BRIEFING *Origin: DG TRADE*	○ **Subject: CETA and EU-Canada Trade issues** ○ **CM Mission Canada: Broader meeting of EU and Canadian Delegations** ○ **26 September 2018 – 10.30-** ○ **Montréal**

OTHER SPS ISSUES- NOT ON AGENDA

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New Breeding Techniques/ precision Breeding Techniques

In July 2018, the Court of Justice of the European Union provided important clarification on the scope of application of the European GMO legislation in relation to organisms obtained by mutagenesis techniques.
According to the Court ruling, the GMO legislation is applicable to organisms obtained by new mutagenesis techniques.
Operators in and outside the EU remain responsible for ensuring that products which are placed on the market are safe and comply with all relevant regulatory requirements.

Question: How will the Commission address the challenge to distinguish new mutagenesis techniques products from organisms obtained through classical mutagenesis or from conventional breeding?
This is one of the questions that the Member States, as enforcement authorities, and the Commission will need to address.

Question: Does the Commission intend to clarify the status of products obtained from new techniques, other than targeted mutagenesis techniques?
There is no such plans at the moment.

Question: Does the Commission have plans to modernise the GMO legislation?
The Commission has no such plans.

In more detail:
The Court of Justice of the European Union was requested to give a preliminary ruling regarding the regulatory status of organisms produced by means of certain biotechnological techniques known as "new mutagenesis techniques", and in particular on whether such techniques are exempted from the GMO-legislation. The Directive on the deliberate release of GMOs contains an exemption applicable to "classical mutagenesis techniques", which already existed before the adoption of the Directive. The ruling was rendered on 25 July 2018.
The outcome of the ruling is that only the organisms obtained by means of techniques or methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are exempted. Therefore, the GMO legislation is applicable to organisms obtained by new mutagenesis techniques, which have emerged since the adoption of the Directive on the deliberate release of GMOs.
In Canada, there is no differentiation between organisms obtained by new mutagenesis techniques (precision breeding techniques) and GMOs as such; they all fall, under certain conditions, under the legislation on novel foods. A plant with a novel trait is a plant that contains a trait, which 1) is new to the Canadian environment and 2) has the potential to affect the specific use and safety of the plant with respect to the environment and human health. These traits can be introduced using biotechnology, classical mutagenesis, or conventional breeding techniques. For example, a herbicide tolerant oilseed rape from the company Cibus, which has been obtained through a new mutagenesis technique (oligonucleotide directed mutagenesis), has been available in Canada since 2017. After the clarification provided by the CJEU, this product would have to comply with the EU GMO legislation (authorisation/detection/traceability/labelling) to be imported in the EU.

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EU-Canada Bilateral Dialogue on Biotech

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Biotech dialogue is a constructive one that allows exchanging information on concerns of Canada and the EU and on the evolution of biotech issues on both sides.

For the EU it is important to be transparent about the content and outcome of the dialogue. This is the only way to build and maintain the trust of our citizens in the dialogue and trade between EU and Canada.

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[Out of Scope]

Question: How will the Commission ensure that the recent ruling of the Court of Justice on mutagenesis will not affect trade in biotech products?

The recent ruling of the European Court of Justice clarifies the scope of our GMO legislation. The Court found that our GMO legislation is applicable to organisms obtained by new mutagenesis techniques.

Operators within and outside the EU remain responsible for ensuring that products which are placed on the market are safe and comply with all relevant regulatory requirements.

The Commission will further analyse the ruling of the Court of Justice to ensure its proper implementation. As necessary, we will reflect on potential further action, including the possible need for further clarification on specific issues.

In more detail:

The EU-Canada Bilateral Dialogue on Biotech

The 10th Dialogue on Biotech took place on 26 April 2018. The EU updated Canada on the state of play of specific GMO applications of Canada's interest. Canada updated the EU on GMO approvals on their side, and products having been developed through new mutagenesis techniques.

This was the first meeting under the CETA agreement and, therefore, with increased transparency (agenda and short report available on the website of DG TRADE). The finalisation of the minutes of the meeting and of the short public report has been a cumbersome exercise due to differences of views on the need for transparency on the discussions, the EU being ready to be very transparent.

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New plant breeding techniques: Court of Justice ruling on mutagenesis

The European Court of Justice (ECJ) was requested to give a preliminary ruling regarding, inter alia, (i) whether organisms produced by new mutagenesis techniques are excluded from the GMO-legislation and; (ii) whether Member States can regulate exempted organisms. The final ruling was delivered on 25 July 2018.

The ECJ reached the following conclusions:

Organisms obtained by mutagenesis techniques/methods which have been conventionally used in a number of applications and that have a long safety record are exempted from the obligations of the GMO legislation. Therefore, the GMO legislation is applicable to organisms obtained by mutagenesis techniques that have emerged since its adoption.

Member States are free to regulate exempted organisms and can subject them to the obligations laid down by the GMO Directive or to other obligations, provided that the measures adopted comply with EU law and in particular the rules on the free movement of goods.

The ECJ ruling does not follow the opinion of the Advocate General, published on 18 January 2018.

Stakeholders have reacted very differently to the ECJ ruling:

France welcomed the clarification given by the ECJ as an important step allowing competent authorities to ensure the protection of consumers and the environment in a harmonised manner and on the basis of the application of the precautionary principle.

From the European Parliament, Greens/EFA welcomed the ruling as a victory of the precautionary principle, and against a corporate attempt to bypass EU GMO laws. They called the Commission to ensure the technical tools necessary to implement the ruling. Concerning safety of new techniques, Greens/EFA also raised the need for an evaluation by EFSA, the Science Advisory Mechanisms or by an ad-hoc expert committee.

Some NGOs have expressed satisfaction with the ruling, which is in line with their claims regarding the need to regulate all new techniques under the GMO legislation in order to ensure appropriate risk assessment and freedom of choice to consumers. They have called on the Commission to ensure appropriate implementation of the judgment and emphasised the need to develop methodologies for tracing the products.

Industry has emphasised the negative effects of the ruling on EU agricultural research, innovation and competitiveness and claimed that many SMEs will not be able to withstand the competition of foreign enterprises with negative implication on jobs, R&D and economic growth. Industry also encouraged public dialogue on new techniques in order to develop risk-proportionate policy approaches and to ensure that innovation in the EU keeps paces with that in other parts of the world.

Most reactions from academic and research institutions expressed disappointment with the ruling, emphasising the negative impact on innovation, scientific development and competitiveness in the EU. They highlighted that most research institutions and smaller companies will not be able to access the market and called for a new regulatory framework to ensure legal certainty and innovation.

Contact persons: [Art. 4.1(b)] **Trade.E.1, ☎** [Art. 4.1(b)] **13 September 2018**
With inputs from [Art. 4.1(b)] [Art. 4.1(b)] **DG TRADE D3; and other services (DG AGRI and DG SANTE).**