Summary of key findings resulting from the legal opinion

prepared by Professor Dr. Dr. Tade M. Spranger

"In-depth analysis of various European directives and regulations with regard to their potential to regulate environmental effects of New Technologies besides Genetic Engineering Law"

There are currently differences of opinion as to whether the so-called new technologies such as CRIPSR/Cas and other genome editing methods are regulated under the existing legal framework of genetic engineering law. If organisms modified by new technologies were not considered as genetically modified organisms (GMOs), they would not be subject to the precautionary provisions of the genetic engineering law. However, it is argued that where appropriate, organisms modified by new technologies could be subject to the diverse general rules which are applicable to the cultivation of crops, animal breeding, safety of food and feed as well as the protection of the environment.

After examining the above-mentioned areas of law, Prof. Spranger concludes that the various European directives and regulations do not guarantee a level of protection comparable to that of genetic engineering law neither individually nor collectively.

In addition applying these would also lead to a significant fragmentation of the authorities' responsibilities. As a result of the resulting gaps in responsibility and testing, the legal areas listed below cannot therefore be used as "catch all regime" for the regulation of high-tech processes due to environmental protection aspects.

Legislation on seeds

European legislation on seeds and the German Seed Marketing Act, adopted pursuant to this Directive, are no adequate legal and control standard for new technologies. The possibility of refusing any placing on the market is linked to discretion and is made on the basis of unspecific criteria. Additionally, legislation on seeds does not aim at evaluating specific risks which may arise from the application of highly technological processes. The purpose of European and national legislation on seeds is to guarantee varietal identity and purity. If and to the extend that seed legislation mentions aspects of consumer protection, this applies only to consumers being protected from buying insufficient seeds. Consumer in this sense is not the end consumer but solely the consumer of seed. Post-control or monitoring are alien to the legislation on seeds.

Furthermore, various restrictions on the legislation on seeds were developed in case law. The legislation on seeds does not have a similar effect as a protective law and is not applicable to wild forms for constitutional reasons.

Plant variety rights are not relevant to the present question.

Food law

European food law is not suitable as a "catch all regime" for new technologies. Regarding Regulation (EC) No. 178/2002[1] it can be stated that a) live animals (unless they are prepared for placing on the market for human consumption), b) plants prior to harvesting, and c) tobacco and tobacco products are no "food" within the meaning of this Regulation. Following an anthropocentric focus, only feed which is fed to animals intended for human consumption is covered by the regime of Regulation (EC) No. 178/2002. However, aspects of the protection of the environment do not play a significant role. The requirements on risk assessment and the precautionary principle are insufficient. Regulation (EC) No. 178/2002 requires a comprehensive risk assessment. At first sight, the mechanism laid down in Artt. 6 and 7 of the Regulation seems comprehensive. But when applying new technologies, one can neither speak of an "agent" nor of a "condition" of food. Thus, there is no "danger" in the sense of the Regulation. Additionally, the precautionary principle has an anthropocentric focus within the scope of Regulation (EC) No. 178/2002. Possible harmful effects on the environment are left aside. The measures and penalties provided by the Regulation (EC) No. 178/2002 are not suitable to be a "catch all regime" for Genetic Engineering Law. Crucial for this is the fact that, following the basic principle of misuse, there is no preventive control or even no obligation to obtain a permit for the distribution of foods. Moreover, it is left to food business operators to achieve those standards, whereas the State has only a general control at a later point.

Regulation (EC) 258/97[2] is limited to certain food and raises doubts both with regard to its field of application and to the criterion of "substantial equivalence". It is questionable whether new technologies would trigger a labelling obligation. Apart from that the Regulation lacks product monitoring obligations and a level of transparency comparable to the one in Directive 2001/18/EC[3]. Despite all innovations the new Regulation (EU) No. 2015/2283[4] shares basic inadequacies with Regulation (EC) No. 258/97. Furthermore, Regulation (EU) No. 2015/2283 is not a "catch all regime" and leaves central questions regarding the monitoring of individual responsibility to the food business operators.

Regulation (EC) No. 1169/2011[5] deals with food information and therefore falls within consumer information law. It becomes clear that the Regulation (EU) No. 1169/2011 is only a supplement to Regulation (EC) No. 178/2002 and therefore shares the deficits of this subordinated framework. Nevertheless, substances produced by new technologies would not be

[1] Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
[2] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.
[3] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.
[4] Regulation (EU) No 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.
[5] Regulation (EU) No. 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No. 1924/2006 and (EC) No. 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No. 608/2004.

considered as 'ingredients' in the sense of Regulation (EU) No. 1169/2011. Since a preventive control does not take place, ethical concerns do not play a role in the context of Regulation (EU) No. 1169/2001.

Animal feed law

Food safety law, especially influenced by Regulation (EC) No. 767/2009[6], has several gaps which stand against the control of new technologies. This applies, in particular, to the completely different regulatory approach to food and feed law. Furthermore, the Regulation acknowledges that priority is given to requirements of highly technological processes. In particular, the Regulation's (EC) No. 767/2009 reference to Regulation (EC) No. 1829/2003[7] and Regulation (EC) 1830/2003[8] shows that Regulation (EC) No. 767/2009 does not aim to achieve a comparable test density. If organisms produced by new technologies were excluded from the scope of Directive 2001/18/EC, this exclusion would also apply to Regulation (EC) No. 1829/2003 and Regulation (EC) No. 1830/2003. This presumption of an inapplicability of Directive 2001/18/EC would necessarily lead to a regulatory and security gap, as food and feed law follow different standards regarding reasoning, mechanisms, control instruments, etc.

Plant protection law

Regulation (EC) No. 1107/2009[9] does not have an effect apart from the narrow area of plant protection products and is only applicable if those effects are targeted. Furthermore, Regulation (EC) No. 1107/2009 can be seen as an addition to the special legal framework of Directive 2001/18/EC but not as a substitute of possible missing requirements of new technologies.

Other legislation

Directive 92/43/EEC[10] provides a general environmental agenda for the European Union but does not offer concrete instruments for the control of new technologies.

Regulation (EC) No. 834/2007[11] assumes a diametrical relation of ecological / biological production on the one hand and GMO on the other hand and deals with ecological / biological

---

[6] Regulation (EC) No. 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No. 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC.

[7] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

[8] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

[9] Regulation (EC) No. 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.

[10] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora.

[11] Council Regulation (EC) No. 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No. 2092/91.

production. Against this background, Regulation (EC) No. 834/2007 would not function as a “catch all regime” in case of an inapplicability of European Genetic Engineering Law on new technologies. This applies all the more as not only the risk assessments mentioned in Regulation (EC) No. 834/2007 but also the administrative enquiry are not comparable to the risk assessment and the obligations provided by Directive 2001/18/EC.

In case of an inapplicability of Directive 2001/18/EC on new technologies, the general categories of Police and Regulatory Law do not apply. The reason for this is – apart from substantial deviations of the different Police laws of the Federal States – in particular the divergence between adverting danger and preventing risk, definition problems concerning the ascertainment of various basic terms of Police and Regulatory Law as well as the lack of professional competence of the general police authorities.