Joint report

1. Opening Remarks

CAN and EU underlined the importance of the dialogue as a forum to exchange information on regulatory and technical issues and challenges affecting trade in agricultural products of modern biotechnology. Both sides further acknowledged that the dialogue is a valuable mechanism for collaboration and discussion under the umbrella of CETA, which took effect in September 2017.

2. GM Event Approvals: EFSA assessment and timelines

2.1 Status of specific applications under EFSA assessment

EFSA presented the state of play of specific applications under risk assessment of particular interest to CAN (list provided in advance of the meeting).

2.2 EFSA assessment process and timelines

CAN noted its concerns that timelines for EFSA review of applications, including stack applications, have expanded over the years, expressed the value of pre-submission applicant-EFSA meetings to increase understanding of requirements and quality of submissions, noted with regret that EFSA guidance documents were applied retroactively, questioned why authorised products are subject to renewal authorisations (CAN noted its view that there is no evidence to support the need for a reassessment), and requested information about EFSA 2020 Strategy. CAN raised these issues as Canadian stakeholders continue to underline the need for improvements in predictability and timelines within the EU GM approvals process in order to facilitate the use of innovative tools in Canada.

EFSA explained that the overall timeline for risk assessing stacked events have not increased over time, explained that the evaluation of stack applications can be started only once all the single events are positively assessed by EFSA, and underlined that single events are not re-assessed. EFSA explained that its guidance documents are not retroactively applied, i.e. only applications submitted and datasets produced after the date of their implementation are subject to the new guidelines. EFSA also explained that it is not the current EFSA policy to have pre-submission meetings with applicants. However during the pre-validation phase of an application, applicants are informed on the completeness of their applications. In case of submission of an incomplete application, companies have the chance to provide the missing information before the risk assessment starts.

COM underlined that the need to assess single events was in line with the legislative framework and that the overall timeline can also depend on the quality of data provided by applicants and on the time need by applicants to reply to EFSA questions.

With regard to new EFSA guidance documents, EFSA explained that applicants are informed of them in advance (through e.g. online public consultations, open plenary meetings and annual meetings between EFSA and the biotech industry), and that transitional periods are always clearly indicated in the documents themselves, with a duration set on a case-by-case basis.

With regard to renewal applications, COM explained that the regulatory framework clearly provides for authorisations over a ten-year period, for the obligation to submit on time *renewal* applications, which are subject to specific requirements (as compared to applications for *new* GMOs).

With regard to EFSA 2020 Strategy, EFSA explained that science remains the driver of its activities, aiming at providing high-quality scientific advice to risk managers. EFSA agreed to send more information on EFSA 2020 strategy.

3. GM Event Approvals: Post EFSA approval process and timelines

3.1 Status of specific applications post-EFSA.

COM presented the state of play of specific applications of particular interest to CAN (list provided in advance of the meeting). COM pointed out the number of authorisations granted since the last EU-CAN bilateral meeting.

CAN welcomed the information provided, as well as recognised the number of authorisations granted since last meeting. CAN expressed concern over the voting pattern in Committee meetings, particularly in regards to the upcoming Brexit. COM took note.

4. EU Policy – Updates

4.1 Member State Food and Feed Opt-Out Proposal

COM explained that the proposal is at Council level, and pointed out that applications continue to be processed in line with the current legislative framework.

4.2 Member State Cultivation Opt-Out

CAN noted its concern that allowing opt-outs for reasons not associated with science-based risk assessments would seem to enable decision makers to ignore science, and undermine public trust in science and regulators.

COM underlined that the EU science-based risk assessment remains unchanged and Member States are allowed to adopt opt-out measures exclusively on grounds not conflicting with it.

4.3 Proposed changes to comitology process

COM explained that the proposal aims at increasing transparency and accountability in the decision-making process, and that the science-based approach of the authorisation process remains unchanged.

4.4 Overview and update on the EC legislative proposal on transparency and sustainability of EFSA Risk Assessments

COM briefly outlined the proposal and the 4 pillars on which it is based.

CAN explained that their analysis of the proposal was not yet finalised and expressed preliminary concerns over its possible impact on the timelines of the authorisation process and potential misinterpretation of highly scientific information.

COM underlined that improved risk communication is expected to enhance understanding of the risk assessment and that the proposed provisions on transparency and consultation are meant to solve issues at the appropriate stage of the process and therefore avoid issues being raised later on in the process causing then additional delays. COM also confirmed that the proposal will be notified to WTO.

4.5 "Precision Breeding Techniques"

COM confirmed that there are no regulatory developments on this topic at EU level. COM informed CAN that the ruling of the EU Court of Justice is still pending.

5. CAN Policy – Updates

5.1 GMOs and new techniques in agricultural biotechnology – Policy update and products approvals

CAN provided a brief update on biotechnology-related policy developments (an overview of recently assessed and authorized GM products in Canada was provided in advance of the meeting). CAN committed to provide available information that may assist the EU in determining whether CIBUS herbicide tolerant oilseed rape is available on the Canadian market. CAN further confirmed that all Canadian products exported to the EU must meet EU import requirements.

COM expressed interest in further discussing Canada's approach to biotechnology and in continuing to exchange on these issues.

5.2 Labelling of GMOs

COM requested an update on the GM labelling regime in Canada. CAN indicated that the approach has not changed; mandatory labelling is required only in the case of food products where there is a health risk or a change in the nutritional composition of the product. CAN reaffirmed that there are no mandatory labelling requirements for GM products that have been assessed to be as safe and nutritious as their conventional counterparts. CAN also indicated that there is a national voluntary labelling standard that Canadian food manufacturers may use, if they wish to inform consumers whether food products contain GM ingredients or not. In light of the 2016 report on GM animals by the Canadian Parliament's Agricultural Committee, CAN explained that there are ongoing discussions on how to increase transparency for GM animals. CAN further confirmed that all Canadian products exported to the EU, including those that are the product of genetic modification, must meet EU import requirements.

5.3 Traceability of GMOs for exports to the EU

COM requested an update on GM salmon in Canada, including traceability. CAN informed that, although GM salmon is approved for food and feed use in Canada, there is currently no GM salmon grow-out in Canada and limited imports into Canada of GM salmon to date. Canada further advised that it maintains health and safety related traceability requirements for fish and seafood, but indicated that there are no additional traceability requirements specific to GM products. In Canada, traceability requirements relate to scientifically justified health and safety concerns and, for the Government of Canada, approved GM foods and feed do not present different health or safety concerns than traditional foods and feed and do not warrant separate traceability requirements.

COM raised the issue of testing as a means of verifying imports and their challenge in acquiring the necessary material. CAN indicated that they do not have a test and confirmed that reference material to facilitate testing of the product can only come from the product developer. CAN further confirmed that all Canadian products exported to the EU, including salmon, must meet EU import requirements.

6. Updates on International Activities

6.1 Update on the Global Low Level Presence (LLP) Initiative (GLI)

CAN provided an update on the ongoing work of the GLI, which it noted has held five face-to-face meetings to date with the most recent meeting in June 2017 in Rome. CAN noted the EU's past participation in the meetings and invited the EU to participate in the 6th meeting of the GLI as an observer, which will be hosted by Brazil in September 2018 (co-chaired by Canada and Brazil).

6.2 International discussions on "Precision Breeding Techniques"

CAN informed COM about international discussions on the trade and economic considerations related to "precision breeding techniques", including an overview of recent meetings in London in September 2017 (alongside an International Seed Federation meeting) and in Colombia in April 2018 (as part of the Genome editing seminar for biotechnology regulators in the Americas). CAN invited the EU to participate in these discussions, once there is more clarity in their domestic approach.

COM expressed interest in receiving information of these international discussions and CAN committed to send further information on this issue.

7. Other Business

CAN asked COM about their views on the rules of procedure for the CETA Joint Committee and for the specialised Committees/Dialogues established under CETA.

COM explained that the CETA rules of procedure would govern the operational aspects of planning and reporting of CETA Committee meetings. On the EU side, the Commission will be empowered by a Council Decision before adoption of the rules of procedure in the CETA Joint Committee. To this end, the Commission will shortly put forward a Proposal, which will be discussed with Member States. CAN noted for its part that the CETA rules of procedure would be useful in providing broad-based guidance in the operation, reporting and transparency of the Biotechnology Dialogue.