

Canadian Regulatory Oversight of Genetically Engineered Animals

Stephen Dugan, PhD
Biologist, Biotechnology Section
New Substances Assessment and Control Bureau
Safe Environments Directorate
Health Canada
E-mail: stephen.dugan@hc-sc.gc.ca

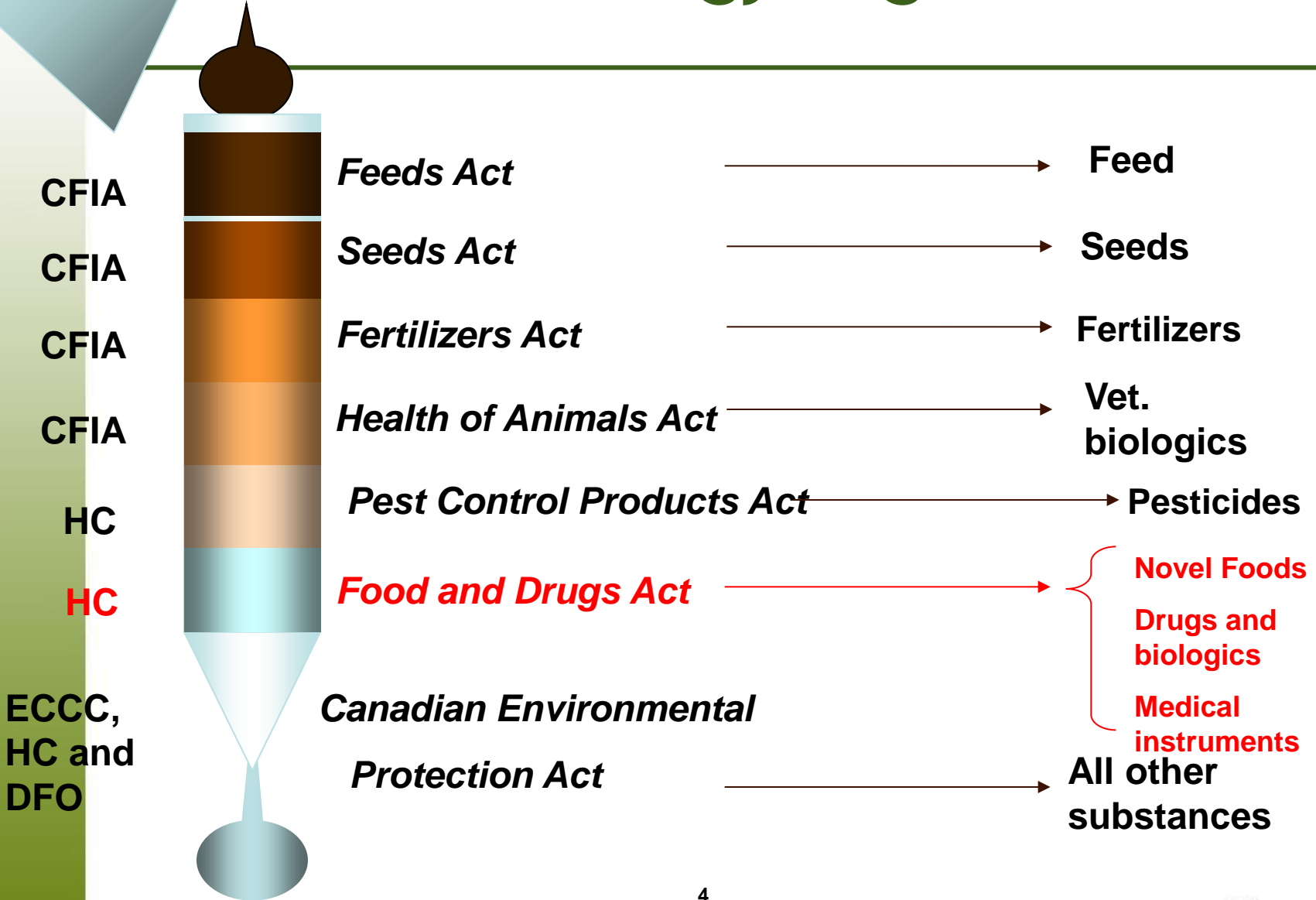
Regulatory Principles: Canadian Regulatory Framework for Biotechnology (1993)

- Intended to ensure that the benefits of biotechnology products and processes are realized in a way that protects health, safety, and the environment
- Use of existing legislation; animals and related food and feed products in Canada were already subject to rigorous health and safety regulations
- Science-based; case-by-case
- Regulation triggered primarily by ‘product’ and not ‘process’
- Animals derived from modern biotechnology techniques as well as their progeny and any related products and by-products, **may be** considered “new” or “novel” and would, therefore, be subject to additional requirements prior to commercialization.

How is biotechnology defined in Canada?

- **"biotechnology** *means the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms.*"
 - Canadian Environmental Protection Act (CEPA)
- This definition of biotechnology describes the application of “science and engineering” either to the organism or in the use of the organism. Applies both to modified organisms (using techniques such as gene editing) and non-modified organisms (used for “science and engineering” purposes).
- Products of biotechnology fall under the jurisdiction of CEPA or CEPA-equivalent acts (eg., *Seeds Act* [plants with novel traits], *Feeds Act* [novel feeds], *Pest Control Products Act* [biopesticides]).

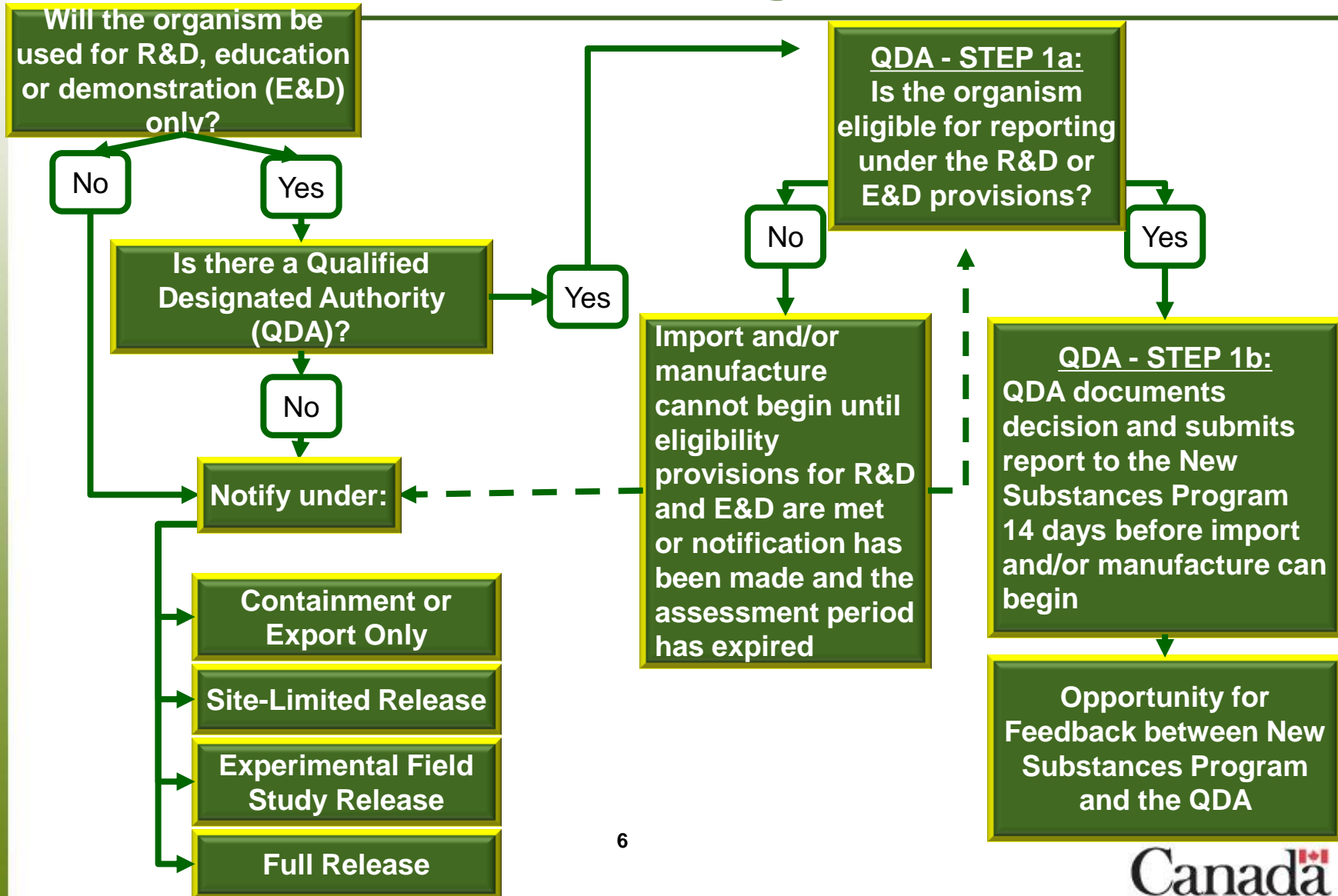
Biotechnology Legislation



Current NSNR(O) Requirements for higher organisms

- A single schedule based on a full release scenario covers diverse uses and a wide variety of organism types (eg. Livestock animals, fish, insects);
- Information requirements are not commensurate with the level of risk, for contained or confined uses or for experimental field trials.
- R&D Exemption Criteria:
 - a **research and development organism** that 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.

Flow Chart of the Proposed Notification and R&D/E&D Reporting Process



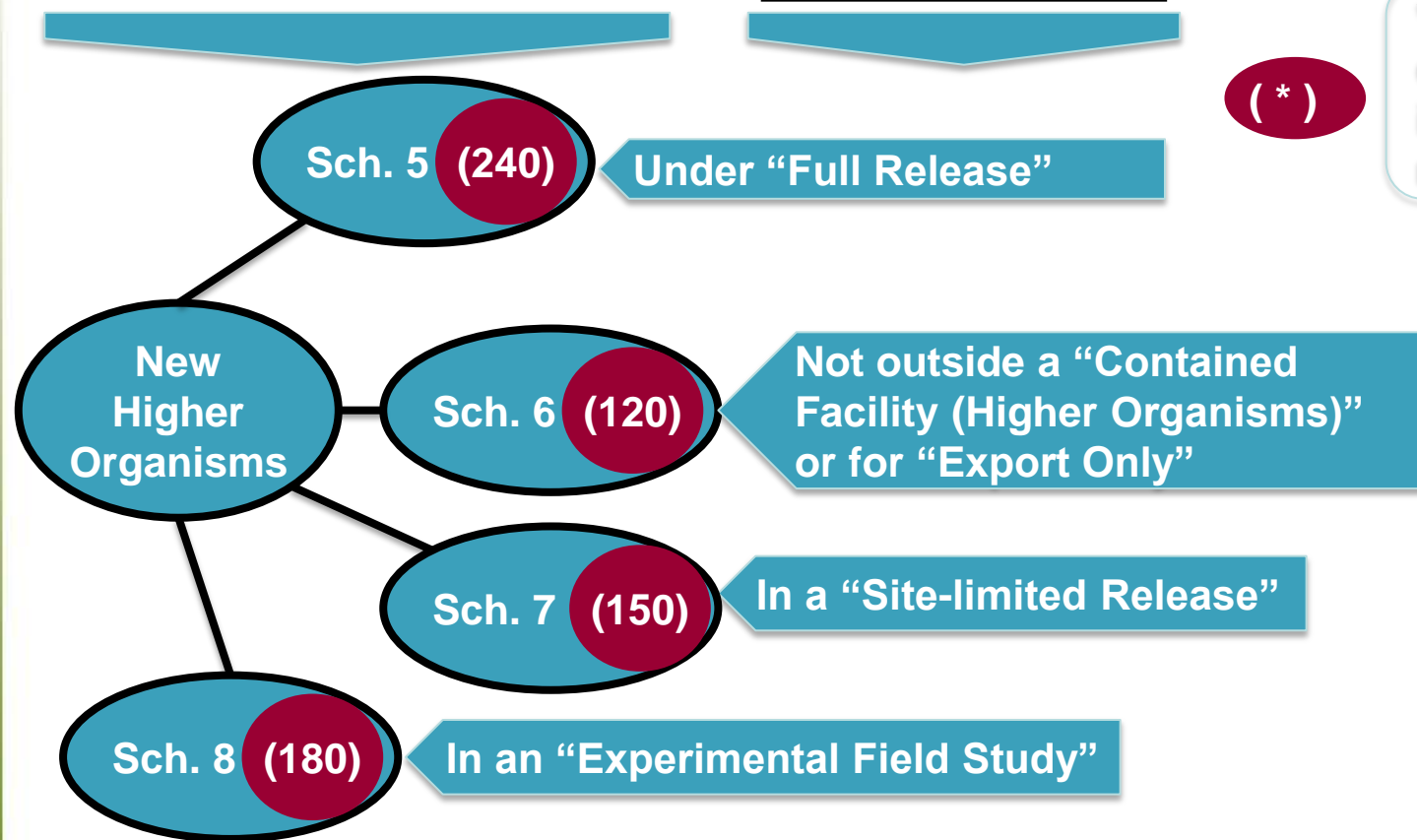
Proposed R&D/E&D Reporting Provisions for Higher Organisms

- Applies to any organism:
 - that meets the definition of higher organism; and
 - that meets the definition of a **research and development organism or education and demonstration higher organism**; and
- To be imported or manufactured in a facility where:
 - a QDA with the required qualifications is available; and
 - a report has been communicated by the QDA (the QDA Report) to ECCC 14 days before import or manufacture confirming that the facility at which the organism will be imported, manufactured and/or used has operational and physical controls in place that
 - (a) prevent escape of the live organism from the facility,
 - (b) prevent the release into the environment of any material naturally capable of unaided propagation of the organism in the Canadian environment, and
 - (c) prevent or minimize the release into the environment of any material from the organism likely to be harmful to human health and/or the environment.

Proposed Notification Schedules for Higher Organisms under the NSNR (O)

Notification Schedules*:

For introduction



* Calendar days before import or manufacture

Proposed Information Elements – Some Notable Features

➤ **Experimental Field Study Schedule**

- Study objectives;
- Details of introduction, procedures for limiting dispersal
- Information on persistence/proliferation of organism.

➤ **Site-Limited Release Schedule**

- Some requirements mirror those of Experimental Field Study (e.g. details of introduction, procedures for limiting dispersal, etc.).

➤ **Containment or for Export only Schedule**

- Description of containment and its effectiveness to prevent release.

➤ **Full Release Schedule**

- Most comprehensive one (similar to the current full release schedule);
- Requirements contain data ⁹elements.

New Substances Program Contact Information

E-mail:

eccc.substances.eccc@canada.ca

Telephone:

In Canada (toll free): 1-800-567-1999

Outside Canada: (819) 938-3232

Facsimile: (819) 953-7155

Website:

<https://www.ec.gc.ca/subsnouvelles-newsups/default.asp?lang=En&n=AB189605-1>

For more information concerning Novel Foods and Livestock feeds in Canada

Health Canada Web address:

<http://www.hc-sc.gc.ca>

HC-Novel Foods Web address :

<http://www.novelfoods.gc.ca>

CFIA Web address:

<http://www.inspection.gc.ca>

CFIA - Feed Web Address:

<http://www.inspection.gc.ca/english/anima/feebet/feebete.shtml>

