



Panel on GE Salmon

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Regulation of Animal Biotechnology
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Federal Players

- Environment Canada (CEPA)
- Health Canada (HC) (both CEPA and F&DA)
- Department of Fisheries and Oceans (DFO)
- Canadian Food Inspection Agency (CFIA) (Feeds, Aquatic Animal Health, Fish Inspection)
- Agriculture and Agri-Food Canada
- Foreign Affairs, Int'l Trade and Development

Biotechnology Related Legislation – GE fish

CFIA

Feed



Feeds Act and Reg.

CFIA

Seeds



Seeds Act

CFIA

Fertilizers



Fertilizers Act

CFIA

Vet. biologics



Health of Animals Act

HC

Pesticides



Pest Control Products Act

HC

Novel Foods, Drugs and biologics, medical devices



Food and Drugs Act

EC, HC and DFO

All other substances



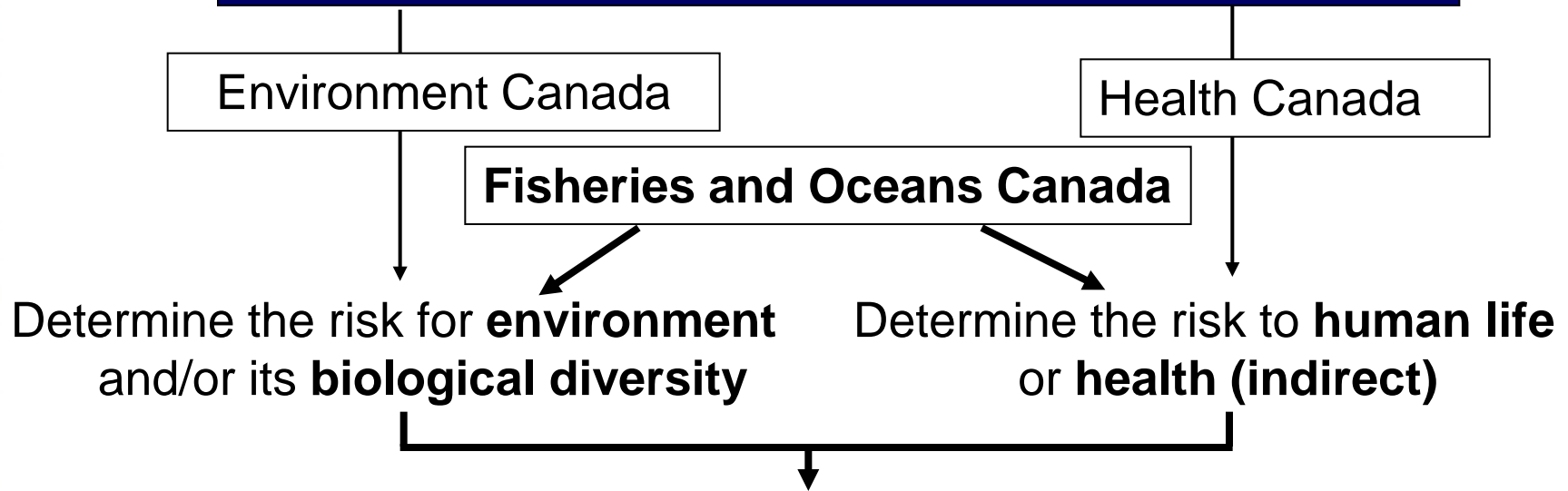
Canadian Environmental Protection Act, 1999

Canadian Environmental Protection Act, 1999 – related to GE fish

- Part 6 of the Act focuses on assessment of organisms (biotech substances) which must happen before the import or production of the organism occurs
- Administered by Environment Canada but both EC and HC jointly conduct risk assessments
- New Substances Notification Regulations (Organisms) [NSNR(O)] under CEPA 1999 prescribe the information that must be provided to the Government prior to the proposed import to or manufacture in (produce in) Canada of GE fish.
- Contained R&D exempt but commercial production of GE fish/eggs subject to NSNR(O)
- Memorandum of Understanding, including GE fish:
 - DFO conducts risk assessment and recommends any risk management to EC
 - EC retains overall responsibility for regulatory decision-making and enforcement

Authority Under the Act – GE fish

Canadian Environmental Protection Act, 1999 (CEPA 1999)



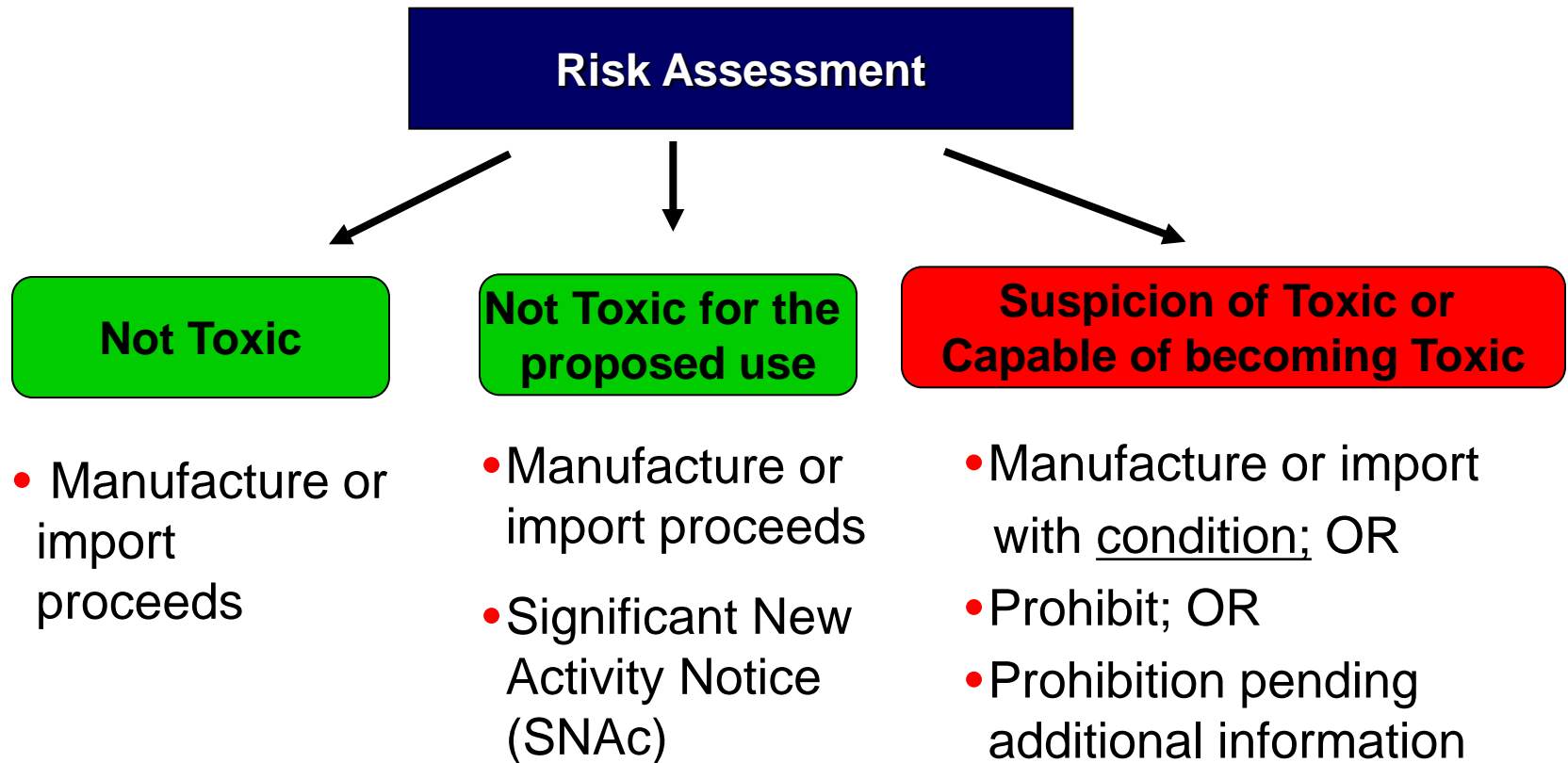
- Collaborative effort on the risk assessment
- Conclusion and proposed measure, if needed

Regulatory Path prior to import/manufacture

Administrative Path for Submission of Notification and Risk Assessment of a GE Fish under CEPA 1999

1. Submission/Receipt of the Notification Package at least 120 days prior to import or manufacture to Environment Canada (EC)
2. Regulatory Screening (EC/DFO) – is the information complete enough to begin the assessment? Decision on any requester waiver.
3. DFO conducts environmental and indirect human health risk assessments within 120 days
4. Assessment Outcome: DFO provides risk assessment and any recommendations for further actions to Environment Canada
5. Company is notified if there are any issues with the assessment or when the 120 day assessment period has lapsed

Potential Outcomes after Risk Assessment



- Not a permitting system
- No labeling required unless part of a condition

Additional Considerations (post CEPA assessment)

- To be consumed as food or feed in Canada, the fish will need approval from HC and CFIA
- Environment Canada's Enforcement Branch may monitor/inspect sites of manufacture in Canada and may take action if non-compliance with respect to any violation under the Act.
- EC Enforcement may conduct joint inspections with DFO and other authorized, relevant parties.
- Judicial review underway

Panel Questions

- Regulatory coordination: domestic and international
 - MOU, letters of agreement
- Challenges
 - Limited time, new steps,
- Environmental Issues
 - Waivers, designing the right experiment, containment
- Lessons learned
 - In best of all possible worlds, put all risk assessors in same room
 - Assume good-will but have contingency plan
 - Details in MOU are important

Links to documents

- Regulations:
 - <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2005-248/page-9.html#h-14>
- Significant New Activity Notice:
 - <http://www.gazette.gc.ca/rp-pr/p1/2013/2013-11-23/html/notice-avis-eng.html#d106>
- Science Response:
 - http://www.dfo-mpo.gc.ca/csas-sccs/Publications/ScR-RS/2013/2013_023-eng.html