EUROPEAN COMMISSION
Directorate-General for Trade

Deputy Director General

Brussels, 17 December 2018
F.2/ (2018)7237936
[Art. 4.1(b)]

NOTE FOR THE ATTENTION OF MARC VANHEUKELEN
HEAD OF THE EU MISSION TO THE WTO

Subject: **Instructions for the regular meeting of the WTO Dispute Settlement Body on 18 December 2018**

Summary:

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Seven returning disputes are listed under **implementation surveillance**: the EU will provide its usual status report on in *EC-Biotech* (DS 291) brought by the US;

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C. EUROPEAN COMMUNITIES – MEASURES AFFECTING THE APPROVAL AND MARKETING OF BIOTECH PRODUCTS: STATUS REPORT BY THE EUROPEAN UNION (WT/DS291/37/ADD.128)

Background

In 2003, the US brought WTO proceedings regarding certain EU level and certain Member State level measures relating to the approval and marketing of biotech products claiming that these affected imports of agricultural and food imports from the United States.

Similar WTO proceedings were brought by Canada and Argentina (the three WTO proceedings were later merged into one single dispute, DS 291). The DSB adopted a panel report in November 2006, which found that the EU violated the SPS Agreement on three grounds:

a) the EU applied a **general *de facto* moratorium** on approval of GM products between June 1999 and August 2003;

b) **undue delays** in the completion of 21 product-specific approval procedures brought forward by the US (out of 25 cases considered by the Panel);

c) **national safeguard measures** taken by 6 Member States, which were found not to be based on appropriate risk assessments.

On 19 December 2006, the EU informed the DSB of its intention to implement the Panel's recommendations and findings. The EU signed final settlements with CAN and with Argentina in 2010. The mutually agreed solutions provide for the establishment of regular bilateral dialogues on agricultural biotechnology market access issues of mutual interest.

Contrary to the other two complainants, the US did not consider the establishment of a dialogue sufficient in terms of compliance of the EU and thus, it was not ready to settle the dispute. To the contrary, it made a retaliation request on 17 January 2008, to which the EU objected. On 15 February 2008, and according to the sequencing agreement concluded with the US, both parties requested the suspension of the sanctions arbitration under Article 22.6 DSU. Those sanction arbitration procedures can only be resumed after conclusion of a compliance procedure based on Article 21.5 DSU.

An EU-US **technical dialogue on plant biotechnology** has been taking place on a regular basis since 2008. The last meeting took place on 17 July 2018.

Recent EU developments

- National restrictions on cultivation (the opt-out Directive)

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- The ruling of the Court of Justice of the European Union concerning new mutagenesis techniques

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 2001/18/EC, on the deliberate release of GMOs, contains an exemption applicable to "mutagenesis techniques", which already existed before the adoption of the Directive. The ruling was rendered on 25 July 2018.

The outcome of CJEU ruling is that the only 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 mutagenesis techniques, which have emerged since the adoption of Directive 2001/18/EC.**

- Statement of the Group of Chief Scientific Advisors on gene-editing

In October 2018, the Group of Chief Scientific Advisors decided to issue a statement following the CJEU ruling on mutagenesis. The statement presents some scientific considerations on the impact of the Court ruling and states that new scientific knowledge and technical developments have made the GMO legislation no longer fit for purpose. The Group concludes recommending a revision of the existing GMO legislation and urging a more inclusive discussion on how we want our food to be produced in the EU. The Group acknowledges that ethical, legal, societal and economic considerations are also important and concludes that there is a need for providing robust and independent evidence to the Court in a systematic and transparent way.

US statement at last regular DSB meeting on 21 November 2018:

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The US also referred to a recent public statement issued by the European Union's Group of Chief Scientific Advisors on 13 November 2018, in response to the ECJ ruling of 25 July 2018 that addresses the forms of mutagenesis that qualify for the exemption contained in EU Directive 2001/18/EC. The US noted that the Directive was a central issue in dispute in these WTO proceedings, and concerns the Deliberate Release into the Environment of Genetically Modified Organisms, or GMOs. The EU Group of Chief Scientific Advisor's statement recognizes that, "in view of the Court's ruling, it becomes evident that new scientific knowledge and recent technical developments have made the GMO Directive no longer fit for purpose." The US again urged the EU to finally act in a manner that will bring into compliance the measures at issue in this dispute.

Line to take

The EU continues to be committed to acting in line with its WTO obligations.

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[Defensive point on the Court ruling, if raised]

- *In July, the Court of Justice of the European Union provided important clarification on the scope of application of the GMO legislation in relation to organisms obtained by mutagenesis techniques.*
- *The CJEU ruled that organisms obtained by means of new techniques/methods of mutagenesis, which have appeared or have been mostly developed since the adoption of Directive 2001/18, fall within the scope of the Directive.*
- *The ruling has not extended the scope of the legislation but has clarified how it should be read.*
- *The Commission is now working to ensure proper implementation of the ruling together with the Member States. Member States are responsible at national level for the relevant control activities regarding the placing on the market of both products produced in the EU and imported ones. To this effect, the Joint Research Centre (JRC) is helping national laboratories to develop relevant detections methods.*

[Defensive point on the statement of the Group of Chief Scientific Advisors, if raised]

- *Group of Chief Scientific Advisors of Scientific Advice Mechanism (SAM) provides independent scientific advice to the Commission.*
- *The recent statement on gene editing initiated by the Group of Chief Scientific Advisors provides a scientific perspective on the latest developments on the use of directed mutagenesis, in particular on their regulatory status, which feeds into discussions with all stakeholders.*

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[e-signed]

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[Art. 4.1(b)] , [Art. 4.1(b)] - ***Permanent Mission of the EU to the WTO***

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