

# Exemptions/Waivers/Special Category Substances

Consultation on the Development of Environmental  
Assessment Regulations

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Health  
Canada

Santé  
Canada

# Overview

- Notification
- Exemptions
- Waivers
- Special Category Substances

# Notification

- Notification is required prior to import or manufacture for all substances that are not listed on the Domestic Substances List (DSL).
- Notification is not required for substances that are exempt from the notification requirements.

# Exemptions

- Under the Canadian Environmental Protection Act 1999 (CEPA 1999), the following substances are exempt from notification:
  - Other Acts of Parliament
  - Transient Reaction Intermediates
  - Impurities
  - Incidental Reaction Products
  - Low-Volume Exemptions
- Health Canada and Environment Canada will examine the need to apply the regulations to:
  - Naturally occurring substances
  - Substances in transit through Canada



# Waivers

- CEPA 1999 allows the Ministers to waive any of the requirements for prescribed information if:
  - In the opinion of the Ministers, the information is not needed in order to determine whether the substance is toxic or capable of becoming toxic;
  - The substance is to be used for a prescribed purpose or manufactured at a location where, in the opinion of the Ministers, the person requesting the waiver is able to contain the substance so as to satisfactorily protect the environment or human health; or
  - It is not, in the opinion of the Ministers, practicable or feasible to obtain the test data necessary to generate the information.



# Special Category Substance

- The New Substance Notification Regulations (NSNR) has Special Category provisions for:
  - A research and development substance
  - A contained site-limited intermediate substance
  - A contained export only substance
- Special Category Substances are substances for which reduced notification requirements are applied
- Health Canada and Environment Canada will examine the need for Special Category provisions for:
  - A substance used in an emergency treatment
  - A substance used in a clinical trial
  - A substance used in new veterinary drugs for experimental studies



# Questions

