Health Canada Santé Canada

Canada

GHS in Canada

Kim Godard
Véronique Lalonde

Presentation to the Society of Chemical Hazard Communication (SCHC)

September 24, 2019

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Presentation Outline

- WHMIS in Canada
- Updates to the Technical Guidance
- Regulatory Initiatives
- Claims for Exemption for Confidential Business Information
- Hazardous Substance Assessments
- Compliance and Enforcement
- Resources

WHMIS IN CANADA

WHMIS in Canada

- In Canada, workplace health and safety is under the jurisdiction of Federal, Provincial and Territorial governments.

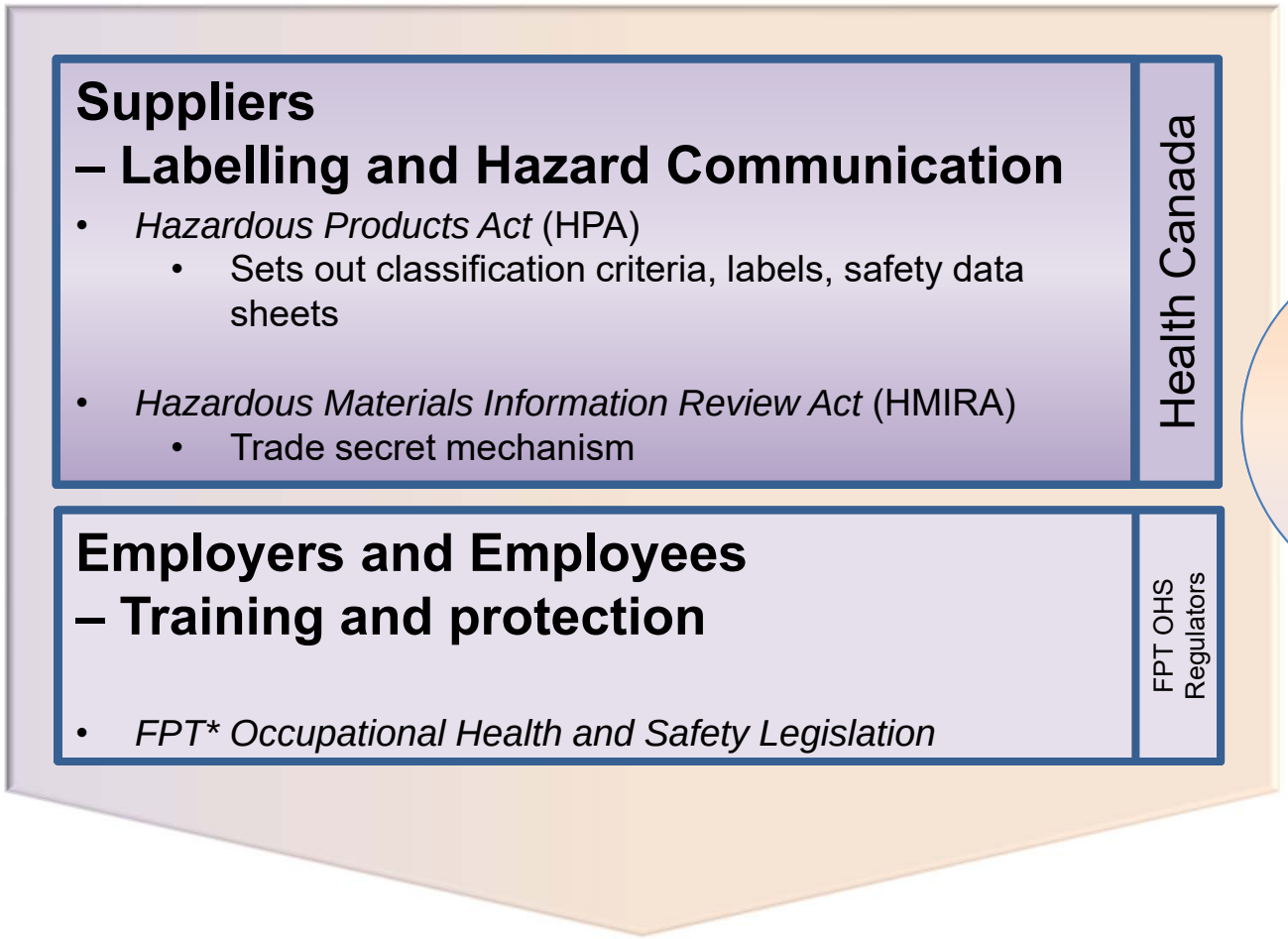
- The Workplace Hazardous Materials Information System (WHMIS) is the national system for classifying workplace chemicals and communicating hazard information to employers and workers.

- Key elements include:
  - ✓ Classification criteria
  - ✓ Labelling
  - ✓ Safety Data Sheets (SDSs)
  - ✓ Worker Education and Training Programs

WHMIS2015
IMPLEMENTATION OF GHS IN CANADA

WHMIS in Canada

- WHMIS is a comprehensive system for **providing information on the safe use** of hazardous products in Canadian workplaces.



* Federal workplaces, Provincial and Territorial

UPDATES TO THE TECHNICAL GUIDANCE

Technical Guidance Updates

1. Prescribed Concentration Ranges

- Updated to reflect the April 2018 amendments to the *Hazardous Products Regulations* (HPR).

- These amendments permit the use of prescribed concentration ranges for hazardous ingredients on safety data sheets if the actual concentration or actual concentration range of these ingredients are withheld as trade secrets.

- The technical guidance was amended to provide updated guidance on:
  - how the prescribed concentration ranges can be used
  - the use of a statement that the concentration is being withheld as a trade secret
  - the circumstances under which prescribed concentration ranges can be combined
  - comparison of ingredient concentration disclosure and Confidential Business Information (CBI) protection requirements

- A Guidance on the Use of Concentration Ranges Pursuant to the HPR is available on the Government of Canada's website.

Technical Guidance Updates

2. Substances Evaluated by IARC and NTP

- Updated to provide clarification regarding the classification of substances that have been evaluated by the International Agency for Research on Cancer (IARC) and the National Toxicology Program (NTP) with regards to carcinogenicity.

- Errata, clarification and amendments to the technical guidance are published on the Government of Canada's website.

Errata, Clarification and Amendments -Technical Guidance on the Requirements of the Hazardous Products Act (HPA) and the Hazardous Products Regulations (HPR) - WHMIS 2015 Supplier Requirements

July 2019

The following errata, clarification and amendments are being published to correct errors, provide clarification, or address amendments to the Hazardous Products Regulations, in the Technical Guidance document.

1. Amendment to the Hazardous Products Regulations to permit prescribed concentration ranges

An amendment to the Hazardous Products Regulations came into force on April 4, 2018, permitting the use of prescribed concentration ranges for hazardous ingredients on safety data sheets if the actual concentration or actual concentration range of these ingredients are withheld as a trade secret. Pursuant to this amendment, certain subparts under "Part 4 Safety Data Sheet" of the Technical Guidance are no longer up-to-date.

Before amendment

A discussion of the former section 4.5 of the Hazardous Products Regulations is found on page 134, with further guidance in Appendix 3 - Guidance on the Disclosure of Ingredient Concentrations and Concentration Ranges on Safety Data Sheets on pages 148 to 154 and Appendix 4 - Comparison of Ingredient Concentration Disclosure and CBI Protection Requirements on page 155.

Page 88 reads "Further information with regard to concentration ranges can be found in Appendix 3 of Part 4 of the Technical Guidance."

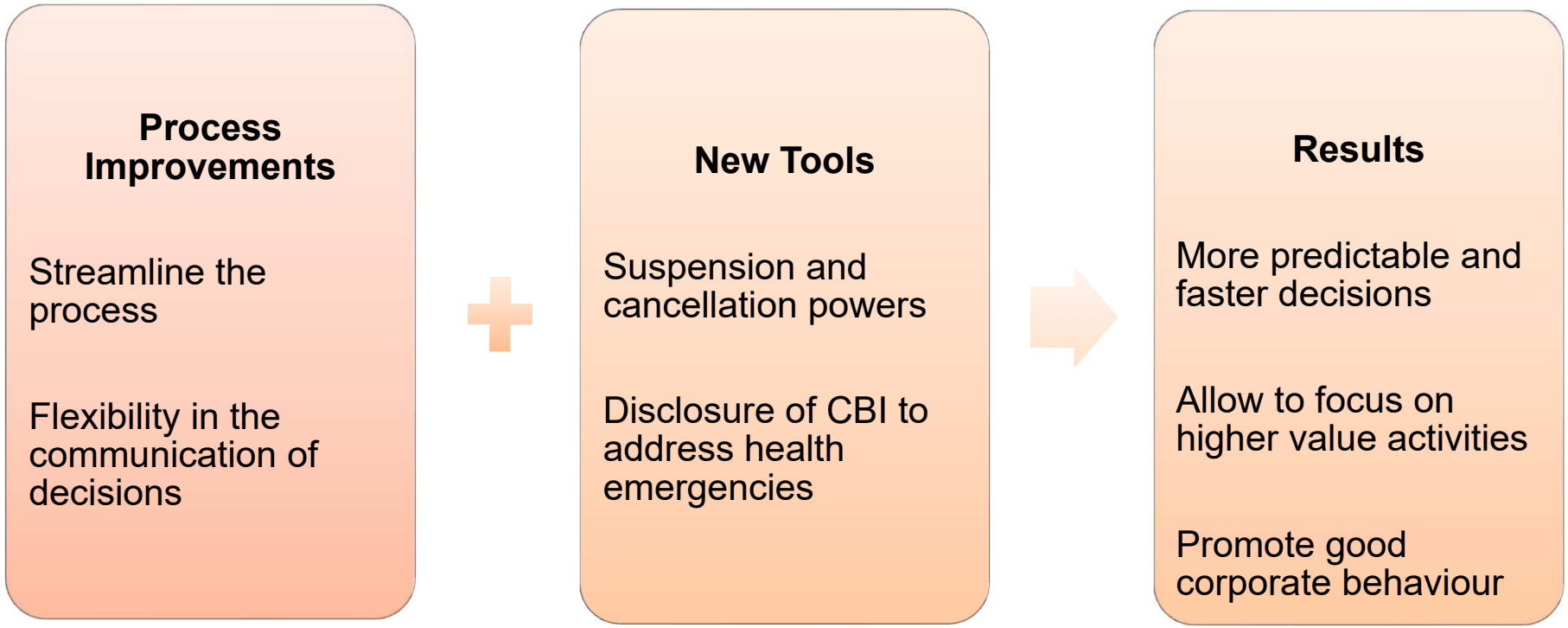
REGULATORY INITIATIVES

Amendments to the HPR to align with GHS Rev.7

- Health Canada's HPR is currently aligned with Rev. 5 of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).
- Health Canada is continuing to work towards updating the regulations to align with Rev. 7 of the GHS, which was published in 2017.
- Health Canada is also proposing other amendments to address clerical/minor issues identified by the Department and by stakeholders:
  - clarification of existing provisions in the HPR
  - amendments to existing provisions
  - corrections
- To inform the regulatory proposal, a questionnaire was sent out to stakeholder associations to distribute to their members.
- The responses received are informing the regulatory proposal.

Modernization of the HMIRA

Bill C-97, which received Royal Assent on June 21, 2019, contains proposed amendments to the HMIRA.



Area of focus 1:
Modernize various elements of the Act

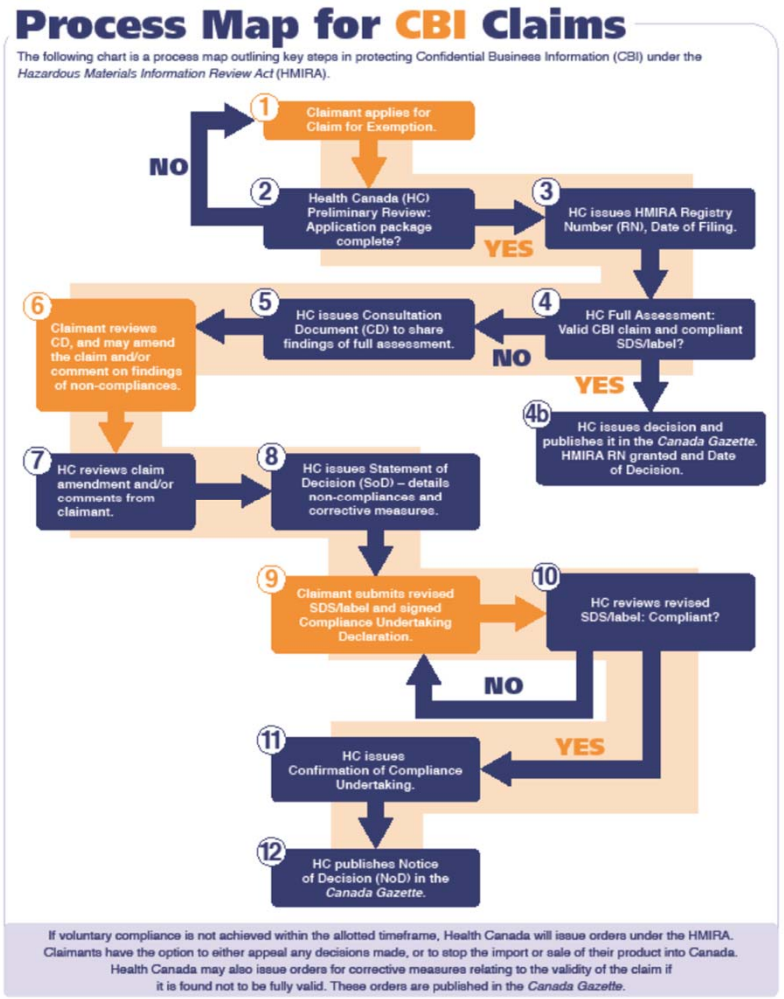
Modernized Elements:
Modernizing the publication of information on claims for exemption (i.e., removing the requirements to use the Canada Gazette as a vehicle to communicate).
Repealing the requirement to use registered mail.
Adding the authority to establish regulations to remit fees, in part or in full.
Repealing the appeals process and the appeals board.
Re-assigning the responsibilities, duties and authorities to the screening officer and Chief Screening Officer to the Minister of Health.
Removing the guarantor requirement.
Allowing the Minister to suspend or annul an exemption under certain conditions.

Area of focus 2:
Information Sharing – Disclosure of CBI

Allowing the disclosure of CBI under specific and stringent conditions:
To address a serious and imminent danger to human health or safety or the environment.
For the purpose of carrying out the protection of human health or safety or the environment from significant risk.
For the purpose of making a medical diagnosis of, or rendering medical treatment to, a person in an emergency (already permitted under the current requirements).
Adding requirements for the Minister to notify the claimant to which the CBI relates when information CBI has been or will be disclosed.

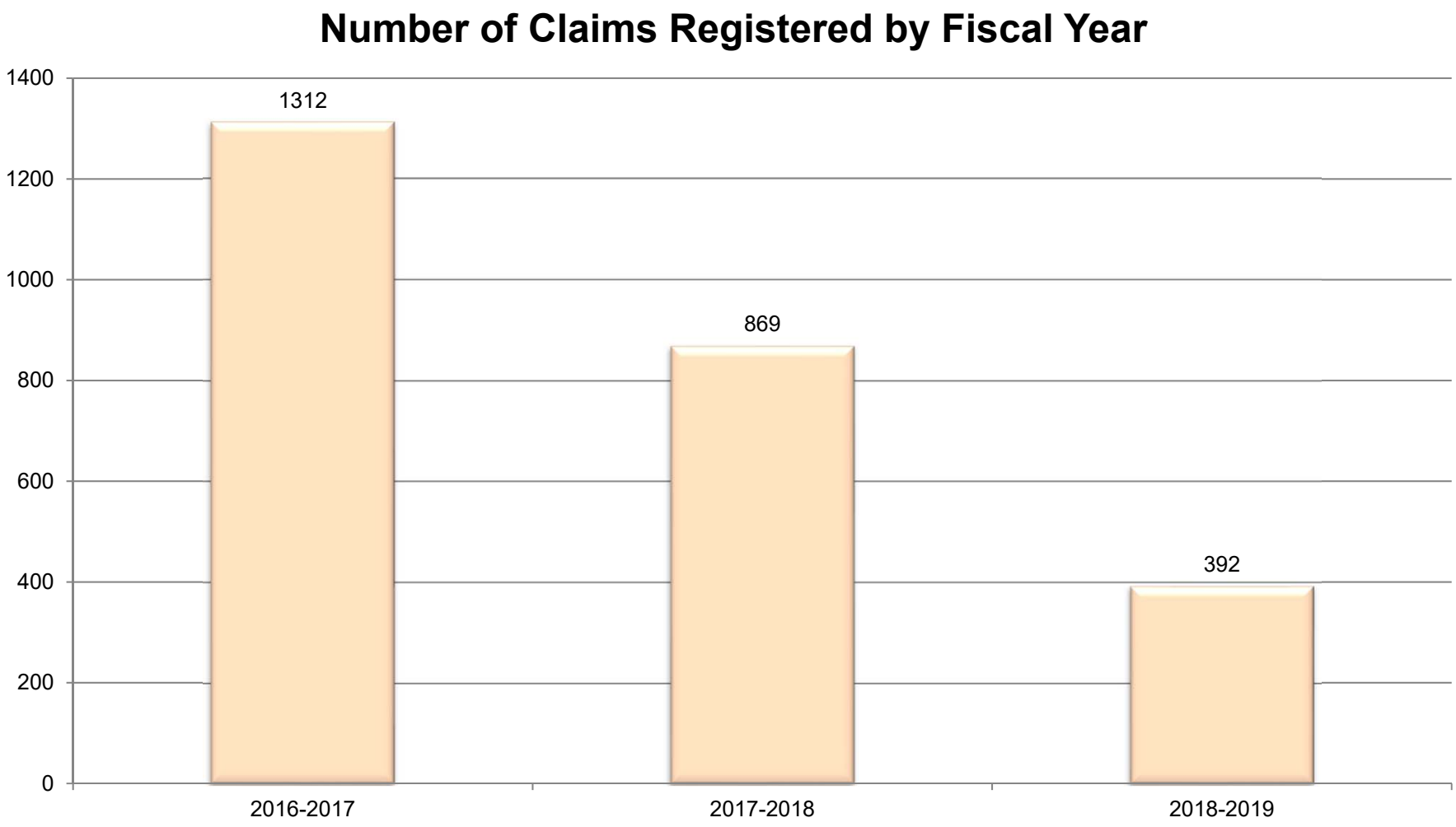
CLAIMS FOR EXEMPTION FOR CONFIDENTIAL BUSINESS INFORMATION

The CBI Protection Process Map



http://whmis.org/documents/CBI_Process_Map_EN.PDF

Statistics – Registration of Claims



HAZARDOUS SUBSTANCE ASSESSMENTS

Hazardous Substance Assessments (HSAs)

- Technical documents that describe the classification of chemicals in the hazard categories outlined in the HPA:
  - 12 Health Hazards
  - 20 Physical Hazards

- Fully cited descriptions of the available data that supports the classification.

<u>HSAs DO:</u>

- provide transparency as to how Health Canada classifies chemicals under the HPA
- serve as an information source that can be used by suppliers or employers to classify their own products
- help to inform Health Canada inspection reviews

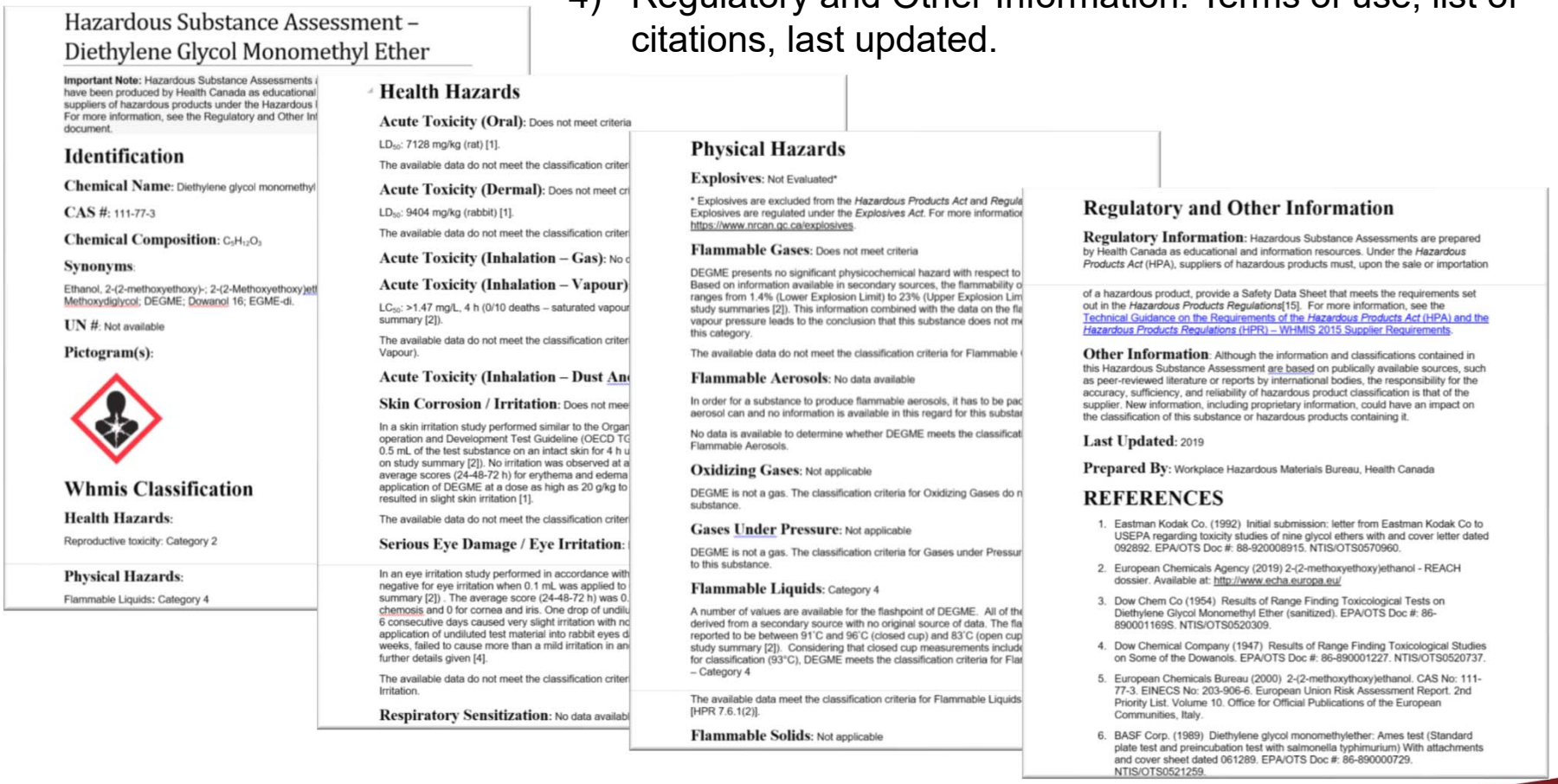
<u>HSAs do NOT:</u>

- represent a “classification decision” for a specific product
- preclude Health Canada’s use of more recent data or available proprietary information provided by the supplier when undertaking an inspection review
- replace or remove the supplier’s responsibility for classifying their products correctly

- HC plans to establish a growing online repository of HSAs, beginning this year.

HSA Breakdown

1) Identification: Chemical overview, identifiers, classification summary.
2) Health Hazards: Full characterization of health hazards.
3) Physical Hazards: Full characterization of physical hazards.
4) Regulatory and Other Information: Terms of use, list of citations, last updated.



Hazardous Substance Assessment – Diethylene Glycol Monomethyl Ether

Important Note: Hazardous Substance Assessments have been produced by Health Canada as educational suppliers of hazardous products under the Hazardous For more information, see the Regulatory and Other In document.

Identification

Chemical Name: Diethylene glycol monomethyl

CAS #: 111-77-3

Chemical Composition: $C_5H_{12}O_3$

Synonyms:

Ethanol, 2-(2-methoxyethoxy)-; 2-(2-Methoxyethoxy)ett Methoxydiglycol; DEGME; Dowanol 16; EGME-di.

UN #: Not available

Pictogram(s):

Whmis Classification

Health Hazards:

Reproductive toxicity: Category 2

Physical Hazards:

Flammable Liquids: Category 4

Health Hazards

Acute Toxicity (Oral): Does not meet criteria

LD_{50}: 7128 mg/kg (rat) [1].

The available data do not meet the classification criter

Acute Toxicity (Dermal): Does not meet cr

LD_{50}: 9404 mg/kg (rabbit) [1].

The available data do not meet the classification criter

Acute Toxicity (Inhalation – Gas): No c

Acute Toxicity (Inhalation – Vapour)

LC_{50}: >1.47 mg/L, 4 h (0/10 deaths – saturated vapour summary [2]).

The available data do not meet the classification criter Vapour).

Acute Toxicity (Inhalation – Dust An

Skin Corrosion / Irritation: Does not mee

In a skin irritation study performed similar to the Organ operation and Development Test Guideline (OECD TG 0.5 mL of the test substance on an intact skin for 4 h u on study summary [2]). No irritation was observed at a average scores (24-48-72 h) for erythema and edema application of DEGME at a dose as high as 20 g/kg to resulted in slight skin irritation [1].

The available data do not meet the classification criter

Serious Eye Damage / Eye Irritation:

In an eye irritation study performed in accordance with negative for eye irritation when 0.1 mL was applied to summary [2]) . The average score (24-48-72 h) was 0. chemosis and 0 for cornea and iris. One drop of undilu 6 consecutive days caused very slight irritation with nc application of undiluted test material into rabbit eyes d weeks, failed to cause more than a mild irritation in an further details given [4].

The available data do not meet the classification criter Irritation.

Respiratory Sensitization: No data availabl

Physical Hazards

Explosives: Not Evaluated*

* Explosives are excluded from the *Hazardous Products Act* and *Regula* Explosives are regulated under the *Explosives Act*. For more informatio https://www.nrcan.gc.ca/explosives.

Flammable Gases: Does not meet criteria

DEGME presents no significant physicochemical hazard with respect to Based on information available in secondary sources, the flammability o ranges from 1.4% (Lower Explosion Limit) to 23% (Upper Explosion Lim study summaries [2]). This information combined with the data on the fla vapour pressure leads to the conclusion that this substance does not m this category.

The available data do not meet the classification criteria for Flammable

Flammable Aerosols: No data available

In order for a substance to produce flammable aerosols, it has to be pac aerosol can and no information is available in this regard for this substar

No data is available to determine whether DEGME meets the classificat Flammable Aerosols.

Oxidizing Gases: Not applicable

DEGME is not a gas. The classification criteria for Oxidizing Gases do n substance.

Gases Under Pressure: Not applicable

DEGME is not a gas. The classification criteria for Gases under Pressur to this substance.

Flammable Liquids: Category 4

A number of values are available for the flashpoint of DEGME. All of the derived from a secondary source with no original source of data. The fla reported to be between 91˚C and 96˚C (closed cup) and 83˚C (open cup study summary [2]). Considering that closed cup measurements include for classification (93°C), DEGME meets the classification criteria for Flar – Category 4

The available data meet the classification criteria for Flammable Liquids [HPR 7.6.1(2)].

Flammable Solids: Not applicable

Regulatory and Other Information

Regulatory Information: Hazardous Substance Assessments are prepared by Health Canada as educational and information resources. Under the *Hazardous Products Act* (HPA), suppliers of hazardous products must, upon the sale or importation

of a hazardous product, provide a Safety Data Sheet that meets the requirements set out in the *Hazardous Products Regulations*[15]. For more information, see the Technical Guidance on the Requirements of the *Hazardous Products Act* (HPA) and the *Hazardous Products Regulations* (HPR) – WHMIS 2015 Supplier Requirements.

Other Information: Although the information and classifications contained in this Hazardous Substance Assessment are based on publically available sources, such as peer-reviewed literature or reports by international bodies, the responsibility for the accuracy, sufficiency, and reliability of hazardous product classification is that of the supplier. New information, including proprietary information, could have an impact on the classification of this substance or hazardous products containing it.

Last Updated: 2019

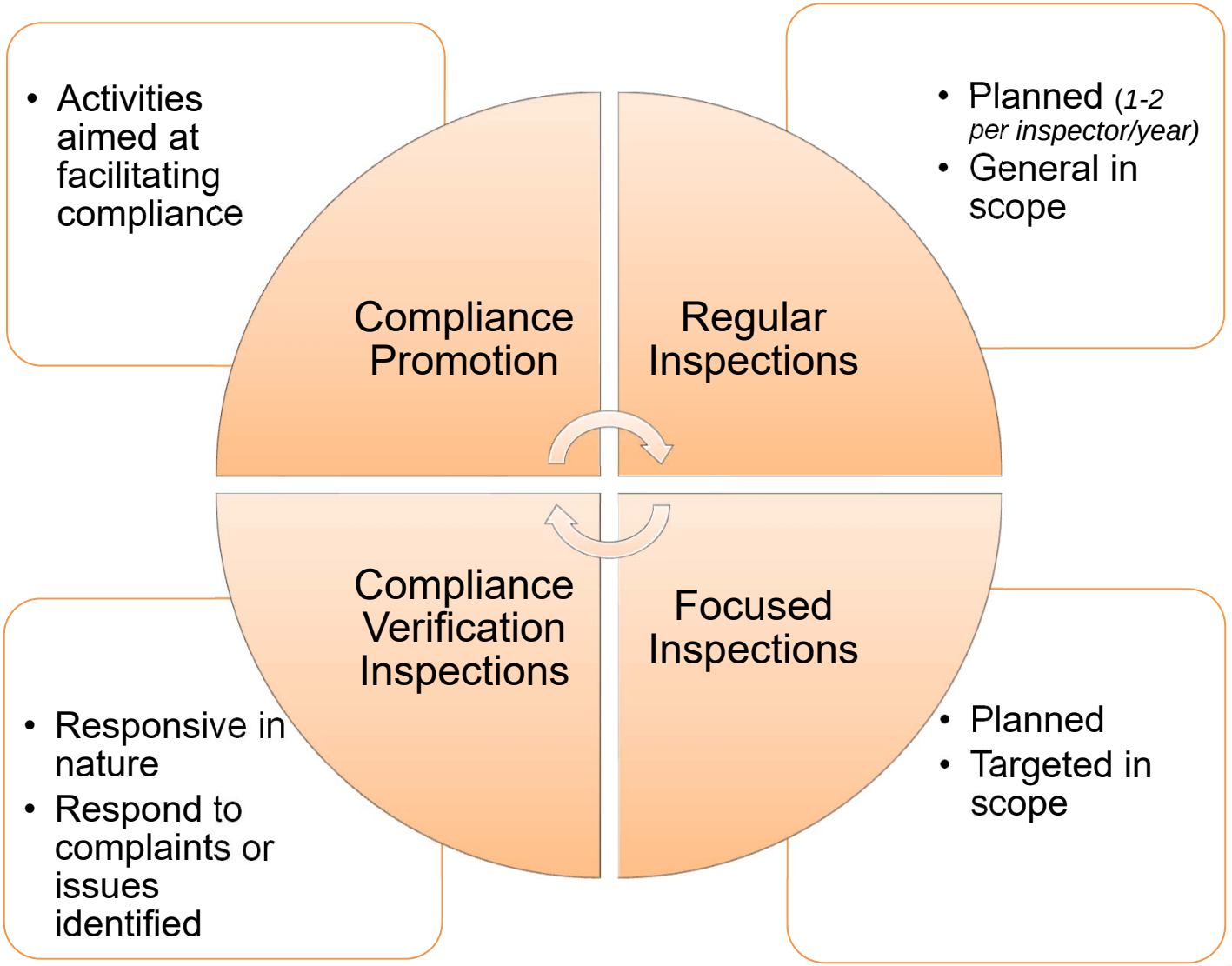
Prepared By: Workplace Hazardous Materials Bureau, Health Canada

REFERENCES

1. Eastman Kodak Co. (1992) Initial submission: letter from Eastman Kodak Co to USEPA regarding toxicity studies of nine glycol ethers with and cover letter dated 092892. EPA/OTS Doc #: 88-920008915. NTIS/OTS0570960.
2. European Chemicals Agency (2019) 2-(2-methoxyethoxy)ethanol - REACH dossier. Available at: http://www.echa.europa.eu/
3. Dow Chem Co (1954) Results of Range Finding Toxicological Tests on Diethylene Glycol Monomethyl Ether (sanitized). EPA/OTS Doc #: 86-8900011695. NTIS/OTS0520309.
4. Dow Chemical Company (1947) Results of Range Finding Toxicological Studies on Some of the Dowanols. EPA/OTS Doc #: 86-890001227. NTIS/OTS0520737.
5. European Chemicals Bureau (2000) 2-(2-methoxythoxy)ethanol. CAS No: 111-77-3. EINECS No: 203-906-6. European Union Risk Assessment Report. 2nd Priority List. Volume 10. Office for Official Publications of the European Communities, Italy.
6. BASF Corp. (1989) Diethylene glycol monomethylether: Ames test (Standard plate test and preincubation test with salmonella typhimurium) With attachments and cover sheet dated 061289. EPA/OTS Doc #: 86-890000729. NTIS/OTS0521259.

COMPLIANCE AND ENFORCEMENT

GHS Compliance Activities



SDS Compliance Promotion

- In FY 2017-18, Health Canada conducted an audit of SDSs to verify compliance with the HPA and the HPR.
  - As presented last year, the audit identified non-compliances within 100% of the SDSs

- Common areas of non-compliance were also observed as part of the regular inspections.

- As a result of the SDS audit and inspection results, Health Canada is developing compliance promotion material.

- The compliance promotion material includes information on common non-compliances, and general tips that provide guidance on best practices and the legislative/regulatory requirements.

- Health Canada is developing the content in collaboration with key stakeholders from industry and organized labour, as well as provincial/territorial representatives.

- The goal is to improve compliance of SDSs through educating on the common non-compliances. Content will be made available online and for print distribution.

RESOURCES

Resources

- **Technical Guidance on the Requirements of the Hazardous Products Act and the Hazardous Products Regulations**
  http://publications.gc.ca/collections/collection_2017/sc-hc/H129-64-1-2016-eng.pdf

- **CBI Process Map**
  http://whmis.org/documents/CBI_Process_Map_EN.PDF

- **Claimants can submit claim inquiries related to CBI Protection process to:**
  hc.whmis.claim-demande.simdut.sc@canada.ca

- **Guidance on the Use of Concentration Ranges Pursuant to the HPR:**
  https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/occupational-health-safety/guidance-hazardous-products-whmis-2015-supplier-requirements/update.html

- **Guidance on Document Retention Requirements for Suppliers of Hazardous Products**
  https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/occupational-health-safety/document-rentention-requirements-suppliers-hazardous-products.html

- **Guidance on Preparing and Maintaining a True Copy of a Label:**
  https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/occupational-health-safety/preparing-maintaining-true-copy-label.html