

**Voluntary Report** – Voluntary - Public Distribution

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**Report Name:** Updated guidance for seed regulations supportive of gene-edited products

**Country:** Canada

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**Report Category:** Grain and Feed, Oilseeds and Products, Planting Seeds, Biotechnology and Other New Production Technologies

**Prepared By:** Erin Danielson

**Approved By:** Philip Hayes

**Report Highlights:**

On May 3, 2023, the Canadian Food Inspection Agency (CFIA) and Agriculture, Agri-Food Canada (AAFC) published updated regulatory guidelines supporting the introduction of gene-edited seeds into the Canadian market.

## Updated guidance for seed regulations supportive of gene-edited products

On May 3, 2023, the Canadian Food Inspection Agency (CFIA) and Agriculture, Agri-Food Canada (AAFC) [announced](#) the publication of updated regulatory [guidelines](#) supportive of the introduction of gene-edited products in the Canadian market.

The guidelines clarify that any plant that releases seed into the environment is subject to pre-market clearance under [Part V](#) of the Seeds Regulations only when: the plant contains foreign DNA; the plant has a new commercially-viable herbicide tolerance trait; or, the plant is of a new crop species or is intended for new uses in Canada.

The guidelines are being praised by agricultural associations for clarifying existing requirements for plant breeders and other stakeholders, creating a predictable and science-based regulatory system that appears to support investment and innovation in Canada. The guidelines are also supportive of farmer access to improved crops, such as crops that are more resistant to drought, extreme temperatures, and plant pests, for example.

Canada's regulations on biotechnology have received pushback from the organic sector. In response, the CFIA and AAFC state in their press release that "to help maintain the integrity of organic certifications, which allow the use of conventional seed but not gene edited seed" it is creating a Government-Industry Steering Committee on Plant Breeding Innovations Transparency to facilitate ongoing discussions. In addition, it will oversee the expansion of the private sector-led [Canadian Variety Transparency Database](#). The database was created by a private association, [Seeds Canada](#), and will be overseen by government authorities to "ensure its completeness and robustness," states the news release.

The new guidelines were informed by a [public consultation](#) held between May and September 2021, in addition to other consultations. A [supplementary rationale](#) with more information is available.

The guidelines are not required to go through a formal Canada Gazette process because they constitute an interpretation of Canada's Seeds Regulations are not regulation in themselves.

## Next steps for regulatory guidance related to new plant varieties

This is the second of three updated guidance documents to be released by respective agencies of the federal government to help plant breeders and other stakeholders determine whether a plant is subject to pre-market clearance.

The first updated guidance, [Guidelines for the Safety Assessment of Novel Foods](#), was published by Health Canada in May 2022 to help industry comply with the [Division 28 of Part B of the Food and Drug Regulations](#). It clarified characteristics of plants that determine pre-market notification and assessment as novel foods.

In the final regulatory guidance document to be published, the CFIA is expected to publish updated guidelines for the assessment of novel feeds derived from plant sources to help industry comply with the [Feeds Regulations, 2022](#).

CFIA has not yet consulted on this piece, but industry contacts expect to see consultation begin very soon, with final guidance to follow.

**Attachments:**

No Attachments.