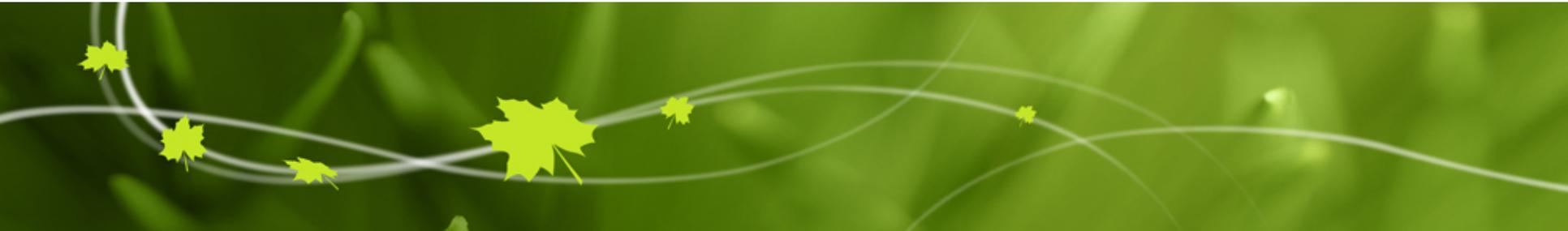




Environment  
Canada

Environnement  
Canada

Canada



# **Environmental Risk Assessment for release of animals developed via biotechnology in Canada**

**2<sup>nd</sup> International Workshop for Regulation of  
Animal Biotechnology**

**August 18-21, 2014**

**Brasilia, Brazil**

**Jim Louter, PhD**

**Environment Canada**

# Overview

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- terminology
- Canada's shared federal approach to protecting the environment and human health from potential adverse effects of products of biotechnology
- Canadian Environmental Protection Act 1999 (CEPA, 1999)
  - Regulations (New Substances Notification – Organisms)
    - Pigs and fish

# Terminology

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- Release
- Contained / Confined
- ‘Genetically Modified’ vs ‘Living Modified Organism’ vs ‘Genetically Engineered’ vs ‘synthetic’

# Canadian Federal Regulatory Partners

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Canadian Food Inspection Agency (now part of Health Canada) – Seeds, Feeds, Fertilizers, Health of Animals

Pest Management Regulatory Agency (part of Health Canada) – pest control products

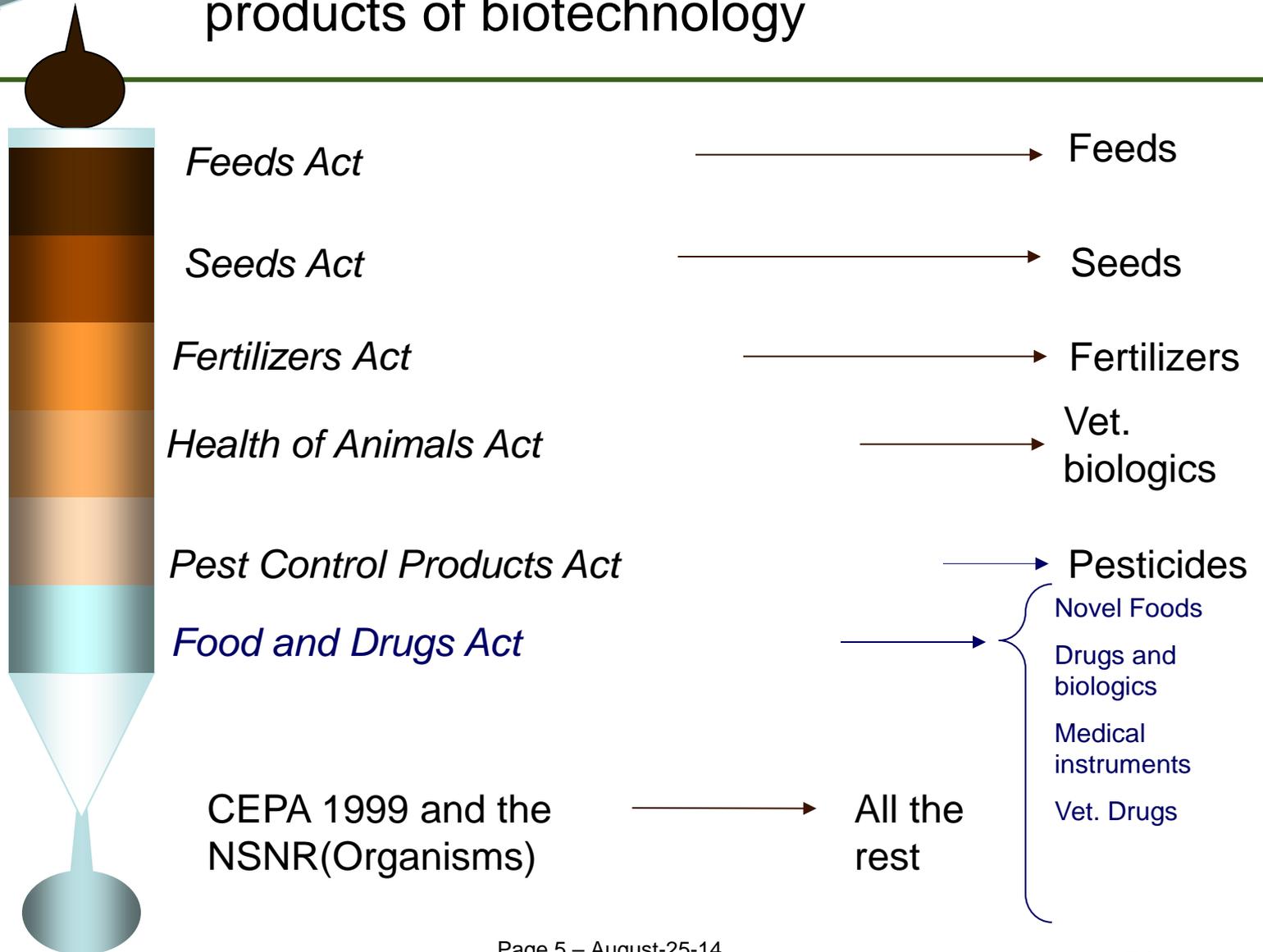
Health Canada (for CEPA, for food) – novel foods

Environment Canada (for CEPA)

Fisheries and Oceans Canada – aquatic organisms

Agriculture and Agri-Food Canada – industry links, trade

# Canadian Federal Regulation of organism products of biotechnology



# The Act and the Regulations:

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- Canadian Environmental Protection Act, 1999
  - New Substances Notification Regulations (Organisms)
- Not commodity based - generic
- Regulates activities (import or 'manufacture') using 'new' living organisms
  - Micro-organisms in containment or bioremediation (any non-agricultural, non-pesticide use)
  - Animals (from insects to mice/fish/livestock)

# The Act and the Regulations:

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- Canadian Environmental Protection Act, 1999
  - pollution prevention and the protection of the **environment** and **human health**
  - New Substances Notification Regulations (Organisms)
- 2 Ministers; 2 Departments
- Risk Assessment Process  
Environment Canada &  
Health Canada



# Canadian Environmental Protection Act, 1999 (CEPA 1999)

Environment Canada

Health Canada

Determine the risk for **environment**  
and/or its **biological diversity**

Determine the risk to **human life**  
or **health\***

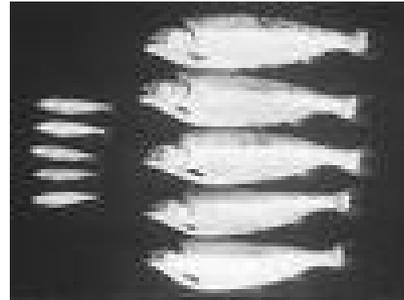
- Collaborative effort on the risk assessment
- Conclusion and proposed measure, if needed



# Examples of New Organisms Covered



**Transgenic grain for processing**



**Transgenic salmon overexpressing a growth hormone**



**Naturally occurring or Genetically Modified micro-organisms**



**GFP-expressing transgenic pig**

# Assessment of New Substances under NSNR(O)

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

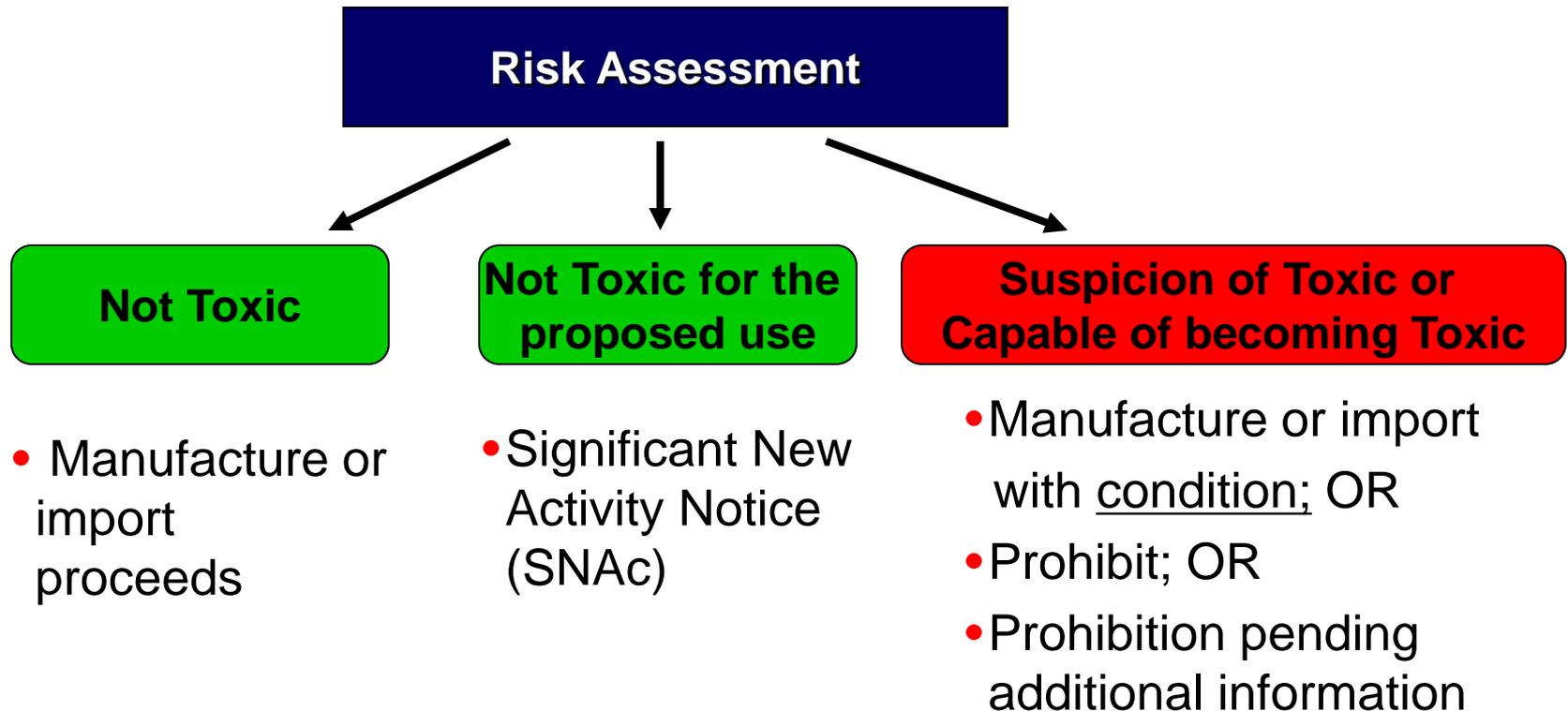


# Transparency vs Confidential Business Information

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- All risk assessments conducted are consistent with international norms
- Internal guidelines have been developed and published
  - <http://www.ec.gc.ca/subsnouvelles-newsups/default.asp?lang=En&n=E621534F-1>
- Public has input during the regulatory development phase but not on individual risk assessments
- Some risk assessments decisions are published
  - <http://www.ec.gc.ca/subsnouvelles-newsups/default.asp?lang=En&n=8AD6A8C1-1>
- Proponent indicates elements that should be considered as confidential business information

# Action to be Taken after Risk Assessment



NB.

-Not a permitting system

-No labeling required

# Examples of Biotech Notifications

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## Higher Organisms

- **Schedule 5 (full release\*):**
  - E.g. Enviropig, Aquabounty GM Atlantic Salmon
  - \*Risk assessment conclusion: not toxic for proposed use, SNAC notice issued (must be raised in building, containment, etc.)

# Challenges

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Heightened sensitivity for animal biotech

Public perception

Co-ordination with other departments  
(not just 'synchrony')

Restricted time lines



# Inquiries

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## The Substances Information Line

Environment Canada

Fontaine Building, 8th Floor

Gatineau, QC K1A 0H3

Telephone:

(800) 567-1999 (Toll Free in Canada)

(819) 953-7156 (Outside of Canada)

Facsimile: (819) 953-7155

E-mail: [substances@ec.gc.ca](mailto:substances@ec.gc.ca)

Web site: <http://www.ec.gc.ca/subsnouvelles-newsubs/>

