



Workshop: “GMO Regulation - quo vadis?”

21st November 2017

Agenda

The Workshop “GMO Regulation - quo vadis?” to be held in the main conference room (Room No. 435) of the Federal Office of Consumer Protection and Food Safety (BVL) on November 21st 2017 in Berlin aims to take a look forward to formulate ideas and expectations for a future regulation of genetic engineering. The main focus is on the foreseeable future which in Europe will likely be shaped significantly by the upcoming ruling of the European Court of Justice (ECJ) in the case C-528/16.

The Workshop on the one hand will therefore deal with some specific questions addressed to the ECJ by the French Conseil d’Etat and their possible answers. But the workshop on the other hand also aims to discuss regulatory alternatives to the current legislative framework in Europe that would be better suited to address the rapid progress of science and technology.

The workshop will bring together lawyers and natural scientists from the branch offices of the Federal Ministry of Food and Agriculture as well as invited guests and speakers.

Time	Topic	Speaker
10.00 am	Greetings	Prof. Dr. Detlef Bartsch, Head of the Department Genetic Engineering (BVL)
10.15 am	Genome Editing and mutagenesis in the sense of Annex IB of Directive 2001/18/EC The Conseil d’Etat asked the ECJ, whether Articles 2 and 3 of Directive 2001/18/EC and its Annexes IA and IB must be interpreted as if to exempt all organisms obtained by mutagenesis including targeted mutagenesis like Genome Editing from precautionary, impact assessment and traceability measures. This topic discusses this and other questions and the expected effects such as, whether there are limitations of what can be regarded as mutagenesis and how the legal requirement “does not involve the use of recombinant nucleic acid molecules” is to be understood.	Prof. Dr. Piet van der Meer, University of Ghent
11.15 am	Regulatory Requirements imposed by EU Primary Law Another question by the Conseil d’Etat is whether the validity of Articles 2 and 3 of Directive 2001/18/EC and its Annexes IA and IB to Directive 2001/18/EC of 12 March 2001 may be questioned bearing in mind the precautionary principle guaranteed by Article 191(2) Treaty on the Functioning of the	Tine Carmeliet, Allen & Overy (Belgium) LLP

Time	Topic	Speaker
	<p>European Union (TFEU) and the exemption of conventional mutagenesis techniques.</p> <p>This topic will discuss the likely answer by the ECJ and will shed light on the content of the precautionary principle according to the jurisprudence by the ECJ and the opinion of the European Commission. This topic will also examine whether Article 114(3) TFEU, which demands high level of protection for legislative proposals concerning environmental issues, imposes further legislative boundaries and whether EU Primary Law sets other limitations - apart from the free movement of goods.</p>	
<p>12.15 – 01.15 pm</p>	<p><i>Lunch Break</i></p>	
<p>01.15 pm</p>	<p>GMO regulation and free trade</p> <p>This topic will outline the limitations for GMO regulations set by international trade law, namely the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), the General Agreement on Tariffs and Trade (GATT) and the Agreement on Technical Barriers to Trade (TBT) as well as the free movement of goods as laid down in the TFEU.</p> <p>It will focus on the question whether or to what extent it is permissible to regulate genome edited organisms that are indistinguishable from naturally occurring mutants or conventionally bred varieties. It will also deal with the question addressed to the ECJ, on whether EU member states have a discretion to define the regime to be applied to organisms obtained by non-targeted mutagenesis.</p>	<p>Prof. Dr. Hans-Georg Dederer, University of Passau</p>
<p>02.15 pm</p>	<p>Regulatory oversight of GMOs in the UK</p> <p>This topic will inform about the regulatory oversight of GMOs, taking into account the current state of science and technology, UK parliamentary inquires and existing regulations in other countries.</p>	<p>Dr. Louise Ball, Department for Environment, Food and Rural Affairs, United Kingdom</p>
<p>03.15 – 03.30 pm</p>	<p>Closing remarks</p>	<p>Prof. Dr. Detlef Bartsch, Head of the Department Genetic Engineering (BVL)</p>
<p>03.30 – 04.30 pm</p>	<p><i>Coffee and Cake</i></p>	