

Contribution to Speaking points for DG Anne Bucher in Roundtable at The American European Community Association on 11-09-2019 (SANTE 4864)

New Breeding Techniques (NBTs)

The CJEU ruling on mutagenesis

In July 2018, the Court of Justice of the EU (CJEU) concluded that organisms obtained by means of new mutagenesis techniques/methods, which have appeared since the adoption of Directive 2001/18 on deliberate release of genetically modified organisms, fall within the scope of this Directive. The ruling has not extended the scope of the legislation but clarified how it should be read.

President Trump's executive order on modernising the regulatory framework for agricultural biotechnology products – 11 June 2019

President Trump signed an order calling, *inter alia*, for regulatory streamlining by all relevant agencies with a view to ensure that regulation on biotechnology products is proportionate to the risks, avoids unjustifiable distinctions across products, and facilitates the development of products with significant health, agricultural or environmental benefits. Specifically, the United States Trade Representative (USTR) was asked to develop (within 120 days) an **international strategy to remove unjustified trade barriers and expand markets** for products of agricultural biotechnology.

EU-US Technical dialogue on plant biotechnology regulation – 12 June 2019

In the last bilateral meeting between the Commission (TRADE/SANTE) and USTR on plant biotechnology, the **US welcomed the recent position expressed by Commissioner Andriukaitis calling for new legislation on biotechnology**, the efficient handling by the Commission services of risk-assessed GMO applications, and the adoption of a number of EFSA opinions on GMO applications in recent months. The Commission stressed the increase of soybeans imports from the US as a sign of the absence of significant trade barrier. The US welcomed the increase in soy trade. The US asked very detailed questions on the July 2018 CJEU ruling on new mutagenesis techniques and follow-up activities. The Commission explained that it was working together with the Member States to ensure that GMO law is implemented in line with the Court's clarification.