GEO Regulation in Canada

Presentation to the International Leopoldina-DFG Conference: Genome Editing in Europe: New Agenda or New Disputes?

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Plant with Novel Traits (PNTs)

- Canada adapted its existing regulatory framework between 1988-94 to regulate the novelty of a trait – product-based regulations
- 3 Acts are utilized:
  - Seeds Act: risk assessment factors of gene flow, invasiveness, weediness, impacts on non-target organisms and other potential negative impacts on biodiversity
  - Feeds Act: risk assessment factors in animals regarding allergenicity, toxicity, digestibility and dietary exposure
  - Food and Drugs Act: risk assessment factors in human involving allergenicity, toxicity, metabolization, nutrition and dietary exposure

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Commercialization of gene-edited varieties

- Cibus used ODM to develop an HT variety, limited adoption
- BASF approved HT variety, however it's not clear if this has been commercialized as BASF was required to sell its Clearfield technology when it acquired Bayer's Liberty Link technology in the Bayer-Monsanto merger

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Regulation of gene editing workshop - 2017

- Organized by CropLife Canada, Canada Grains Council & Canadian Seed Trade Association to discuss potential barrier to the use of gene editing
- Workshop identified that more clarity regarding 'novelty' was required, leading to multiple calls for modernization as this was identified as a key issue for Canadian agriculture
- Plant breeders need to know what can be done within the existing gene pool without triggering novelty, especially for yield increases
- Post-2017 workshop initiatives:
  - Health Canada has held 2 years of industry roundtable consultations
  - Full public consultation will be held in January 2021
  - A revised program to be delivered by Health Canada in April 2021

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Breeder use of gene editing technologies

- A 2018 survey of 96 public and private plant breeders regarding the use of gene editing technologies found:
  - one-third were using gene editing
  - two-thirds anticipating using the technology by 2021
  - top reason for using gene editing was easier regulatory pathway to commercialization (90%)
- 100% of public breeders identified easier regulatory pathway to commercialization as their top reason

Source: Gleim et al. 2020. CRISPR-Cas9 application in Canadian public and private plant breeding. The CRISPR Journal 3: 1: 44-51.

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PNT regulations are a barrier to innovation

Survey asked respondents about the impact of PNT regulations on their research, finding:

- 77% indicated PNT regulations need updating to reflect current knowledge and advancements in plant breeding technologies
- 22% had research proposals turned down due to PNT uncertainty
- 34% ended research when self-determination indicated PNT status
- 19% altered research to ensure the variety would not be a PNT
- 18% experienced delay once PNT status was applied
- 26% disagreed that PNT regulations encourage investment

Source: Smyth et al. 2020. Regulatory barriers to innovative plant breeding in Canada. Frontiers in Genome Editing. doi: 10.3389/fgeed.2020.591592.

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Summary

- The confusion regarding ‘novelty’ to some gene-edited traits is restricting conventional plant breeding innovation within Canada
- Canada is not expected to treat gene-edited varieties any differently than any other plant breeding technology, following the 2021 Health Canada consultations
- One-third of the variety development initiated in Canada is ended due to the likely PNT status
- $800M-$1B is annually invested in ag R&D in Canada resulting in a potential direct innovation loss of $100-300M
- The spill-over loss in the delay new varieties to Canadian farmers could reach $1B annually

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