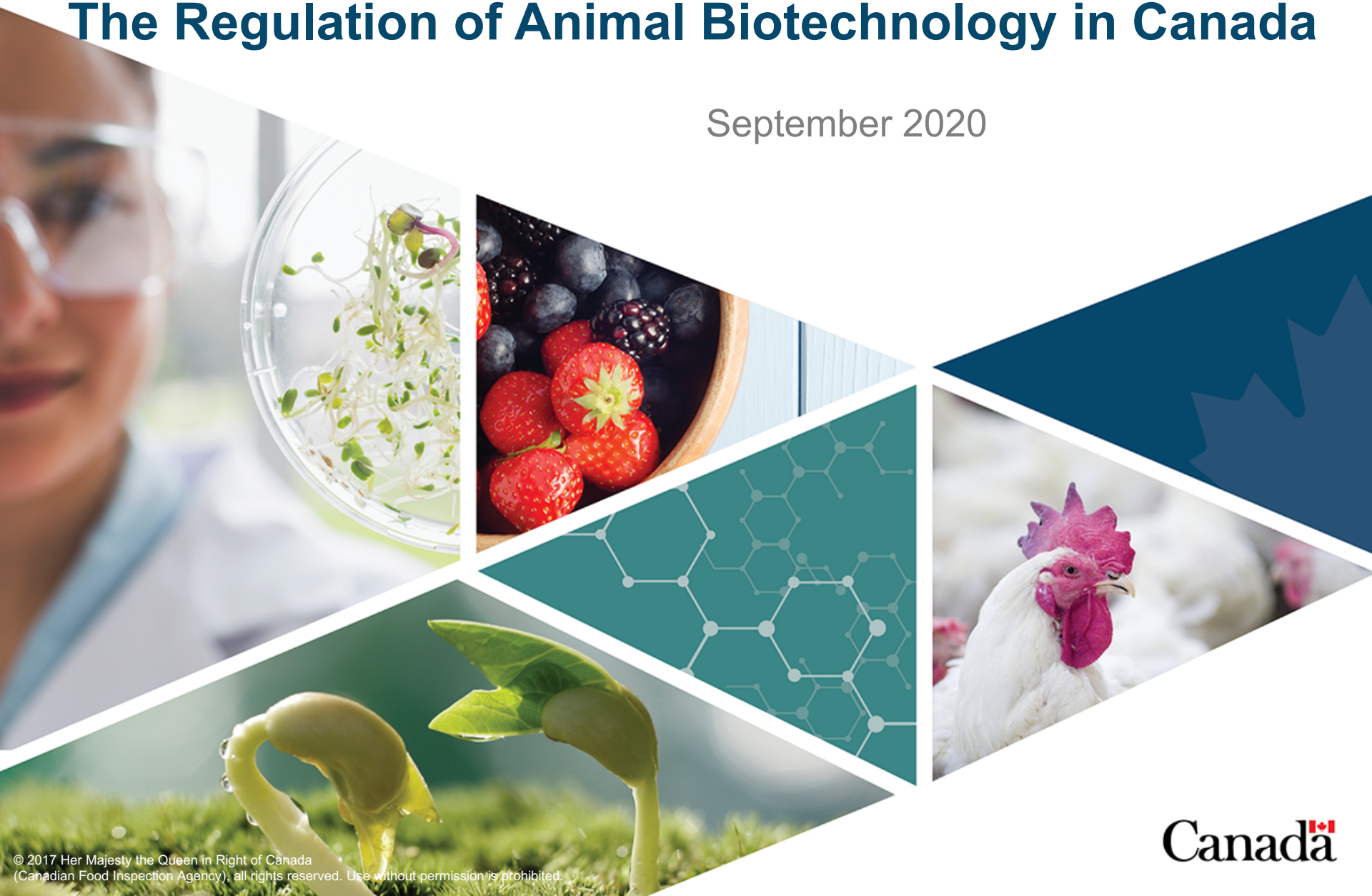
Canadian Food Inspection Agency | Agence canadienne d'inspection des aliments
Environment and Climate Change Canada | Environnement et Changement climatique Canada
Health Canada | Santé Canada

The Regulation of Animal Biotechnology in Canada

September 2020



Canada

Biotech-Related Oversight in Canada

Lead	Product	Regulation
Canadian Food Inspection Agency	Livestock feed	*Feeds Act*
	Seeds (Plants with Novel Traits)	*Seeds Act*
	Fertilizer	*Fertilizers Act*
	Veterinary biologics	*Health of Animals Act*
Health Canada	Pesticides	*Pest Control Products Act*
	Novel foods, drugs, and biologics, medical devices	*Food and Drugs Act*
ECCC, HC, DFO	Living Organisms that are "new" to Canada	*Canadian Environmental Protection Act*
AAFC, GAC, ISED	Non-regulatory considerations	*Market access, industrial policy, socio-economic impacts, trade*

ECCC – Environment & Climate Change Canada; DFO - Fisheries & Oceans Canada; AAFC – Agriculture &Agri-Food Canada; GAC – Global Affairs Canada; ISED – Innovation, Science &Economic Development Canada

Canadian Regulatory Approach

- Product-based system

- Canada requires a pre-market safety assessment for agriculture biotechnology products, including animals, only if they are novel (i.e., express a new characteristic or modify an existing characteristic) and could therefore pose a new risk.

Risk-Based Regulatory Approach

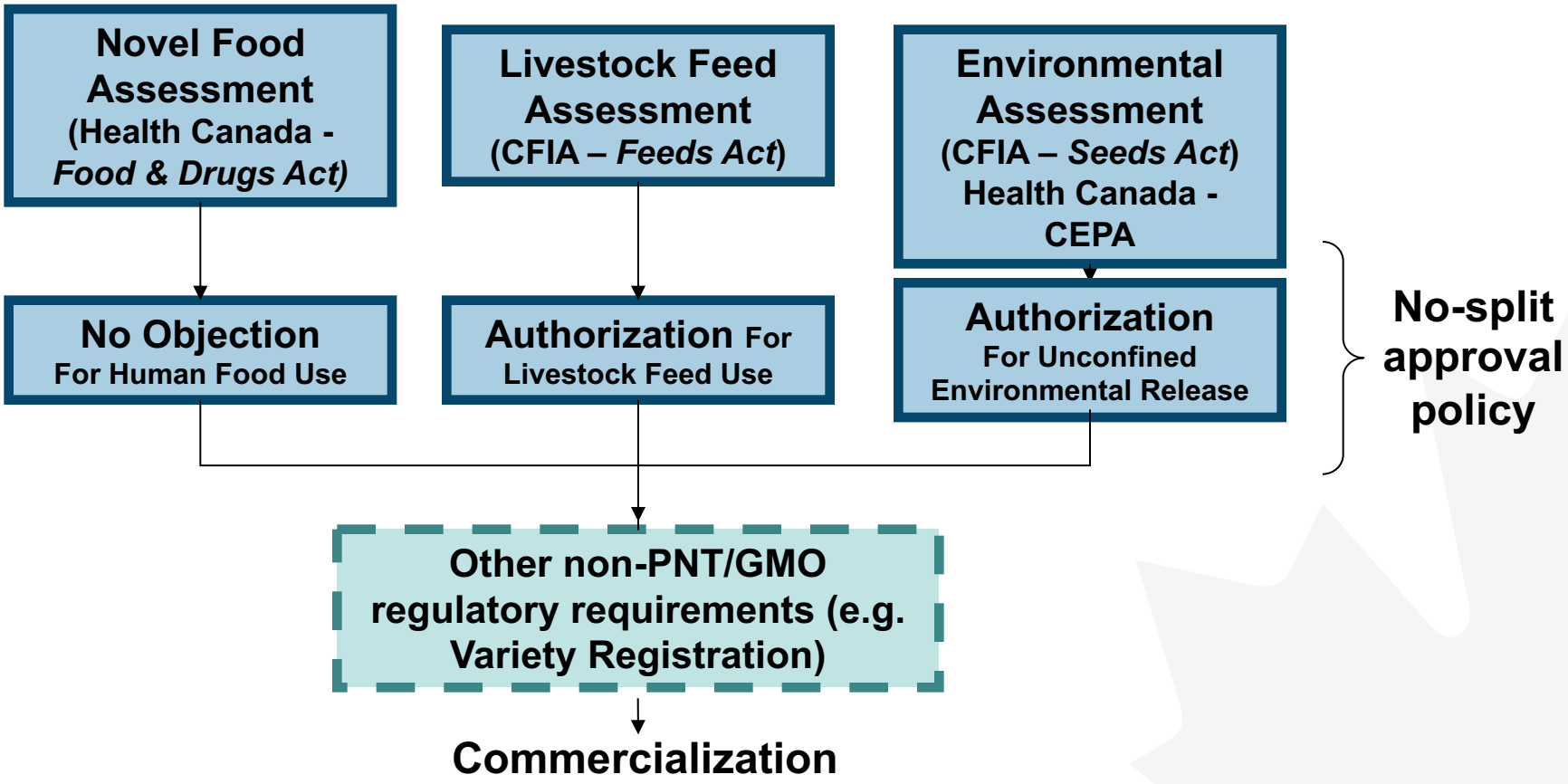
Risk-Appropriate Regulation

- Pre-market assessment required for “novel” products

Flexibility of Information Requirements

- Not prescriptive
- Case-by-case
- Outcome based
- Codex based

Authorization Process



Novel Food Definition

- A food that is derived from a plant, animal or microorganism that has been genetically modified such that:
  - the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
  - the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
  - one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism

Novel Food Notification of GM Animals

- Data describing both the methods and results required for the following:
  - Molecular Characterization
  - Nutritional Composition
  - Toxicology and Allergenicity
  - Chemical Contaminants
  - Animal Health

Novel Feeds

- Any feed ingredient that is new (i.e., not listed in the Regulations), or has been modified such that it differs from conventional parameters, is required to undergo a pre-market assessment

- Only feed ingredients that have been approved and evaluated by the CFIA may be used in livestock feeds; approved ingredients are listed in Schedules IV and V of the *Feeds Regulations*

- Feeds with novel traits can be developed by such methods as traditional breeding, mutagenesis, cell fusion, recombinant DNA techniques, etc.

- Products derived from Biotechnology (microbial, plant or animal sources) are treated the same as non-biotech feeds

Novel Feed Notification of GM Animals

- Data describing both the methods and results required for the following:
  - Molecular Characterization
  - Nutritional Composition
  - Toxicology Data

Regulating Genome-Edited Animals in Canada under CEPA

- Under Part 6 of the *Canadian Environmental Protection Act* (CEPA), genome-edited animals (whether used for food or not) are considered '**animate products of biotechnology' (living organisms)**.

- The New Substances Program (NSP), a joint program of Environment & Climate Change Canada (ECCC) and Health Canada (HC), is responsible for administering Part 6 of CEPA.

- Regulatory oversight under Part 6 ensures that "**new**" products of biotechnology that are "living organisms" (e.g. livestock, fish, insects) are assessed for potential risks to the environment and human health before **manufacture** or **import** into Canada.

- The regulatory system applies a science-based risk assessment and a number of regulatory instruments to mitigate risks that may result from manufacturing, importing or using new living organisms resulting from new innovations or technologies fitting the CEPA definition of 'biotechnology'.

GM Animal Notification under CEPA

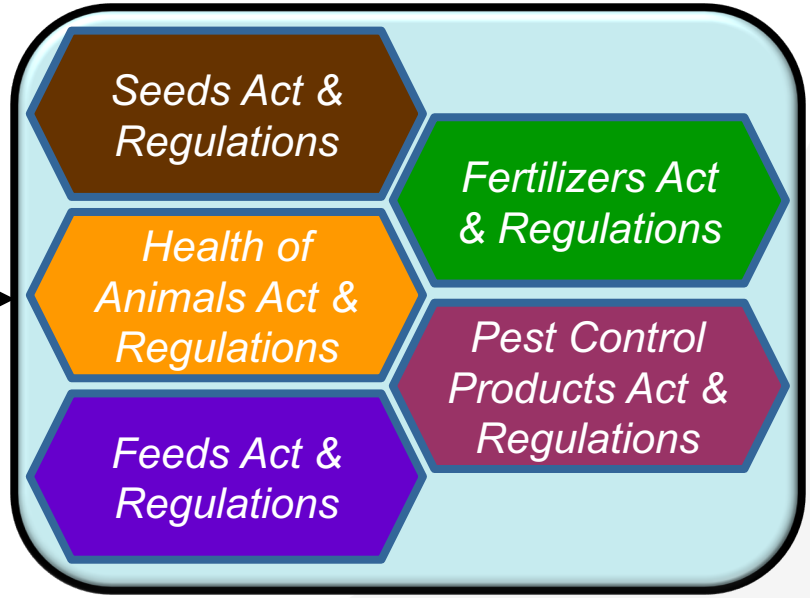
- Data describing both the methods and results required for the following:
  - information about the organism;
  - manufacturing and import information;
  - information on the introduction;
  - information on the site of introduction (Schedules 3 and 4)
  - information on the experimental field study (Schedule 3)
  - environmental fate information;
  - ecological effects information;
  - human health effects information;
  - additional information.

Notification Under the NSNR(O) of Import or Manufacture of Genome-Edited Animals

"A person who manufactures or imports an organism other than a micro-organism must provide the information* specified in Schedule 5."

Unless, if the organism is:

- regulated by another Act or Regulation listed under Schedule 4 of CEPA (ss. 2(1));
- in transit (ss. 2(2)); or
- used for research and development (ss. 2(4)).

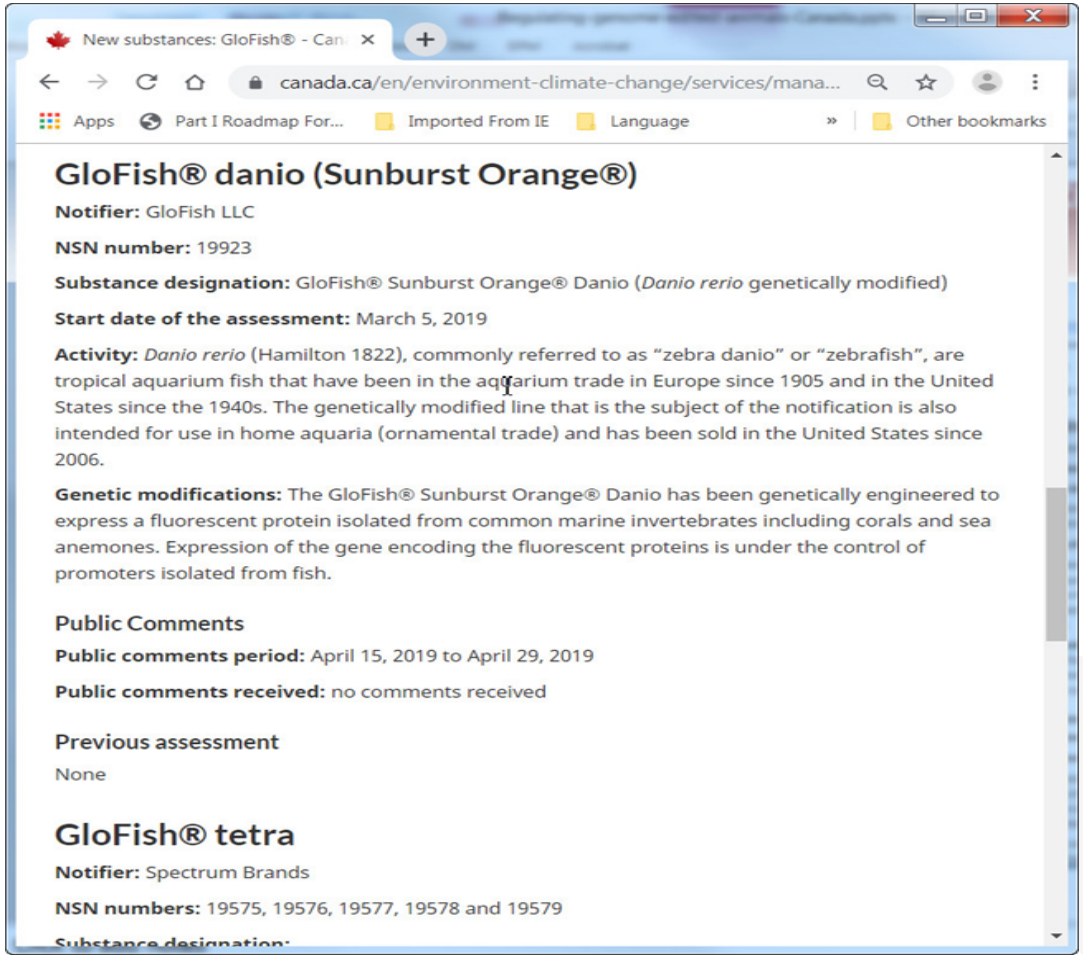


*Assessment period: 120 days.

Voluntary Public Engagement and Transparency Initiative

- The NSP is working to promote more public engagement and transparency in the risk assessment of genetically modified animals.
- Under a new voluntary engagement initiative,
  - the NSP will publish summaries of higher organism notifications when received; and
  - invite stakeholders to share scientific information and test data related to potential risks to the environment or human health, to help inform the risk assessment process.
- This voluntary engagement initiative is expected to shape future engagements with stakeholders for genome-edited animals.
- The NSP is also publishing risk assessment summaries for select notifications.

Voluntary Public Engagement and Transparency Initiative



Stakeholder Engagement

- Proponents are encouraged to contact regulatory authorities early in the product development process to discuss:
  - Potential regulatory requirements (Pre-submission consultations)
  - Novelty determinations

- Regulators regularly engage with stakeholders:
  - Biotechnology working groups
  - Technical meetings with industry and academia

Take Home Messages

- Since there are many biotechnological techniques that can be used to achieve the same result, the consistent risk-based regulatory approach is to treat comparable products alike.
- Canada regulates PRODUCTS, which may include some products of plant or animal breeding innovations (e.g., CRISPR).
- Canada's regulations have the flexibility to include evolving technologies, when a product is novel or new.
- Ultimately, this is a system that allows for consistent decision-making and a clear regulatory path.