

Notes of a Meeting held on Wednesday 14 June 2023

Meeting Room P, Portcullis House and via Zoom

Gene editing developments in Canada

In attendance:

Sir Robert Goodwill MP (chair) Lord Grantchester Earl of Caithness Lord Taylor of Holbeach David Duiguid MP Earl of Leicester Baroness Bakewell of Hardington Mandeville Duke of Montrose

Guest speakers:

Greg MacDonald, Agriculture Counsellor at Canada's Permanent Mission to the World Trade Organisation; Chair of WTO's Sanitary and PhytoSanitary Measures (SPS) Committee

Krista Thomas, Vice President of Trade Policy and Seed Innovation, Canada Grains Council

Jodi Souter, Plant breeder & Adjunct Professor of Biology, University of British Colombia

Attendees:

Dr Janet Talling, Defra; Rebecca Sudworth, FSA; Jon Williams, BASF; Dr Craig Lewis, Genus plc; Anthony Keeling, Elsoms Seeds; Ian Munnery, SesvanderHave; Jonny Hazell, Royal Society; Stefano Brizzi, BASF; Prof Huw Jones, Aberystwyth Univ & ACNFP; Scott Pepe, NFU; Alvaro Eseverri-Sabate, BASF; Nigel Moore, KWS; Prof Helen Sang, Roslin Institute; Prof Tina Barsby, Univ of Cambridge; Karen Holt, Regulatory Consultant; Prof Julian Smith, Rothamsted Research; Milika Buurman, Elsoms Seeds; Tim Mordan, Defra; Dr Petra Jorasch, Euroseeds; Nancy Podevin, Corteva; Becky Smith, NFU; Rob Hill, Rothamsted Research; Saskia Hervey, Earlham Institute; Genny Enfissi, Royal Holloway University; Dr Elena Rice, Genus plc; Kim Matthews, Head of Genetics & Breeding, AHDB; Robert Graveland, HZPC; Prof Richard Napier, Warwick Univ; Dr Mark Fife, Aviagen; Lucy Thursfield, FSA; Alessia Cogliandro, KWS; Dr Conchi Novillo, Bayer; Ollie Szyszka, Defra; Samantha Brooke, BSPB; Mark Buckingham, Bayer CropScience; Ed Barker, AIC; Hellen Mbaya, Edinburgh Univ; Gini Hill, Inari; Colin Barker, Canadian High Commission; Prof Louise Manning, Univ of Lincoln; Anja Matzk, KWS; Melanie Demuth, KWS; Liz Scott, NIAB; Prof Ian Graham, Univ of York; Clint Nesbitt, Genus; Louise Courts, Defra; Daniel Pearsall, Group Co-ordinator.

1. Introduction

Chairing the session, Sir Robert Goodwill MP (RG) welcomed guest speakers and attendees to the meeting, briefly introducing the topic for discussion. He noted that the All-Party Group had first led calls for regulatory divergence from EU rules on gene editing during the passage of the Agriculture Act in 2020, and that the recent granting of Royal Assent for the Genetic Technology

(Precision Breeding) Act 2023 was the culmination of those efforts and represented a major step forward. However, with more detailed implementing rules still to be developed and finalised, particularly in relation to food and feed marketing, RG noted that this was a timely and unique opportunity to hear from regulators and practitioners in Canada, which recently announced that the products of gene editing technologies would be regulated in the same way as conventionally bred. In developing a proportionate and enabling regulatory system here, RG indicated that there was much to learn from the Canadians – the scientific basis for their approach, and what it will mean for investment and innovation in Canada's plant breeding sector.

2. Guest speakers

(Copies of guest speakers' slides are available to download via the Meetings section of the All-Party Group web-site <u>www.appg-agscience.org.uk</u>)

Greg MacDonald, Agriculture Counsellor at Canada's Permanent Mission to the World Trade Organisation

Introducing policy context for Canada's approach to regulating the products of plant breeding, Greg MacDonald (GM) noted that innovation is needed to help address global challenges, such as enhancing food security and improving the sustainability and climate resilience of agricultural production. Science- and risk-based regulatory frameworks are also needed to encourage investment and innovation, while facilitating trade and protecting health and safety.

GM underlined the importance of ensuring regulatory oversight is consistent and proportionate to the risk, and takes account of the need for international cooperation and policy alignment where possible.

He explained that following a request from seed developers in Canada to clarify the application of 'novelty' in relation to the products of plant breeding, based on the product's characteristics rather than the breeding technology used, Health Canada and the Canadian Food Inspection Agency (CFIA) recently updated their regulatory guidance.

Health Canada published a scientific opinion on the regulation of gene edited plant products in the context of the Novel Food Regulations, while the CFIA published a rationale for updated guidelines on which plants are regulated under the Seeds Regulations. The key conclusions from both reviews were that:

- gene editing technologies do not pose any unique risks to food or environmental safety compared with other plant breeding practices;

- gene-edited plant products should be regulated like all other plant products;

- a product-based approach to regulating "novel" foods and seeds should be maintained;

- regulation remains based on the characteristics and not the specific process used to introduce those characteristics

GM explained that the new guidance outlines five criteria to determine which foods derived from new genetic technologies (NGTs) will not require pre-market notification and assessment as novel foods. Products meeting all 5 criteria_are not considered novel and do not require notification to Health Canada for a pre-market food safety assessment.

Essentially these criteria ask developers the following questions:

1 – Did you alter an existing (non-allergenic, non-toxic) protein in a plant to turn it into an allergen or toxin?

- 2 Did you increase <u>a known</u> allergen or toxin in that plant species?
- 3- Did you change the nutritional composition of the food
- 4- Did the change alter the food use of the plant
- 5- Did the plant introduce foreign DNA

GM noted that if a plant derived from an NGT answered yes to any of these questions, it would be considered a novel product and require a pre-market notification and safety assessment.

In addition, updated guidance in relation to seed from CFIA published on 2 May 2023 stipulated that plants developed by inserting foreign DNA, as well as all herbicide tolerant plants, require separate CFIA assessment and authorisation.

GM added that to address public interest in greater transparency regarding gene-edited plant products, Health Canada has developed a Transparency Initiative. This seeks to provide information on the types of gene-edited plant products that may be used as food in the Canadian market and, with support from the seed sector, to maintain an industry-led Canadian Variety Transparency Database to indicate which varieties have been developed with gene editing, with government oversight to monitor the database for completeness and accuracy.

Krista Thomas, Vice President of Trade Policy and Seed Innovation, Canada Grains Council

Opening her presentation, Krista Thomas noted that the global grain handling system is globally important as a source of affordable nutrition. Disruptions to the system can seriously affect food prices and availability. To illustrate this point, KT showed a picture of a typical Panamax cargo ship carrying wheat which holds enough calories to sustain 91 million people for one day, or 250,000 people for one year.

She explained that the affordability of the global grain trading system depends on sophisticated infrastructure capable of handling large volumes, as well as the interchangeability of supply in response to unanticipated events and shocks to supply.

KT noted that regulatory systems in export markets around the world directly impact the ability of Canadian farmers to grow gene edited varieties, and therefore to take advantage of technologies which can help farmers producer food more sustainably. She suggested that more sustainable agriculture with reduced climate and less consumption of natural resources is not a country-specific objective, but a global one, and internationally harmonised regulations should facilitate farmers' access to gene edited varieties to help produce food more reliably in the face of climate change.

Highlighting the Canadian grain industry's commitment to transparency, KT explained that Seeds Canada launched the Canadian Variety Transparency Database in autumn 2022. This complements information from Health Canada in relation to novel products of plant breeding but also provides a greater level of information about gene edited and other crop varieties available to farmers. She outlined how these systems, working together, enable choice and provide the basis for producers and their supply chains to meet market and consumer demands for information.

KT noted that regulators can be sensitive to prevailing public preferences and perceptions, pointing to 2021 consumer research by the Canadian Centre for Food Integrity which indicated that Canadian consumers have less negative views about 'plant breeding' than genetic modification or, to a lesser extent, gene editing. But she cautioned against reading too much into opinion polls such as this, since the public generally have a low understanding of modern plant breeding methods, or awareness that all seed is already highly regulated, and that many common foods contain anti-nutrient compounds that are controlled by plant breeders.

In conclusion, KT observed that regulations or policies, once in place, are not easy to change, and that aligning with trading partners early on will help to set the stage for future opportunities in regulatory cooperation. She emphasised that regulatory requirements should be risk-based and sufficient to protect the public. Adding extra requirements beyond what is necessary in terms of scientific evidence of risk does not make consumers feel safer and comes with a global cost. Regulatory capacity is a further consideration, she noted, in view of the thousands of new plant varieties released to farmers every year.

Dr Jodi Souter, Plant breeder & Adjunct Professor of Biology, University of British Colombia

Dr Jodi Souter (JS) introduced herself as an independent plant breeder and co-owner of J4 Agri-Science, an Adjunct Professor at the University of British Columbia, a farmer on the family farm in Saskatchewan, and a 2020 Nuffield Scholar.

Offering a plant breeder's perspective on the opportunities provided by Canada's regulatory approach to gene editing, JS explained that, over recent decades, progressive improvements in technological innovation have enabled the field of plant breeding to progress from only selecting for visual traits with simple genetic controls to solving more complex issues. Incrementally, these advances have made plant breeding a faster and more flexible process, allowing breeders to respond more effectively to global challenges.

JS noted that gene editing is the latest tool that plant breeders can add to their arsenals and use responsibly to achieve needed improvements in crop varieties. Compared to other breeding methods, she suggested that gene editing allows plant breeders to be much more precise and accurate in their efforts to solve the multi-faceted problems facing the entire food system.

To illustrate the tool analogy, she likened gene editing to a multi-bit screwdriver set vs. a butter knife when faced with the task of opening a box secured by different headed screws (see pic).



Once a potential trait of interest has been identified, she added that gene editing allows for an accelerated development process to introduce the trait, removing the need for lengthy crossing, back-crossing and selfing to remove unwanted traits, potentially achieving in just 2 years what currently requires 3-6 years or even longer. But JS emphasised that this accelerated development through gene editing does not change or remove the need for rigorous assessment

through field testing, seed multiplication and official variety registration, a six-year process for most crop types which underpins the plant breeding industry's impeccable track record of due diligence and delivery of safe products to market.

JS welcomed the updated guidance on products of gene editing from Health Canada and CFIA, which she considered would give independent plant breeding companies like hers greater confidence to use these new tools – especially those working in smaller niche and speciality crops.

But JS also highlighted the need for a harmonised international approach to regulation of new breeding technologies, noting that her own gene editing research into short-strawed flax could run into commercial challenges because the EU is a major importer of 'non-GM' flax from Canada. She suggested that these regulatory differences could deter the commercial uptake of gene edited varieties in Canada, and yet the short strawed trait offered major environmental advantages by avoiding the need for straw burning. The environmental impacts of such practices are not confined to national boundaries, and require a common, global approach to providing solutions.

Concluding the meeting, RG thanked guest speakers and attendees for their contribution to an informative and thought-provoking session, noting that members of the EFRA Committee were due to visit Canada later in the year when they would have an opportunity to learn more about the impact of a more enabling approach to regulation of new innovations in plant breeding.