



BRIEFING

Origin: DG TRADE

- o Subject: Sanitary and phytosanitary (SPS) and pharmaceutical issues
- o Meeting: DG SANTE-TRADE senior management meeting
- o Date: 26 March 2019
- o Place: DG SANTE

SCENE SETTER

Out of scope

Ms. Bucher and Mr. Plewa had a similar meeting (12 February), where they discussed, inter alia,

Out of scope

new breeding techniques and their potential market disruption in the EU;

Out of scope

Out of scope

KEY OBJECTIVES & MESSAGES

[Out of Scope]

[Out of Scope]

[Out of Scope]

[Out of Scope]

[Out of Scope]

[Out of Scope]

[Out of Scope]

[Out of Scope]

[Out of Scope]

M	BRIEFING <i>Origin: DG TRADE</i>	<ul style="list-style-type: none"> ○ Subject: Sanitary and phytosanitary (SPS) and pharmaceutical issues ○ Meeting: DG SANTE-TRADE senior management meeting ○ Date: 26 March 2019 ○ Place: DG SANTE
----------	--	--

[Redacted]

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

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

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

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

4. SPS specific issues – Defensive issues

Objectives:

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

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

- Get SANCO views on the prospects that the next Commission regulates new breeding techniques.

Key messages:

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



BRIEFING

Origin: DG TRADE

- o Subject: Sanitary and phytosanitary (SPS) and pharmaceutical issues
- o Meeting: DG SANTE-TRADE senior management meeting
- o Date: 26 March 2019
- o Place: DG SANTE

[Redacted]

- [Redacted]
[Out of Scope]

- [Redacted]
[Out of Scope]

- [Redacted]
[Out of Scope]

[Redacted] **On new plant breeding techniques**, do you see any room for the next Commission to take the initiative and regulate the issue, given that the Group of Chief Scientific Advisors said GMO legislation isn't fit-for-purpose? The current situation creates uncertainty for businesses, which are already marketing products issued from those new techniques in other countries.

- [Redacted]
[Out of Scope]

- [Redacted]
[Out of Scope]

[Redacted]
[Out of Scope]

[Redacted]
[Out of Scope]

[Redacted]
[Out of Scope]



BRIEFING

Origin: DG TRADE

- o Subject: Sanitary and phytosanitary (SPS) and pharmaceutical issues
- o Meeting: DG SANTE-TRADE senior management meeting
- o Date: 26 March 2019
- o Place: DG SANTE

4. SPS SPECIFIC ISSUES – DEFENSIVES (EU LEGISLATION)

4.1. PESTICIDES, GMOs, NEW BREEDING TECHNIQUES

SCENE SETTER

[Out of Scope]

[Out of Scope]

[Out of Scope]

[Out of Scope]

[Out of Scope]

[Out of Scope]

[Out of Scope]

[Out of Scope]

[Out of Scope]

New plant breeding techniques (NPBTs):

In July 2018, the Court of Justice of the European Union (CJEU) gave 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. 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.

M	BRIEFING <i>Origin: DG TRADE</i>	<ul style="list-style-type: none"> o Subject: Sanitary and phytosanitary (SPS) and pharmaceutical issues o Meeting: DG SANTE-TRADE senior management meeting o Date: 26 March 2019 o Place: DG SANTE
----------	--	--

The outcome of ECJ 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.

In October 2018, the Group of Chief Scientific Advisors issued a statement following the CJEU ruling on mutagenesis. It 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.

At the regular meetings of the DSB, the US now quotes regularly the public statement issued by the Group of Chief Scientific Advisors.

On the Court ruling, the Commission has so far announced that it will not propose a new legislative initiative under this term. But the line of defence with third countries (summarised below) might need to be beefed up in the future:

- the ruling has not extended the scope of the legislation but clarified how it should be read;
- Member States are responsible for the relevant control activities regarding the placing on the market of both products produced in the EU and imported ones;
- the Commission is working with the Member State to implement properly the ruling. Notably , JRC is helping national laboratories to develop relevant detections methods;
- the Group of Chief Scientific Advisors provides independent scientific advice to the Commission but its statement on biotechnology is only one among many views and feeds into on-going discussions with all stakeholders.

CHECKLIST OF KEY MESSAGES

[Out of Scope]

■ [Redacted]
[Out of Scope]
[Redacted]

■ [Redacted]
[Out of Scope]
[Redacted]
[Redacted]
[Redacted]

