



**EUROPEAN COMMISSION**

Directorate-General for Trade

Directorate D - Sustainable Development; Economic Partnership Agreements - African, Caribbean and Pacific; Agri-food

**Agriculture, Sanitary and Phytosanitary Market Access, Biotechnology**

Brussels,  
TRADE.DGA1.D.3

**MEETING REPORT**

**Subject: EU-US technical dialogue on plant biotechnology regulation,  
17 July 2018**

The US delegation was led by [Art. 4.1(b)], [Art. 4.1(b)] USTR for [Art. 4.1(b)] [Art. 4.1(b)]USDA, FDA, the US Department of State and the US Mission to the EU were also represented. The EU delegation was led by [Art. 4.1(b)], [Art. 4.1(b)] D3, DG TRADE. DG SANTE, EFSA and DG AGRI were also represented.

The US recalled that their priority in the dialogue was to normalise trade in biotechnology products, with the goal to reduce GMO approval delays in the EU and facilitate mutually beneficial trade.

Both sides confirmed their agreement that this dialogue is a good opportunity to exchange information on biotechnology policy developments in both the EU and the US.

[Redacted]  
[Out of Scope]  
[Redacted]

[Redacted]  
[Out of Scope]  
[Redacted]

At the request of the US, the Commission explained that:

- [Redacted] [Out of Scope] [Redacted]
- [Redacted] [Out of Scope] [Redacted]

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1 [Redacted]  
2 [Redacted]

- [Out of Scope]
- no regulatory development was ongoing in the EU on new plant breeding techniques and the ruling of the EU Court of Justice was still pending;

- [Out of Scope]

[Out of Scope]

On the modernisation of the US Coordinated Framework for the Regulation of Biotechnology, the US explained that the USDA statement of 28 March 2018 on plant breeding innovation aimed at clarifying whether specific products fall within the scope of USDA’s statutory regulation powers in the field of biotechnology. The US indicated that USDA-APHIS had just issued a notice of intent to Prepare Draft Programmatic Environmental Impact Statement on its Biotechnology Regulations.<sup>4</sup> FDA briefly presented Commissioners Gotllieb and Abram’s statement of 6 June 2018 on FDA’s New Efforts to Advance Biotechnology Innovation, announcing the agency’s policy focus in that field<sup>5</sup>; FDA is currently working on an Action Plan with specific timelines and goals to implement Commissioners' statement. FDA also mentioned that Congress mandated the agency to carry out a consumer outreach initiative. In addition, FDA referred to a report by the National Academies of Sciences, Engineering and Medicine on future products of biotechnology, commissioned by the three agencies and published in 2017.<sup>6</sup>

[Out of Scope]

[Out of Scope]

<sup>3</sup> [Out of Scope]

<sup>4</sup> [https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/brs-news-and-information/2018\\_brs\\_news/2018-noi-dpeis](https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/brs-news-and-information/2018_brs_news/2018-noi-dpeis).

<sup>5</sup> «First, advancing and protecting public and animal health by promoting innovation through an efficient and predictable science- and risk-based regulatory framework; second, strengthening public outreach and communication through strong, effective and transparent engagement with stakeholders; and third, increasing engagement with domestic and international partners through coordinated and collaborative actions to support regulatory alignment and efficiency.»

See: <https://blogs.fda.gov/fdavoices/index.php/tag/biotechnology/>.

<sup>6</sup> National Academies of Sciences, Engineering, and Medicine, 2017. *Preparing for Future Products of Biotechnology*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24605>.