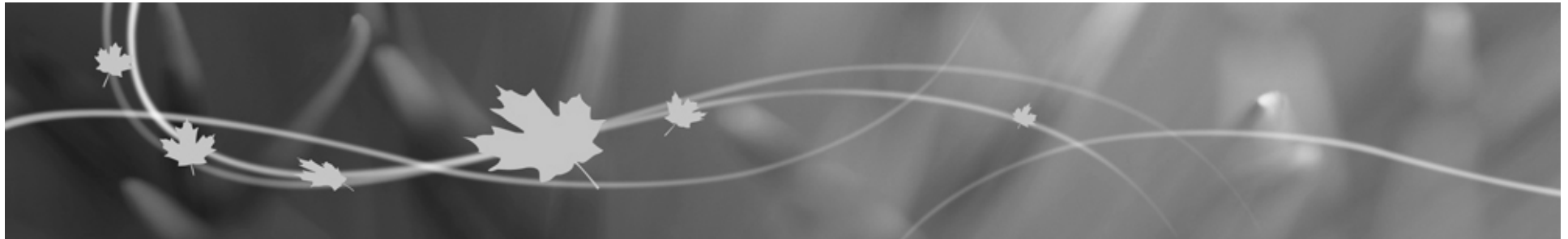




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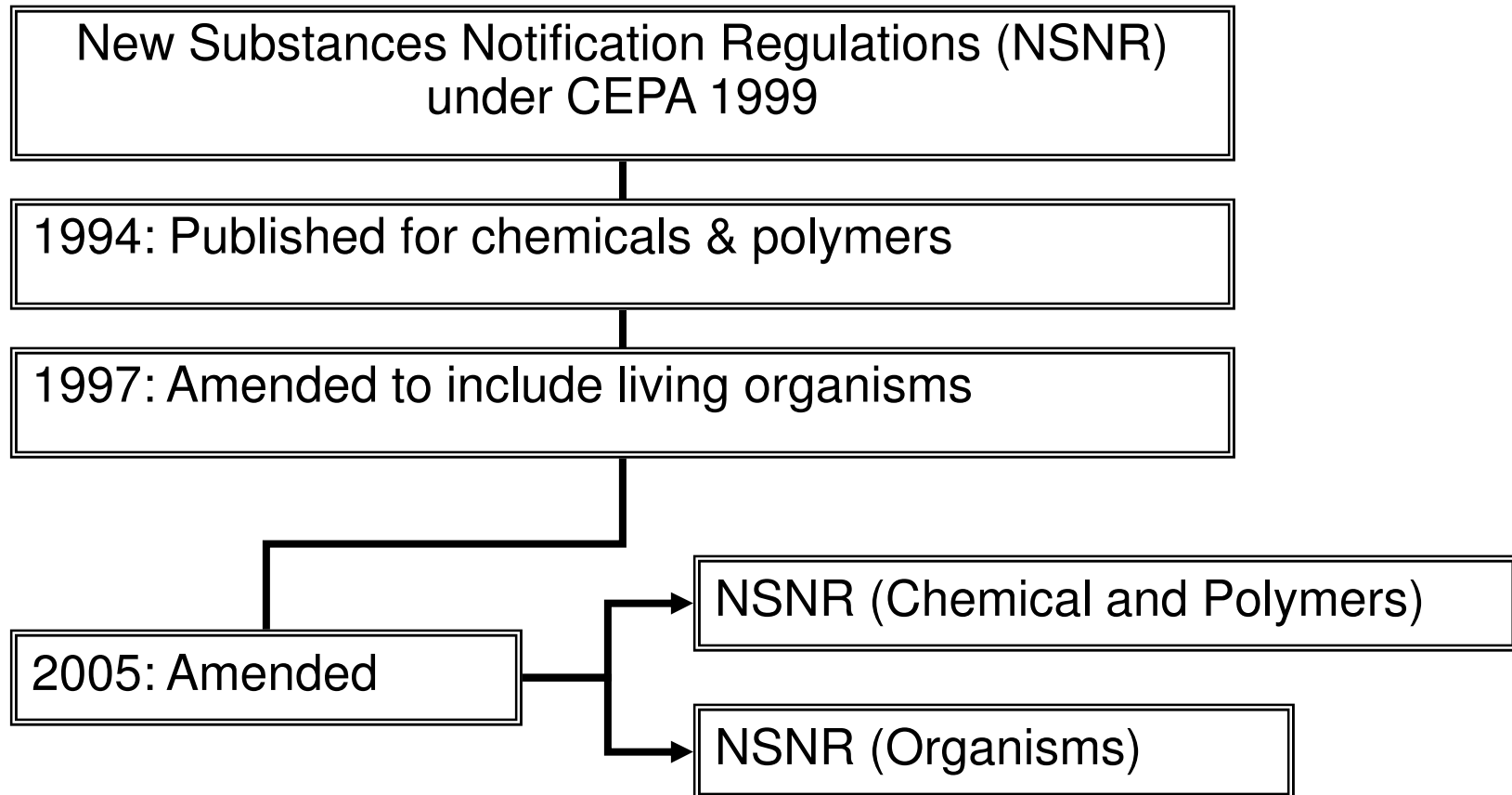
Proposed regulatory amendments to the New Substances Notification Regulations (Organisms): What could it mean to the R&D community?

**Canadian Biosafety Symposium 2010
Winnipeg, MB
Presented by: Arash Shahsavarani
Biotechnology Section
Science and Technology Branch
June 9th, 2010**

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

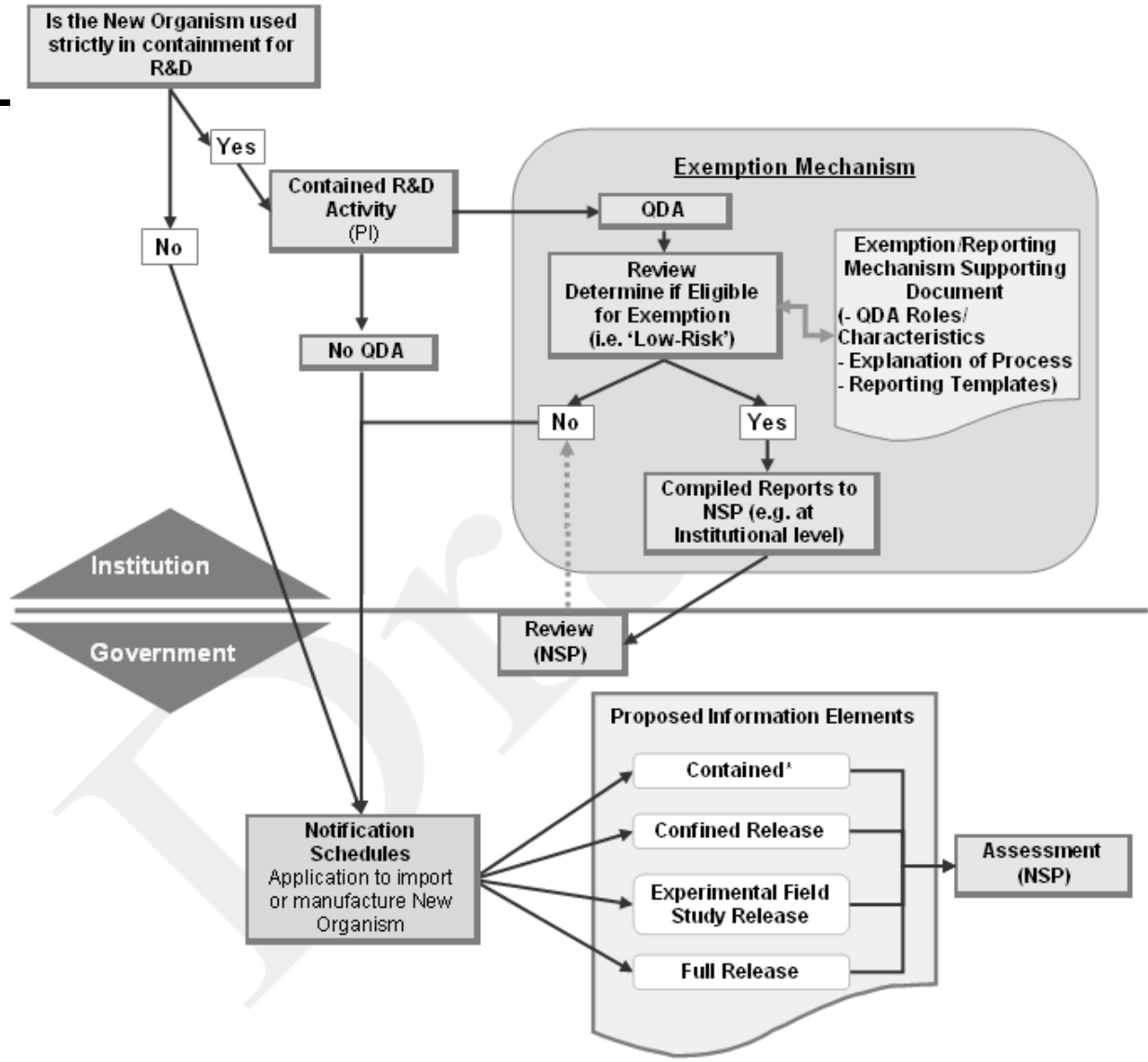
Science Expert Group Meeting

- 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

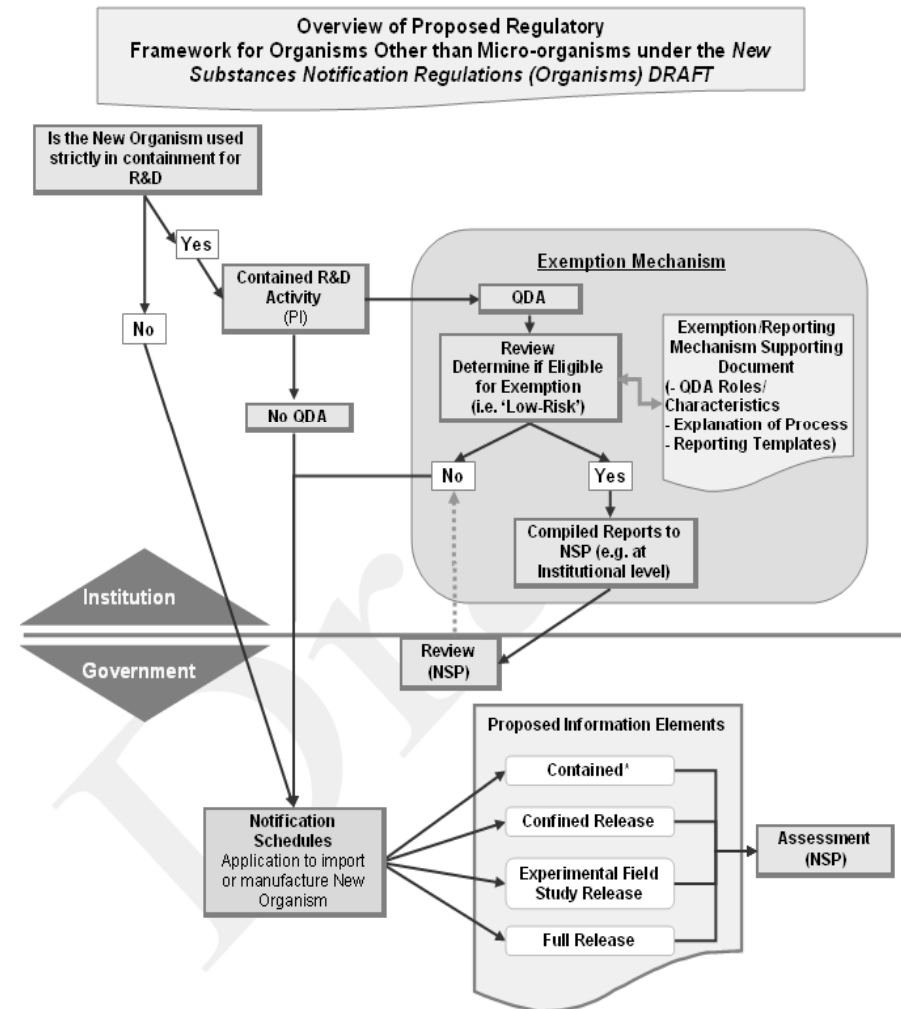
NSP Review Process for Reports

- 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