Environment Canada Environnement Canada

Canada

# Review of the New Substances Notification Regulations (Organisms) – an Update

**CCAC National Workshop 2010**
**Crowne Plaza Hotel, Ottawa, ON**
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**Science and Technology Branch**
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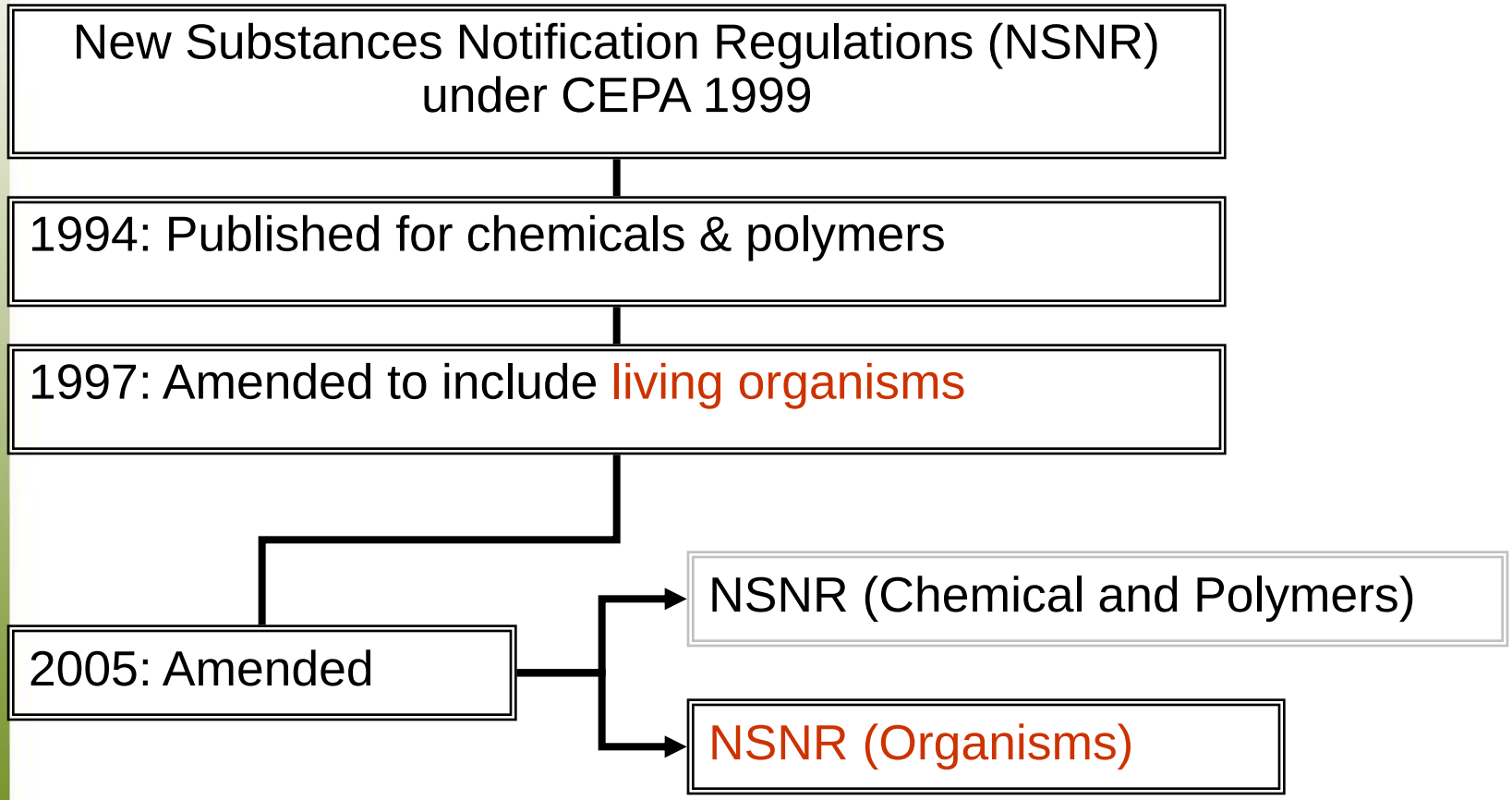
# Outline

- Legal Framework
- Rationale for amendment
- Proposal
- Next Steps

# New Substances Notification Regulations



# NSNR (Organisms)

**Prescribes**

- Information and administrative requirements for the manufacture or importation of **"living organisms"** not listed on the DSL
- Notification and Assessment timeframes
- Conditions and circumstances for exempting certain living organisms from the notification requirement

**Living Organisms:**

-Micro-organisms; and

-Organisms other than micro-organisms

**Authority:**

Shared between Health Canada and Environment Canada (unique federal arrangement)

**Guidance document:**

Guidelines for Notification and Testing of New Substances: Organisms

# Current Schedules

| Schedule | Type of Organism | Description | Assessment Period (days) |
|---|---|---|---|
| **1** | Micro-organism | Introduction anywhere in Canada | 120 |
| **2** | Micro-organism | Contained facility OR export only | 30 |
| **3** | Micro-organism | Experimental field trials | 90 |
| **4** | Micro-organism | Introduction at the same site where isolated and manufactured | 30 |
| **5** | Other than micro-organism | All | 120 |

# Why Review the NSNR (Organisms)?

- New developments, rapid evolution of science
- Public concerns over rapid development of biotechnology; regulations have not kept pace
- Current all-or-nothing approach for higher organisms is inefficient and inadequate.
- Coherence and alignment with other government policies/initiatives
- Accidental releases of transgenic animal carcasses from R&D facilities (i.e. are there sufficient ‘checks and balances’ in the system)

# Current vs Proposed

- Current
  - All R&D, irrespective of risk, exempted IF contained
  - 1 Notification Schedule
- Proposed
  - To be exempted, R&D in containment limited to “Low-Risk”
  - Requirement for Adequate Containment
  - Minimal Reporting of R&D activities
  - Tiered Notification Scheme

# On-going Consultations

- 1st Multi-Stakeholder Consultation – June 2006
- 2nd Multi-Stakeholder Consultation – December 2007
- Science Expert Group Meeting – December 2009
- On-going bi-lateral discussions with various stakeholders including the CCAC and ABSA Canada

# Science Expert Group Meeting

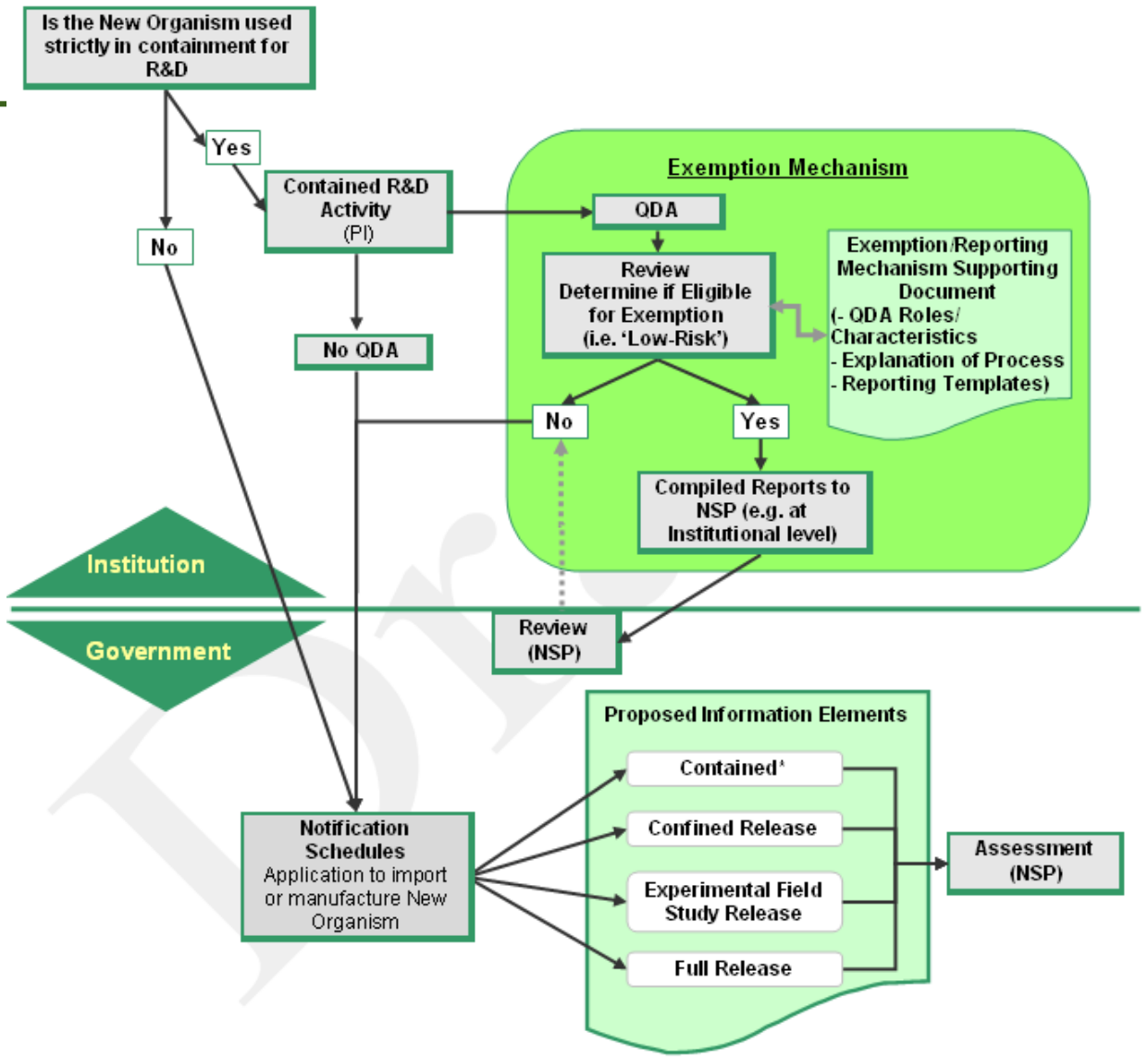
- Took place on December 10th & 11th, 2009 in Gatineau

- Representation was diverse and comprehensive: members from academia, industry, ENGOs, relevant associations and government departments, with expertise in a range of organism types including invertebrates, fish, mammals

# Proposed notification model

- Tiered notification scheme similar to that applicable to micro-organisms
- Graduated approach to information requirements in parallel with changing level of risk (hazard and exposure)
- Four overarching activities:
  - Containment (May be eligibility for exemption)
  - Confined releases
  - Experimental Field Studies
  - Full (unrestricted) release

# Overview of Proposed Regulatory Framework for Organisms Other than Micro-organisms under the *New Substances Notification Regulations (Organisms) DRAFT*



# Human Pathogens and Toxins Act Requirements

**Biological Safety Officers**

- ss.36(1) “An applicant shall, before a licence may be issued, designate an individual as a biological safety officer for the requested licence. The individual designated may also be the applicant.”
- ss.36(3) “An individual may be designated as a biological safety officer only if the individual has the qualifications set out in the regulations”
- ss.36(5) “The biological safety officer may exercise the powers and shall carry out the functions set out in the regulations.”
- ss.36(6) “If an individual ceases to act as a biological safety officer, the licence holder shall, without delay, designate another individual and inform the Minister of the new designation.”

# BSO vs QDA

**Input from SEG highlighted certain important points to consider:**

- Role may be best fulfilled by committee rather than individual, depending on institution
- Human resources and/or breadth of expertise may not be readily available at certain institutions
- Risk that animal care committee may be burdened with this, despite the dichotomy in focus and scope

# R&D Activities and Eligibility for Exemption

- Eligible for exemption from notification?
  - QDA on site?
  - Is this a ‘Low-Risk’ organism?
  - Is there adequate containment to mitigate possible risks?
  - Periodic reporting

- If not
  - Notification for assessment of a contained organism; or
  - Notification for assessment of a non-contained organism.

# Containment under R&D: Currently what needs to be "contained"

- Subsection 2(4) of the NSNR (Organisms) states:

"The regulations do not apply in respect of an organism, other than a micro-organism, that is a research and development organism and is imported to or manufactured in a facility from which there is no release into the environment of:

(a) the organism;

(b) the genetic material of the organism; or

(c) material from the organism involved in toxicity".

# Proposed Exemption from notification for Low-Risk R&D Organisms/Activities

- Considerations and guidance for low-risk and containment adequacy determination

- Reporting to and guidance from the NSP

# NSP Review Process for Reports

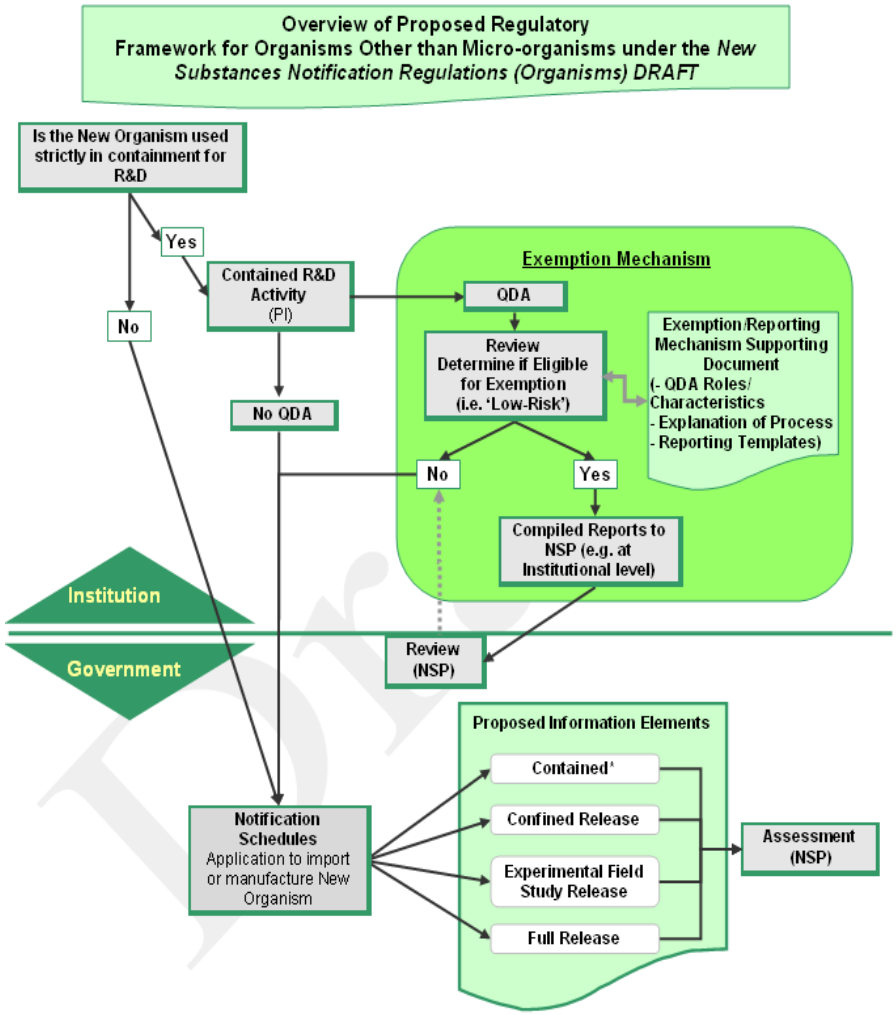
- NSP will review reports (after the fact) for adequacy of risk determination and adequacy of containment – will use this information for education/followup purposes

- Reporting timetable or frequency to be determined based on input during June stakeholder consultations

# Proposed New Notification Scheme

Notification Scheme:

1. Contained
2. Confined Release
3. Experimental Field Study
4. Full Release



# Next Steps in 2010

- 3rd multistakeholder consultation (June 2010)
  - Exemption mechanism
  - Information elements in new Schedules
- Incorporate comments from stakeholders
- Develop drafting instruction
- Publish in Canada Gazette