



COMPREHENSIVE ECONOMIC AND TRADE AGREEMENT (CETA)

14TH MEETING OF THE BILATERAL DIALOGUE ON BIOTECH MARKET ACCESS ISSUES

**23 SEPTEMBER 2022
(BY VIDEOCONFERENCE)**

JOINT REPORT

The fourteenth meeting of the EU-Canada Dialogue on Biotech Market Access Issues (“Biotech Dialogue”) took place on 23 September 2022 through an online meeting with participants in Brussels, Ottawa, and Parma.

1. Introductions and Opening Remarks

Both Canada and the European Commission (‘EC’) perceive the Biotech Dialogue as an important instructive meeting where both parties can discuss aspects related to biotech legislation & approvals. Canada also underlined and shared its support for an intersessional meeting of the Dialogue, which could allow for more technical and focused discussions.

Canada called on the EC to conduct approvals for genetically modified (GM) events as efficiently as possible. In light of Russia’s invasion of Ukraine, Canada underlined the importance of ensuring global food security, and conveyed its views on the positive contribution of GM products to sustainability, reduction of environmental footprint, and resilience of the supply chain. Canada communicated appreciation that timelines for GM approvals and renewals by the EU have improved over the past two years, but that delays in the approval of stacks remain of serious concern to Canada.

The EC stressed that both jurisdictions need to respect their own internal procedures, which may sometimes be perceived as complicated by the other party.

2. GM Event Approvals

2.1. Status of specific applications under EFSA assessment/post-EFSA approval

Canada brought forward a list of 39 applications that are in the risk assessment or approval process, seeking an update. The European Food Safety Authority (EFSA) and the EC provided information focusing on the priority applications identified by Canada

and committed to a written update on the full list following the conclusion of the Dialogue.

2.2. Pre and post EFSA assessment process and timelines

EFSA presented an update on the implementation of the Transparency Regulation in the context of the biotech assessment process.

Canada asked for details on the pre-submission advice process, and for clarifications on requesting a derogation for data requirements. EFSA explained that the legislation provides that such a derogation is requested by applicants when submitting their application. The EC clarified that derogations on data requirements should be exceptional, and do not replace exploring all options to generate the required data. Canada highlighted that in its view pre-submission advice would be most useful if it allowed for case-specific advice.

Canada is pleased that timelines for the assessment and authorisation process for GMOs are improving, but considers that further efficiencies are possible, notably on the use of concepts such as familiarity when assessing stacks.

3. EU Stacked GM Event Review and Approval Process

3.1. Overview of EU's regulatory approach to assessing stacked GM events with examples

3.2. Discussion on opportunities and challenges

Canada and the EC exchanged information on their respective approaches to the approval of stacked events.

The EC explained that the EU genetically modified organism (GMO) legislation requires an authorisation for all GMOs on the EU market (which includes stacks) and that it contains specific provisions related to stacked GM events, requiring that both the individual single GM events and the resulting stacked GM event undergo risk assessment. EFSA explained that, in addition to the aspects covered for the composing single GM events, the risk assessment of stacked GM events focuses on the integrity of each individual GM event when combined in the stack and the expression and possible interactions between the newly expressed proteins present in the stacked event; the assessment also verifies potential additive synergistic or antagonistic effect for human, animals, and the environment resulting from the combination of the transformation events in relation to toxicology, allergenicity and nutritional aspects.

Canada asked the EU whether EFSA considers familiarity in instances where a stack contains a previously authorised single GM event. EFSA explained that in such cases the risk assessment is comparable to a renewal, checking the updated bioinformatics and literature review. Canada asked about a threshold or process in place for the EU to determine whether data based on familiarity can be taken into account in the assessment process. EFSA explained that this is done on a case-by-case basis based on the traits and protein expressed in the plant.

The EU asked Canada to share its process for the approval of stacks, to which Health Canada responded that unless there are synergistic effects, Canada does not consider a stack to be novel and therefore does not require a full pre-market risk assessment.

Canada asked the EU to share information on limitations for conducting parallel assessments for stacks – meaning assessment of each trait and the full stack at the same time – to which the EC pointed to its regulatory requirement of having to conduct a risk assessment of each single trait as part of the process. EFSA noted that for previously approved traits, it does consider the original data that was provided by the applicant as part of the stack review process, but that some of the requested information will need to be provided again, including updated bioinformatics (any new information since authorization) on each single event.

4. EU Consultation on plants produced by certain new genomic techniques initiative

4.1. Overview of objectives &

4.2. Risk assessment considerations

Canada expressed support for the EC's initiative on legislation for plants produced by certain new genomic techniques (NGTs), and encouraged the EC to develop innovation friendly, trade-facilitative, science-based and risk-proportionate policy options.

The EC recalled the objectives of the policy initiative on plants developed by cisgenesis and targeted mutagenesis: maintaining a high level of protection of human and animal health and of the environment whilst creating an enabling legal framework allowing these techniques to contribute to achieving the goals of the European Green Deal and its Farm to Fork strategy. Since the last Dialogue, the EC has organised the public consultation¹ during which over 2000 reactions were received from a wide range of stakeholders. A factual summary of responses is published in the EC's website, and the EC reported on the main points reported there. An additional targeted consultation of Member States and expert stakeholders, and other targeted consultation activities, have been completed or are underway. The possible adoption of a legal proposal – if warranted by the impact assessment – is planned for the second quarter of 2023, after which the legislative procedure in Council and European Parliament starts.

Canada asked whether the EU plans to once again consult stakeholders as it develops its approach to regulating NGTs, to which the EU responded that it is not planning any further consultation process as part of this initiative.

Canada noted that in its view the EU's regulatory framework for products of NGTs should focus on the safety of a product for humans, animals, and the environment. A product's contribution to sustainability objectives is important, it should be separate from the marketing authorization. The EC responded that sustainability is a relevant aspect considered when developing agri-food policies in the context of the European Green Deal.

Canada and the EU discussed issues concerning transparency and traceability for products of NGTs, noting that this work is ongoing on both sides.

¹ https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en

5. EU Policy - Updates

5.1. EU Green Deal and Farm to Fork Strategy in relation to biotechnology

Canada asked the EU to share any developments related to biotechnology under the EU Green Deal and Farm to Fork Strategy.

The EC reported that the NGT initiative is the only policy initiative specifically related to biotechnology in the context of the European Green Deal and Farm to Fork Strategy. Further work related to Green Deal and Farm to Fork is ongoing, and horizontal initiatives such as the EU framework for sustainable food systems would apply horizontally to all types of products including those of biotechnology.

5.2. EU Sustainable Food Systems Initiative

The EC reported that the work on an EU framework for sustainable food systems is progressing in parallel to the NGT initiative, with its factual report on the public consultation also available through the EC's Have your Say website². While this initiative is not specific to biotechnology, it will apply to products of NGTs.

6. CAN Policy - Updates

6.1. Policy update: Novel Food Regulations in Canada and recent guidance updates

Canada provided an update on its novel food regulations and recent guidance updates. Canada and the EU discussed how to manage stakeholder concerns related to novel foods, and Canada highlighted the importance of making references to the science behind the decision making process. On the topic of transparency, Health Canada pointed to the database of novel products, which has been well received and utilized by Canadian industry stakeholders.

6.2. Policy update: Canadian efforts to update guidance related to Seeds Regulations

CFIA provided an overview of efforts to update guidance related to Seeds Regulation, placing emphasis on the fact that there are no expected regulatory changes but rather just guidance that will provide greater clarity to industry and developers.

6.3. Policy update: Update to recent guidance for Feed Regulation

Canada shared that a consultation process will soon begin, and that the guidance will aim at providing new categories that align with HC guidance for food. A publication of the guidance is expected in 2023.

7. Updates in International Activities

Canada highlighted that the 8th Meeting of the Global low level Presence Initiative (GLI) took place in March 2022 and expressed gratitude for the EC's attendance at past

² https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13174-Sustainable-EU-food-system-new-initiative_en

events. Canada also invited the EU to attend a webinar that Canada will be hosting under the APEC High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB) in November 2022. The webinar will outline the activities carried out by Canadian regulators to date for the purpose of developing new guidance focused on plant breeding, including those developed through gene editing, in order to enhance clarity and predictability surrounding the oversight of these products. Canada committed to sharing details on the upcoming webinar with the EU after the dialogue.

8. Any other business

On the topic of an intersessional meeting, Canada once again reiterated its interest in having more recurrent (perhaps shorter) meetings to discuss technical issues related to biotechnology. The EC indicated it would discuss internally and come back on this proposal.

Closing remarks:

Canada appreciated the possibility to include in the agenda some more detailed technical discussion and reiterated the possibility of an intersessional technical meeting, thus allowing for a shorter and more efficient Dialogue.

During the closing remarks, both delegations expressed gratitude for the open dialogue and opportunity to exchange information.

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