EUROPEAN COMMISSION
Directorate-General for Trade

Deputy Director General

Brussels, 21 June 2019
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[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 24 June 2019**

Summary:

[Out of Scope]

Eight returning disputes are listed under **implementation surveillance**: the EU will provide its usual status report on in *EC-Biotech* (DS291) 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.134)

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 12 June 2019.

Recent EU developments

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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 28 May 2019:

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For the remaining of the US statement, the US touched upon the same issues it normally does under this agenda item (i.e. long approval processes, opt-out Directive, statement by the EU's Group of Chief Scientific Advisors, invitation to bring measures at issue into compliance).

Line to take

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

Speaking points

- *The EU continues to progress with the authorisations where the European Food Safety Authority has finalised its scientific opinion and concluded that there are no safety concerns.*

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Second intervention to address recurring US arguments:

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- *In relation to the statement of the Group of Chief Scientific Advisors, the EU would like to recall that the Group of Chief Scientific Advisors is an independent group of scientific experts providing scientific advice to the European Commission.*

- *First, the EU would like to reiterate that this statement focuses on the future challenges for products obtained by new mutagenesis techniques, and not on the "conventional GMOs". The statement does not state nor imply that Directive 2001/18 is not fit for purpose as regards "conventional GMOs".*

- *Second, there have been many reactions to the judgement of the Court of Justice of the European Union, bringing forward a wide range of different views. The statement to which the United States referred, feeds into on-going discussions on new mutagenesis techniques with all stakeholders. Some stakeholders agree with that statement. However, many others consider that the current legislation is adequate to address the risks from new biotechnology developments.*

- *The European Commission has a strong interest in this debate, which should go beyond the regulatory status of new technologies and focus on the way new products could help address societal challenges, such as climate change or reduction of use of pesticides, without negative consequences on health and environment protection.*

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[e-signed]

Sandra GALLINA

C.c.: S. Weyand, H. König, I. Garcia Bercero, P. Sandler, M. Martin-Prat, D. Redonnet, [Art. 4.1(b)], L. Rubinacci,

[Art. 4.1(b)]

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[Art. 4.1(b)] ***– EEAS***

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