

**"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"**

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## **I. Subject matter**

The so-called 'new technologies' (aka new techniques) not only triggered a discussion about practical applications but also led to a political and legal discourse. The core question is whether new technologies fall under the scope of the European genetic engineering law or not.

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. More particularly, there would not be a risk assessment with regard to their impact on human life and health, the environment with its interacting systems, fauna, flora and material assets. However, 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.

Thus, the question arises which regulatory areas - beyond the European genetic engineering law - have to be considered when assessing the properties of organisms treated by new technologies. The answer of this question is of central importance with regard to the consequences of a potential deregulation of these technologies in genetic engineering law.

This expert opinion analyses different Directives and Regulations of the European Union with regard to their applicability as well as to their regulatory alternatives regarding new technologies. Additionally, it looks at the question whether and, if so, which national regulatory margins may be exercised.

## II. Directive 2001/18/EC as a benchmark

The main object of this expert opinion is to clarify whether and under which conditions the mechanisms provided by the Directive 2001/18/EC<sup>1</sup> could be substituted by other elements of European Law in the event that this Directive is not applicable to organisms produced by new technologies. For this reason, it is necessary to give a brief overview of the benchmark. The requirements and mechanisms for response laid down in the Directive 2001/18/EC have to be described briefly in order to identify the mechanisms and their protective effect on other secondary legislation.

In the field of release, according to Art. 6 (8), the principle of preventive control in form of a reservation on approval applies.<sup>2</sup> This principle is also applicable to so-called differentiated procedures and the so-called streamlined procedure.<sup>3</sup>

Art. 6 (2) lit. b of the Directive requires the implementation of a prior environmental risk assessment by the notifier.<sup>4</sup> The details of the environmental risk assessment are set out in Annex II of the Directive. In general terms, according to Annex II letter A: the "objective of an e.r.a. is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment which the deliberate release or the placing on the market of GMOs may

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<sup>1</sup> 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, Official Journal L 106/1, 17. April 2001.

<sup>2</sup> Herdegen, M., and Dederer, H.G. (2015) Internationales Biotechnologierecht, update No. 50, Heidelberg, Directive 2001/18/EC recital 74.

<sup>3</sup> Herdegen, M., and Dederer, H.G. (2015) Internationales Biotechnologierecht, update No. 50, Heidelberg, Directive 2001/18/EC recitals 74 and 75.

<sup>4</sup> In general: Winter (2006) Naturschutz bei der Freisetzungsgenehmigung für gentechnisch verändertes Saatgut. In: ZUR 2006, 456 - 464, pp. 458 . et seq.

have. The e.r.a. should be conducted with a view to identifying if there is a need for risk management and if so, the most appropriate methods to be used.”

Within the framework of any administrative decision, Art. 4 (1) sentence 1 determines the criteria for the decision. When dealing with the prevention of harmful effects on human health and environment, there is no significant margins for a risk benefit analysis.<sup>5</sup> In contrast to the case of e.g. variety release, the requirement for any release authorization is that harmful consequences for the environment are not expected according to the result of the risk assessment.

Furthermore, for transparency reasons, Directive 2001/18/EC requires the participation of the public resp. public access to information.<sup>6</sup>

According to Art. 8 (1) of the Directive, the notifier has comprehensive downstream obligations:

“(1) In the event of any modification of, or unintended change to, the deliberate release of a GMO or of a combination of GMOs which could have consequences with regard to risks for human health and the environment after the competent authority has given its written consent, or if new information has become available on such risks, either while the notification is being examined by the competent authority of a Member State or after that authority has given its written consent, the notifier shall immediately:

(a) take the measures necessary to protect human health and the environment;

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<sup>5</sup> Herdegen, M., and Dederer, H.G. (2015) Internationales Biotechnologierecht, update No. 50, Heidelberg, Directive 2001/18/EC recitals 95 et seq.

<sup>6</sup> See the overview in Herdegen, M., and Dederer, H.G. (2015) Internationales Biotechnologierecht, update No. 50, Heidelberg, Directive 2001/18/EC fn. 125.



(b) inform the competent authority in advance of any modification or as soon as the unintended change is known or the new information is available;

(c) revise the measures specified in the notification." According to Art. 10 sentence 1 half sentence 1 of the Directive, these obligations are complemented by disclosure obligations of the notifier towards the competent national authority. Relating to the dominant view, the necessity of implementation of official post-controls is implied by this reporting obligations.<sup>7</sup>

Apart from these post-controls, the member states "shall ensure that the competent authority organises inspections and other control measures as appropriate, to ensure compliance with this Directive" (Art. 4 (5) sentence 1).

For placing products on the market, the principle of prior notification (Art. 13 (1)) applies, too. The scope and content of the notification is described in Art. 13 (2) as follows:

"[t]he notification shall contain:

(a) the information required in Annexes III and IV. This information shall take into account the diversity of sites of use of the GMO as or in a product and shall include information on data and results obtained from research and developmental releases concerning the impact of the release on human health and the environment;

(b) the environmental risk assessment and the conclusions required in Annex II, section D;

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<sup>7</sup> Herdegen, M., and Dederer, H.G. (2015) Internationales Biotechnologierecht, update No. 50, Heidelberg, Directive 2001/18/EC recital 108.

(c) the conditions for the placing on the market of the product, including specific conditions of use and handling;

(d) with reference to Article 15 (4), a proposed period for the consent which should not exceed ten years;

(e) a plan for monitoring in accordance with Annex VII, including a proposal for the time-period of the monitoring plan; this time-period may be different from the proposed period for the consent;

(f) a proposal for labelling which shall comply with the requirements laid down in Annex IV. The labelling shall clearly state that a GMO is present. The words "this product contains genetically modified organisms" shall appear either on a label or in an accompanying document;

(g) a proposal for packaging which shall comprise the requirements laid down in Annex IV;

(h) a summary of the dossier. The format of the summary shall be established in accordance with the procedure laid down in Article 30 (2).

If on the basis of the results of any release notified under part B, or on other substantive, reasoned scientific grounds, a notifier considers that the placing on the market and use of a GMO as or in a product do not pose a risk to human health and the environment, he may propose to the competent authority not to provide part or all of the information required in Annex IV, section B.

If and to the extent Art. 12 (1) of the Directive allows exceptions in scope for placing products on the market, appropriate procedures must guarantee that "[the] requirements as regards risk management, labelling, monitoring as appropriate, information to the

public and safeguard clause [are] at least equivalent to that laid down in this Directive.”

Art. 15 enables the commission or the authorities of the member states to raise objections. The scope of this article also allows to provide socio-economic or ethical reasons.<sup>8</sup>

As well as in case of release, when placing products on the market, various measures concerning the public participation must be taken into account. Additionally, one need to make an entry in the register on genetic modifications in GMOs.<sup>9</sup>

After placing the product on the market, the notifier faces comprehensive obligations concerning the issue of monitoring resp. product monitoring<sup>10</sup> which are accompanied by measures of administrative monitoring.<sup>11</sup>

Infringement of the requirements for release or for placing products on the market shall be penalised. For this purpose, Art. 33 of the Directive stipulates that: “Member States shall determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive. Those penalties shall be effective, proportionate and dissuasive.”

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<sup>8</sup> Herdegen, M., and Dederer, H.G. (2015) Internationales Biotechnologierecht, update No. 50, Heidelberg, Directive 2001/18/EC, recital 129.

<sup>9</sup> Herdegen, M., and Dederer, H.G. (2015) Internationales Biotechnologierecht, update No. 50, Heidelberg, Directive 2001/18/EC, recitals 148 et seq.

<sup>10</sup> For more details: Hofmann, C. (2014) Öffentlich-rechtlich statuierte Produktbeobachtungspflichten als Mittel der Sicherheitsgewährleistung im Produkt-, Stoff- und Technikrecht, Baden-Baden, p. 53 et seq. and p. 82 et seq.

<sup>11</sup> Herdegen, M., and Dederer, H.G. (2015) Internationales Biotechnologierecht, update No. 50, Heidelberg, Directive 2001/18/EC recitals. 167 et seq.

### III. European legislation on seeds

#### 1. Standards of European legislation on seeds

The European legislation on seeds is characterised by a wide diversity of special legislation. Currently, secondary law contains the following 11 Directives:

- Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed<sup>12</sup>
- Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed<sup>13</sup>
- Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine<sup>14</sup>
- Council Directive 92/33/EEC of 28 April 1992 on the marketing of vegetable propagating and planting material, other than seed<sup>15</sup>
- Council Directive 92/34/EEC of 28 April 1992 on the marketing of fruit plant propagating material and fruit plants intended for fruit production<sup>16</sup>
- Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants<sup>17</sup>

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<sup>12</sup> Official Journal 125, 11/07/1966 pp. 2298 - 2308 amended most recently by Directive 2004/55/EC, Official Journal L 114, 21/04/2004 p. 0018.

<sup>13</sup> Official Journal 125, 11/07/1966 pp. 2309 - 2319 amended most recently by Directive 2003/61/EC, Official Journal L 165, 03/07/2003 pp. 0023 - 0028

<sup>14</sup> Official Journal L 093, 17/04/1968 pp. 0015 - 0023 amended most recently by Regulation (EC) No. 1829/2003, Official Journal L 268, 18/10/2003 pp. 0001 - 0023.

<sup>15</sup> Official Journal L 157, 10/06/1992 pp. 0001 - 0009 amended most recently by Regulation (EC) No. 806/2003, Official Journal L 122, 16/05/2003 pp. 0001 - 0035.

<sup>16</sup> Official Journal L 157, 10/06/1992 pp. 0010 - 0018 amended most recently by Regulation (EC) No. 806/2003, Official Journal L 122, 16/05/2003 pp. 0001 - 0035.

<sup>17</sup> Official Journal L 226, 13/08/1998 pp. 0016 - 0023 amended most recently by Regulation (EC) No. 806/2003, Official Journal L 122, 16/05/2003 pp. 0001 - 0035.

- Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species<sup>18</sup>
- Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed<sup>19</sup>
- Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed<sup>20</sup>
- Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes<sup>21</sup>
- Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants<sup>22</sup>

The attempt of the commission to combine these highly specific Directives into one EU Seed Regulation and thereby harmonising seed legislation at a European level failed in 2014.<sup>23</sup>

Consequently, the coexistence of diverse sectoral Directives for seed legislation remains. In Germany, for instance, they are implemented in national law by the German Seed Marketing Act ("Saatgutverkehrsgesetz")<sup>24</sup> and also by some specific Regulations. The transposition obligation that applies to Directives, the summarization of the large majority of European Seed Market-

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<sup>18</sup> Official Journal L 193, 20/07/2002 pp. 0001 - 0011 amended most recently by Regulation (EC) No. 1829/2003, Official Journal L 268, 18/10/2003 pp. 0001 - 0023.

<sup>19</sup> Official Journal L 193, 20/07/2002 pp. 0012 - 0032 amended most recently by Directive 2003/61/EC, Official Journal L 165, 03/07/2003 pp. 0023 - 0028.

<sup>20</sup> Official Journal L 193, 20/07/2002 pp. 0033 - 0059 amended most recently by Regulation (EC) No. 1829/2003, Official Journal L 268, 18/10/2003 pp. 0001 - 0023

<sup>21</sup> Official Journal L 193, 20/07/2002 pp. 0060 - 0073 amended most recently by Directive 2003/61/EC, Official Journal L 165, 03/07/2003 pp. 0023 - 0028.

<sup>22</sup> Official Journal L 193, 20/07/2002 pp. 0074 - 0097 amended most recently by Directive 2003/61/EC, Official Journal L 165, 03/07/2003 pp. 0023 - 0028.

<sup>23</sup> Cf. <http://www.zeit.de/politik/ausland/2014-03/eu-parlament-saatgutverordnung> [Accessed 25. September 2017].

<sup>24</sup> German Seed Marketing Act in the version published on 16 July 2004 (BGBl. I p. 1673), amended most recently by article 1 of the law of 20 December 2016 (BGBl. I p. 3041).

ing Law in one national instrument as well as the congruency of the regulatory objectives and the fundamental understandings are good reasons to explain the functioning of seed legislation - pars prom toto - by means of the German Seed Marketing Act. However, the legal analysis reflects both European and international regulatory approaches and will therefore be completed by references to relevant legislation on the European level.

## **2. No adequate risk assessment by seed legislation**

The authorisation of plant varieties is a requirement for the commercial marketing of seed for agricultural plant species and vegetables.<sup>25</sup> The requirements for the variety registration are defined in Sec. 30 of the Seed Marketing Act. Subject to its para. 5 and 6, a variety can be permitted, if it is distinguishable, homogeneous as well as stable, has a value for cultivation and is qualified by a registrable variety denomination (Sec. 30 (1)). According to Sec. 30 (1) sentence 2 of the Seed Marketing Act, the registration of a variety can be refused, if sufficient grounds exist, i.e. the variety creates a risk for public health, animals, plants or the environment. According to Sec. 30 (1) sentence 3 of the Seed Marketing Act, the refusal shall be rejected insofar as ancillary provisions can eliminate the reasons for refusal.

### **a. No concretisation of legal standards**

The options provided in Sec. 30 (1) sentence 2 of German Seed Marketing Act concerning a possible refusal of

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<sup>25</sup> <http://www.bundessortenamt.de/internet30/index.php?id=28&L=0> [Accessed 25 September 2017].

the placing on the market are weakened in different ways: on the one hand, a possible refusal could only be considered, if "reasonable grounds for the presumption of a risk" exist. However, the question when a "level of indications" for such a presumption is achieved as well as the question which term for risk or which type of risk assessment is applicable remains unclear. On the other hand, when assuming a risk, this does not necessarily go along with a refusal of the placing on the market. In fact, it is a discretionary clause ("can"). Accordingly, the vague wording of Art. 30 (1) sentence 2 of the Seed Marketing Act is neither addressed in jurisdiction nor in literature.<sup>26</sup>

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<sup>26</sup> See for example Norer, R. (2015) Chapter 7. In: Grimm, C. and Norer R. Agrarrecht. 4th ed., Munich, recitals 22 et seq.

**b. Control density not comparable to genetic engineering law**

None of the European Directives mentioned above - neither on the basis of an isolated interpretation, nor as an interacting set of normative standards - establish control measures which are comparable to the control density enshrined in Directive 2001/18/EC. This is also reflected by the Seed Marketing Act:

Sec. 3 (1) sentence 1 of the Seed Marketing Act clarifies that this law is not able to provide the same risk assessment as the genetic engineering law. The provision regulates that, for commercial reasons, seed may only be placed on the market if it falls within one of the nine categories. Therefore, the marketing of the product is based on the principle that everything which is not authorised is prohibited.<sup>27</sup> According to Sec. 3 (1) sentence 1 No. 9 of the Seed Marketing Act, the placing on the market is only allowed if it results "within the framework of an authorised release according to Sec. 14 (1) No. 1 of genetic engineering law." Consequently, Sec. 3 (1) sentence 1 No. 9 of the Seed Marketing Act states an order of priority of a permission under genetic engineering law, compared with the permission under the Seed Marketing Act.

The Seed Marketing Act only lays down additional labelling requirements: "who places seed on the market, which organisms are genetically modified in the sense of Sec. 3 No. 3 of German Genetic Engineering Law, shall give clear indications on this fact in sales cat-

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<sup>27</sup> Leßmann, H. Würtenberger, G. (2009) Deutsches und europäisches Sortenschutzrecht, 2nd ed., Nomos, § 1 recital 37.



alogues or in any other written offer." These requirements show that the legislator did obviously not assume that the Seed Marketing Act is able to evaluate specific risks which result from highly technological processes. Consequently, discussions that arose a few years ago concerning cases of seed contamination did only consider genetic engineering law but not the Seed Marketing Act.<sup>28</sup>

### 3. Ratio of seed legislation

The fact that possible risks for humanity, animals, plants or the environment are not the focus of variety release illustrate, in particular, the general requirements of variety release which rather target the guarantee of varietal identity and purity (see, inter alia, Annex I to Directive 68/193/EEC). If and to the extent that seed legislation mentions aspects of consumer protection, this is only about consumers being protected from buying insufficient seeds. Consumer in terms of this law is not the end consumer but solely the consumer of seed.<sup>29</sup> Seed legislation is characterised by this concept of exclusion of these "ordinary citizens": the reason of the authorisation of higher and audited qualities is only to achieve the highest and best yield at harvest.<sup>30</sup>

Without doubt, this basic regulatory approach is also shaping European seed legislation. For example, even

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<sup>28</sup> Mecklenburg, W. (2006) Zur Störfallbewältigung im Gentechnikrecht - Aussaat von mit gentechnisch veränderten Organismen verunreinigtem Saatgut. NuR 2006, 229 - 233, pp. 229 et seq.; Schröder, M. (2010) Gentechnik im Saatgut - ein wiederkehrendes Problem. NuR 2010, 770 - 778, pp. 770 et seq.

<sup>29</sup> BGH, Judgment of 27 April.2017 - I ZR 251/15, BechRS 2017, 114502, recital 21; Norer, R. (2015) Chapter 7. In: Grimm, C. and Norer R. Agrarrecht. 4th ed., Munich, recital 22.

<sup>30</sup> Leßmann, H. Würtenberger, G. (2009) Deutsches und europäisches Sortenschutzrecht, 2nd ed., Nomos, § 1 recital 32.

the first European framework dedicated to seed legislation addressed this issue. Recital 1 - 4 of Directive 66/401/EEC state:

"Whereas fodder plant production occupies an important place in the agriculture of the European Economic Community;

Whereas satisfactory results in fodder plant cultivation depend to a large extent on the use of appropriate seed ; whereas to this end certain Member States have for some time restricted the marketing of fodder plant seed to high-quality seed ; whereas they have been able to take advantage of the systematic plant selection work carried out over several decades which has resulted in the development of sufficiently stable and uniform fodder plant varieties which, by reason of their characters, promise to be of great value for the purposes in view;

Whereas greater productivity will be achieved in Community fodder plant cultivation if for the choice of the varieties permitted to be marketed the Member States apply uniform rules which are as strict as possible;

Whereas it is, however, justifiable to restrict marketing to certain varieties only if the user can be sure of actually obtaining seed of those varieties (...)."

#### **4. National perspective: seed legislation is no protective law (Schutzgesetz)**

The German Seed Marketing Act cannot be seen as an instrument of control for new technologies. It is settled case-law that the German Seed Marketing Act is no protective law. The Higher Regional Court of Munich, for instance, stated recently:

"Sec. 3 (1) of the German Seed Marketing Act does not provide any protective norm in favour of the farmer who

purchases the seed. The only purpose of the German Seed Marketing Act is consumer protection as well as transparency and truth by placing seed and young plants on the market (Bundestag-Drucksache 10/700 of 30 November 1983, p. 2). This is not even changed by the fact that, in terms of Sec. 2 (1) No. 12 of the German Seed Marketing Act, the commercial sale of seed to farmers describes also a placing on the market which is subject to a reservation of approval according to Sec. 3. The prohibition of misleading ("Irreführungsverbot") in Sec. 23 of the German Seed Marketing Act does not contribute to this question either. The former guarantee rule in Sec. 24 of the German Seed Marketing Act has been abolished.

The Senate agrees with the ruling of the Regional Court of Osnabrück of 26 January 1999 (7 O 362/98, NJW-RR 2000, 617) which dismissed the classification as a protective norm for the former Sec. 24 as well as for the German Seed Marketing Act as a whole. The German Federal Court of Justice also stated in several decisions that the official auditing and monitoring obligations of the German Seed Marketing Act only contribute to the support of agriculture and horticulture in general as well as to the general consumer protection. But they do not serve to the protection of the asset interests of agricultural or horticultural businesses which produce or process seed [...]."<sup>31</sup>

In fact, the German Federal Court shared its clear opinion to this question as follows:

"Concerning the German Act on Forest Seed and Plant Scheme (Gesetz über forstliches Saat- und Pflanzgut)

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<sup>31</sup> Higher Regional Court Munich (2015). In: NJW-RR 2015, 435 - 441, recitals 81 and 82.

[...] and the German Seed Marketing Act [...], the Senate stated that official obligations of control, monitoring and auditing only contribute to agriculture and horticulture in general as well as to consumer protection, i.e. to the public interest. But they do not aim to protect individual asset interests of third parties which target at making a profit by selling agricultural products [...]. The same applies in some extent to the Plant Protection Acts whose purpose is to protect plant and plant products against harmful organisms and against the risks to public and animal health as well as the ecosystem. Even the explicit consulting, information and training in the field of plant and stored products protection by the plant protection service seems to serve only the public interest, regarding its scope of protection."<sup>32</sup>

#### **5. National perspective: constitutionally required exclusion of wild forms**

Even if the possibility of a refusal of the placing on the market is interpreted in a very extensive way, the described purpose of the German Seed Marketing Act entails that not all propagating material is included in the scope. In fact, case-law pointed out that the ratio of the German Seed Marketing Act does not justify an extension of the scope to wild forms intended for greening. Insofar, there are serious constitutional doubts concerning a wider application of the German Seed Marketing Act. The Regional Federal Court Ellwangen stated in that regard:

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<sup>32</sup> The German Federal Court (2002). In: NVwZ 2002, 1276 - 1278, p. 1277.

"[t]he court doubts whether the provisions of the German Seed Marketing Act can be applied literally to the defendant's conduct. The primary objective of the German Seed Marketing Act is not the security of supply of agriculture and horticulture with high quality seed but the seed consumer's protection. This is also reflected in the fact that the disputed grass species are listed under the heading "feed" in the variety directory. This purpose is not jeopardized by the fact that the defendant sells wild forms of these species for greening. We are not dealing with a use in agriculture or horticulture. If the sale of these wild forms depended on the recognition and admission under the German Seed Marketing Act, the sale would be impossible. The recognition of these wild forms is not possible under the German Seed Marketing Act because they do not fulfil the criteria for the variety release of Sec. 30 (1) of the German Seed Marketing Act (in particular with regard to homogeneity and stability) at all. This consequence would affect the defendant's constitutional right to choose an occupation, as enshrined in Art. 12 of the German Basic Law, and the constitutionally embodied requirement of environmental protection (Art. 20a of the Basic Law). There is strong evidence that the German Seed Marketing Act should be interpreted in a constitutional manner so that the sale of wild forms by the defendant do not depend on the recognition and authorisation of seed under the German Seed Marketing Act."<sup>33</sup>

These constitutional doubts stress that it is not even possible to provide seamless control for all varieties of seed under the German Seed Marketing Act.

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<sup>33</sup> Federal Court Ellwangen (2004). Case No. 5 O 423/04, recital 26 in Juris.

## **6. In particular: no effective post control**

None of the Directives mentioned above establishes an effective post control system or any other approach towards an ex post analysis of potential hazards or risks for human health and / or the environment. Instead, due to the restricted ratio of European seed legislation, European seed law focusses on the ex ante requirements for marketing. Again, this is reflected by national legislation, e.g. the Seed Marketing Act:

According to Sec. 36 (1) of the Seed Marketing Act, the variety registration is valid until the end of the 10th year. Concerning vine and fruit, the registration remains valid until the end of the 20th year after the following calendar year of the registration. The Seed Marketing Act does not allow a risk-adequate post control in this period. This may surprise at first sight as Sec. 9 (1) of the Seed Marketing Act reads: "[t]he Federal Ministry of Food and Agriculture is authorised, with the admission of the Federal Council (Bundesrat) and for consumer protection reasons, to verify whether certified seed or its growth, considering the biological circumstances,

1. meet the important characteristics of the variety (sufficient identity) and
2. show that the requirements for the health standards were met, if such a post control is required."

"Requirements for the health standards" do not mean the health of the end consumer but only the health of the produced plants. This is clarified by Sec. 16 of the Regulation on the Marketing of Seed of Agricultural Va-

rieties and Vegetables (Saatgutverordnung)<sup>34</sup> which concretises the requirements of post control. Seed legislation allows, with regard to public health or environmental damage, no monitoring which could eventually identify new evolving problems.

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<sup>34</sup> Seed Regulation in the version published 8 February 2006 (BGBl. I p. 244), amended by article 2 of the Regulation published 9 June 2017 (BGBl. I p. 1614).

## **7. National margins**

The coexistence of different Directives and, in particular, the recent failure of the EU Seed Regulation show that there are very diverse interests which play a role for seed authorisation. Substantially, the question of market entry for old varieties and rarities is concerned. In this context, the member states insist on maintaining their basic national margins which, however, cannot be used to achieve a level of protection comparable to the standards enshrined in Directive 2001/18/EC.

## **IV. Regulation (EC) No. 178/2002**

The "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"<sup>35</sup> represents a key element of European food law.

### **1. Scope**

Aim and scope of application of the Regulation (EC) No. 178/2002 are described in Art. 1 as follows:

"1. This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market. It

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<sup>35</sup> OJ L 31/1, 01. February 2002.



establishes common principles and responsibilities, the means to provide a strong science base, efficient organisational arrangements and procedures to underpin decision-making in matters of food and feed safety.

2. For the purposes of paragraph 1, this Regulation lays down the general principles governing food and feed in general, and food and feed safety in particular, at Community and national level.

It establishes the European Food Safety Authority.

It lays down procedures for matters with a direct or indirect impact on food and feed safety.

3. This Regulation shall apply to all stages of production, processing and distribution of food and feed. It shall not apply to primary production for private domestic use or to the domestic preparation, handling or storage of food for private domestic consumption."

The Regulation does not only provide the necessary administrative framework for food safety but also sets the protection of the human health as a central objective. According to Art. 1 (3) first sentence of the Regulation, all production, processing and distribution stages of food and feed fall within this scope. So, at first sight, there is a comprehensive protection scheme for all food and feed, regardless of the technology applied. Thus, it could be assumed that food and feed are subject to comprehensive supervision which identifies resp. prevents potential risks of new technologies in this area. However, a closer analysis shows that the scope as well as the reason and the instruments of the Regulation (EC) No. 178/2002 are incomplete.

**a. In particular: exceptions from the scope**

The supposed "comprehensive" scope of the Regulation (EC) No. 178/2002 are put into perspective when looking at the definition. According to Art. 2 (1), "food", for the purpose of this Regulation, is defined as "any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans". According to Art. 2 (2), this definition applies also to additives.

**aa. Plants prior to harvesting/animals not intended for human consumption**

"Food" does not include "live animals unless they are prepared for placing on the market for human consumption" (Art. 2 (3) lit. b), "plants prior to harvesting" (Art. 2 (3) lit. c) and "tobacco and tobacco products within the meaning of Council Directive 89/622/EEC" (Art. 2 (3) lit. f). This shows that all questions of "green genetic engineering" that need to be answered prior to harvesting do not fall within the scope of the Regulation (EC) No. 178/2002. Thus, as a result, all issues relating to the law on release are ignored.

The same applies to live animals which fall within the scope of the Regulation (EC) No. 178/2002 only to the extent that they are prepared for placing on the market for the purpose of human consumption. It is therefore with this restriction that a considerable amount of all farm animals do not fall within the scope of the Regulation: farm animals that are not intended to be consumed are excluded as well as animals that are intended for human consumption but have not yet been "prepared" accordingly.

**bb. Feed**

Central restrictions to the scope also apply to feed. According to Art. 3 No. 4, "feed" (or "feedingstuff"), for the purpose of this Regulation, means any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals. If this definition creates the impression that the Regulation does actually apply to all feed, this is a misunderstanding. The Regulation only applies to feed which is fed to animals intended for human consumption. According to this, Art. 15 (1) and (2) of the Regulation on requirements for feed safety, for instance, reads as follows:

"(1) Feed shall not be placed on the market or fed to any food-producing animal if it is unsafe.

(2) Feed shall be deemed to be unsafe for its intended use if it is considered to:

- have an adverse effect on human or animal health;
- make the food derived from food-producing animals unsafe for human consumption."

This anthropocentric focus of feed safety becomes apparent elsewhere. The 12<sup>th</sup> and 13<sup>th</sup> recital of the preamble emphasizes that feed safety does not constitute an intrinsic value. It shall be ensured for the sake of food safety:

"(12) In order to ensure the safety of food, it is necessary to consider all aspects of the food production chain as a continuum from and including primary production and the production of animal feed up to and including sale or supply of food to the consumer because each element may have a potential impact on food safety.

(13) Experience has shown that for this reason it is necessary to consider the production, manufacture, transport and distribution of feed given to food-producing animals, including the production of animals which may be used as feed on fish farms, since the inadvertent or deliberate contamination of feed, and adulteration or fraudulent or other bad practices in relation to it, may give rise to a direct or indirect impact on food safety."

**b. In particular: protection of the environment**

Regulation No. 178/2002 is not an instrument of environmental protection as such. The possible effects of dangerous food and feed on the environment are included only in homeopathic extent into official considerations. Recital 19 clarifies that it is "recognised that scientific risk assessment alone cannot, in some cases, provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls."

This general reference to "environmental considerations" is not connected to any audit engagement or procedure. More precisely, the term of environmental considerations does not refer to any specific procedure and remains vague.

Recital No. 37 of the preamble states: "[s]ince some products authorised under food law such as pesticides or additives in animal feed may involve risks to the environment or to the safety of workers, some environmental and worker protection aspects should also be as-

essed by the Authority in accordance with the relevant legislation." Out of this derive many interesting findings for the present analysis:

- Regulation No. 178/2002 takes environmental factors only by referring to a few products into account.
- These products must be authorised under food law.
- Legal standard is insofar the "relevant legislation" of environmental protection.

In opposition therefore, Regulation No. 178/2002 only examines environmental effects in very specific contexts<sup>36</sup>, and in doing so applying special law of environmental law, but does not establish an environmental law testing scheme itself.

These findings are also affected by Art. 5 (1) Regulation No. 178/2002, which describes the general objectives of food law: "Food law shall pursue one or more of the general objectives of a high level of protection of human life and health and the protection of consumers' interests, including fair practices in food trade, taking account of, where appropriate, the protection of animal health and welfare, plant health and the environment."

The term of environmental protection is complemented by "crop protection". However, according to the explicit wording of Art. 5 (1) of the Regulation, the protection of both goods is no aim of food law. For the purpose of the two primary aims<sup>37</sup>, environmental and crop protection should additionally be "taken into account". Such a consideration is not mandatory, it only takes place "when appropriate", which means if and to the extent to

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<sup>36</sup> See also recital 60 of the preamble.

<sup>37</sup> Protection of human life and health on the one hand and the protection of consumers' interests (including fair practices in food trade) on the other hand.

which it is required by the protection of the mentioned primary objectives.

## **2. Risk analysis and precaution not applicable**

Regulation (EC) No. 178/2002 achieves its aims on the basis of a risk assessment in consideration of the precautionary principle. Recital 17 of the preamble stresses that: "[w]here food law is aimed at the reduction, elimination or avoidance of a risk to health, the three interconnected components of risk analysis - risk assessment, risk management, and risk communication - provide a systematic methodology for the determination of effective, proportionate and targeted measures or other actions to protect health."

### **a. Basics of risk assessment and precautionary principle**

The relevant mechanisms are described by Art. 6 and 7 of the Regulation as follows:

"Article 6: Risk analysis

(1) In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature of the measure.

(2) Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

(3) Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22, other factors legitimate to the matter under consideration and the

precautionary principle where the conditions laid down in Article 7 (1) are relevant, in order to achieve the general objectives of food law established in Article 5.

Article 7: Precautionary principle

(1) In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

(2) Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment."

The term of risk does not only play a central role regarding the actual risk assessment but also with regard to the application of the precautionary principle, as the implementation of the precautionary principle empowers to take "risk management measures". The question of what should be exactly understood by this term is defined in Art. 3 No. 9 to 12 of the Regulation. "Risk" means "a function of the probability of an adverse

health effect and the severity of that effect, consequential to a hazard" (Art. 3 No. 9 of the Regulation). "Risk analysis" means "a process consisting of three interconnected components: risk assessment, risk management and risk communication" (Art. 3 No. 10 of the Regulation). "Risk assessment" means "a scientifically based process consisting of four steps: hazard identification, hazard characterisation, exposure assessment and risk characterization". Finally, "risk management" means "the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options" (Art. 3 No. 12 of the Regulation).

**b. The term of hazard as a requirement of risk analysis and precautionary principle**

Both, risk analysis and precautionary principle require an explicit hazard or the possibility of a hazard. Here, "hazard" means, according to Art. 3 No. 14 of the Regulation, only "a biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect".

**aa. No agent**

Taking this into account, the application of the entire instruments for risk analysis resp. the implementation of the precautionary principle on organisms produced by new technologies is not possible: an agent means an ac-



tive ingredient.<sup>38</sup> Even though a mutation caused by new technologies takes effect, it is very questionable whether it can be considered as an active ingredient on the basis of scientific criteria. However, there is the fundamental problem that mutations caused by new technologies cannot be separated from natural mutations. Consequently, as far as one wants to talk about an "agent", the existence of such an agent cannot be proved. If one considers Directive 2001/18/EC as not applicable (due to the lack of detectability of such a modification), one cannot speak of an agent within the meaning of Art. 3 No. 14 of the Regulation (EC) No. 178/2002.

**bb. No condition**

For the same reason, it is not possible to say that through the application of new technologies the concerned food is put into a specific "condition". On the one hand, it is very questionable whether a mutation caused by new technologies can be considered as a "condition of food" at all. On the other hand, an identification of such a condition would already fail because of the lacking detectability of the used procedure.

**cc. Intermediate result**

The instruments of risk analysis and precautionary principle mentioned in Regulation (EC) No. 178/2002 cannot be applied to food which was produced by organisms using new technologies. The reason for this is

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<sup>38</sup> Agens. (1994) [Online]. In: Lexikon der Biologie. Spektrum Akademischer Verlag. Available at: <http://www.spektrum.de/lexikon/biologie/agens/1466> [Accessed 20 July 2017].

that it lacks a hazard required by Art. 3 No. 14 of the Regulation.

**c. In addition: precautionary principle and human health**

As already stated, the precautionary principle, in form of Art. 7 of the Regulation (EC) No. 178/2002, does not apply to the evaluation of new technologies for definition reasons. But even if one found Art. 7 of the Regulation to be applicable, a significant 'protection gap' would appear. Essential for this is that Art. 7 of the Regulation narrows the precautionary principle in the light of the general aim of the Regulation and concretises it for the purpose of food safety.

Art. 7 clarifies in (1) as well as in (2) that the precautionary principle applies only for the purpose of achieving a sufficient level of health protection. This shows again the anthropocentric approach of the Regulation. Consequently, possible harmful effects on the environment resp. non-human organisms do not trigger any preventive actions. Additionally, Art. 7 (2) sentence 1 of the Regulation requires a reconnection of preventive actions as specific trade interests: protective measures need to be not only proportionate in general but they shall also not affect trade more than necessary.

Even if Art. 7 of the Regulation was applicable, this norm would not lead to a level of precaution which could reach the level of the precautionary principle laid down in Art. 1 (1), Art. 4 (1), Annex II Part B of the Directive 2001/18/EC.

### **3. Measures and penalties**

The basic requirements concerning the safety of food and feed are laid down in Art. 14 and 15 of the Regulation (EC) No. 178/2002. For reasons of better clarity, the following explanations focus on the procedures for food safety only. Art. 14 of the Regulation reads as follows:

"1. Food shall not be placed on the market if it is unsafe.

2. Food shall be deemed to be unsafe if it is considered to be:

(a) injurious to health

(b) unfit for human consumption.

3. In determining whether any food is unsafe, regard shall be had:

(a) to the normal conditions of use of the food by the consumer and at each stage of production

(b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.

4. In determining whether any food is injurious to health, regard shall be had:

(a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;

(b) to the probable cumulative toxic effects;

(c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.

5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by

extraneous matter or otherwise, or through putrefaction, deterioration or decay.

6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.

7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.

8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.

9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice

to the Treaty, in particular Articles 28 and 30 thereof."

The overall picture of the requirements show that multiple effective instruments are available for monitoring the safety of food. This results from the prohibition of placing food on the market that is unsafe, the order to take probable cumulative toxic effects into account and the probable effects on subsequent generations as well as the possibility of taking appropriate measures to impose restrictions based on suspicion. Nevertheless, Art. 14 of the Regulation cannot be applied to and used for new technologies in the necessary manner.

Crucial for this is the fact that - with regard to the standards of genetic technology law - Art. 17 of the Regulation provides an insufficient distribution of responsibilities. Pursuant to Art. 17 (1), it is the responsibility of food and feed business operators to ensure that food or feed satisfy the requirements of food law at all stages of producing, processing and distribution within the businesses under their control. They are further responsible to verify that such requirements are met.

Pursuant to Art. 17 (2) sentence 1, the Member States are obliged to monitor and verify that the requirements are fulfilled: "[f]or that purpose, they shall maintain a system of official controls and other activities as

appropriate to the circumstances, including public communication on food and feed safety and risk, food and feed safety surveillance and other monitoring activities covering all stages of production, processing and distribution.”<sup>39</sup> Pursuant to Art. 17 (2) sentence 3, all Member States are further required to set rules on measures and penalties that are imposed for infringement of food and feed law and that are effective, proportionate and dissuasive.

Following the basic principle of misuse<sup>40</sup>, there is no preventive control or even not an obligation to obtain a permit for the distribution of foods. Moreover, food business operators are obliged to achieve those standards. The State has a general downstream control. Additionally, imported food does not have to comply with these requirements but with “conditions equivalent thereto”. On closer examination, the duty to supply information is diminished remarkably.<sup>41</sup>

The fact that the responsibilities of health protection are carried by the business operators is further illustrated by Art. 19 (1) and (3) of the Regulation: “(1) If a food business operator considers or has reason to believe that a food which it has imported, produced, processed, manufactured or distributed is not in com-

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<sup>39</sup> Art. 17 (2) sentence 2 of Regulation (EC) No. 178/2002.

<sup>40</sup> Kraft, F., Grugel, C. and Preußendorff, G. (2008) Vom Jäger zum Sammler zur modernen Industriegesellschaft - Verbots- und Missbrauchsprinzip im Lichte der technologischen Entwicklungen bei der Herstellung von Lebensmitteln. In: ZLR 2008, 321 - 334, pp. 321 et seq.; von Jagow, C. (2007) Auf dem Weg zum Verbotsprinzip? In: ZLR 2007, 479 - 497, pp. 479 et seq.

<sup>41</sup> To this: Teufer, T. (2013) „Too much information“? - Aktuelles zur staatlichen Kommunikation im Lebensmittelrecht. In: K&R 2013, 629 - 633, pp. 629 et seq.

pliance with the food safety requirements, it shall immediately initiate procedures to withdraw the food in question from the market where the food has left the immediate control of that initial food business operator and inform the competent authorities thereof. Where the product may have reached the consumer, the operator shall effectively and accurately inform the consumers of the reason for its withdrawal, and if necessary, recall from consumers products already supplied to them when other measures are not sufficient to achieve a high level of health protection. (3) Food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food."

The new principle of traceability<sup>42</sup>, the implementation of a rapid alert system<sup>43</sup> and the extension of the area of competence of the European Food Safety Authority concerning questions relating to the "identification of emerging risks"<sup>44</sup> represent innovative concepts that have been integrated into European food law. However, this does not change anything with regard to the issue of preventive control or authorisation. The duty of the

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<sup>42</sup> Art. 18 of Regulation (EC) No. 178/2002.

<sup>43</sup> Art. 35 of Regulation (EC) No. 178/2002.

<sup>44</sup> Art. 34 of Regulation (EC) No. 178/2002.



European Food Safety Authority is not to include any active monitoring but rather to provide scientific guidance as well as scientific and technical support to the Community's legislation and policies.<sup>45</sup>

The emergency measures laid down in Art. 53 of the Regulation do not, a fortiori, have any preventive effect. In fact, the Commission can take these measures only if there are insufficient reactions of the Member States in situations which are explicitly identified as "emergencies". Even those "ultima ratio constellations" only apply in cases "where it is evident" that food is likely to constitute a serious risk.

Even recital No. 39 which refers explicitly to aspects of genetic technology law does not change this result in any way: "[i]n order to avoid duplicated scientific assessments and related scientific opinions on genetically modified organisms (GMOs), the Authority should also provide scientific opinions on products other than food and feed relating to GMOs as defined by Directive 2001/18/EC and without prejudice to the procedures established therein." Irrespective of the fact that the recitals are not legally binding, there is no modification of the repartition of competence. Taking into account, the Food Safety Authority's competence in the matter of food safety, this expertise shall only be used to develop different fields of regulation.

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<sup>45</sup> Art. 22 (2) of Regulation (EC) No. 178/2002.

#### **4. National margins**

The fact that the Regulation represents a regulatory instrument underlines that the European legislator intended to achieve overall harmonization and reduce the national margins. Actually, the Regulation does not provide any significant opening clauses. Apart from that, Art. 60 of the Regulation implements a mediation procedure which shall be activated in case of conflict. Regardless the described substantive inadequacies of the Regulation on the control of new technologies, no significant margins for national regulations are indicated.

#### **V. Regulation (EC) No. 258/97 and Regulation (EU) No. 2015/2283**

Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients<sup>46</sup> (so-called "Novel Food Regulation") constitutes the core element of the law on novel foods. It is supplemented by various instruments which have updated and completed the regulatory area.

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<sup>46</sup> OJ L 43/1, 14. February 1997.

## 1. Additional regulations and scopes of application

The Novel Food Regulation pursues the aim of health protection: novel food must not present a danger for the consumer, mislead the consumer and must not differ from any food they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer (Art. 3 (1)).

In the field of food production, the use of genetic engineering is already, in particular for corn and soya, at an advanced stage. Nevertheless, some of these products have not fallen within the scope of the Novel Food Regulation, provided their licensing took place before the Regulation came into force. Due to the high practical relevance of these products, the material labelling rules of the Novel Food Regulation were extended to these products by Regulation (EC) No. 1813/97. After debates between the Commission and the Council, Regulation No. 1813/97 was replaced by Regulation (EC) No. 1139/98 which itself was amended by Regulation No. 49/2000.

Art. 1 (2) concretises the scope of the Regulation as follows:

"[t]his Regulation shall apply to the placing on the market within the Community of foods and food ingredients which have not hitherto been used for human con-

sumption to a significant degree within the Community and which fall under the following categories:

(a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC;

(b) foods and food ingredients produced from, but not containing, genetically modified organisms;

(c) foods and food ingredients with a new or intentionally modified primary molecular structure;

(d) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;

(e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use;

(f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances."

Initially, food additives and flavourings were excluded from the scope of the Regulation. But today, Regulation No. 50/200 provides a labelling requirement adapted to the Novel Food Regulation.

## 2. Normative instruments

The Novel Food Regulation uses different instruments to achieve its protection aims. First, in Art. 4 et seq. of the Novel Food Regulation, a preventive notification and authorisation procedure, i.e. a product registration procedure has been established. This preventive registration procedure of the Novel Food Regulation means a change of the system insofar as the principle of misuse is no longer applicable to food law.<sup>47</sup> According to this principle, there was free marketability of food. Today, the prohibition principle in form of a "ban with an authorisation option" applies.

In case of substantial equivalence of novel foods (as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein) and existent foods, there is a simple notification procedure (Art. 5) instead of an authorisation procedure (Art. 3 (4)):

"[I]n the case of the foods or food ingredients referred to in Article 3 (4), the applicant shall notify the Commission of the placing on the market when he does so. Such notification shall be accompanied by the

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<sup>47</sup> Kraft, F., Grugel, C. and Preußendorff, G. (2008) Vom Jäger zum Sammler zur modernen Industriegesellschaft - Verbots- und Missbrauchsprinzip im Lichte der technologischen Entwicklungen bei der Herstellung von Lebensmitteln. In: ZLR 2008, 321 - 334, pp. 321 et seq.; von Jagow, C. (2007) Auf dem Weg zum Verbotsprinzip? In: ZLR 2007, 479 - 497, pp. 479 et seq.

relevant details provided for in Article 3 (4). The Commission shall forward to Member States a copy of that notification within 60 days and, at the request of a Member State, a copy of the said relevant details. The Commission shall publish each year a summary of those notifications in the 'C' series of the Official Journal of the European Communities.

With respect to labelling, the provisions of Article 8 shall apply."

In cases of "substantial equivalence", only the requirement of labelling remains. In case of absence of equivalence, the basis of labelling follows a scientific approach: there is only a labelling obligation if the use of a genetic engineering procedure can be scientifically proved.

According to Art. 8 (1) lit. b) of the Regulation, one shall be informed about the presence of materials which are not present in any equivalent foodstuff and which may have implications for the health of certain population groups, e.g., because of eating habits. For instance, the scope of Art. 8 (1) lit. b) applies if the food contains a new or increased allergic potential. The labelling requirement applies also to materials which are not present in equivalent foodstuff and which give rise to ethical concerns (Art. 8 (1) lit. c)). As an example for such ethical concerns is the presence of an animal gene (protein) in traditional vegetarian

products or the presence of a "pig gene" in food for Muslims.

Regulation No. 49/2000 provides a specific provision for corn and soya to react to the possibility of accidental contamination. Accordingly, a random contamination which does not exceed 0.9% for every single ingredient does not preclude a comprehensive labelling requirement. Setting such a threshold proves to be critical with regard to the existence of very different detection methods.

Modifications are also provided in the "Regulation (EC) No. 1830/2003 of the European Parliament and of the Council 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" as well as in the "Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on genetically modified food and feed".

### **3. Normative gaps**

The question whether the described regimes are suitable to provide (at least sectoral) compensation in case of inapplicability of the genetic engineering law on new technologies has to be negated. A cursory comparison shows several normative gaps:



- The control system described is extended solely to foodstuff and food ingredients. Accordingly, all other product categories are excluded.

- If the genetic technology law cannot be applied to new technologies, it is more than doubtful whether the field of application of the Novel Food Regulation is opened. Although the instruments of the Novel Food Regulation are not limited to genetically modified foods, it is not possible to know with certainty whether food which is produced by use of new technologies could fall within Art. 1(2) lit. c), e) or f).

- If the scope of the Novel Food Regulation is opened to foods which are produced by new technologies, the question arises whether those foods are not substantially equivalent to their composition, nutritional value, metabolism, intended use and level of undesirable substances. In this case, the product licensing procedure would be replaced by a notification procedure with labelling requirements.

- The question whether the use of new technologies activates the labelling requirements according to Art. 8 (1) lit. b) and c) must be analyzed on a case-by-case basis and is questionable.

- Notwithstanding the possibility of intervention according to Art. 12 of the Regulation, the applicant

does not have any specific product monitoring obligations and therefore no specific reporting obligations.

- The labelling regime of the Novel Food Regulation aims to protect the "well-informed consumer". However, it does not achieve the level of transparency of Directive 2001/18/EC.

#### **4. National margins**

As the Regulation does not provide any margins for its implementation into national laws and as it does not provide any opening clauses, there is no room for national margins. Provided that a Member State takes emergency measures according to Art. 12, those measures have to be of temporary nature. According to Article 12 (2), the ultimate decision is exclusive to the Commission.

#### **5. In particular: the new Regulation (EU) No. 2015/2283**

The "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"<sup>48</sup> replaces the previous regime of Regulation

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<sup>48</sup> OJ L 327/1, 11. February 2015.

(EC) No 257/98. Even though Art. 34 and Art. 36 of Regulation (EU) No 2015/2283 make clear that a change of the regulatory framework will take place only on January 1st 2018, its consequences shall already be examined here.

The new Regulation may include in some cases important innovations such as with regard to nano products.<sup>49</sup> However, the new legal framework has no significant impact on the relevant question. The law on novel food is still not suitable to replace Directive 2001/18/EC:

- The regulatory regime applies only to food and food additives and ignores all other product categories.

- In case of inapplicability of the genetic engineering law to new technologies, there are doubts that its scope of application would be open. Even though Art. 3 Para. 2 lit. a No. i) of Regulation (EU) No 2015/2283 states that "'novel food' means any food that was not used for human consumption to a significant degree within the Union before 15 May 1997, irrespective of the dates of accession of Member States to the Union, and that falls under at least one of the following categories: food with a new or intentionally modified molecular structure, where that structure was not used as, or in, a food within the Union before 15 May 1997". Art. 2 Para. 2 lit. a) of the Regulation (EU) No 2015/2283 clarifies that the Regulation does not apply

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<sup>49</sup> See the overview of Loosen (2016) Die neue Novel Food-Verordnung - Übersicht und erste Bewertung. In: ZLR 2016, pp. 3 et seq.

to genetically modified food within the meaning of Regulation (EC) No 1829/2003. The Regulation (EU) No 2015/2283 is thus not a "catch-all regime".

- If the scope of the Regulation on novel food and food emerged from new technologies is opened up, a preventive control with regard to the safety of such food does not take place. Rather, Art. 4 Para. 1 and 2 of the Regulation (EU) No. 2015/2283 read as follows: "(1) Food business operators shall verify whether or not the food which they intend to place on the market within the Union falls within the scope of this Regulation. (2) Where they are unsure whether or not a food which they intend to place on the market within the Union falls within the scope of this Regulation, food business operators shall consult the Member State where they first intend to place the novel food. Food business operators shall provide the necessary information to the Member State to enable it to determine whether or not a food falls within the scope of this Regulation."

- Regardless of the responsibilities of the food business operator which result from Art. 21 and Art. 25 of the Regulation (EU) No. 2015/2283, the system of penalties is subject to different restrictions. In particular, Art. 29 of the Regulation transfers the competence for the establishment of a system of penalties to the Member States.

## **VI. Regulation (EU) No. 1169/2011**

The "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"<sup>50</sup> provides main instruments for various aspects of food information.<sup>51</sup> This means that the Regulation (EU) No. 1169/2011 belongs also to consumer information law.

### **1. Scope of application**

The scope of application of the Regulation (EU) No. 1169/2011 is stated in Art. 1. According to Art. 1 (1) the "Regulation provides the basis for the assurance of a high level of consumer protection in relation to food information, taking into account the differences in the perception of consumers and their information needs

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<sup>50</sup> OJ L 304/18, 22. November 2011.

<sup>51</sup> Meisterernst (2012) Kein Öl an die Karotte! 5 Jahre VO (EG) Nr. 1924/2006 über Nährwert- und gesundheitsbezogene Angaben. In: WRP 2012, 405 - 413, pp. 406 et seq.

whilst ensuring the smooth functioning of the internal market.”

For this purpose, Art. 1 (2) states that the Regulation establishes the “general principles, requirements and responsibilities governing food information, and in particular food labelling. It lays down the means to guarantee the right of consumers to information and procedures for the provision of food information, taking into account the need to provide sufficient flexibility to respond to future developments and new information requirements. Food business operators and under certain conditions also catering services are bound by the Regulation (Art. 1 (3)).”

Thus, the focus lies on the food sector. In this sense, “food” within the meaning of Art. 2 (1) lit. a is identical with the definition of the Regulation (EC) No. 178/2002. Here, it already becomes clear that the Regulation (EU) No. 1169/2011 is a supplement to the food law outlined above.<sup>52</sup> This connection is also emphasised in recital No. 4 of Regulation (EU) No. 1169/2011: “[a]ccording to Regulation (EC) No. 178/2002 (...) it is a general principle of food law to provide a basis for consumers to make informed choices in relation to food they consume and to prevent any practices that may mislead the consumer.”

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<sup>52</sup> See IV.

Since the Regulation (EC) No. 1169/2011 only fulfills a complementary function under the umbrella of the legal regime of Regulation (EC) No. 178/2002, reference can be made to the relevant explanations to Regulation (EC) No. 178/2002. In particular, the scope of application of Regulation (EC) No. 1169/2011 cannot go beyond the scope of application of Regulation (EC) No. 178/2002. Thus, the restrictions of the Regulation (EC) No. 178/2002 apply here, too.

## **2. Additional notes: regulation possibilities**

Since the Regulation only aims to provide the foundations for the "informed consumer", the focus of the substantive requirements is on aspects of food labelling. Art. 4 provides the principles for compulsory food information, Art. 9 et seq. provides more information in detail.

### **a. In particular: ingredients**

The mandatory information also refer to ingredients. According to Art. 2 (2) lit. f, the term "ingredient" means "any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as 'ingredients'". In light of the specific effects of new technologies which shall no longer

be present in the final product, an assignment to the term of ingredient cannot be made. Irrespective of this, there would be blatant exceptions to the requirement of an ingredient list for e.g. unpeeled fruit, cheese, butter, and milk products.<sup>53</sup>

**b. In particular: ethical information**

Regardless this specific aspect, the mechanisms established by Regulation (EU) No. 1169/2011 are not applicable to food where new technologies were used in the production process. The list of mandatory information in Art. 4 (1) of the Regulation is not conclusively ("in particular"). Nevertheless, it becomes clear that it shall be primarily informed about components and aspects of food which might have any effect on the consumer.

At first sight, Art. 4 (2) of the Regulation relaxes these measures: "[w]hen considering the need for mandatory food information and to enable consumers to make informed choices, account shall be taken of a widespread need on the part of the majority of consumers for certain information to which they attach significant value or of any generally accepted benefits to the consumer." Regarding this, it seems possible that general reservations concerning the use of new technologies can cause a corresponding obligation of information, too.

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<sup>53</sup> See Art. 19 of Regulation (EU) No. 1169/2011.



Opposed to this view, Art. 3 (1) of the Regulation does not lay down any obligation of information regarding ethical and social concerns. It only states that ethical and social concerns should be taken into account: "[t]he provision of food information shall pursue a high level of protection of consumers' health and interests by providing a basis for final consumers to make informed choices and to make safe use of food, with particular regard to health, economic, environmental, social and ethical considerations." It thereby appears very unlikely that Regulation (EU) No. 1169/2011 justifies an obligation of information regarding the case where new technologies were used in the food production process. This also applies, if the modifications achieved by new technologies are considered to be a "substance still present in the finished product".

The view expressed here that the Regulation (EU) No. 1169/2011 has no relevance for the use of new technologies in the food sector is not contrary to recital 25: "[i]n order to inform consumers of the presence of engineered nanomaterials in food, it is appropriate to provide for a definition of engineered nanomaterials. Taking into account the possibility of food containing or consisting of engineered nanomaterials being a novel food, the appropriate legislative framework for that definition should be considered in the context of the upcoming review of Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients."

The Regulation (EU) No. 1169/2011 explicitly refers to the so-called Novel Food Regulation. It applies exclusively to nano-foodstuffs and not to the categories of genetically modified foodstuffs. However, as nano-materials are usually detectable in the final product, the scope of the Regulation (EU) No. 1169/2011 is open to nanomaterials as ingredients. The mentioned connection between Regulation (EU) No. 1169/2011 and Regulation (EC) No. 258/97 cannot be regarded as evidence that the scope applies also to foodstuffs in which new technologies have played a role.

### **3. In particular: no preventive control**

Following the general principle of food law, according to which the free marketability of foodstuffs is initially assumed<sup>54</sup>, the Regulation (EU) No. 1169/2011 does not establish any preventive authorisation and licensing procedures.

Here again, as in the case of Regulation (EC) No. 178/2002<sup>55</sup>, one can see that the Regulation (EU) No. 1169/2011 imposes specific labelling obligations on the food business operator. In the event of their infringement, the authorities responsible for food law may take downstream measures. An official harmless test before placing on the market does not take place.

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<sup>54</sup> Kraft, F., Grugel, C. and Preußendorff, G. (2008) Vom Jäger zum Sammler zur modernen Industriegesellschaft - Verbots- und Missbrauchsprinzip im Lichte der technologischen Entwicklungen bei der Herstellung von Lebensmitteln. In: ZLR 2008, 321 - 334, pp. 321 et seq.; von Jagow, C. (2007) Auf dem Weg zum Verbotsprinzip? In: ZLR 2007, 479 - 497, pp. 479 et seq.

<sup>55</sup> See IV.

#### 4. National margins

Notwithstanding the described concerns regarding the scope of Regulation (EU) No. 1169/2011 and the suitability of the measures laid down therein, it becomes clear that the Member States have no possibility to make specific additions beyond this with regard to new technologies. In Art. 38 and 39 of the Regulation, the margins for national measures are described as follows:

"Article 38: National measures

1. As regards the matters specifically harmonised by this Regulation, Member States may not adopt nor maintain national measures unless authorised by Union law. Those national measures shall not give rise to obstacles to free movement of goods, including discrimination as regards foods from other Member States.

2. Without prejudice to Article 39, Member States may adopt national measures concerning matters not specifically harmonised by this Regulation provided that they do not prohibit, impede or restrict the free movement of goods that are in conformity with this Regulation.

Article 39: National measures on additional mandatory particulars

1. In addition to the mandatory particulars referred to in Article 9 (1) and in Article 10, Member States may, in accordance with the procedure laid down in Article 45, adopt measures requiring additional mandatory particulars for specific types or categories of foods, justified on grounds of at least one of the following:

a) the protection of public health

b) the protection of consumers

c) the prevention of fraud

d) the protection of industrial and commercial property rights, indications of provenance, registered designations of origin and the prevention of unfair competition

2. By means of paragraph 1, Member States may introduce measures concerning the mandatory indication of the country of origin or place of provenance of foods only where there is a proven link between certain qualities of the food and its origin or provenance. When notifying such measures to the Commission, Member States shall provide evidence that the majority of consumers attach significant value to the provision of that information."

As Art. 39 (1) is limited to "specific types or categories of foods", the vague term of "consumer protection" (Art. 39 (1) lit. b) and, in particular, by linking national regulations to the protection of the free movement of goods (Art. 38.(2)), the margins for national measures are minimal.

## **VII. Regulation (EC) No. 767/2009**

"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"<sup>56</sup> lays down specific requirements for feed safety.

### **1. Scope**

According to Art. 1 of the Regulation (EC) No. 767/2009, the aim is to ensure a high level of feed safety and thus a high level of protection of public health, an adequate information for users and consumers and to strengthen the effective functioning of the internal market. The scope of the Regulation covers, according to Art. 2 (1), the "rules on the placing on the market and use of feed for both food-producing and non-

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<sup>56</sup> OJ L 229/1, 1. September 2009.

food producing animals within the Community, including requirements for labelling, packaging and presentation."

**a. Limited focus**

The Regulation is characterized by the term of "feed", which shall be interpreted in accordance with Regulation (EC) No. 178/2002 (Art. 3 (1) lit. a). This reveals that Regulation No. 767/2009 as a component of European food and feed law follows - as stated before<sup>57</sup> - a completely different regulatory approach. Thus, it has a completely different focus and does not even provide verification mechanisms which would be comparable to those of genetic engineering law. In this respect, it can be referred to the former analysis.

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<sup>57</sup> See IV.

**b. Genetic engineering law as *lex specialis***

From the outset on, the purpose of Regulation (EC) No. 767/2009 is not to answer questions of genetic engineering and similar high tech applications. This emerges explicitly from Art. 2 (2) lit. e and lit. f of the Regulation which states as follows:

"[t]his Regulation shall apply without prejudice to other Community provisions applicable in the field of animal nutrition, in particular:

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

f) 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; (...)."

Regarding the general understanding of its terminology, there is a precedence of the (EC) No. 1829/2003 and No. 1830/2003 as far as it concerns genetic modified food

and feed. An analysis of the term "without prejudice" in German and European law leads to this result, too.<sup>58</sup> Thus, Regulations (EC) No. 1829/2003 and 1830/2003 are *leges speciales* from which one can only derogate in case of an obvious error in drafting.<sup>59</sup>

#### **aa. Regulation (EC) No. 1829/2003**

The reason why priority should be given to Regulations (EC) No. 1829/2003<sup>60</sup> and 1830/2003<sup>61</sup> over Regulation (EC) No. 767/2009 from the European legislator's point of view is illustrated in the recitals of the preamble. For instance, recitals No. 3 to 8 of the preamble to Regulation (EC) No. 1829/2003 state:

"(3) In order to protect human and animal health, food and feed consisting of, containing or produced from genetically modified organisms (hereinafter referred to as genetically modified food and feed) should undergo a safety assessment through a Community procedure before being placed on the market within the Community.

(4) Differences between national laws, Regulations and administrative provisions concerning the assessment and authorisation of genetically modified food and feed may

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<sup>58</sup> Wolff, J. (2012) „Unbeschadet“ - Zum praktischen Verständnis eines beliebten Wortes in deutschen und europäischen Normen und Verträgen. In: JZ 2012, 31 - 35, pp. 31 et seq.

<sup>59</sup> Wolff, J. (2012) „Unbeschadet“ - Zum praktischen Verständnis eines beliebten Wortes in deutschen und europäischen Normen und Verträgen. In: JZ 2012, 31 - 35, p. 35.

<sup>60</sup> OJ L 268/1, 18. October 2003.

<sup>61</sup> OJ L 268/24, 18. October 2003.



hinder their free movement, creating conditions of unequal and unfair competition.

(5) An authorisation procedure involving Member States and the Commission has been established for genetically modified foods in Regulation (EC) No. 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients(5). This procedure should be streamlined and made more transparent.

(6) Regulation (EC) No. 258/97 also provides for a notification procedure for novel foods which are substantially equivalent to existing foods. Whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself. In order to ensure clarity, transparency and a harmonised framework for authorisation of genetically modified food, this notification procedure should be abandoned in respect of genetically modified foods.

(7) Feed consisting of or containing genetically modified organisms (GMOs) has so far been authorised, subject to the authorisation procedure provided by Council Directive 90/220/EEC of 23 April 1990(6) and 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; no authorisation procedure exists for feed produced from

GMOs; a single, efficient and transparent Community authorisation procedure for feed consisting of, containing or produced from GMOs should be established.

(8) The provisions of this Regulation should also apply to feed intended for animals which are not destined for food production."

Therefore, the GMO entry in food and feed triggers a full safety check which is made within the framework of a special authorisation procedure. Here, the free marketability with ex post control which characterises food law is firmly abandoned. The individual responsibility of the food and feed business operator is also not emphasised. However, an official ex ante control is implemented. To the European legislator, pure notification systems - which were possible for specific feed - appeared to be no more appropriate. Finally, it is clarified that Regulation (EC) No. 1829/2003 integrates into the complementary regime of the system and the release Directive resp. the Novel Food Regulation.

Consequently, Art. 4 of the Regulation establishes a strict authorisation regime which establishes high requirements concerning the authorisation of products. The existence shall be proved by the applicant:

"Article 4: Requirements

(1) Food referred to in Article 3(1) must not:

(a) have adverse effects on human health, animal health or the environment;

(b) mislead the consumer;

(c) differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.

(2) No person shall place on the market a GMO for food use or food referred to in Article 3(1) unless it is covered by an authorisation granted in accordance with this Section and the relevant conditions of the authorisation are satisfied.

(3) No GMO for food use or food referred to in Article 3 (1) shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that it satisfies the requirements of paragraph 1 of this Article."

**bb. Regulation (EC) No. 1830/2003**

Regulation (EC) No. 1830/2003 adds a traceability system to the network of European rules concerning genetic engineering law. Decisive for this advance of the European legislator is the fact that the corresponding requirement of Directive 2001/18/EC was implemented too inconsistently. As a result, corresponding harmonization measures were required.<sup>62</sup> Recitals No. 3, 4, 5, 8 and 9 of the preamble to Regulation (EC) No. 1830/2003 explain the interconnection of the different instruments:

"(3) Traceability requirements for GMOs should facilitate both the withdrawal of products where unforeseen adverse effects on human health, animal health or the environment, including ecosystems, are established, and the targeting of monitoring to examine potential effects on, in particular, the environment. Traceability should also facilitate the implementation of risk management measures in accordance with the precautionary principle.

(4) Traceability requirements for food and feed produced from GMOs should be established to facilitate accurate labelling of such products, in accordance with the requirements of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, so

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<sup>62</sup> Clearly indicated in recital 1 and 2 of the preamble of Regulation (EC) No. 1830/2003.

as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner as well as to enable control and verification of labelling claims. Requirements for food and feed produced from GMOs should be similar in order to avoid discontinuity of information in cases of change in end use.

(5) The transmission and holding of information that products contain or consist of GMOs, and the unique codes for those GMOs, at each stage of their placing on the market provide the basis for appropriate traceability and labelling for GMOs. The codes may be used to access specific information on GMOs from a register, and to facilitate their identification, detection and monitoring in accordance with Directive 2001/18/EC.

(8) Guidance on sampling and detection should be developed in order to facilitate a coordinated approach for control and inspection and provide legal certainty for operators. Account should be taken of registers containing information on genetic modifications in GMOs established by the Commission in accordance with Article 31 (2) of Directive 2001/18/EC and Article 29 of Regulation (EC) No. 1829/2003.

(9) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation."

In order to specify these considerations, the Regulation contains detailed provisions concerning

- the traceability for food and feed produced by GMOs<sup>63</sup>
- the application of a system for unique identifiers (and if necessary its development)<sup>64</sup>
- the implementation of inspection and control measures<sup>65</sup> as well as
- the mandatory establishment of viable penalty mechanisms.<sup>66</sup>

It is not necessary to describe these mechanisms in detail. It may also not be necessary to look at details of the Regulation such as the adjustment of the threshold in Directive 2001/18/EC by Art. 7 No. 2 of the Regulation (EC) No. 1830/2003. It is obvious that the system of traceability established in Regulation (EC) No. 1830/2003 such as the mechanisms of Regulation (EC) No. 1829/2003 cannot be found in the general food and feed law.

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<sup>63</sup> Art. 5 of Regulation (EC) No. 1830/2003.

<sup>64</sup> Art. 8 of Regulation (EC) No. 1830/2003.

<sup>65</sup> Art. 9 of Regulation (EC) No. 1830/2003.

<sup>66</sup> Art. 11 of Regulation (EC) No. 1830/2003.

## **2. Quintessence of the overall view**

As a quintessence of the overall view, the general European food and feed law is an entirely inappropriate instrument to replace authorisation procedures of genetic engineering law. Moreover, food and feed law acknowledges the priority of the European genetic engineering law as *leges speciales*. In particular, Regulation (EC) No. 767/2009 mentions the relationship of subordination.

It has to be pointed out that the question whether the emerging regulatory gap, in case of an inapplicability of Directive 2001/18/EC on organisms produced by new technologies, could be compensated by applying European food and feed law, is enriched by the relationship of the regulatory requirements discussed above.

If Regulation (EC) No. 767/2009 recognises that the regulated authorisation procedures are classified as *lex specialis* (by referring to Regulation (EC) No.1829/2003 and 1830/2003) and if these Regulations are integral part of the European genetic engineering law, i.e. the Directive on the Contained Use of Genetically Modified Micro-Organisms and the Directive on Deliberate Release of GMOs into the Environment as well as the Novel Food Regulation, the following applies: if organisms produced by new technologies were excluded

from the scope of Directive 2001/18/EC, this exclusion would also apply to the Regulations (EC) No. 1829/2003 and 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.

#### **VIII. Directive 92/43/EEC**

The "Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora"<sup>67</sup>, also known as the Directive on Habitats, Flora and Fauna, pursues in Art. 2 the following objectives:

"(1) The aim of this Directive shall be to contribute towards ensuring bio-diversity through the conservation of natural habitats and of wild fauna and flora in the European territory of the Member States to which the Treaty applies.

(2) Measures taken pursuant to this Directive shall be designed to maintain or restore, at favourable conservation status, natural habitats and species of wild fauna and flora of Community interest.

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<sup>67</sup> OJ L 206/7, 22. July 1992.



(3) Measures taken pursuant to this Directive shall take account of economic, social and cultural requirements and regional and local characteristics."

These objectives are pursued mainly by the survey using the lists of sites<sup>68</sup>, by creating the necessary conservation measures for special areas of conversation<sup>69</sup>, and by safeguard measures for certain species of animals and plants<sup>70</sup>. The Directive 92/43/EEC is therefore a more general environmental agenda for the European Union<sup>71</sup> than a specific instrument for evaluating or averting specific risks. Requirements for the general protection of certain habitats and species are therefore suitable to create social or political awareness. However, the Directive 92/43/EEC does not allow any specific reviews or assessments of certain new technologies that are structured and bundled in a process.

#### **IX. Regulation (EC) No. 834/2007**

The "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"<sup>72</sup> responds to the increasing share of the ecologi-

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<sup>68</sup> Art. 4 of Directive 92/43/ECC.

<sup>69</sup> Art. 6 of Directive 92/43/ECC.

<sup>70</sup> Art. 12 et seq. of Directive 92/43/ECC.

<sup>71</sup> Cf. Mayr/Weyland (2016) Die Naturschutzrichtlinien: Bewährt und doch auf dem Prüfstand. In: NuR 2016, 96 - 100.

<sup>72</sup> OJ L 189/1, 20. July 2007.

cal/biological agricultural sector and to the growing consumer demand for the corresponding products.<sup>73</sup>

#### **1. Aim and scope of Regulation (EC) No. 834/2007**

Art. 3 of the Regulation (EC) No. 834/2007 defines the aims of the Regulation as follows:

"Organic production shall pursue the following general objectives:

(a) establish a sustainable management system for agriculture that

(i) respects nature's systems and cycles and sustains and enhances the health of soil, water, plants and animals and the balance between them

(ii) contributes to a high level of biological diversity;

(iii) makes responsible use of energy and the natural resources, such as water, soil, organic matter and air;

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<sup>73</sup> See recital 2 of the preamble of Regulation (EC) No. 834/2007.

(iv) respects high animal welfare standards and in particular meets animals' species-specific behavioural needs;

(b) aim at producing products of high quality;

(c) aim at producing a wide variety of foods and other agricultural products that respond to consumers' demand for goods produced by the use of processes that do not harm the environment, human health, plant health or animal health and welfare."

Pursuant to Art. 4 lit. a (iii), the ecological/ biological production has to be based on the principle that "the appropriate design and management of biological processes based on ecological systems using natural resources which are internal to the system by methods that (iii) exclude the use of GMOs and products produced from or by GMOs with the exception of veterinary medicinal products."

Within the general production rules, Art. 9 of the Regulation (EC) No. 834/2007 prohibits the use of genetic engineering procedures for all relevant product groups:

"(1) GMOs and products produced from or by GMOs shall not be used as food, feed, processing aids, plant protection products, fertilisers, soil conditioners,

seeds, vegetative propagating material, micro-organisms and animals in organic production.

(2) For the purpose of the prohibition referred to in paragraph 1 concerning GMOs or products produced from GMOs for food and feed, operators may rely on the labels accompanying a product or any other accompanying document, affixed or provided pursuant to Directive 2001/18/EC, Regulation (EC) 1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed or Regulation (EC) 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms.

Operators may assume that no GMOs or products produced from GMOs have been used in the manufacture of purchased food and feed products when the latter are not labelled, or accompanied by a document, pursuant to those Regulations, unless they have obtained other information indicating that labelling of the products in question is not in conformity with those Regulations.

(3) For the purpose of the prohibition referred to in paragraph 1, with regard to products not being food or feed, or products produced by GMOs, operators using such non-organic products purchased from third parties shall require the vendor to confirm that the products supplied have not been produced from or by GMOs.

(4) The Commission shall decide on measures implementing the prohibition on the use of GMOs and products produced from or by GMOs in accordance with the procedure referred to in Article 37 (2)."

## **2. Consequences for the question**

The production of ecological/biological products regulated and supported by Regulation (EC) No. 834/2007 is diametrically opposed to the production of corresponding products as or by GMOs. There are the following consequences arise for the question to be investigated:

### **a. In case of applicability of Directive 2001/18/EC**

Assuming the applicability of Directive 2001/18/EC on new technologies, the products in terms of Art. 9 (1) and (2) of the Regulation (EC) No. 834/2007 may not be used in organic products at all. Moreover, Regulation (EC) No. 834/2007 would not be applicable. This is due to the fact that the requirements for agricultural, plant, livestock and other specific products<sup>74</sup> do only apply to the production of feed<sup>75</sup>, food<sup>76</sup> and labelling rules<sup>77</sup>, if the corresponding products are qualified as organic. Equally, the mechanisms of control<sup>78</sup> explicit-

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<sup>74</sup> Art. 11 et seq. of Regulation (EC) No. 834/2007.

<sup>75</sup> Art. 18 of Regulation (EC) No. 834/2007.

<sup>76</sup> Art. 19 et seq. of Regulation (EC) No. 834/2007.

<sup>77</sup> Art. 23 et seq. of Regulation (EC) No. 834/2007.

<sup>78</sup> Art. 27 et seq. of Regulation (EC) No. 834/2007.

ly<sup>79</sup> apply only if we are dealing with obligations of the Regulation.

**b. In case of inapplicability of Directive 2001/18/EC**

Assuming, on the other hand, that Directive 2001/18/EC is not applicable to new technologies, Art. 9 of the Regulation (EC) No. 834/2007 could not display a suspensory effect. Consequently, Regulation (EC) No. 834/2007 would apply on the corresponding production and labelling.

The applicability of Regulation (EC) No. 834/2007 on the corresponding products would be, in principal, possible. However, this would not enable adequate control mechanisms for new technologies. This is particularly true for the principle of Art. 4 lit. a) iv) of the Regulation which states that biological processes must be based on risk assessment and, if necessary, on the implementation of precautionary and preventive measures. The reason for this is that the mentioned risk assessment may not be confused with the risk assessment in terms of Directive 2001/18/EC. This applies when looking at the purpose of Regulation (EC) No. 834/2007 and the absence of sufficient parameters for the implementation of risk assessment.

Furthermore, Art. 90 of the "Commission Regulation (EC) No. 889/2008 of 5 September 2008 laying down detailed

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<sup>79</sup> Art. 27 (1) of Regulation (EC) No. 834/2007.

rules for the implementation of Council Regulation (EC) No. 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control"<sup>80</sup> determines that within the framework of their control visits the control authority or control body shall make a "general evaluation of the potential risks of non-compliance with the organic production rules".

Hence, we are not dealing with the risks that a special product could pose for human health or the environment but with risks that could be posed by production conditions resp. by non-compliance of regulations that qualifies the production as "organic".

The other requirements of Regulation (EC) No. 834/2007 would also not be appropriate to establish a level of protection for new technologies which could equal the level of protection of Directive 2001/18/EC. Due to the described dualism "organic vs. genetic", the legislator has not seen any reason to regulate technical procedures that use genetic engineering which cannot be proved in the end product.

Against this background, the detailed specifications of Regulation (EC) No. 834/2007 can, in fact, focus on aspects such as the biological activity of the soil<sup>81</sup>, the use of fertilisers<sup>82</sup>, collection of wild seaweeds

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<sup>80</sup> OJ L 250/1, 18. September 2008.

<sup>81</sup> Art. 12 (1) lit. b) of Regulation (EC) No. 834/2007.

<sup>82</sup> Art. 12 (1) lit. d) and e) of Regulation (EC) No. 834/2007.

and parts thereof<sup>83</sup>, the placement of apiaries<sup>84</sup>, or the water quality required for shellfish industry<sup>85</sup>. However, the possible risks of new technologies can obviously not be captured.<sup>86</sup>

This asymmetry is completed if one considers Art. 27 et seq. of Regulation (EC) No. 834/2007. The established control system is a system of administrative enquiry. There is neither an authorisation of specific procedures and technologies nor any preventive control of corresponding production methods.

## **X. Directive 98/58/EC**

"Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes"<sup>87</sup> cannot really be discussed as an instrument for the regulation of new technologies.

Recital 1 of the preamble of Directive 98/58/EC clarifies that the Directive aims to implement the European Convention for the Protection of Animals Kept for Farming Purposes.<sup>88</sup> However, according to Art. 1 sentence 1 of this convention, it refers exclusively to "the keeping, care and housing of animals, and in particular to

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<sup>83</sup> Art. 13 (1) lit. a) of Regulation (EC) No. 834/2007.

<sup>84</sup> Art. 14 (1) lit. b) ix) of Regulation (EC) No. 834/2007.

<sup>85</sup> Art. 15 (1) lit. e) iii) of Regulation (EC) No. 834/2007.

<sup>86</sup> See also: Jaksche (2015) Reformbedarf des gesundheitlichen Verbraucherschutzes. In: LMuR 2015, 4 - 7, p. 4.

<sup>87</sup> Official Journal L 221, 08/08/1998 pp. 0023 - 0027.

<sup>88</sup> Council of Europe (1976) European Convention for the Protection of Animals kept for Farming Purposes. Strasbourg: European Treaty Series (No. 87).



animals in modern intensive stock-farming systems." Therefore, it concerns general aspects regarding the keeping, food and care<sup>89</sup> but not the use of high complex technical procedures in case of any (genetic) engineered modification of these animals. This is also clarified by Art. 3 of the Directive 98/58/EC which states that every owner or keeper "take(s) all reasonable steps to ensure the welfare of animals under their care and to ensure that those animals are not caused any unnecessary pain, suffering or injury."

## **XI. Regulation (EC) No. 1107/2009**

The "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"<sup>90</sup> displays various similarities regarding questions of genetic engineering. Not only because of the wide scope of the Regulation, as described in Art. 2 but also due to some specific requirements in the text of the Regulation.

### **1. In general: genetic engineering and plant protection**

Art. 48 of Regulation (EC) No. 1107/2009 determines the placing on the market and the use of plant protection products containing a genetically modified organism and

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<sup>89</sup> See Art. 3 of the Convention and recital 3 of the preamble of Directive 98/58/EC.

<sup>90</sup> Official Journal L 309/1, 24. November 2009.

requires the cumulative implementation of both authorisation procedures:

"(1) A plant protection product which contains an organism falling within the scope of Directive 2001/18/EC shall be examined in respect of the genetic modification in accordance with that Directive, in addition to the assessment under this Chapter.

An authorisation under this Regulation shall not be granted for such a plant protection product unless written consent, as referred to in Article 19 of Directive 2001/18/EC, has been granted for it.

(2) Unless otherwise specified, all provisions relating to authorisations under this Regulation shall apply."

Furthermore, Art. 53 (4) of the Regulation clarifies that the requirements for emergency situations in plant protection shall not apply to plant protection products containing or consisting of GMOs. Additionally, according to Art. 54 (3) of the Regulation, an authorisation for the release of GMOs granted for experiments is inadmissible if the release has been accepted under Directive 2001/18/EC.

## **2. Consequences for the question**

The scope of Regulation (EC) 1107/2009 is exceptionally wide and covers products, e.g., plant growth regulators influencing the life processes of plants<sup>91</sup> but also micro-organisms having general or specific action against harmful organisms on plants.<sup>92</sup> The scope of application is also opened up, if the corresponding effects are achieved by new technologies, as the achieved impacts are of relevance and not the classification of the necessary techniques.

### **a. In case of applicability of Directive 2001/18/EC**

If organisms produced or modified by new technologies are qualified as GMO in terms of Directive 2001/18/EC, the Directives and Regulations operate in a consistent way, as formerly described. Consequently, phytosanitary legislation is applicable in addition to genetic engineering law which has priority and which is more extensive.

### **b. In case of inapplicability of Directive 2001/18/EC**

Assuming an inapplicability of Directive 2001/18/EC on new technologies, the mechanisms of the Regulation apply exclusively. In particular, the approval procedure

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<sup>91</sup> Art. 2 (1) lit. b) of Regulation (EC) No. 1107/2009.

<sup>92</sup> Art. 2 (2) of Regulation (EC) No. 1107/2009.

(Art. 7 et seq.), the comprehensive approval criteria for active substances (Art. 4 et seq.) as well as the detailed authorisation procedure (Art. 33 et seq.) – in consideration of the requirements and the content of Art. 28 et seq. – would apply.

As Art. 1 (4) and Art. 13 (2) of the Regulation clarify, the precautionary principle would apply as well: "The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory."

Comparing Regulation (EC) No. 1107/2009 to all other analysed instruments, it can be concluded that this Regulation is most likely to fill gaps created by an inapplicability of Directive 2001/18/EC on new technologies. However, the high density of controls remains completely insufficient. This applies less to the instruments introduced by the Regulation than to its scope. Even though the Regulation – as indicated above – is based on wide concepts in many respects, its scope is limited to a maximum.

Art. 2 of the Regulation reads:

"(1) This Regulation shall apply to products, in the form in which they are supplied to the user, consisting of or containing active substances, safeners or synergists, and intended for one of the following uses:

a) protecting plants or plant products against all harmful organisms or preventing the action of such organisms, unless the main purpose of these products is considered to be for reasons of hygiene rather than for the protection of plants or plant products;

b) influencing the life processes of plants, such as substances influencing their growth, other than as a nutrient;

c) preserving plant products, in so far as such substances or products are not subject to special Community provisions on preservatives;

d) destroying undesired plants or parts of plants, except algae unless the products are applied on soil or water to protect plants;

e) checking or preventing undesired growth of plants, except algae unless the products are applied on soil or water to protect plants.

These products are referred to as 'plant protection products'.

(2) This Regulation shall apply to substances, including micro-organisms having general or specific action against harmful organisms or on plants, parts of plants or plant products, referred to as 'active substances'.

(3) This Regulation shall apply to the following:

a) substances or preparations which are added to a plant protection product to eliminate or reduce phytotoxic effects of the plant protection product on certain plants, referred to as 'safeners';

b) substances or preparations which, while showing no or only weak activity as referred to in paragraph 1, can give enhanced activity to the active substance(s) in a plant protection product, referred to as 'synergists';

c) substances or preparations which are used or intended to be used in a plant protection product or adjuvant, but are neither active substances nor safeners or synergists, referred to as 'co-formulants';

(d) substances or preparations which consist of co-formulants or preparations containing one or more co-

formulants, in the form in which they are supplied to the user and placed on the market to be mixed by the user with a plant protection product and which enhance its effectiveness or other pesticidal properties, referred to as 'adjuvants'."

The scope of the Regulation is therefore

- limited to plant protection products as well as to corresponding active substances and excludes all possible use which does not deal with the narrow field of plant protection
- opened up only if the described effects are explicitly targeted. It is required that the products are "intended to be used" for the mentioned purpose, that the substances are added "to achieve an effect" or that any other "provision" exists. If those effects turn out to be a "side effect", they should not be covered by the scope of the Regulation.
- designed to have only a supportive role because of the interaction with Directive 2001/18/EC in the field of genetic engineering. This suggests that the mechanisms of control in the field of procedures of genetic engineering - and also measures having the same effect - cannot reach the density of Directive 2001/18/EC.

An analysis of the established case-law shows that the criterion of "purpose" leads to an imponderability. The following decision of the Celle Higher Regional Court

(OLG Celle) shall illustrate to what extent the qualification as plant protection product can be affected:

"The distinction between fertilizers and soil additives on the one hand and plant protection products on the other hand has to be made according to its purpose and not only according to its composition.

The Baden Württemberg Higher Administrative Court (...) stated that the Plant Protection Act and the Fertilizers Act refer to each other. This means that the distinction in case of products containing a "double purpose" has to be made according to the predominant purpose (Baden Württemberg Higher Administrative Court, Decision of 27<sup>th</sup> August 1992 - 10 S 1105/92, juris recital 10). The Higher Administrative Court explained that the predominant purpose of the concrete product is not made according to the subjective view of the producer or the person who puts the product on the market but according to objective standards (...), i.e. according to the type of ingredients of the product, the name and promotion as well as the instructions for the use of the producer that have an impact on the public perception (...).

(The Federal Administrative Court stated:) What is crucial is how the product is seen by an average well-informed customer. The "purpose" - the intended use - becomes clear when assessing the material composition of the specimen, its layout, and selling technique. Its



appearance creates expectations and ideas about its purpose or it relates to existing opinions about the purpose of comparable means and their layouts (...).

This is in line with the recent case law of the Lüneburg Higher Regional Court which states that, according to the decision of the Federal Administrative Court, the material composition of the specimen, its layout, and selling technique is relevant for the classification as a plant protection product and not the way it is produced or its chemical properties."<sup>93</sup>

Furthermore, the Regulation (EC) No. 1107/2009 has the following weakness: Even though Art. 6 lit. i) emphasises "the need to impose risk mitigation measures and monitoring after use", it does not establish any monitoring system or any obligation for monitoring. On the contrary, according to Art. 6 lit. i), the authorisation is subject to „conditions and restrictions“ with regard to the above mentioned measures and the monitoring. It is thus a simple arbitrary decision of the proceeding authority. If and to what extent or on what basis appropriate measures can be demanded is decided by the respective responsible person within the scope of its discretion.

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<sup>93</sup> Higher Regional Court Celle (2017). In: AUR 2017, 299 - 304, recitals 40 et seq in Juris.

### **XIII. Additional Aspects**

In the following, further possible "catch all regime options" that may apply if Genetic Engineering Law is not applicable to new technologies shall be discussed.

#### **1. Variety Protection Law**

In political discourse, to variety protection law is occasionally referred to as a potential substitute for Directive 2001/18/EG. However, this may possibly be the result of terminological confusion with the seed legislation. Because as is generally known, variety protection law aims to protect the interests of plant breeders and grants them a protective right similar to a protection by patent if the legal requirements are met.

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#### **2. Police and Regulatory Law (Polizei- und Ordnungsrecht)**

In case of the inapplicability of Directive 2001/18/EG, German Police and Regulatory Law may be considered as a "catch all regime" at least on the national level. This approach might be surprising with regard to the territorial limitations of German law. However, as this pos-

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<sup>94</sup> Norer, R. (2015) Chapter 7. In: Grimm, C. and Norer R. Agrarrecht. 4th ed., Munich, recitals 47 et seq.

sibility is suggested explicitly in literature<sup>95</sup>, this idea needs to be analyzed thoroughly.

#### **a. Legal requirements**

First, it has to be ensured that the requirements for an intervention by the police in case of danger arising from new technologies are met. This requires a short overview of the legal requirements for an intervention by the police.

##### **aa. Legal basis**

In the absence specific regulations, the crucial norm is the general clause of Police Law laid down e.g. in Sec. 8 para. 1 of the Police Law of North Rhine-Westphalia.

"The police can take the necessary measures to repel a case-based definite danger to public security and public order that persists (danger), as long as Sections 9 to 46 do not provide specific competencies to the authorities of the police."

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<sup>95</sup> Cf. Dederer (2011) GVO-Spuren im Saatgut. In: NuR 2011, 489 - 493, p. 492 for the constellation of unintentional distribution of GMO, only present in traces in conventional seed.

Within the competence of the general regulatory authorities, Sec. 14 para. 1 of the Regulatory Authorities Act of North Rhine-Westphalia (OBG NRW) reads:

"The regulatory authorities can take the necessary measures to repel a case-based definite danger to public safety and public order (danger)."

**bb. In particular: The term of danger**

As the central term of danger is not legally defined by the law in North Rhine-Westphalia, a general definition has to be used. "Danger" is a factual situation which would lead to the occurrence of damages with a sufficient degree of likelihood if the course of events was unhindered. Damages describe a reduction of an actual existing amount of assets that are police protected.

For the distinction between damages relevant to and protected by Police Law on the one hand and irrelevant mere harassments on the other hand, the verification of the legality as well as the intensity of the measures in question are decisive. Legal measures cannot constitute the violation of protected legal assets. With regard to the distinction between legality and illegality, it comes down to the result of considering and weighing colliding constitutional rights and police protected assets.

A sufficient degree of likelihood of the occurrence of damages is not only achieved when damages are most definitely expected. Then again, mere speculations are not sufficient to justify any state intervention. If damages cannot be ruled out completely but a likelihood of damages is not indicated otherwise, this constitutes a mere risk. A risk can be the legal basis for statutory provisional measures in specific laws but is principally not sufficient for Police and Regulatory Law. The sufficient likelihood is therefore "more" than the almost preclusive likelihood but "less" than the safe knowledge or rather the certainty of the occurrence of damages. In the course of events, the requirements related to the likelihood decrease with the significance of the anticipated damages.

Therefore, objects of protection of the Police Law are public safety and public order. The legal field of public safety is composed of three sections that overlap in part. The inviolability of the legal system, the inviolability of legal rights and legal assets of the individual and the inviolability of institutions and activities of the state.

With regard to public order, the requirements are significantly less specific. "Public Order comprises all unwritten (largely ethical) rules of conduct considered as indispensable to human and civic communal life"<sup>96</sup>. Considering these standards is - with regard to the respective dominating opinion - crucial for a beneficial

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<sup>96</sup> Reimann, Mathias, Zekoll, Joachim(eds.), 2005, Introduction to German Law, Second Edition, The Hague, Kluwer Law International, p. 109.

cohabitation within a certain area. Due to the ambiguity of the term as well as severe concerns regarding legal certainty and the potential for a violation of minority rights, the "prevailing opinion" attempts to ease the aggravating constitutional concerns by particularly reconnecting to constitutional standards.

**cc. In particular: Definite, abstract, objective, subjective, apparent, putative danger and suspected risk**

Furthermore, the type of danger needs to be clarified. "Definite danger" describes a factual situation in which the threat of damages affects a singular case with regard to spatial-temporal aspects. "Abstract danger" describes the general-abstract consideration of certain types of behavior patterns or conditions that lead to the result that damages may occur with a sufficient degree of likelihood in singular cases and thus has to be prevented by general-abstract measures, i.e. legal provisions. Therefore, not only scientific-statistical contemplations but also general life experience play a decisive role.

The sole function of the term "abstract danger" is to provide a legal basis for regulations that avert danger. Abstract dangers are met with regulations, definite dangers are eliminated by measures taken with regard to the individual case. Insofar their legal requirements vary. Therefore, lawfulness problems occur

if a regulation is the reaction to a definite danger or if a case-by-case measure is the reaction to an abstract danger.

The legality of measures taken based on "objective danger" depends on the question whether or not a danger actually exists. Measures taken by the police based on wrong assumptions are illegal when there is no objective danger. The term of "subjective danger" depends on the acting official's assumption regarding the existence of danger. The decision of the acting official must necessarily reflect the kind of accuracy, wisdom and prudence that can be expected from the typical official. Therefore, danger exists in the situation of apparent or putative danger and suspected risk.

"Apparent danger" is a factual situation which was considered as dangerous by the police and which, viewed objectively, was also dangerous according to a reasonable assessment and sufficient fact-finding measures but which turns out to be not dangerous. The relevance of apparent danger as an "independent category" is disputed. Apparent danger is partly classified as danger respectively suspected risk. It is especially controversial whether or not the affected person can be granted a compensation, if they are not responsible for the apparent danger such as in case of a „non-disturber“ (Nichtstörer).

A "suspected risk" describes the uncertainty of the acting official in a factual situation even though they have reasonably assessed and sufficiently clarified the facts of the case and have not assumed actual danger but the possibility of danger. The categories of apparent danger and suspected risk commonly merge into one another.

However, important differences appear with regard to the legal consequences: the proportionate reaction to a suspected risk is usually not a final intervention to avert the danger. In fact, it is rather a preliminary action which aims at gaining certainty over the relevant level of danger. Regularly, this leads to measures to explore the risk or rather to the ordering of necessary (preliminary) security measures. At the same time, there are "measures aiming at exploring the disturber" (Störererforschungseingriff). Those actions are regularly based on the general clause of Police Law. The suspected risk is only as an exception based on explicit legal provisions, e.g. Sec. 39 para. 1 no. 2 of the Police Law of North Rhine-Westphalia. Especially, the question of costs and compensation are disputed.

"Putative danger" describes the case in which the acting official assumes danger even though a danger does not exist according to the subjective and objective term of danger. Thus, the official's assessment contradicts a typical official's reasonable assessment and clarification of the facts of the case and is not justifiable. The actions are illegal.



## **b. Implementation of the requirements of an intervention**

It must be generally doubted if the above described requirements for an intervention by the police are suitable for preventing possible dangers that may arise from the use of highly technological applications. The indication that the police and regulatory authorities could simply „request legal assistance from the authorities which have the knowledge of genetic technologies“ in case of „definite danger“<sup>97</sup> is not convincing. On the one hand, not only the complex, unspecific requirements of Police and Regulatory Law but also (sic!) the legal requirements for legal assistance must be met and, in addition to this, the authority asking for legal assistance has to take action to the desired extent.

On the other hand, mandatory for any request for legal assistance is that the requesting authority is aware of the necessity of such procedures. In other words, the general police and the regulatory authorities may not recognize danger due to a lack of scientific-technological expertise and therefore cannot request legal assistance. Apart from that, the question whether such permanent use of genetic-technological expertise of federal authorities by the relevant police and regulatory authorities subjected to state laws would be admissible in terms of competencies and administration remains open.

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<sup>97</sup> Dederer (2011) GVO-Spuren im Saatgut. In: NuR 2011, 489 - 493, p. 492.

It is also questionable whether sufficient likelihood of the occurrence of damage „can still be determined when the possible cause of damage, damage progression and extent of damage are still in the gloominess of scientific future“. As with regard to highly valued legal assets, „even a definite suspected risk is sufficient for a security-related order“.<sup>98</sup> As described, the suspected risk is not without any requirements which leads to the above-mentioned issues on the categories of Police Law.

Due to the previous findings, further insufficiencies that arise from Police and Regulatory Law are not set out in detail. It is sufficient to highlight that the general clauses of Police and Regulatory Law are subject to substantial dogmatic discussion and that Police and Regulatory Law subjected to state laws shows massive discrepancies from one federal state to another. A nationwide management cannot be guaranteed.

### **c. Preventing risk and averting danger**

In addition to those general insufficiencies of Police and Regulatory Law, severe concerns arise with regard to the fundamental suitability of this branch of law. The Federal Constitutional Court has already explicitly stated that the risk which is attached to application questions of new technologies cannot be covered by the

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<sup>98</sup> Dederer (2011) GVO-Spuren im Saatgut. In: NuR 2011, 489 – 493, p. 492.

general Police and Regulatory Law whose primary aim is to avert danger:

„The restriction of the definition of a genetically modified organism in Sec. 3 No. 3 Genetic Engineering Law (GenTG) and therefore the restriction of the scope of the Genetic Engineering Law to genetic-technological modifications would lead to the exclusion of its descendants from any legal control. This affects not only the placing on the market (Sec. 14 et seq., Sec. 16d GenTG) but also the proper use of products that have already been placed on the market (Sec. 16b GenTG), their surveillance (Sec. 16c GenTG), their labelling (Sec. 17b GenTG), the obligation to notify the business owner and other participants (Sec. 21 GenTG) and the power of authorities (Sec. 20, 25, 26, 28 et seq. GenTG). The intended protection of legal assets and interests mentioned in Sec. 1 No. 1 and 2 GenTG would not be fully covered by Police and Regulatory Law which aims at averting danger and not at preventing risk.“<sup>99</sup>

Case law shares this assessment and assumes that Police and Regulatory Law is not applicable:

„The legislator did not explicitly regulate the case of unintentional seeding of GMO. Rather, the complex regulatory framework of Genetic Engineering Law provides a tiered model of the planned handling of GMOs (genetic-technological work, deliberate release, putting on the

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<sup>99</sup> Decision of the Federal Constitutional Court 128, pp. 1 et seq., recital 140 in Juris.

market, use). The legislator provided an extensive instrument that is based on the purpose of averting and preventing danger which takes into account the ongoing scientific knowledge, especially with regard to the evaluation of correlations and long-term impacts of the use of genetic technologies (...). Such an instrument based on the prevention and risk principle does far more justice to the constitutional protection mandate than the general Police and Regulatory Law which aims at averting danger and not at preventing risk (...)."<sup>100</sup>

„The Genetic Engineering Law aims for an „extensive purpose of protection and prevention (...), namely by taking into account ethical values, life and health of people, the environment within its causal network, animals, plants and material assets and by protecting those from the harmful consequences of genetic-technological procedures and products and by providing rules for the occurrence of such dangers (Sec. 1 para. 1 GenTG). This shows that the Genetic Engineering Law constitutes a special law which already “intervenes” before an actual danger occurs. Therefore, it contains an extensive admission regime with approval requirements for various activities. The precautionary purpose of the law “intervenes” before danger emerges and is based on a preceding (preventive) calculation of risks. The extensive protective purpose along with the various possibilities for an intervention of the competent authorities in case of - future - illegal actions with regard to GMO (Sec. 26 GenTG) show the conclusive char-

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<sup>100</sup> Administrative Court Augsburg (2011). In: NuR 2011, 523 - 529, recital 44 in Juris.

acter of the GenTG which does not permit the recourse to general Police and Regulatory Law."<sup>101</sup>

#### **d. Interim result**

On the national level, the German Police and Regulatory Law aims at preventing danger and does not provide a "catch all regime" for potential risks that arise from new technologies in case of inapplicability of Directive 2001/18/EC.

### **XIII. Conclusion and substantial results**

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 as-

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<sup>101</sup> Administrative Court Schleswig- Holstein, decision of 07. November 2007, case No.: 1 B 33/07, recital 66 in Juris.

pects 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.

European food law is not suitable as a "catch all regime" for new technologies. Regarding Regulation (EC) No. 178/2002 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 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.

Despite all innovations the new Regulation (EU) No. 2015/2283 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 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 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.

Food safety law, especially influenced by Regulation (EC) No. 767/2009, 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 and Regulation (EC) 1830/2003 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.

Directive 92/43/EEC 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 assumes a diametrical relation of ecological / biological production on the one hand and GMO on the other hand and deals with ecological / biological 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.

Directive 98/58/EC deals with the housing, food and care of animals kept for farming purposes and does not play a role for the normative handling of new technologies.

Regulation (EC) No. 1107/2009 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.

Plant variety rights are not relevant to the present question.

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 averting 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.