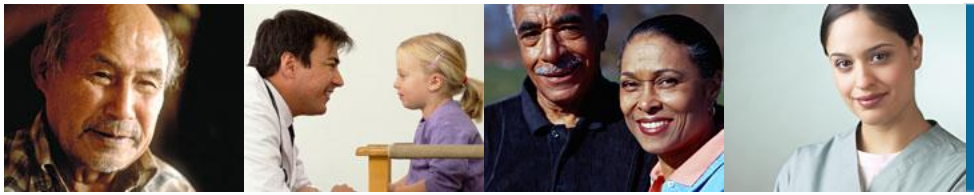
- Claimant must submit an application package containing:
  - i. Completed application forms
  - ii. Copy of (M)SDSs and/or label
  - iii. 100% composition of the product
  - iv. Payment information (*between $80 to $1800 per claim; fee depends on the number of claims filed, the type of claim and the size of the company*).
- If claimants have supporting information (e.g., toxicological studies) to be used for the review of the claim validity and/or the compliance of the (M)SDS and/or label, they must also submit it
- A HMIRA Registry Number (RN) is assigned to the product within 7 days of the receipt of a complete application package



A Complete Application Package

A complete application package is assessed at submission. Items addressed may include:

- Product name on (M)SDS matches product name on application form
- Generic chemical identities for confidential ingredients on (M)SDS match the names given on the application form
- No essential information on the application is missing (financial numbers given, payment information present)
- (M)SDS or application form is not missing pages
- Formulation (product composition) is complete (no missing chemical identities, no unaccounted for percent concentrations)



Step 1 of CBI Process

A Complete Application Package

- The Generic Chemical Identity must be provided in both English and French

PART VII – Confidential Business Information

Confidential Business Information (CBI) - to be completed for Supplier Claims

Use for claims where subject matter pertains to:

A. the chemical identity *and/or;*

B. the concentration of one or more ingredients in a hazardous product *and/or;*

C. name of toxicological study.

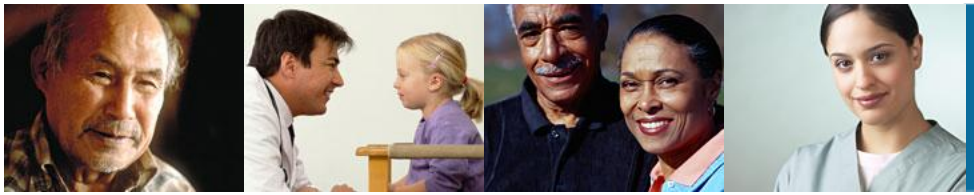
Each Product Identifier (PI) entered in Part III is repeated in this Section.

Please list **all** ingredients in the products, indicating the elements considered confidential business information in column 1, using the table below.

PI-1 **Previous Registry Number**

Indicate the CBI for each ingredient	**A.** Generic chemical identity (GCI) of the ingredient for which exemption is claimed (English and French)	Specific chemical identity of the ingredient (CBI)	CAS Registry number of the ingredient	**B.** Ingredient Concentration (%)	**C.** State the name of the toxicological study that identifies this ingredient, material, or substance
ID & Concentratic	Please enter the English GCI Please enter the French GCI				

Add another ingredient for PI-1 Concentration Total: 0%



Step 1 of CBI Process

A Complete Application Package

- Additionally, during transition, claimants must indicate which regulations they are aiming to comply with:
  - WHMIS 1988 (CPR), or
  - WHMIS 2015 (HPR-GHS)

PART III - Hazardous Product(s): Information

Each Product Identifier (PI) entered below is repeated as required in Parts IV and VII. Changes or deletions relative to PI entries can only be done in Part III.

To add another PI, just click the **Add Another Product** button at the bottom of this section. If you want to remove a particular PI, just click the **Delete** button on the right of it's entry.

You may come back to Part III at any time while you are completing the form.

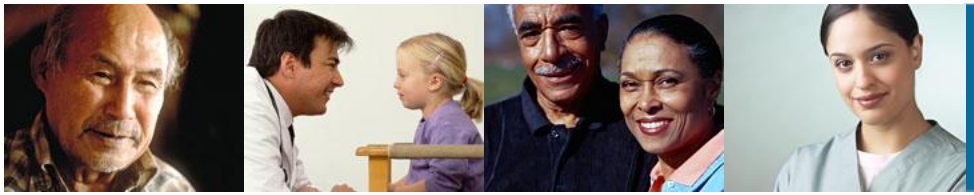
Product Identifier(s)	**Registry Number**	**Subject of Claim**
List a Product Identifier **for each hazardous product** included in the claim or claims for exemption.	Indicate the Registry Number previously assigned to each hazardous product listed (if re-filing)	Indicate the subject of each claim for exemption by entering the letter(s) that correspond to the subject of the claim, as listed in Part II

PI-1

- Complying with **WHMIS 2015** (HPR-GHS)
- Complying with **WHMIS 1988** (CPR)

New Claim: Please indicate the source of information used to prepare the Safety Data Sheet (SDS) for this product:

Add Another Product



Step 1 of CBI Process

- Once a HMIRA Registry Number (RN) has been issued, the claimant is able to sell the product without disclosing the CBI as long as the RN and the date of filing are disclosed on the SDS.
- This temporary market access extends until a decision on the claim is issued.

Product Composition

Substance	CAS Number	% (w/w)
Methanol	67-56-1	20%
Trichloroisocyanuric Acid	87-90-1	0.1%
Water	7732-18-5	79.9%

(M)SDS Section 3: Composition / Information on ingredients

Substance	CAS Number	% (w/w)
Alcohol *	Proprietary *	Proprietary (15-30%)*
Trichloroisocyanuric Acid	87-90-1	0.1%

* HMIRA RN: 3333 – Filing Date January 1, 2021

Disclosure of a replacement range is encouraged

Step 2 of CBI Process

2) The claim is evaluated for validity and compliance

a) Validity:

Is it truly a trade secret? (i.e., confidentiality, financial worth)

b) Compliance:

Is the (M)SDS / label compliant with the *Hazardous Product Act / Hazardous Product Regulations (Controlled Product Regulations)?*

- Complete review based on the product's formulation
- The Toxicology unit verifies classification(s)
- The Regulatory unit verifies compliance with legislative requirements

Step 3 of CBI Process

3) Consultation with claimant may be initiated

- If issues are found during the evaluation of claim validity and (M)SDS/label compliance, a Consultation Document (CD) outlining those findings may be sent to the claimant for their review and feedback.

- Health Canada takes into account any responses received from the claimant when preparing the final decisions on claim validity and (M)SDS/label compliance.

Step 4 of CBI Process

4) Health Canada issues a decision

… if non-compliances are found, the claimant is offered an undertaking to voluntarily comply. Failure to voluntarily comply leads to orders.

… if valid, the HMIRA Registry Number is granted and the date granted must be disclosed and replace the date of filing on the SDS.

(M)SDS Section 3: Composition / Information on ingredients

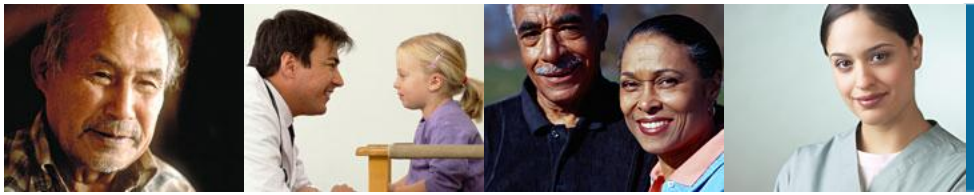
Substance	CAS Number	% (w/w)
Alcohol *	Proprietary *	Proprietary (15-30%)*
Trichloroisocyanuric Acid	87-90-1	0.1%

* HMIRA RN: 3333 – Date granted January 3, 2022

… if invalid, an order to comply with the disclosure requirement will be issued.

All decisions are published in the *Canada Gazette*.

! **A claim is valid for 3yrs. One may re-apply if the trade secret remains valid after 3yrs.**

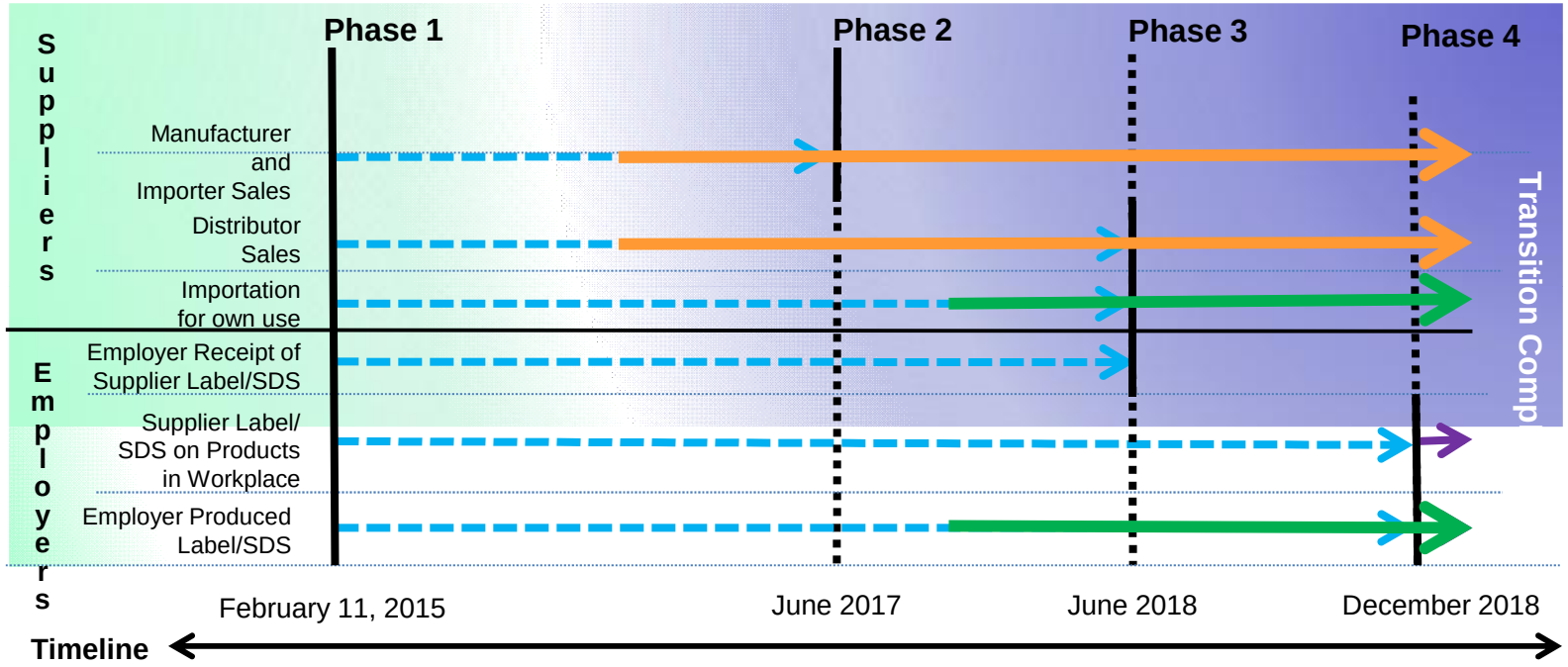


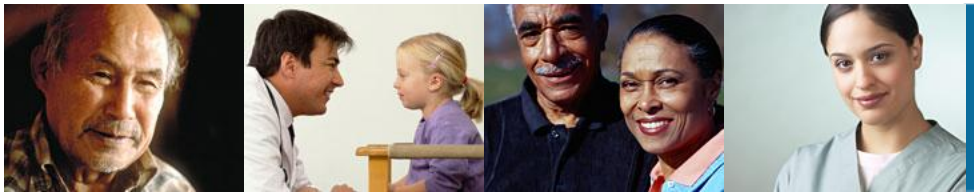
Transition for CBI Claims for Exemption

Supplier claims: WHMIS 2015 (GHS) SDS for all claims submitted as of **June 2016**.

Employer claims: WHMIS 2015 (GHS) SDS for all claims submitted as of **December 2017**.

Before then, claims for exemption will be assessed under the system under which the (M)SDS is submitted.





Compliance and Enforcement

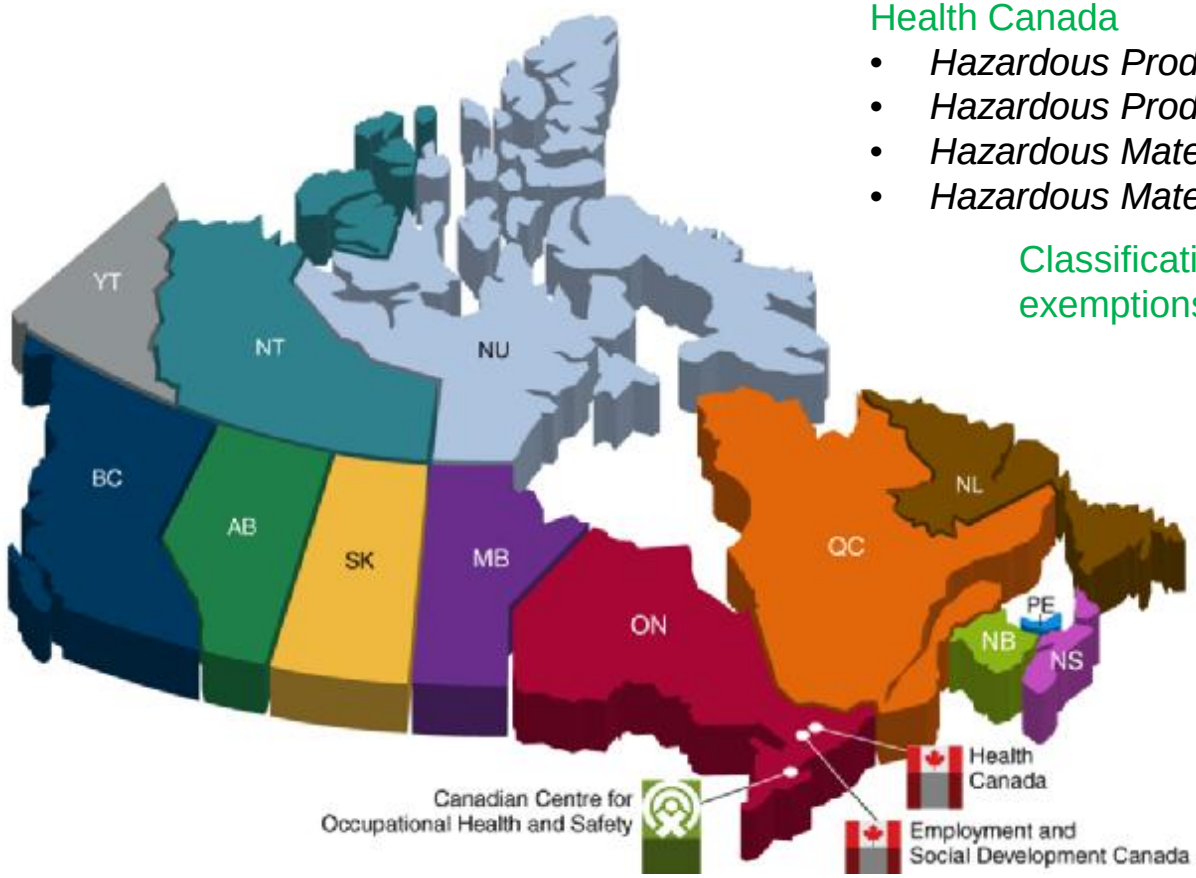
Compliance and Enforcement

Suppliers:

Health Canada

- *Hazardous Products Act*
- *Hazardous Products Regulations*
- *Hazardous Materials Information Review Act*
- *Hazardous Materials Information Review Regulations*

Classification criteria; labelling; SDS; trade secret exemptions

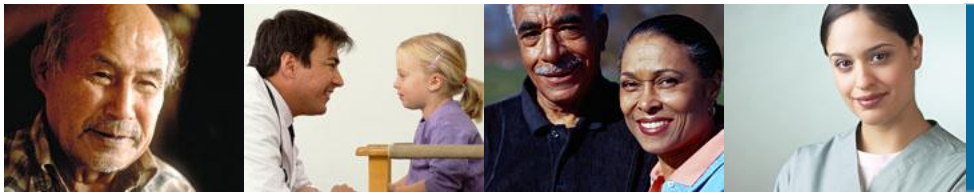


Employers:

12 Provincial / Territorial OSH agencies
1 Federal OSH agency

- Provincial legislation
- Canada Labour Code

Workplace labelling;
worker accessibility to SDSs;
worker education and training programs



Compliance and Enforcement

Guiding Principles

- Primacy of occupational health and safety
- Fairness, equity and consistency
- Transparency and Accountability
- Collaboration and harmonisation
- Risk-based approach

Compliance and Enforcement

WHMIS 2015 is a new system:

- Communication and education are key and will be standard approach in the beginning.
- Health Canada will react to issues of non-compliances, and seek voluntary compliance in most cases.
- During transition, when both WHMIS 1988 and WHMIS 2015 are acceptable, enforcement actions are only possible under WHMIS 2015.

! i.e., in the case of a non-compliance with WHMIS 1988, where voluntary compliance is not achieved, the supplier/employer would be required to comply with WHMIS 2015

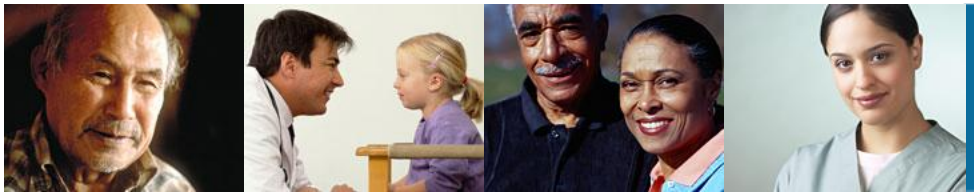
Resources

Resources

A priority for Heath Canada is to provide useful, broadly-accessible information and guidance on WHMIS and the HPR (GHS).

Health Canada's approach to guidance will be founded on effective communication with WHMIS stakeholders by:

- Enhancing awareness and promoting compliance with the new regulatory requirements (the HPR)
- Raising awareness of stakeholder roles and responsibilities
- Identifying key milestones during transition
- Bringing stakeholders together to preserve national consistency



Resources

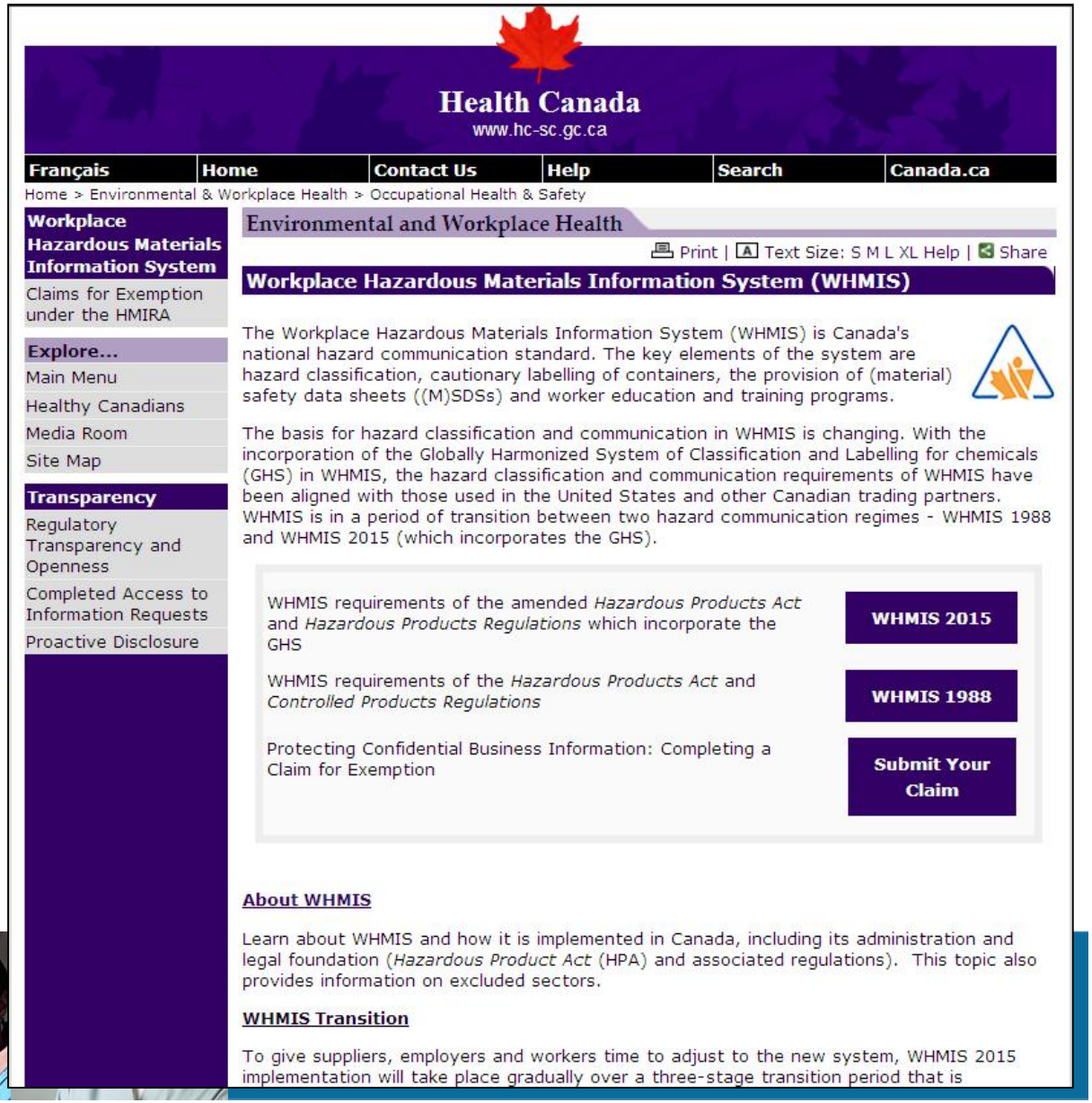
Health Canada Website (WHMIS.gc.ca)

Basic information on:

- SDSs
- Labels
- Exemptions
- Transition
- Canada/U.S. variances

Detailed information on:

- WHMIS 1998
- WHMIS 2015 (GHS)
- CBI (Trade secret) claims for exemption



Resources

WHMIS.org and SIMDUT.org (French)

A central repository with information on:

- New and existing WHMIS requirements in each jurisdictions

Resources: Examples of Educational Products

E-courses

WHMIS After GHS: An Introduction ***FREE!***

Get ready for WHMIS after GHS.

Language: English/French
Format: e-Course

VIEW COURSE
(opens in a new window)

WHMIS 2015 for Workers

Learn about the new WHMIS hazard classes and pictograms, the labels on products, and safety data sheets in this introductory course.

Language: English/French
Format: e-Course
Single-seat: **$10*** CAD

BUY ONLINE

***Save up to 80%** with Multi-seat Licenses.

Fact Sheets

- Chemicals & Materials: GHS
- WHMIS (after GHS) Education and Training
- WHMIS (after GHS) Pictograms
- WHMIS (after GHS) Hazard Classes and Categories

Webinars

WHMIS 2015 – How Canada is Adopting the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) for Workplace Chemicals ***FREE!***

Presenter: Health Canada
Availability: On demand – Watch it now
Price: Free

REGISTER

GHS Classification of Mixtures: An Introduction ***FREE!***

Presenter: CCOHS
Availability: On demand – Watch it now

REGISTER

How to Write a GHS Label ***FREE!***

Presenter: CCOHS
Availability: On demand – Watch it now

REGISTER

WHMIS After GHS For Employers ***FREE!***

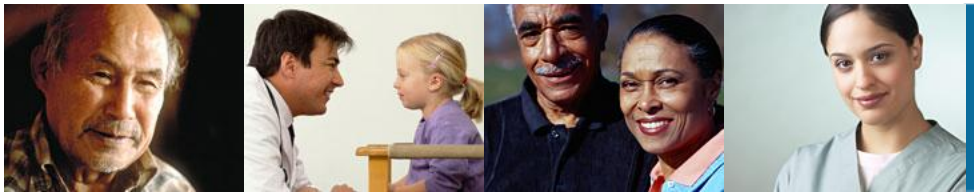
Presenter: Sandy Bello, Technical Specialist, CCOHS
Availability: On demand - watch it now

REGISTER

http://www.ccohs.ca/resources

Resources: Future Awareness Pieces

- General information webinars coinciding with key milestones in program transition.
- FAQs and compliance promotion materials as the need arises. For example, Health Canada receives questions on the following requirements:
  - WHMIS exclusions
  - Bilingual labels and SDSs
  - Supplier identifier
  - Precautionary statements
  - Ingredient disclosure
- Canada-U.S. fact sheets under RCC workplan



Next Steps

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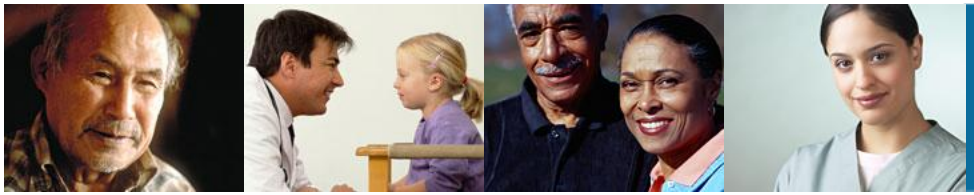
- Consequential amendments of FPT OSH legislation and regulations.
- Health Canada is developing guidance for all stakeholders and is supporting the development of worker training materials.
- Health Canada will follow trends of non-compliance and develop Compliance Promotion Material as needed.
- Continue to work with U.S. OSHA to harmonize both systems to the extent possible.



Contact Information

Website:

- **WHMIS.gc.ca**

General enquiry:

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