

Origin: DG TRADE

Subject: Sanitary and phytosanitary (SPS) and pharmaceutical issues
 Meeting: DG SANTE-TRADE senior management meeting
 Date: 26 March 2010

o Date: 26 March 2019 O Place: DG SANTE

INDEX

Page

2

Scene setter, key objectives and messages

	Back	sground files	
1.	[Out	t of Scope]	
	1.1.		
	1.2.		
	1.3.		
	1.4.		
2.	[Ou	at of Scope]	
3.	[Out	of Scope]	
	3.1.		
	3.2.		
	3.3.		
	3.4.		
	3.5.		
4.	SPS	specific issues – Defensives (EU legislation)	
	4.1.	EU legislation: Pesticides, GMOs, new breeding techniques	44
	4.2.	[Out of Scope]	
5.	Out	of Scope]	
	5.1.	or scope ₁	
	5.2.		
6.	[Ou	at of Scope]	
	6.1.		
	6.2.		
	6.3		
	6.4		



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SCENE	SET	\mathbf{r}

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			
potential market disruption in the EO,			
Out of scope			
KEY OBJECTIVES & MESSAGES			
[Out of Scope]			
[Out of Scope]			



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4. SPS specific issues – Defensive issues

Objectives:

[Out of Scope]

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

Key messages:

[Out of Scope]



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	[Out of Scope]
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	[Out of Scope]
	On now plant buseding techniques do
	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.
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	FO-1 - CG 1
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4. SPS SPECIFIC ISUES – DEFENSIVES (EU LEGISLATION)

4.1. PESTICIDES, GMOs, NEW BREEDING TECHNIQUES

SCENE SETTER	
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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.



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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	
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- 1		
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	[Out of Scope]	



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[Out of Scope]	

New plant breeding techniques:

- The July 2018 CJEU ruling on mutagenesis has sparked very strong criticism from WTO members and in particular from the US. The statement of the Scientific Advice Mechanism, according to which the GMO legislation is not fit for purpose from a scientific angle, is clearly not playing in favour of keeping the status quo.
- Products issued from those new techniques are reaching the market in other countries and that is creating very significant uncertainties for businesses.
- What are your prospects for the next Commission on this? Will DG SANTE put forward a legislative initiative on new mutagenesis techniques and/or to fill the gap for other new plant breeding techniques?

Contact person: [Art. 4.1(b)] Unit TRADE.D3 14 March 2019 [Art. 4.1(b)]