



COMPREHENSIVE ECONOMIC AND TRADE AGREEMENT (CETA) FULL NAME OF THE AGREEMENT

MEETING OF THE DIALOGUE ON BIOTECH MARKET ACCESS ISSUES, VIDEOCONFERENCE, 26 APRIL 2018

REPORT

The tenth meeting of the EU-Canada Dialogue on Biotechnology took place on 26 April 2018 by videoconference between Brussels, Parma and Ottawa. The European Commission and Canada underlined the importance of the Dialogue as a forum to exchange information on regulatory and technical issues affecting trade in agricultural products of biotechnology.

The Commission and the European Food Safety Authority (EFSA) presented the state of play of the applications for genetically modified organism (GMO) authorisation in the EU.

Canada expressed concerns over specific issues of the EU risk assessment, including the existing timelines for risk assessing GMO applications, including stacked events, the EU's 10-year expiry of authorizations which then necessitate renewal applications, and the retroactive application of EFSA guidance documents. Canada also expressed the usefulness of possible pre-submission meetings between applicants and EFSA to increase understanding of requirements and quality of submissions. EFSA confirmed that timelines for risk assessing stacked events have not increased, and that the evaluations of stacked events applications start only once all the relevant GMO single events are positively assessed by EFSA, underlining that those single events are not re-assessed. The Commission underlined that this is in line with the EU GMO regulatory framework. EFSA explained that its guidance documents are not retroactively applied, that applicants are informed of them in advance and that transitional periods set on a case-by-case basis are indicated in the documents themselves. The Commission explained that the EU GMO regulatory framework provides for authorisations over a ten-year period and sets out the obligation to submit renewal applications on time, which are subject to specific requirements (as compared to applications for new GMO events).

The Commission updated Canada on the state of play of the Commission's proposals on the possibility for the Member States to restrict or prohibit the use of GM food and feed in their territory and on changes to the comitology process. The Commission briefly

outlined its proposal on the transparency and sustainability of EFSA risk assessments and noted that the proposal would be formally notified to the WTO.

The Commission confirmed that there were no regulatory developments on the topic of new breeding techniques at the EU level and that the ruling of the EU Court of Justice is still pending.

Canada provided a brief update on biotechnology-related policy developments, including an overview of recently authorized GM products in Canada. COM expressed interest in further discussing Canada's approach to biotechnology and in continuing to exchange on these issues.

Upon request of the Commission, Canada provided an update on the GM labelling regime, as well as on recent discussion over the issue of GM animals in Canada.

The Commission requested an update specifically on GM salmon, including its traceability requirements. Canada informed the Commission that there is currently no GM salmon grow-out in Canada and there have been only limited imports to date. The Commission raised the issue of testing as a means of verifying imports coming into the EU. Canada noted that reference material to facilitate testing can only come from the product developer. Canada reaffirmed that products exported to the EU, including salmon, must meet EU import requirements.

Canada provided an update on the ongoing work of the Global Low Level Presence Initiative (GLI) and informed the Commission about international discussions on the trade and economic considerations related to new breeding techniques in which Canada is participating. The Commission expressed interest in receiving information on these international discussions and Canada committed to send additional information on these issues.

Upon Canada's request, the Commission elaborated on the rules of procedure for the CETA Joint Committee and for the specialised Committees and Dialogues established under CETA. The Commission also informed Canada of the procedure to discuss this with Member States. Canada noted that the CETA rules of procedure would be useful in providing broad-based guidance in the operation, reporting and transparency of the Dialogue on Biotechnology.