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MY REFERENCE 222-17600/0001

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Via E-Mail

Attachments: -2-

Dear Mr. Chairman,

regarding the Inquiry into mechanisms for compensation for economic loss to farmers in Western Australia caused by contamination by genetically modified Material I can confirm that in Germany we have statute based liability provisions according to Part V of the German Genetic Engineering Act — Gentechnikgesetz GenTG - that also cover damages to property. You will find the legal provisions §§ 32-37 GenTG here: http://www.gesetze-im-internet.de/gentg/index.html

The general concept of Part V of the German Genetic Engineering Act is one of strict liability, i.e. not a liability based on negligence. If a farmer sues for compensation also contractual and general liability provisions (based on the Civil Code) will apply, these depend on negligence, provided a contract does not lawfully stipulate otherwise.

For an overview over the development of the German Genetic Engineering Act in the recent decade the judgment of the Constitutional Court of 24/11/2010 might be useful (Press Release and judgement attached).

Also there are at least two Civil Court decision, though on quite specific items: Oberlandesgericht München, judgement of 28.08.2018, 24 U 2956/12 and Oberlandesgericht Frankfurt, judgement of 06.02.2009, 2 U 128/07. For copy right reasons these decisions may be requested by the mentioned courts directly or via a legal research database.

For a general overview over legal provisions concerning Genetic Engineering in Germany you may also consult the internet page of the Federal Office of Consumer Protection and Food

Safety (in English language):

https://www.bvl.bund.de/EN/06 Genetic Engineering/03 Applicants/08 LegalFramework/genetic engineering legal framework node.html

I hope this information is of help to you.

Best regards

Dr. Christoph von Heydebrand

Headnotes

to the judgment of the First Senate of 24 November 2010 - 1 BvF 2/05 -

- 1. Art. 74 sec. 1 no. 26 of the Basic Law (*Grundgesetz* GG) allows the Federation to pass laws on genetic engineering, which includes human genetic engineering and animal and plant genetic engineering.
- 2. In light of the fact that the scientific knowledge is, to date, not conclusive in assessing the long-term consequences of genetic engineering, the legislature has a particular duty of care, and must adhere to the mandate in Art. 20a GG to protect natural resources, *inter alia* out of responsibility for future generations.
- 3. The creation of transparency in relation to an intentional introduction of genetically modified organisms into the environment (§ 16a GenTG) contributes to the process of public formation of opinions; it constitutes an independent and legitimate purpose of legislation.
- 4. [...]

FEDERAL CONSTITUTIONAL COURT

- 1 BvF 2/05 -

Pronounced
on 24 November 2010
Kehrwecker
Amtsinspektor
as Registrar
of the Court Registry



IN THE NAME OF THE PEOPLE

In the proceedings for constitutional review

of § 3 numbers 3 and 6, § 16a secs. 1, 3, 4 and 5, § 16b secs. 1 to 4 and § 36a of the Act on the Regulation of Genetic Engineering (Gesetz zur Regelung der Gentechnik, Gentechnikgesetz, Genetic Engineering Act – GenTG), as most recently amended by Art. 1 of the Act to Amend the Genetic Engineering Act, to Amend the Genetic Engineering Implementation Act and to Amend the Novel Foods and Novel Food Ingredients Regulation (Gesetz zur Änderung des Gentechnikgesetzes, zur Änderung des EG-Gentechnik-Durchführungsgesetzes und zur Änderung der Lebensmittel- und Lebensmittelzutatenverordnung) of 1 April 2008 (Federal Law Gazette, Bundesgesetzblatt – BGBI I p. 499)

Land government of Saxony-Anhalt,

- Applicant:

represented by the Minister of Economics and Labour,

Hasselbachstrasse 4, 39104 Magdeburg

- authorised representatives:

Rechtsanwälte Freshfields Bruckhaus Deringer,

Potsdamer Platz 1, 10785 Berlin -

the Federal Constitutional Court - First Senate -

with the participation of

Justices Vice-President Kirchhof,

Hohmann-Dennhardt,

Bryde,

Gaier,

Eichberger,

Schluckebier,

Masing,

Paulus

held on the basis of the oral hearing of 23 June 2010:

Judgment:

§ 3 numbers 3 and 6, § 16a sections 1 to 5, § 16b sections 1 to 4 and § 36a of the Act on the Regulation of Genetic Engineering as most recently amended by Article 1 of the Act to Amend the Genetic Engineering Act, to Amend the Genetic Engineering Implementation Act and to Amend the Novel Foods and Novel Food Ingredients Regulation of 1 April 2008 (BGBI I p. 499) are compatible with the Basic Law (Grundgesetz – GG).

Reasons:

A.

The application for judicial review concerns the compatibility of provisions of the Act on the Regulation of Genetic Engineering (Gesetz zur Regelung der Gentechnik, Gentechnikgesetz, Genetic Engineering Act – GenTG [...]) with the Basic Law. Specifically, it challenges provisions that define "genetically modified organism" and "placing on the market" (§ 3 nos. 3 and 6 GenTG), the provision concerning the location register (§ 16a secs. 1, 3, 4 and 5 and § 16b sec. 1a GenTG), rules on dealing with products placed on the market (§ 16b secs. 1, 2, 3 and 4 GenTG) and rules on damage claims (§ 36a GenTG), as legislated in the Act on the Reform of the Law of Genetic Engineering (Gesetz zur Neuordnung des Gentechnikrechts, hereinafter: Genetic Engineering Reform Act 2004, Gentechnikneuordnungsgesetz 2004 – GenTNeuOG 2004) of 21 December 2004 (BGBI I 2005 p.186) and the Act to Amend the Genetic Engineering Act, to Amend the Genetic Engineering Implementation Act and to Amend the Novel Foods and Novel Food Ingredients Regulation, hereinafter: Genetic Engineering Amendment Act 2008 (Gentechnikänderungsgesetz 2008 – GenTÄndG 2008) of 1 April 2008 (BGBI I p. 499).

I.

1. The intentional recombination of genetic material of living organisms by technological means (genetic engineering [...]) creates the opportunity to systematically alter the genetic makeup in order to create organisms with desired characteristics that could not be achieved by conventional breeding and cultivation methods. As defined by the Genetic Engineering Act, therefore, a genetically modified organism (GMO) is an organism, with the exception of human beings, whose genetic material has been altered in a way that does not occur naturally by crossbreeding or natural recombination (§ 3 no. 3 GenTG).

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The application for judicial review does primarily relate to the use of genetic engineering for cultivated plants, for commercial purposes, as in agriculture and seed production, as well as for purposes of research. This technology, colloquially referred to in German as "green" genetic engineering, is meant to achieve agronomically desirable results such as an increase in productivity or a reduction of environmental damage. As an example, plants shall acquire more nutritional advantages and taste better, shall endure storage over longer periods of time, supply raw materials or be of pharmaceutical use. Risks and opportunities of this use of genetic engineering are in dispute and have not been conclusively established. The transfer of genetic material across species may, on the one hand, intentionally modify desired characteristics, while there is also, on the other hand, the risk of unintended side-effects. By releasing GMOs into the environment, as scientific experiments or as commercial products, they may reproduce and spread. Such effects may be irreversible.

Against this background, extensive legislation serves to control the risks associated with the deliberate release of GMOs into the environment, in order to protect human health and the environment, and to create a basis for the use of the new technology as well as to protect the interests of agriculture free from genetic engineering. Essential requirements of European Union law are to be found in Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of GMOs and repealing Council Directive 90/220/EEC (OJ L106, p. 1; hereinafter: Directive 2001/18/EC) and in Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, p.1; hereinafter: Regulation (EC) 1829/2003).

Federal German law on introducing GMOs into the environment consists primarily of the Genetic Engineering Act, which came into force in 1990 and has since been amended several times, specifically with its provisions on the release of such organisms and the placing on the market of products that contain or consist of GMOs.

2. [...]

The main emphasis of the Genetic Engineering Reform Act 2004 was to implement Directive 7 2001/18/EC and to guarantee the coexistence of different types of agricultural crops.

a) [...]

- b) Based on Art. 26a of Directive 2001/18/EC, inserted by Art. 43 of Regulation (EC) 1829/2003, several instruments serve to prevent the unintended presence of GMOs in other products and to guarantee the coexistence of different types of agricultural crops. In addition, there was the intention to ensure that producers and consumers enjoy freedom of choice and to, beyond the discussion of risks, achieve social peace (Bundestagsdrucksache, *Bundestag* document BTDrucks 15/3088, pp. 19 and 21). The legislature assumed that cultivating a genetically modified crop on a large area, or releasing it on a smaller scale, might result in cross-pollination on neighbouring land and thus affect economic actors who wish to act without the use of genetic engineering or who are obliged to work without it under current provisions on organic agriculture and the labelling of organically produced products. In order to take these developments in agriculture and the food industry into account, the statute defined its purpose to be the guarantee of coexistence (§ 1 no. 2 GenTG). The purpose of the Genetic Engineering Act, under § 1 GenTG, is now defined as
 - 1. taking into account ethical values, to protect the life and health of human beings, the environment in its interactive structure, animals, plants and material goods from harmful effects of genetic engineering operations and products and to take precautions against the emergence of such risks,
 - 2. to ensure that it is possible for products, in particular food and feed, to be produced and placed on the market conventionally, organically or with the use of GMOs,
 - 3. to create the legal framework for research into and for the development, use and promotion of the scientific, technological and economic possibilities of genetic engineering.

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The aim of guaranteeing coexistence was also defined in greater detail in the provisions on the location register, on the treatment of products placed on the market and on claims in the case of interference with use that are subject to the challenge at hand.

aa) In order to implement European Union law requirements under Art. 31 sec. 3 of Directive 2001/18/EC and to ensure coexistence, the legislature established a location register (§ 16a GenTG. Art. 1 no. 14 GenTNeuOG 2004). According to § 16a sec. 1 sentences 1 and 2 GenTG, the location register is kept by the Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) as the competent superior federal authority (cf. § 31 sentence 2 GenTG), it records the obligatory data on the release and cultivation of GMOs for the whole territory of the Federal Republic of Germany, and it does so to monitor any effects of GMOs on the interests and concerns recognised in § 1 nos. 1 and 2 GenTG and to inform the public. If an authorised release is to take place, the actor (cf. § 3 no. 7 GenTG) must, at the latest three working days before the release is made, notify the release, the designation of the GMO, its genetically modified characteristics, the location and the size of the release area, and the period of release, to the Federal Office of Consumer Protection and Food Safety (§ 16a sec. 2 sentences 1 and 2 GenTG). If an approved genetically modified plant is to be cultivated, the farmer (cf. § 3 no. 13a GenTG) must notify the Federal Office of this intention at the latest three months before the sowing, must state the designation and the unique identifier of the GMO, its genetically modified characteristics, the name and address of the person who farms the area, the location and size of the cultivated area (§ 16a sec. 3 sentences 1 and 2 GenTG). Any changes, including the decision not to release, must be notified without delay (§ 16a sec. 2 sentence 3 and 16a sec. 3 sentence 3 GenTG). Some parts of the location register are accessible to the public. Data on the designation and - in the case of cultivation - on the unique identifier of the GMO, its genetically modified characteristics and the release or cultivation land, and the size of the area, may be automatically retrieved on the internet (§ 16a sec. 4 GenTG). The remaining data, which are not publicly accessible, are usually disclosed if the applicant gives prima facie evidence of a justified interest and if there is no reason to assume that the person affected has an interest warranting protection and a refusal of such data that carries more weight (§ 16a sec. 5 GenTG). In addition, the registry must take measures that comply with the current state of the art to guarantee data privacy and data protection (§ 16a sec. 6 sentence 1 GenTG). Data in the federal register are deleted on the expiry of fifteen years after they are first stored (§ 16a sec. 6 sentence 2 GenTG).

bb) To further contribute to guarantee coexistence, the legislature introduced a precautionary duty and requirements of good professional practice in dealing with GMOs (§ 16b GenTG, Art. 1 no. 14 GenTNeuOG 2004) [...].

cc) Finally, private law in relation to neighbours was put into precise terms and supplemented by legislation on claims for interference with use, in order to ensure that there is, in the case of substantial interference with use by the introduction of GMOs, a civil claim to defend a status quo and a claim for compensation (§ 36a GenTG, Art. 1 no. 24 GenTNeuOG 2004).

(1) [...]

3. [...]

The purpose of the most recent amendment to the genetic engineering law [by the 25 Genetic Engineering Amendment Act 2008] was to promote research into and use of genetic engineering in Germany. However, the protection of human beings and the environment were to remain the priority of the genetic engineering law, pursuant to the precautionary principle, and freedom of choice of farmers and consumers as well as the coexistence of different types of agricultural crops were to be guaranteed. Against this background, operations of genetic engineering facilities were simplified and statutory exemptions for particular GMOs were extended. Subject to certain conditions, permission was given for the use of products that contain proportions of organisms not authorised to be placed on the market.

§ 16b sec. 1 sentence 2 GenTG old was deleted without replacement, and instead, § 16b sec. 1 sentences 2 to 4 GenTG contained an exemption from the precautionary duty (with regard to § 16b sec. 1 sentence 2 GenTG, below, the old and new versions are distinguished from each other). Now, it is not necessary to comply with the duty to take precautions with regard to concerns of another person set out in § 1 no. 2 GenTG, insofar as the latter waives protection in a written agreement or, in response

to an enquiry by the person charged with the precautionary duty, does not provide the necessary information for this protection within one month, if the duty in that specific case exclusively serves to protect the other person (§ 16b sec. 1 sentence 2 GenTG new). A permissible deviation from good professional practice must be notified to the competent authority under § 16b sec. 1 sentence 4 GenTG in good time before sowing or planting, and it must be, in compliance with the newly introduced § 16b sec. 1a GenTG, notified to the location register (§ 16a GenTG). The farmer, in addition to the information under § 16a sec. 3 sentence 2 GenTG, must inform the Federal Office of Consumer Protection and Food Safety, within no more than one month before sowing or planting and designating the land affected of the fact that an agreement under § 16b sec. 1 sentence 2 GenTG new has been reached, or of the fact that no information has been received from the neighbour in response to an enquiry if the farmer intends to deviate from the requirements of good professional practice because of the failure to supply information (§ 16b sec. 1a sentence 1 GenTG). Information on deviations from good professional practice relating to the land in question (§ 16b sec. 1a sentences 1 and 2 GenTG) is made accessible to the public. Apart from this, data collected under § 16b sec. 1a GenTG are governed by § 16a GenTG with the necessary modifications (§ 16b sec. 1a sentence 3 GenTG).

II.

In its application for judicial review [...] [the applicant] ultimately challenges [...] the incompatibility of "§ 3 nos. 3 and 6, § 16a secs. 1, 3, 4 and 5, § 16b secs. 1 to 4 and § 36a GenTG" as amended by Art. 1 GenTNeuOG 2004 as most recently amended by Art. 1 GenTAndG 2008 with the Basic Law. [...]

[...] § 16a sec. 2 GenTG read[s] as follows:

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[...]

§ 16a

(1) For the purpose of monitoring any effects of genetically

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Location register

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- modified organisms on the legal interests and concerns set out in § 1 nos. 1 and 2 and for the purpose of informing the public, the information to be notified under subsection 2 on the release of genetically modified organisms and the information to be notified under subsection 3 on the cultivation of genetically modified organisms shall be recorded in a federal register. The register will be kept by the competent superior federal authority and will contain the information notified under subsection 2 or subsection 3 for the whole territory of the Federal Republic of Germany. Pursuant to subsection 4, the register must be publicly accessible.
- (2) The operator shall notify the competent superior federal authority at the latest three working days before the authorised release that the release of genetically modified organisms will actually be effected. The notification shall comprise the following information:

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1. the designation of the genetically modified organism,

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2. its genetically modified characteristics,

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3. the release land and the size of the release area,

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4. the period of release.

Changes in the information and the termination of the release shall 49 be notified without delay.

(3) The cultivation of genetically modified organisms shall be notified to the competent superior federal authority by the person who farms the area at the latest three months before the sowing. The notification shall comprise the following information:

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1. the designation and the unique identifier of the genetically modified organism,

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2. its genetically modified characteristics,

3. the name and the address of the person who farms the area, 53 54 4. the cultivation land and the size of the cultivated area. Changes in the information shall be notified without delay. 55 56 (4) The publicly accessible part of the register comprises: 1. the designation and the unique identifier of the 57 genetically modified organism, 58 2. its genetically modified characteristics, 59 3. the release or cultivation land and the size of the area. Information from the publicly accessible part of the register will be available for 60 automatic retrieval on the internet. (5) The competent superior federal authority will provide information from the part 61 of the register which is not publicly accessible, including information on personal data, where the applicant gives prima facie evidence of a justified interest and there is no reason to assume that the person affected has an interest warranting protection in the refusal of information which carries more weight. 62-85 The applicant regards these provisions as substantively unconstitutional. In essence, it submits the following reasons: 87 1. In § 36a GenTG, the legislature intervened substantially in the liability regime, which was characterised by mutual consideration and balanced, of §§ 906, 1004 and 823 BGB and created a special liability law for the use of genetic engineering exceeding the previously applicable provisions. a) This is not consistent with the occupational freedom of the farmers and seed producers using 88-91 genetic engineering, which is protected by Art. 12 sec. 1 GG. [...] b) § 36a GenTG interferes without justification with the property of users of genetic engineering and 92 with a business enterprise established and operated by the farmers and seed producers affected by the liability (Art. 14 sec. 1 GG). [...] 93 2. The location register governed by § 16a GenTG violates the right to informational selfdetermination (Art. 2 sec. 1 in conjunction with Art. 1 sec. 1 GG) of the users of genetic engineering. When personal data on the cultivation of GMOs and the name, address and land of the persons affected are collected, stored and made accessible to third parties - in part, to the public -, it encourages politically motivated destruction of fields and endangers the property of the users of genetic engineering. Conversely, the location register is neither suitable nor necessary to achieve the goal of monitoring potential effects on the environment of GMOs admitted to the market or to achieve the intended transparency and the coexistence of various crops. In particular, this objective and the requirements of EU law cannot be satisfied by publishing the municipality of the relevant location. [...] 95 § 16a GenTG also violates Art. 12 sec. 1 and Art. 14 sec. 1 GG [with regard to the protection of trade and business secrets]. [...] 96

[...]

c) [...]

3. [...]

4. With regard to the definition of the term "placing on the market" in connection with the definition of the GMO, § 3 nos. 3 and 6 GenTG is incompatible with Art. 5.3 sentence 1 and Art. 12.1 GG. For a placing on the market needing authorisation also exists if a farmer of conventional or organic crops supplies or stores products which have been mixed together with GMOs from a permitted release, either accidentally or because this was not technologically avoidable. The defensive claims and claims for compensation under § 36a.1 no. 1 GenTG would then apply; these have a massively

deterrent effect. As a result of this, it becomes considerably more difficult, if not impossible, for university and non-university research institutions in particular to conduct release experiments for the purpose of researching into and developing transgenic plants. [...]

III.

[...] 98-100 1. The Federal Government defends the challenged provisions as constitutional, [...] 102-111 112 2. [...] 3. [...] 113 4. [...] 114 B. 115-119 [...] C. The application for judicial review is unfounded. [...] 120 The challenged provisions are formally constitutional. 121 [...] 122-129

The challenged provisions are substantively constitutional.

1. The Federal Constitutional Court may decide on the application without a referral for a preliminary ruling from the Court of Justice of the European Union under Art. 267 of the Treaty on the Functioning of the European Union (TFEU). It is true that, in particular in changing the definitions of "genetically modified organism" and "placing on the market" in § 3 nos. 3 and 6 GenTG and in establishing the location register in § 16a GenTG, the legislature intended to implement requirements to this effect in Art. 2 nos. 2 and 4 and Art. 31 sec. 3 of Directive 2001/18/EC (BTDrucks 15/3088, pp. 22 and 26). However, since all the provisions challenged are compatible with the Basic Law, the interpretation of Community or European law provisions is not relevant to the decision. In this case, a referral is neither required nor permissible (cf. BVerfG, Judgment of the First Senate of 2 March 2010 – 1 BvR 256/08 and others –, para. 185).

II.

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2. § 3 nos. 3 and 6 GenTG are compatible with Art. 12 sec. 1 and Art. 14 sec. 1 and with the 132 academic freedom guaranteed by Art. 5 sec. 3 sentence 1 GG.

[...]

- 3. The provisions on the location register in § 16a secs. 1, 3, 4 and 5 and § 16b sec. 1a 149 GenTG are, where they are linked to the cultivation of GMOs, compatible with the fundamental right to informational self-determination (Art. 2 sec. 1 in conjunction with Art. 1 sec. 1 GG) and with occupational freedom (Art. 12 sec. 1 GG), with the guarantee of property (Art. 14 sec. 1 GG) and with academic freedom (Art. 5 sec. 3 sentence 1 GG) (a to d). Exactly the same applies insofar as § 16a secs. 1, 4 and 5 GenTG relate to information on releases of GMOs which are to be notified under § 16a sec. 2 GenTG; this subsection is also unobjectionable (e).
- a) The fundamental right to informational self-determination (Art. 2 sec. 1 in conjunction with Art. 1 sec. 1 GG) is not violated by provisions on the location register which relate to the cultivation of GMOs.

The fundamental right to informational self-determination guarantees the authority of the individual to decide in principle independently when and within what limits real-world personal fact situations may be revealed (cf. BVerfGE 65, 1 <43>; 78, 77 <84>; 84, 192 <194>; 96, 171 <181>; 103, 21 <32-

33>; 113, 29 <46>; 115, 320 <341>). In particular, the right grants those who hold it protection against unlimited collection, storage, use or transmission of data relating to them which are individualised or can be individualised (cf. BVerfGE 65, 1 <43>; 67, 100 <143>; 84, 239 <279>; 103, 21 <33>; 115, 320 <341>).

aa) The persons that the information on the cultivation of GMOs collected in the location register 152 under § 16a secs. 1 and 3, § 16b sec. 1a sentence 1 GenTG refers to, that is made accessible under § 16a secs. 4 and 5, § 16b sec. 1a GenTG, are farmers of the cultivated areas and their "neighbours" set out in § 16b sec. 1a GenTG. Under § 16a sec. 3 sentence 1, § 16b sec. 1a sentence 1 GenTG, the duty to notify the necessary information to the office keeping the register is that of the farmers of the cultivated areas.

Under § 3 no. 13a GenTG, a farmer is "a legal or natural person or an association of persons 153 without legal personality who or which has the power of disposition and physical control of an area for the cultivation of GMOs". A neighbour is a person who, under § 16b sec. 1 sentence 2 GenTG new, waives protection by written agreement or has not given the information necessary for this protection.

If the persons affected are natural persons, they hold the fundamental right to informational selfdetermination under Art. 2 sec. 1 in conjunction with Art. 1 sec. 1 GG. Legal persons under private law are only recognised as holders of the fundamental right to informational self-determination provided that this fundamental right is based on Art. 2 sec. 1 GG (cf. BVerfGE 118, 168 <203>). The difference in the scope of protection between natural and legal persons, however, is not relevant in the present case of abstract review of a statute, since natural persons are among those affected by the statute and protection of legal persons is no more extensive than that of private persons.

bb) § 16a secs. 1 and 3, § 16b sec. 1a sentence 1 GenTG provide that personal data are recorded 155 in the location register.

156 The scope of protection of the fundamental right to informational self-determination only comprises personal data (cf. BVerfGE 118, 168 <184> with further references). Personal data means particular information on the personal or factual circumstances of a specific or ascertainable person (cf. BVerfGE 65, 1 < 42 >).

First and foremost, this relates to the information to be notified under § 16a sec. 3 sentence 2 no. 3 157 GenTG, thus the name and address of the person who farms the cultivated area and corresponding information on the neighbour under § 16b sec. 1a sentence 1 GenTG. Details of the factual circumstances of specific or ascertainable persons are part of the information on the designation and the unique identifier of the GMO, its genetically modified characteristics and the cultivated land and the size of the cultivated area (§ 16a sec. 3 sentence 2 nos. 1, 2 and 4 GenTG) and of the information relating to land with a restriction of protective measures in relation to a third party (§ 16b sec. 1a GenTG). In each case, the office keeping the register may unequivocally establish the reference person from the notification, in that this links information on the personal and factual circumstances of those affected, and in that the data are stored together.

In relation to this, the value and sensitivity of a piece of information are not relevant. It is true that the name and address of a person are merely elementary information necessary for identification. International and European law already require that information contained in public parts of the location register on the designation, the unique identifier and the genetically modified characteristics of the GMO (§ 16a sec. 3 sentence 2 nos. 1 and 2, § 16a sec. 4 sentence 1 nos. 1 and 2 GenTG) are made accessible to the public, and that they can be retrieved on the internet, in particular in the Living Modified Organism (LMO) Registry of the Biosafety Clearing-House (Art. 20 of the Cartagena Protocol of 29 January 2000 on Biosafety to the Convention on Biodiversity (http://bch.cbd.int/protocol/, BGBI II 2003 p. 1506) and in the Community register of genetically modified food and feed (Art. 28 of Regulation <EC> no. 1829/2003). Finally, the location and size of a cultivated area can usually be ascertained by the public, for farming does not take place in private but in the social realm. In its natural surroundings, however, the cultivated area cannot generally be ascertained without further ado, either with regard to the farmer or with regard to the cultivation of a particular organism. However, the protection of the right to informational self-determination covers all information that gives any evidence as to the reference person. It also covers basic data such as name and address, and information that is common knowledge or publicly accessible. Under the conditions of automated data processing, there

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are in principle no data that are now irrelevant (cf. BVerfGE 65, 1 <45>). Because they are linked, data on personal and factual circumstances recorded in the location register also do acquire new significance. In particular, they do, when taken together, provide information that a particular GMO is being cultivated by a particular person on a particular site.

cc) The provisions on the location register under review in the present case authorise the office 159 keeping the register to collect and process such personal data on the cultivation of GMOs, and thus interfere with the right to informational self-determination.

Interference with the right to informational self-determination may be constituted in particular by the acquisition, storage, use and transmission of personal information.

- (1) The provisions on the notification (collection) and recording (storage) of personal data on the cultivation of GMOs in § 16a secs. 1 and 3, § 16b sec. 1a GenTG and on the supply of information from the part of the register that is not publicly accessible (transmission) in § 16a sec. 5 GenTG therefore constitute an interference with fundamental rights.
- (2) The supply of information from the publicly accessible part of the register under § 16a sec. 4 and 162 § 16b sec. 1a sentences 1 and 2 GenTG on personal data by automatic online retrieval is a special form of state transmission of data and thus a form of data processing (cf. § 3 sec. 4 sentence 2 no. 3 letter b of the Federal Data Protection Act [Bundesdatenschutzgesetz BDSG] in the version promulgated on 14 January 2003, BGBI I p. 66). If the law allows personal data to be transmitted this way, it constitutes an interference with the right to informational self-determination.

However, the legislature has provided that the publicly accessible part of the location register is to contain only information on factual circumstances (§ 16a sec. 4, § 16b sec. 1a sentence 2 GenTG). By contrast, information on personal circumstances, such as the name and address of a person, is recorded in the part of the register that is not publicly accessible, and is referred to by the legislature as "personal data" (§ 16a sec. 5 GenTG). However, this distinction does not strip the data uploaded to the internet of their personal character. This personal character remains as long as the reference person is "ascertainable" or "identifiable". Therefore, and notwithstanding the distinction chosen by the legislature between personal data in § 16a sec. 5 GenTG and other data in § 16a sec. 4, § 16b sec. 1a sentence 2 GenTG, the sole determining factor regarding the question of an interference with fundamental rights is the distinction between ascertainability and non-ascertainability of the reference person. This is the criterion by which, in the present case, personal information can be retrieved on the internet. It must be assumed that an undetermined number of recipients have additional knowledge which makes it possible for them to identify the reference person in a short time and without great financial cost. In particular, those who live in the area may, without further ado, know who farms which units that are listed in the cadastral of a local subdistrict. The office keeping the register is authorised by § 16a sec. 4, § 16b sec. 1a sentence 2 GenTG to transmit personal data, at least with regard to these cases.

dd) The interference is constitutionally justified.

The right to informational self-determination is not guaranteed without limits. The individual 165 must accept restrictions of this right which are in the predominant interest of others or of the public. Such restrictions must have a statutory basis from which the requirements and the scope of the restrictions follow clearly and in a way discernible to the citizen (1) and which satisfies the principle of proportionality (2). In addition, the effective protection of fundamental rights requires that the procedures are structured in a way that satisfies such objective requirements (3).

(1) The collecting and processing of data on the cultivation of GMOs under § 16a secs. 1, 3, 4 and 5 and § 16b sec. 1a GenTG satisfy the requirement that a provision be clear and specific.

The basis of this requirement with regard to the right to informational self-determination is in Art. 2 sec. 1 in conjunction with Art. 1 sec. 1 of the Basic Law itself. The occasion, the purpose and the limits of the interference must, in principle, be set out in the authorising law in a way that relates specifically to the relevant area, and is precise and well-defined (cf. BVerfGE 100, 313 <359-360, 372>; 110, 33 <53>; 113, 348 <375>; 118, 168 <186-300>). In the present case, these requirements are satisfied.

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Under § 16a sec. 1 sentence 1, § 16b sec. 1a sentence 3 GenTG, the collection and processing of data serve the purpose of monitoring any effects of GMOs on the legal interests and concerns set out in § 1 nos. 1 and 2 GenTG and for the purpose of informing the public.

169 Under § 16a sec. 1 sentence 2 GenTG, the register is to be kept by the superior federal authority, competent under § 31 sentence 2 GenTG, to which, under § 16a sec. 3 sentence 1, § 16b sec. 1a GenTG, the necessary information must be notified and which, under § 16a secs. 4 and 5, § 16b sec. 1a sentences 2 and 3 GenTG, provides information from the register. § 16a sec. 1 sentence 1, 16a sec. 3 and § 16b sec. 1a sentence 1 GenTG define precisely who must notify what information at what time. In addition, § 16a sec. 4, § 16b sec. 1a sentence 2 GenTG state what information may be retrieved in what way from the publicly accessible part of the register.

170 Finally, § 16a sec. 5 (where applicable in conjunction with § 16b sec. 1a sentence 3) GenTG defines with sufficient precision the requirements for granting information from the part of the register that is not publicly accessible. That the legislature uses broad legal terms in relation to this does not conflict with the principle of certainty. The terms "justified interest" and "interest warranting protection that carries more weight" are also used in the provisions on the location register, which narrows their meaning, which is why they are sufficiently specific in this context.

- (2) The provisions under review on the collection and processing of data on the cultivation of GMOs 171 under § 16a secs. 1, 3, 4 and 5 and § 16b sec. 1a GenTG are not disproportionate.
- 172 (a) In these provisions, the legislature pursues legitimate aims of public interest. The provisions implement Community law, create reasonable transparency and serve the purposes of § 1 GenTG. Their constitutional basis is found, in particular, in Art. 2 sec. 2 sentence 1, Art. 12 sec. 1, Art. 14 sec. 1 GG and in the constitutionally mandated aim of the state to protect natural resources in Art. 20a GG.

§ 16a sec. 1 sentence 1 GenTG provides that the location register serves to inform the public. The introduction of GMOs into the environment by release and cultivation is to be made transparent for the public (cf. BTDrucks 15/3088, p. 26). Here, the creation of transparency is an independent and legitimate purpose of legislation (cf. Federal Constitutional Court, Order of the First Chamber of the First Senate of 25 February 2008 - 1 BvR 3255/07 -, [...]). In a democratic and pluralistic society, the information recorded and published in the location register on the release and cultivation of GMOs is an important contribution to the process of public formation of opinions. The public exchange of opinions and the involvement of society in such decisions relevant to the environment and their implementation not only protects the individual, but also strengthens effective control of activities of the state. In order to create such transparency, it is legitimate to make particular public data generally accessible to the public, without further connection to a particular purpose. The right to informational self-determination does, in principle, not prevent the creation of records generally accessible to the public, even if they are personal. In particular, the location register represents the high value accorded by Directive 2001/18/EC to the public's interest in information that is freely available. Under Art. 25 sec. 4 of Directive 2001/18/EC, the EU Member States are prohibited from treating as confidential information that is submitted in the authorisation procedure of a general description of GMOs, the name and address of the registrant, the purpose and site of the release (cf. Art. 2 no. 3 of Directive 2001/18/EC) and the intended purposes of use. In its judgment of 17. February 2009, the Court of Justice of the European Union stated that the notification of information set out in Art. 25 sec. 4 of Directive 2001/18/EC cannot be challenged based on an exception relating to the protection of public order or other interests protected by law (cf. ECJ, Judgment of 17 February 2009, C-552/07, ECR 2009, I-00987 <1029 and 1030> para, 55 and operative part no. 2).

The location register also contributes to the surveillance of any effects of GMOs on the legal 174 interests named in § 1 no. 1 GenTG (§ 16a sec. 1 sentence 1 GenTG). In particular, it thus serves to protect human health, the environment and the property of others against harmful effects of the cultivation of genetically modified crops and it serves to take precautions against such risks.

In addition, the location register is intended to monitor any effects of GMOs on the guarantee of 175 coexistence under § 1 no. 2 GenTG, and to ensure that potentially affected third parties are informed of the planned cultivation (§ 16a sec. 1 sentence 1 GenTG). In this way, it contributes to implement the concern of coexistence (§ 1 no. 2 GenTG), which became a purpose of the statute according to the Genetic Engineering Reform Act 2004, in line with the European concept of coexistence on which this is

based (on this, cf. Art. 26a of Directive 2001/18/EC; Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops, OJ C 200, p. 1). The aim of an amicable coexistence of various agricultural production methods has its constitutional basis not only in the freedom protected by Art. 14 sec. 1 GG of other producers to use their property in a self-determined manner, but also in their occupational freedom protected by Art. 12 sec. 1 GG.

Finally, the location register serves the purpose of creating the legal framework for research into and for the development, use and promotion of the scientific, technological and economic possibilities of genetic engineering (§ 1 no. 3 GenTG). In particular, information on the introduction of GMOs into the environment may enable the public to form its own opinion on the state authorised and monitored use of genetic engineering and improve the acceptance of decisions taken by state authorities.

(b) The provisions relating to cultivation in § 16a secs.1, 3, 4 and 5 and § 16b sec. 1a GenTG are. 177 suitable to achieve these purposes.

The location register can support the effective surveillance of any effects of GMOs on the legal interests and concerns set out in § 1 nos. 1 and 2 GenTG; in this way, it contributes to avert dangers and take precautions against risks, and also to guarantee coexistence.

Giving information to the competent authorities on areas where genetically modified crops are cultivated enables authorities in particular to observe and monitor the cultivation and its effects on the environment, to deliberately control production processes, to guarantee that coexistence measures are applied correctly and to carry out accompanying scientific research in the area in order to record long-term or unforeseen effects.

The location register is suitable to inform the public and those potentially affected on the introduction of GMOs into the environment, and thus to promote the desired transparency, coexistence and social peace. In particular, neighbouring enterprises and other persons potentially affected may inform themselves in good time of the intended cultivation of such organisms and take measures to protect themselves against a spread into their products.

(c) The provisions relating to cultivation in § 16a secs. 1, 3, 4 and 5 and § 16b sec. 1a GenTG are necessary to attain the purposes of the statute. Taking into account the scope for judgment and prognosis accorded the legislature in assessing necessity (cf. BVerfGE 102, 197 <218>; 115, 276 <309>; 116, 202 <225>), there is no method of collecting and processing data on the cultivation of GMOs that is evidently equally effective but less burdensome for those affected.

The competent state agencies have no comparable information which they could use to achieve the purposes of the location register. In particular, it is not the case that this information is already available as a result of the process for authorisation of placing on the market. The authorisation process does not relate to the farmer of cultivated areas, but to the person who first places a product on the market (cf. § 15 sec. 3 sentence 3 no. 1 in conjunction with § 3 no. 7 GenTG).

The legislature was also entitled to define the notification period of three months before the sowing or planting under § 16a sec. 3 sentence 1 GenTG as necessary in order to implement the concept of a coordinated planning of cultivation. This is so because before genetically modified plants are sown, not only must the notification to the location register be made. The neighbour must also be informed, and if appropriate, the neighbour's information must be taken into account by adapting the cultivation plans. In addition, agreements in writing may be made on good professional practice. These alterations and agreements in turn must be notified to the location register. In addition, in-company deviations from good professional practice must be notified to the competent authorities.

Similarly, data processing under § 16a secs. 1, 4 and 5, § 16a sec. 1a GenTG is necessary to attain the intended purpose. Application procedures for the supply of information on the precise location of cultivation would not be suitable implement the purposes pursued by the statutory provisions as effectively. Also, the high degree of transparency aimed for could not be achieved if it were only the municipality or local subdistrict of the site under § 16a sec. 4 GenTG to be posted on the internet. The possibility of early planning, agreement and coordination of conflicting user interests and the economic efficiency of the supply of information would also not be guaranteed in the same way by application procedures.

Also, it would not adequately ensure that persons potentially affected would be informed to the 185 extent intended by the legislature if the justified interest in the supply of information under § 16a sec. 5 GenTG were restricted to cases of the risk of "substantial impairment of property" and "substantial impairments of the neighbour's property". In particular, at the time of cultivation planning, it will generally not be foreseeable whether such disadvantages are to be expected, with the consequence that information on the name and address of farmers may be given either in a restricted way or not at all. The possibility of using the location register to coordinate local production structures with each other by cultivation planning and to coordinate the separation of genetically modified and non-genetically modified crops would then not be available to a comparable extent.

186 (d) The provisions relating to cultivation in § 16a secs. 1, 3, 4 and 5 and § 16b sec. 1a GenTG also comply with the requirement of proportionality in the narrow sense.

Collecting and processing personal data on the cultivation of GMOs in the form envisaged, however, 187 do constitute a serious interference with fundamental rights.

The data to be notified under § 16a sec. 3 and § 16b sec. 1a GenTG is linked in the location 188 register, with the result that it creates new information beyond the data provided. The collection of data acquires additional weight because violations carry fines under § 38 sec. 1 no. 9 GenTG. In addition, the processing of personal data under § 16a sec. 4, § 16b sec. 1a sentence 2 GenTG by automatic retrieval on the internet is a particularly comprehensive form of interference with the right to informational self-determination (cf. BVerfG, Order of the First Chamber of the First Senate of 25 February 2008 - 1 BvR 3255/07 -, [...]). After retrieval, such data may be further processed, linked and used at will for many purposes, including the planning of criminal offences to the detriment of a farmer or neighbour.

However, under certain aspects the seriousness of this interference is mitigated.

The occasion for the interference with fundamental rights is given by the persons affected themselves, by conduct that may have considerable effects on the environment and the legal interests of third parties and therefore gives rise to the need for state observation and an interest of the public in having freely available information. In addition, the effort to collect the data is relatively small. There is a regulatory offence under § 38 sec. 1 no. 9 GenTG in cases of no or incorrect or untimely notification under § 16a sec. 3 sentence 1 or 3 GenTG, but lawful conduct does not entail any particular difficulties for the farmer. The information to be notified under § 16a sec. 3 GenTG relates solely to farmers and their occupational work, and farmers can check whether they are complete and correct. Also, the weight that publication on the internet carries is qualified by the fact that the recipients can only relate the information published to a person if they have additional knowledge or information from the part of the register that is not accessible to the public. For the overwhelming majority of the relevant recipients of information worldwide, the reference persons thus remain anonymous, and these recipients of such information will usually also have no interest in relating a specific cultivation to a particular person.

In view of the legitimate public interests served by the location register, the interference is therefore not inappropriate. In dividing the register into a section accessible to the public and a section not accessible to the public, the legislature created a workable and constitutionally unobjectionable compromise between the state's and the public's interest in information freely available on the one hand and in confidentiality of the reference persons on the other hand.

Nor is it an objection to the statutory provisions that the establishment of the location register 192 increases the likelihood of wilful destruction of crops. Even before the location register was introduced, there were repeated obstructions of the release and cultivation of GMOs; these had to be dealt with by police law and criminal law. Against this background, the legislature implemented and developed its concept of an amicable coexistence of various means of production and of social peace. One component of the concept - notwithstanding the requirements of Community law, which apply in any case - is, on the one hand, transparency in informing the public on the use of genetic engineering, and, on the other hand, protection of the users of genetic engineering against danger emanating from this public, by closing one part of the location register to the public as well as by means of police law and criminal law. As in other cases where freedom of property, occupational freedom or freedom of research is obstructed by third parties, the state has a duty to promote and protect the unobstructed

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exercise of fundamental rights in every individual case. To date, it is not apparent that the location register has created a dangerous situation of farmers that would oblige the legislature to create more extensive protective mechanisms against unlawful and criminal destruction of fields.

Nor do the provisions on the part of the location register that is not publicly accessible, in § 16a sec. 193 5 GenTG, limit the right to informational self-determination inappropriately. Under § 16a sec. 5 GenTG, information from the publicly inaccessible part of the register may be supplied only if the applicant gives prima facie evidence of a justified interest and if there is no reason to assume that the person affected has an interest warranting protection, and thus to refuse information, that carries more weight. Those applying the law are therefore obliged to weigh interests, which makes it possible to assess all relevant interests in an individual case.

(3) Finally, the protection of fundamental rights is also safeguarded by an appropriate organisation of procedures.

The use of personal data must be limited to the purpose laid down by statute (cf. BVerfGE 65, 1 195 <46>). Duties of explanation, information and deletion are also important (cf. BVerfGE 65, 1 <46>). These requirements are satisfied in the present case.

The legal situation, which is clear in this respect, ensures that all persons affected are informed, before data are collected, of what data can be retrieved on the internet and according to which conditions information may be given on personal data supplied. It is constitutionally unobjectionable that particular data are also made accessible to the general public without further limitation of use to specific purposes.

Information on the notification to the location register may be given to the neighbour affected under § 16b sec. 1a GenTG as part of the explanation of the legal consequences of a written agreement or of the failure to give information under § 16b sec. 1 sentence 3 GenTG. In any event, the neighbour is adequately protected by the fact that the collection, storage and transmission of the data in § 16b sec. 1a GenTG is expressly provided for by statute. Accordingly, under § 19a sec. 2 no. 3 BDSG there is no duty to inform a person affected without whose knowledge the data were collected on the basis of an express statutory provision.

It is not necessary to inform the person affected about the retrieval of data from the publicly accessible part of the register, because the person affected knows even at the time when the data are collected which data will be made public, and the person affected may then prepare for this. Apart from this, § 19 BDSG provides for extensive duties of information on data collected and transmitted, and this applies with the necessary modifications to legal persons under § 16a sec. 7 GenTG. There are no constitutional objections to § 19 BDSG in this context (cf. also BVerfGE 120, 351 <365>).

In addition, the purpose of the collection and processing of data on the cultivation of GMOs, which is related and limited to a specific project, requires that all data that are not needed or are no longer needed to achieve the purpose are deleted (cf. BVerfGE 113, 29 <58>). In the present case, the deletion of data fifteen years after it is first stored is ordered by statute in § 16a sec. 6 sentence 2, § 16b sec. 1a sentence 3 GenTG, which satisfies this requirement.

- b) The provisions on the cultivation of GMOs in § 16a secs. 1, 3, 4 and 5 and § 16b sec. 1a GenTG 200 are compatible with Art. 12 sec. 1 GG.
- aa) The obligation to notify information on cultivation to the location register under § 16a sec. 3 201 GenTG does not violate the occupational freedom guaranteed by Art. 12 sec. 1 GG under the aspect of the protection of trade and business secrets.

In principle, the fundamental right of occupational freedom also guarantees the protection of trade 202 and business secrets (cf. BVerfGE 115, 205 <229>). If trade and business secrets are disclosed by the state or if the state requires their disclosure, this impinges on the area of protection of Art. 12 sec. 1 GG. In this connection, trade and business secrets include all facts, circumstances and events relating to an enterprise which are not known to the public but are accessible only to a restricted category of persons and whose non-disclosure is in the justified interest of the holder of the right.

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Thus, neither do the data to be collected under § 16a sec. 3 GenTG relate to the GMO and its location trade and business secrets, nor does the collection and processing of such data seem qualified to entail considerable competitive disadvantages. Since the cultivation takes place in the public realm, observation and knowledge of it is not restricted, from the outset, to the agricultural business or enterprise concerned. Also, the GMO, its genetically modified characteristics and the unique identifier are published on the internet. In addition, the desire for confidentiality must arise from justified interests, and it is therefore irrelevant whether an enterprise wishes to avoid a negative image which may be associated with the use of genetic engineering.

bb) The duty of farmers to notify information to the register authority within specific periods of time is a regulation of the practice of an occupation or a profession, and thus interferes with Art. 12 GG; however, this is justified based on public interest of pre-eminent importance as set out above.

Apart from this, the fundamental right of occupational freedom offers, in principle, no protection against information measures by the state which extends beyond the right to informational self-determination (cf. BVerfGE 118, 168 <205>).

- c) For the same reason, a violation of Art. 14 sec. 1 GG under the aspect of the protection of trade and business secrets or of the danger of violations of property by genetic engineering opponents is out of the question.
- d) The provisions in § 16a secs. 1, 3, 4 and 5 and § 16b sec. 1a GenTG on the cultivation of GMOs are compatible with Art. 5 sec. 3 sentence 1 GG.

If the cultivation is carried out for scientific purposes, the duty of the farmers to supply information on the cultivation to the register authority within certain periods of time also applies to the conditions for carrying out the research project, and thus impinges on the area of protection of Art. 5 sec. 3 sentence 1 GG. However, the restriction constituted by this does not carry great weight when set against the freedom of research, and it is justified by the protection of the legal interests of constitutional status set out above which conflict with it.

- e) On the same reasoning, the provisions in § 16a secs. 1, 4 and 5 GenTG on the information to be notified to the Federal Office of Consumer Protection and Food Safety by the operator under § 16a sec. 2 GenTG on the release of GMOs are compatible with the fundamental right to informational self-determination (Art. 2 sec. 1 in conjunction with Art. 1 sec. 1 GG) and with Art. 12 sec. 1, Art. 14 sec. 1 and Art. 5 sec. 3 sentence 1 GG. [...]
- 4. § 16b secs. 1, 2, 3 and 4 GenTG are compatible with Art. 12 sec. 1 GG. Nor can a violation of Art. 210 5 sec. 3 sentence 1, Art. 3 sec. 1 and Art. 2 sec. 1 GG be established.
- a) § 16b secs.1, 2, 3 and 4 GenTG, as most recently amended by Art. 1 GenTÄndG 2008, are 211 compatible with Art. 12 sec. 1 GG.
- aa) § 16b secs. 1, 2, 3 and 4 GenTG interfere with the right to occupational freedom. In these provisions, the legislature provides for the treatment of products permitted to be placed on the market that contain or consist of GMOs. Here, § 16b sec. 4 and § 16b sec. 1 sentence 1 GenTG, with regard to placing products on the market, relate directly to activity for profit-making purposes; the other provisions challenged have an objective tendency to regulate an occupation or profession. They typically relate to dealing for profit or for commercial purposes with products permitted to be placed on the market, and they primarily constitute basic legal conditions for the practice of an occupation or profession. Here, the obligation to take precautions against substantial interference with those legal interests and concerns set out in § 1 nos. 1 and 2 GenTG reaches beyond warding off specific dangers, and enables the authority to intervene at an point in time that is earlier than the moment at which danger may be warded off under police law.
 - bb) The interference with the right to occupational freedom is constitutionally justified.

(1) The provisions are sufficiently specific.

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In § 16b sec. 1 sentence 1 GenTG, the legislature defines the contents and the aim of the precautionary duty to the effect that particular legal interests and concerns may not be "substantially interfered with". Whether an interference is substantial can be determined with the help of established rules of interpretation. The legislature intends to implement European thresholds on

labelling, and states the term to be defined in more detail by means of the rules of interpretation in § 36a sec. 1 GenTG (BTDrucks 15/3088, p. 27). § 36a sec. 1 GenTG takes up the term "substantial interference" used in § 906 BGB. Rules of interpretation developed in relation to this provision may therefore be consulted to interpret § 36a sec. 1 GenTG.

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§ 16b sec. 1 sentence 2 GenTG new cannot be objected to on the grounds of a violation of the requirement of specificity under the rule of law. The actual requirements of the legal effect contained in § 16b sec. 1 sentence 2 GenTG new are recognisable in a way that can be reasonably expected of the persons affected. In any case, they can be determined by way of interpretation with the help of the recognised rules of interpretation. In addition, the options of more detailed legislation are limited, in relation to the nature of the real-world factual situation at hand. In fact, it may only be determined in each and every individual case whether and how far the precautionary duty may be waived, taking the specific local circumstances into account. Questions of liability that arise from the application of § 16b sec. 1 sentence 2 GenTG new were not dealt with by the legislature in § 16b GenTG. The legislature was therefore able to rely on the general law of contractual and non-contractual liability and the principles developed in this field - including the contractual waiver of a favourable legal position. Taken as a whole, § 16b sec. 1 sentence 2 GenTG new gives rise to no inescapable objections with regard to the requirement of specificity under the rule of law.

§ 16b secs. 2 and 3 GenTG are also sufficiently specific. It is unobjectionable that the legislature did not provide for exhaustive principles of good professional practice in § 16b sec. 3 GenTG ("includes without limitation"). In drafting these principles in open terms, the legislature was entitled to take the variety of real-world factual situations into account. The concept of good professional practice is, on the one hand, wide enough to allow for new developments, and, on the other hand, suited to create a framework within which farmers can and must act. What good professional practice means in a specific case can be adequately determined by interpreting the relevant provisions, in particular in conformity with evaluations the examples given in the provisions are based on, applying recognised methods of interpretation. Apart from this, in § 16b sec. 6 GenTG, the legislature provided for the Federal Government to authorise delegated regulation that may put the principles of good professional practice in more specific terms.

Finally, the requirements imposed on the suitability of persons and equipment in § 16b sec. 4 218 GenTG are sufficiently described. In describing these requirements, the legislature uses indefinite legal terms such as "reliability" and "knowledge", which have always been used in statutes on economic administration (e.g. § 35 sec. 1 of the Industrial Code (*Gewerbeordnung*) and § 4 sec. 1 sentence 1 no. 1 of the Licensing Act (*Gaststättengesetz*)). These terms have been given substance in a long tradition of legislation, administrative activity and case-law in such a way that there can be no doubt as to their certainty under the rule of law, even though they have to be defined afresh for every new area of application (cf. BVerfGE 49, 89 <134>). Similarly, the terms "skills" and "equipment" used in § 16b sec. 4 GenTG can be sufficiently defined using the traditional methods of interpretation. The purpose of the suitability of persons and equipment is also sufficiently defined in the reference to satisfying the precautionary duty under § 16b sec. 1 GenTG.

- (2) The interference with the right to occupational freedom is proportionate.
- (a) The provisions on the precautionary duty and good professional practice in § 16b secs. 1, 220 2 and 3 GenTG are permissible as provisions on the practice of an occupation or a profession because they are legitimated by sufficient reasons of public interest, are suitable and necessary to attain aims of public interest and do not unreasonably burden the persons affected (cf. BVerfGE 30, 292 <316>; 36, 47 <59>; 61, 291 <312>; 68, 272 <282>; 103, 1 <10>; established case-law). The expert knowledge requirements of § 16b sec. 4 GenTG do also regulate of the practice of an occupation or a profession.
- (b) The challenged provisions on the precautionary duty, good professional practice and the 221 suitability of persons and equipment serve legitimate aims in the public interest.

The precautionary duty is intended to achieve a responsible treatment of GMOs, and thus to guard 222 against a substantial interference with the legal interests of § 1 nos. 1 and 2 GenTG by the introduction of these organisms (§ 16b sec. 1 sentence 1 GenTG). This aim is also pursued by the principles of good professional practice and the requirements placed on the suitability of persons and

equipment, which in each case relate to compliance with the precautionary duty (§ 16b secs. 2, 3 and 4 GenTG). In creating the precautionary duty, the legislature takes account of the uncertainty of knowledge and prognosis – that also exists with regard to the treatment of GMOs –, which results from the current state of science and technology and from uncertainties in these. The precautionary duty and good professional practice are intended to, as far as possible, avoid the spread of such organisms from the outset or, if this is unavoidable, to reduce it to a minimum (BTDrucks 15/3088, pp. 26 and 27). The requirements of persons and equipment (§ 16b sec. 4 GenTG) are intended to ensure that the user is competent and prepared to do this and thus to guarantee that the work is carried out properly (BTDrucks 15/3088, p. 27).

§ 16b secs. 1, 2, 3 and 4 GenTG thus serve the purpose of taking precautions against harmful effects of genetic engineering procedures and products on human life and health, the environment in its interactive structure, animals, plants and physical goods (§ 1 no. 1 GenTG). The provisions also put into precise terms the guarantee of coexistence (§ 1 no. 2 GenTG), and in this way serve, in particular, to protect occupational freedom and freedom of property of persons potentially affected, as well as pursue the goal of preserving freedom of choice for producers and consumers, to create certainty of law and reliability in planning and to establish social peace by guaranteeing an amicable coexistence of agricultural crops (BTDrucks 15/3088, pp. 19 and 27). Finally, the legislature also has the aim of creating the legal framework for research into and development, use and promotion of the scientific, technological and economic possibilities of genetic engineering (§ 1 no. 3 GenTG).

(c) The provisions on the precautionary duty and good professional practice and the suitability of persons and equipment are suitable to achieve these purposes.

Insofar as the legislature, in the Genetic Engineering Amendment Act 2008, removed the prohibition of acts endangering coexistence in § 16b sec. 1 sentence 2 GenTG old and replaced it for the benefit of the users of GMOs with an exception from the precautionary duty, the amendment remains within the priority of assessment and prognosis accorded it. It does not result in the provision being unsuitable for failure to pursue the aim of precaution with sufficient focus.

(d) The challenged provisions on the precautionary duty and good professional practice and the 226 suitability of persons and equipment are necessary to achieve the statutory purposes. Taking into account the scope for judgment and prognosis accorded the legislature also in assessing necessity (cf. BVerfGE 102,·197 <218>; 115, 276 <309>; 116, 202 <225>), no equally effective means that is less burdensome for those affected is apparent to achieve the intended responsible dealing with GMOs.

In particular, the argument that the protection of the legal interests set out in § 1 no. 1 GenTG is already achieved by the assessment and authorisation procedure in the course of authorisation for placing on the market cannot be used to deny the necessity of the provisions on the precautionary duty and good professional practice. Admittedly, granting authorisation for placing on the market is fundamentally associated with the assessment that unjustifiable harmful effects on the legal interests set out in § 1 no. 1 GenTG, such as human health and the environment, shall not be expected (§ 16 sec. 2 sentence 1 GenTG). However, this decision is a prognosis that cannot exclude the possibility of unforeseen harmful effects, for example on human health or the environment. The purpose of the precautionary duty relating to the interests protected by § 1 no. 1 GenTG is precisely to guarantee, supplementing the conditions for the authorisation of placing on the market, responsible dealing with the GMOs permitted to be placed on the market, and thus to protect legal interests after placing on the market as comprehensively and completely as possible.

(e) The challenged provisions on the precautionary duty, good professional practice and the 228 conditions for the suitability of persons and equipment are also proportionate in the narrow sense.

The public-law obligations laid down in § 16b secs. 1, 2, 3 and 4 GenTG contain strict requirements 229 for the practice of an occupation or profession using GMOs permitted to be placed on the market and therefore interfere to a considerable extent with the occupational freedom protected by Art. 12 sec. 1 GG.

However, the burden created by this is already eased by the fact that the Act accepts a spread of GMOs for the benefit of the use of "green" genetic engineering that does not lead to a substantial interference with the interests protected by § 1 nos. 1 and 2 GenTG. The weight of the interference is

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also mitigated by the possibility existing under § 16b sec. 1 sentences 2 to 4 GenTG new of not complying with existing requirements that exist solely for the protection of the neighbour's economic coexistence (§ 1 no. 2 GenTG) in the individual case, where that neighbour either consents in writing or fails to respond. In addition, the requirements for conduct contained in § 16b sec. 3 GenTG are only part of good professional practice "insofar as this is necessary to comply with the precautionary duty under subsection 1". They contain - at present supplemented and put into precise terms by the Regulation on Good Professional Practice in the Breeding of Genetically Modified Plants (Verordnung über die gute fachliche Praxis bei der Erzeugung gentechnisch veränderter Pflanzen, Gentechnik-Pflanzenerzeugungsverordnung, Genetic Engineering Plant Breeding Regulation – GenTPflEV – of 7 April 2008, BGBI I p. 655) - the recommendations of the European Union for coexistence measures (cf. Commission Recommendation of 13 July 2010 on guidelines for the development of national coexistence measures to avoid the unintended presence of GMOs in conventional and organic crops. OJ C 200, p. 1) and the provisions for use laid down in the accompanying product information (§ 16b sec. 5 GenTG) normative requirements, to which a user of GMOs and a person potentially affected can adapt themselves. As a result of this, the certainty of law and the reliability in planning has improved for the users as well. In addition, the operational measures necessary to implement the statutory requirements can rely on already existing practices or procedures of separating crops and on existing experience of the treatment of identity-protected plant cultivars and seed production practices. Finally, there is the possibility of cooperating with neighbouring producers. Management and production may be coordinated and, for example, cultivars with different flowering times may be used, different sowing times be agreed on or crop rotation processes be coordinated. In doing so, the cost of the separation of genetically modified and unmodified crops may already be considerably reduced, the risk of crosspollination with neighbouring cultures be minimised, compliance with the thresholds for labelling food and feed be enabled and ultimately, even cases of liability may be avoided in advance (cf. BTDrucks 15/3088, p. 27 with reference to Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming - 2003/556/EC -, OJ L 189, p. 36).

In contrast, the legitimate aims of public interest, which caused the legislature to provide for a precautionary duty, for good professional practice and for the suitability of persons and equipment, carry more weight. Notwithstanding the classification of § 16b sec. 4 GenTG as the regulation of the practice of an occupation or a profession, they could even justify legislation on the choice of an occupation or profession. The protection of humans, animals, plants and the environment in its interactive structure are constitutionally established in Art. 2 sec. 2 sentence 1, Art. 12 sec. 1 and Art. 14 sec. 1, and in Art. 20a GG. The legislative aims set out above also pursue important concerns in the interest of the public, and, as for example consumer protection, are also recognised in European Union law.

In pursuing these aims, the legislature, precisely against the background of a broad social and scientific debate on the use of genetic engineering and its appropriate government regulation, must be given broad discretion.

If one relates these constitutionally protected rights and interests affected to each other and 233 includes the additional legislative aims pursued, in a balancing of interests, the weighting made by the legislature is unobjectionable.

The provisions challenged on the precautionary duty, on good professional practice and on the suitability of persons and equipment do not unreasonably burden persons involved in the treatment of GMOs (§ 16b secs. 1, 2, 3 and 4 GenTG), nor are the requirements of persons and equipment out of proportion in relation to the intended purpose of proper performance of work (§ 16b sec. 4 GenTG).

The legislature also left sufficient latitude to the authorities and regular courts to ensure that § 16b 235 secs. 1, 2, 3 and 4 GenTG are proportionately applied in the individual case. In particular, this relates to the question of what, in a given case, constitutes precautionary duty and good professional practice. The requirements on precautionary duty and good professional practice that are broadly defined here allow that the de facto basic conditions of treatment of GMOs are appropriately taken into account in an

individual case, in particular at the actual cultivation sites, and it allows for the scope of the duties to be limited to the degree necessary in each case to avoid substantial interference with the protected interests of § 1 nos. 1 and 2 GenTG.

The latitude given to those applying the law remains within reasonable limits. The necessary 236 standards must gradually be developed based on administrative and judicial parameters, observing the principle of proportionality. In this process, it must be taken into account that the use of genetic engineering is generally permitted and that the legislature intends it to further exist. § 16b GenTG requires no absolutely certain precautions to exclude risks to the interests defined in § 1 nos. 1 and 2 GenTG, which thus may, in effect, result in a prohibition of dealing with GMOs that are permitted to be placed on the market. Instead, the spread of these organisms shall only be avoided as far as possible, by responsible treatment, and, if unavoidable, be reduced to a minimum (BTDrucks 15/3088, pp. 26 and 27). Therefore, under present law, requirements may only go as far as necessary and reasonable in the circumstances of an individual case. Within such limits, all persons involved will at present find further standards to assist them in putting the challenged provisions into precise terms in the Genetic Engineering Plant Breeding Regulation, the recommendations of the European Union for coexistence measures (cf. Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops, OJ C 200, p. 1) and the provisions for use laid down in the accompanying product information (§ 16b sec. 5 GenTG). Remaining uncertainties do not create an unreasonable burden for the users of GMOs.

The restrictions associated with § 16b sec. 4 GenTG are justified by the facts of the case. They are based on the fact that special theoretical and practical knowledge and an appropriate operational structure are necessary in order to avoid introduction of GMOs into other cultures or to reduce them as much as possible, and that the exercise of the occupation or profession in question would be improper if it did not satisfy such requirements and would entail dangers to the interests protected by § 1 nos. 1 and 2 GenTG.

- b) § 16b secs. 1, 2 and 3 GenTG are also compatible with academic freedom (Art. 5 sec. 3 238 sentence 1 GG).
- aa) The challenged provisions on the precautionary duty and good professional practice must be measured by the standard of academic freedom, unless they apply exclusively to treatment for profit or for commercial or comparable purposes. In any event, experimental research at universities is protected by academic freedom.
- bb) The requirements for the precautionary duty and good professional practice in the treatment of GMOs permitted to be placed on the market interfere with the freedom granted by Art. 5 sec. 3 sentence 1 GG to freely determine questions and methodology as well as the actual conduct of a research project.
- cc) The legitimate public-interest concerns that justify the interference with Art. 12 sec. 1 GG, that is, human life and health, occupational freedom and the freedom of property of persons potentially affected (Art. 2 sec. 2 sentence 1, Art. 12 sec. 1, Art. 14 sec. 1 GG) and the protection of natural resources (Art. 20a GG) are important values of constitutional status which, for the reasons stated above, also justify an interference with academic freedom.
- c) § 16b secs. 1, 2, 3 and 4 GenTG do not violate Art. 2 sec. 1 GG.

Art. 2 sec. 1 GG may be used as a standard of constitutional review for the restriction of 243 foreigners of the freedom to engage in business activities and for imposing an obligation on private persons who do not deal with GMOs for profit if and when these persons are not protected by the right to occupational freedom (Art. 12 sec. 1 GG). But the interference with the right to general freedom of action is justified for the reasons set out regarding Art. 12 sec. 1 GG (C II 4 a bb above).

Where § 16b sec. 1 sentence 2 GenTG new creates legal consequences if one remains silent, this does not entail an unreasonable burden for the neighbour. Even if the provision is interpreted as a fictitious declaration of intent and an interference with freedom of contract, it is at all events justified.

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Under § 16b sec. 1 sentence 2 GenTG new, legal consequences are deemed to follow from silence; this removes uncertainties as to the consent to a particular planned cultivation and thus improves reliability in planning and certainty of law in the use of land that has to be notified under § 3 GenTPflEV and under § 16b sec. 1 sentence 4 GenTG. This is related to the legislature's concern that agreement on cultivation planning should be encouraged as a means to ensure coexistence, and that at the same time the user of genetic engineering should not be burdened more than necessary to the benefit of protected interests. § 16b sec. 1 sentence 2 GenTG new is suitable and necessary to achieve this legitimate aim.

It is also appropriate. When creating categories of persons, the legislature treats those who are to be notified of the cultivation of GMOs as deserving protection. A person who farms conventionally or organically must be able to rely on the fact that potentially interfering cultivation be notified or consulted on. On the other hand, the legislature requires the persons so protected to declare themselves within one month as to their need for protection in response to an enquiry from the user of GMOs. Otherwise, it is presumed that there is no need for protection, and the user can carry out the planned cultivation. The user is thus also relieved of the uncertainty of having to consider whether the silence constitutes an implied waiver. This balancing of interests that may conflict with each other is within the limits of the legislature's discretion.

d) Nor do the challenged provisions on the precautionary duty, good professional practice and the suitability of persons and equipment violate the principle of equality before the law of Art. 3 sec. 1 GG.

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The unequal treatment of users of genetic engineering who have a precautionary duty compared to conventional or organic farmers follows from the particular characteristics of the products that contain or consist of GMOs. In differentiating, the legislature pursues legitimate public-interest aims so important that they justify not only the interference with Art. 12 sec. 1 and Art. 5 sec. 3 sentence 1 GG, but also the unequal treatment.

Where § 16b GenTG distinguishes between those persons who deal with GMOs for profit or in a comparable manner and other users of genetic engineering, this is based, first, on the fact that GMOs are normally used for the purpose of profit to a larger extent than for other purposes and the protected interests are thus endangered to a greater degree. Second, the additional requirements of dealing with GMOs for profit are typically also accompanied by greater advantages from the use of genetic engineering. These circumstances justify the unequal treatment.

The unequal treatment of the users of GMOs permitted to be placed on the market, who have a precautionary duty, compared to those who release such organisms for experimental purposes, is ultimately related to the fact that the authorisation for release can include the safety measures adequate to the state of art of scientific and technological knowledge in each individual case, and may be adjusted to the specific experiment and location (§ 16 sec. 1 no. 2 GenTG). In the authorisation for placing on the market, in contrast, it is not usually possible to take appropriate account of actual conditions of cultivation, since this authorisation is granted for a large number of cultivation sites, and generally valid for each Member State. This circumstance justifies the differentiation.

- 5. § 36a GenTG is compatible with Art. 14 sec. 1, Art. 12 sec. 1, Art. 5 sec. 3 sentence 1 and Art. 3 sec. 1 GG.
- a) In the concept of law relating to neighbours of § 36a GenTG, those potentially liable are owners 252 or users of land from which the interference emanates, insofar as they determine the type of use that causes an interference, and, if the interference results from an installation, it is those who run the installation and on whose will its removal depends (cf. BGHZ 155, 99 <102>).

Primarily, therefore, § 36a GenTG affects the users of GMOs in research, agriculture, forestry and gardening. The category of persons liable under this law also includes legal persons under public law, such as, for example, universities, in all cases in which the use of land from which the interference emanates is not solely government action but constitutes an activity governed by private law, with these persons therefore subject to liability under civil law. It is not necessary to finally determine whether they are also the target group of § 36a GenTG, if the use is solely government action. As previous case-law shows, the liability of government research institutions is not excluded under private law on neighbour

relations (cf. Stuttgart Higher Regional Court (*Oberlandesgericht*), Judgment of 24 August 1999, [...] – 14 U 57/97 –, [...]). As a result, the question as to whether there has been a violation of academic freedom of, in particular, universities must be included in this review.

b) § 36a GenTG is compatible with Art. 14 GG.

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aa) In conjunction with §§ 906, 1004 BGB, which are provisions on the content and limits of property under Art. 14 sec. 1 sentence 2 GG (cf. BVerfGE 72, 66 <75-76>), this provision governs legal relations between neighbours on neighbouring plots.

§ 36a GenTG is not an independent liability provision. Rather, it puts into precise terms and supplements the existing strict liability for a nuisance by neighbours established in private law (§§ 1004, 906 BGB). In the interpretation and application of key concepts of law relating to neighbours, § 36a GenTG establishes mandatory rules of interpretation and thus guarantees for a defensive and a compensatory claim under the law relating to neighbours in cases in which introductions of GMOs, in particular in the form of unintended cross-pollination, substantially interfere with the use of another person's land (§ 36a secs. 1 to 3 GenTG). In addition, private law relating to neighbours is supplemented by a provision that removes difficulties regarding proof of causality (§ 36a sec. 4 GenTG).

Not only do these new rules on liability take up § 906 BGB and its elements, in the wording of § 36a 257 secs. 1 to 3 GenTG. They are also integrated into the structure of liability law for nuisance between neighbours. As previously, it is the law that substantial interference that is either not customary in the locality, or is customary in the locality but may be prevented with reasonable financial effort, need not be accepted. Interference of this kind is unlawful. In general, persons affected by it have a defensive claim for forbearance or removal under § 1004 sec. 1 BGB. On the other hand, if a neighbour must tolerate an interference, there may be a claim to reasonable monetary compensation under § 906 sec. 2 sentence 2 BGB or in analogy to this provision (compensatory claim under the law relating to neighbours). This is without prejudice to protective precautions under § 23 sentence 1 GenTG and the claim to monetary compensation under § 23 sentence 2 GenTG, particularly where a non-contestable release authorisation exists that was granted after a hearing (§ 18 sec. 2 GenTG).

Admittedly, there is no provision comparable to § 36a sec. 4 GenTG in the Civil Code. However, the provision may be regarded as a further development of the case-law of the Federal Court of Justice (*Bundesgerichtshof* – BGH) on joint liability of more than one landowner from whose land the interference emanates, and on the application of § 830 sec. 1 sentence 2, § 840 BGB and § 287 ZPO to the compensation claim under the law relating to neighbours, under § 906 sec. 2 sentence 2 BGB (cf. *Entscheidungen des Bundesgerichtshofes in Zivilsachen* –BGHZ 66, 70 <77>; 85, 375 <386-387>; 101, 106 <111 et seq.>).

This interpretation is supported by background material from Parliament, which shows that § 36a 259 secs. 1 to 3 GenTG were intended to put into precise terms central elements of the provisions on law relating to neighbours (§§ 906, 1004 BGB) and that § 36a sec. 4 GenTG was intended to enact liability according to § 830 sec. 1 sentence 2, § 840 sec. 1 BGB (cf. BTDrucks 15/3088 p. 31).

§ 36a GenTG therefore, by its meaning and purpose, is a provision on the liability for nuisance 260 under the law relating to neighbours. This does not create a new type of liability in the system of the private law relating to neighbours. §§ 906, 1004 BGB also govern the coexistence of neighbours.

Under the case-law of the Federal Court of Justice, the claim to reasonable compensation by analogy to § 906 sec. 2 sentence 2 BGB does not create strict liability (cf. BGHZ 155, 99 <103-104>). Rather, and in contrast to strict liability for a dangerous installation in the relationship between neighbours, the compensatory claim under the law relating to neighbours by analogy to § 906 sec. 2 sentence 2 BGB does not concern responsibility for damages that arise solely from the lawful presence of an installation or a permitted activity, but rather state liability for nuisance from land use in accordance with its purpose that is unlawful but has to be tolerated for factual reasons. The case-law of the Federal Court of Justice holds that the compensation is assessed, as in § 906 sec. 2 sentence 2 BGB, pursuant to the principles on compensation for expropriation (cf. BGH, Judgment of 30 May 2003).

- V ZR 37/02 - [...], with further references). This obligation to pay compensation under the principles of the law relating to neighbours does not necessarily coincide with a damage claim; to the contrary, there is scope for an evaluative decision (cf. BGH, Judgment of 30 May 2003 - V ZR 37/02 -, [...]).

Competing farmers whose agriculture is either conventional or organic, just like other persons 20 responsible for interference, are also subject to no-fault liability for a nuisance in the law relating to neighbours. The reference to limits established by public law (§ 906 sec. 1 sentences 2 and 3 BGB) is as familiar in the liability for nuisance under the law relating to neighbours as is the presumption of cause to overcome difficulties in proving causality where there is more than one person who set a cause (§ 830 sec. 1 sentence 2 BGB and § 287 ZPO). The fact that it may be impossible to appropriately calculate and insure against the risks of a use of land does not exclude the liability for a nuisance under the law relating to neighbours. If, therefore, the users of GMOs were exempted from the no-fault liability in the law relating to neighbours, this would ultimately not remove a disadvantage, but would rather treat them more favourably than other persons responsible for an interference.

bb) § 36a GenTG provides, for the introduction of GMOs, whether and subject to what 263 requirements, defensive claims under § 1004 BGB and compensation claims under or by analogy with § 906 sec. 2 sentence 2 BGB may be brought against land owners or users of the land from which the interference emanates.

Similar to §§ 906, 1004 BGB, this provision of the Act defines rights and duties of landowners in general and abstract terms, and is thus a provision that determines the content and limits of ownership under Art. 14 sec. 1 sentence 2 GG. It complies with those constitutional requirements a provision determining content and limits of property shall meet.

(1) The provision is sufficiently specific.

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It is unobjectionable that it refers to provisions on the labelling of products that are 266 promulgated by another legislature, especially the European legislature, and may be amended by it.

Under § 36a sec. 1 nos. 2 and 3 GenTG, the obligation to label products as genetically modified (no. 2) or the loss of a possibility of labelling with regard to a particular method of production (no. 3), as the consequence of an introduction of GMOs, does substantially interfere with ownership within the meaning of § 906 BGB. § 36a sec. 1 nos. 2 and 3 GenTG, therefore, does presuppose the existence of "provisions" or "legal provisions" on labelling, in order to define a factual situation that triggers the defensive claim under § 1004 sec. 1 in conjunction with § 906 sec. 1, 906 sec. 2 sentence 1 BGB or the compensation claim under § 906 sec. 2 sentence 2 BGB. However, this is not a reference to the relevant labelling provisions. Neither do they become part of § 36a sec. 1 nos. 2 and 3 GenTG, nor does the Act alter its scope, status or quality. Instead, the legislature has described a legal situation which is detrimental to the person who brings a claim, and has attributed the consequences to the person against whom the claim is brought as being responsible. A comparable form of drafting by reference to a general clause can be found in § 823 sec. 2 BGB, which presupposes the existence of protective statutes.

Apart from this, the legislature also took all the substantial decisions itself. It is the intention of the legislature that the defensive claim under § 1004 sec. 1 in conjunction with § 906 sec. 1, § 906 sec. 2 sentence 1 BGB and the compensation claim under § 906 sec. 2 sentence 2 BGB exist if the person entitled to use a neighbouring plot of land is subjected to a statutory duty of labelling or loses a statutory possibility of labelling because of a transfer or other introduction of GMOs. The requirements for labelling may of course change, for example as a result of the lowering or raising of particular thresholds. This is without prejudice to the fundamental decision of the legislature, relevant for liability, that a legal labelling duty or the loss of the possibility of labelling attributable to the originator of the nuisance constitutes a substantial interference with the use of neighbouring land. This also includes an aggravation of liability as a result of the reduction of labelling thresholds.

There are also no objections to § 36a sec. 1 GenTG with regard to the constitutional requirement of specificity, insofar as the groups of cases of substantial interference have not been exhaustively laid down ("including without limitation").

§ 36a sec. 1 GenTG defines and puts into precise terms the indefinite legal concept contained in § 906 BGB of "substantial interference" regarding the introduction of GMOs. Where the legislature has not exhaustively described the cases of substantial interference ("including without limitation"), this is because of the large number of conceivable sets of circumstances; at present, it may be simply impossible to envisage them all.

- (2) The legislature did also put the interests of those involved and the public interest in a just 2' equilibrium and a well-balanced relationship (cf. BVerfGE 87, 114 <138>; 95, 48 <58>; 98, 17 <37>; 101, 239 <259>; 102, 1 <17>).
 - (a) By including § 36a GenTG, the legislature pursues legitimate aims of public interest.

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These arise both from the function of the provisions of the law relating to neighbours (in particular § 906 BGB) that are supplemented and put into precise terms by § 36a GenTG, and also from the aims of the Genetic Engineering Act (§ 1 GenTG).

(aa) Like § 906 BGB, § 36a GenTG is intended to achieve the necessary balancing of interests of persons with neighbouring plots of land in the case of particular types of impact emanating from another plot. This provision does also protect the landowners affected by impacts in their liberty interest guaranteed by Art. 14 sec. 1 GG, to use their property according to their own wishes and to decide freely on the use of their property. Like §§ 1004, 906 BGB, § 36a GenTG imposes factual and financial responsibility for the (substantial) types of impact emanating from their land to the originators of nuisance. Where the originator has an obligation under § 1004 BGB or under or by analogy with § 906 sec. 2 sentence 2 BGB of forbearance, removal or appropriate compensation, the originator - and not uninvolved third parties or the general public - is liable for the costs arising from this. This attribution of liability is based on the reason that the originator of nuisance was responsible for the interference, that the originator can best and most effectively remove the interference, and that the originator benefits from the advantages arising from the interference that uses the land. Finally, § 36a sec. 4 GenTG, just like § 830 sec. 1 sentence 2 BGB, aims at overcoming a problem of evidence of the person who is harmed. This person's 'claim for compensation shall not fail because it is impossible to determine, with absolute certainty, which act by which of several persons involved may have caused the harm or the interference, und who was thus was the actual originator (cf. BGHZ 55, 96 <98>; 101, 106 <111>). Also, the interest of the owner, user or operator of an installation to be liable only to the extent that he or she has a (contributing) responsibility for the interference is taken into account, in that the impact to be attributed to the owner, user or operator must be suitable, under the actual circumstances of the individual case, to cause the interference (§ 36a sec. 4 sentence 1 GenTG). Here, joint and severed liability is based on the point of view, which also applies under § 840 sec. 1 BGB, that the injured person may not be burdened with the risk if more than one person that causes the damage were only proportionately liable.

(bb) In protecting neighbours, § 36a GenTG also serves to further coexistence, which was made part of the statutory purpose by the Genetic Engineering Reform Act 2004 (§ 1 no. 2 GenTG) and the European concept of coexistence (Art. 26a of Directive 2001/18/EC; cf. BTDrucks 15/3088, p. 30). Under § 1 no. 2 GenTG, it is the aim of the Act to guarantee that products, in particular food and feed, may be produced and placed on the market both conventionally and organically, and with the use of genetic engineering. As set out above, the basis of this objective is Art. 12 sec. 1 and Art. 14 sec. 1 GG.

In order to pursue this aim, § 36a GenTG is to ensure that a defensive claim and a claim for compensation under the law relating to neighbours exist in cases in which introductions of GMOs, in particular in the form of unintended cross-pollination, substantially interfere with the use of third-party property (cf. BTDrucks 15/3088, pp. 19 and 30). While the precautionary duty and good professional practice achieve a responsible treatment of GMOs, and while any substantial interference, caused by introducing these organisms, with the legal interests and concerns set out in § 1 nos. 1 and 2 GenTG is to be avoided from the outset, § 36a GenTG is meant to shield property from interference (that occurs nonetheless), and to compensate associated property loss of neighbouring producers (cf. BTDrucks 15/3088, p. 30). Freedom of choice of producers needs to be preserved and the property in the crops involved needs to be protected (cf. BTDrucks 15/3088, p.19). The exercise of one method of production may not lead to an economic threat to persons who use another method.

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The guarantee of coexistence (§ 1 no. 2 GenTG) is also meant to preserve freedom of choice of consumers, by providing for a broad, transparently labelled range of products, and it ensures certainty of law and reliability in planning for all involved, as it achieves, beyond the discussion of risks, an amicable coexistence of various methods of production and social peace (cf. BTDrucks 15/3088, pp. 19 and 21).

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Finally, § 36a GenTG implements the European concept of coexistence on the national level. This gives additional weight to the purposes pursued in § 36a GenTG. In particular, among the central concerns on the European level are also the aim of giving farmers free choice between conventional and organic cultivation methods and genetically modified crops, in compliance with the rules for labelling and/or varietal purity, and also the aim of giving consumers free choice between products free of genetic engineering and products produced with genetic engineering (cf. Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops, OJ C 200, p. 1). Insofar as § 36a sec. 1 no. 1 GenTG defines as a substantial interference, the prohibition of placing on the market because of the introduction of GMOs, without a corresponding authorisation for marketing, does conform with the prohibition under European law of cultivation and marketing of GMOs that are not permitted to be placed on the market as products or in products (Art. 6 sec. 9, Art. 19 sec. 1 of Directive 2001/18/EC).

- (cc) § 36a GenTG also promotes the aims of § 1 no. 1 GenTG, and thus protects important values of constitutional status, such as human life and health, the environment, but also freedom of property of persons potentially affected (Art. 2 sec. 2 sentence 1, Art. 14 sec. 1 and Art. 20a GG). § 36a GenTG supports these aims not only as a preventive instrument to enforce the precautionary duty and good professional practice. Another element which serves to protect the interests set out in § 1 no. 1 GenTG against possible dangers of genetic engineering is that it specifies and supplements the provisions of the law relating to neighbours, which gives the neighbour an option to avert (particular) introductions. This applies in particular where the organisms are not yet permitted to be placed on the market (§ 36a sec. 1 no. 1 GenTG).
- (dd) § 36a GenTG also serves to create the legal framework for research into and development, use and promotion of scientific, technological and economic possibilities of genetic engineering (§ 1 no. 3 GenTG). Release and cultivation of genetically modified crops are basically accepted. As a rule, neighbours must tolerate interference resulting from introductions of GMOs insofar as the tolerance thresholds defined by statute are not exceeded, and insofar as the methods of good professional practice are adhered to. Such equal treatment from the point of view of liability of the cultivation of genetically modified plants and traditional cultivation (§ 36a sec. 3 GenTG) does allow for the promotion of use of genetically modified crops on a large scale.
- (b) In view of the broad latitude that Art. 14 sec. 1 sentence 2 GG gives to the legislature in determining the content and limits of property (cf. BVerfGE 53, 257 <293>), the specification and supplementation of private law relating to neighbours in § 36a GenTG is suitable and necessary to achieve the aims of public interest pursued by the Act.

No equally suitable but less burdensome means is apparent that the legislature could have chosen. 282 Approaches to a solution such as the introduction of mediation proceedings and special cultivation areas for genetically modified crops and for organic products rely on a different concept to handle coexistence problems and are not suitable to implement the aims pursued by § 36a GenTG in their entirety in a comparable way.

The option that has been discussed in the legislative procedure to establish a voluntary liability fund of trade and industry has been rejected by the seed industry (cf. Deutscher Bundestag, transcript of the 61st session of the Committee on Food, Agriculture and Consumer Protection (*Wortprotokoll der 61. Sitzung des Ausschusses für Ernährung, Landwirtschaft und Verbraucherschutz*) of 26 November 2007 – transcript no. 16/61 –, p. 12 question no. 3). To establish a liability fund that is at least partly financed by the state is not an equally suitable means to reach the aims pursued by § 36a GenTG. A liability fund serves other aims. Legally, users of genetic engineering would be at least in part released from the responsibility for consequences of them being the originators of nuisance, and thus, they would be treated more favourably than their competitors in conventional and organic production. From the point

of view of the national economy, they would no longer have the incentive to take account of negative external effects of their activities in addition to private or business costs. Harmful effects of the use of land for third parties would be borne by the public, by way of a state liability fund, and this would be a way to subsidise genetically modified products.

- (c) Finally, to supplement and specify private law relating to neighbours is an appropriate and well-balanced adjustment of the conflicting interests.
- (aa) On the one hand, the supplementation and specification of private law relating to neighbours by 36a GenTG does create stricter basic conditions for the use of land for authorised release and authorised cultivation for placing on the market. In particular, without relying on fault, there are claims under the law relating to neighbours even if introductions of GMOs cannot be prevented by methods of good professional practice.

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(bb) On the other hand, the requirement of mandatory interpretation rules for central elements of the provisions of law relating to neighbours results in more certainty of law and in reliability in planning for the users of genetic engineering as well. Before § 36a GenTG was introduced, the courts applied §§ 1004, 906 BGB to introductions of DNA by pollen, seeds or in other ways, but there had not yet been established case-law. As a result of the latitude for interpretation, legal positions were unclear, not only for those potentially affected but also for the users, and therefore, the risk of liability was difficult to calculate. This situation has now improved. Thus, § 36a sec. 1 nos. 2 and 3 GenTG do link the existence of a substantial interference to thresholds defined in Community law and also in German law, that is, to normative standards which apply to the persons entitled to use who are involved, and for which neighbours can prepare themselves. Equal treatment under liability law of the cultivation of genetically modified plants and traditional cultivation (§ 36a sec. 3 GenTG) enables and encourages wide-scale cultivation of genetically modified plants in particular areas. It is not apparent that the users of genetic engineering have a relatively stricter "special liability" and are not protected against interference from neighbouring agriculture. Where substantial interference under §§ 1004, 906 BGB emanates from neighbouring fields which are farmed without the use of genetic engineering, they may avert this or, if obliged to tolerate it, they may claim appropriate financial compensation. Here as well, the existing no-fault liability of originators of nuisance under the law relating to neighbours does lay down the basic conditions for the practice of an occupation or profession of farmers who work conventionally or organically. With regard to ease the burden of proof defined in § 36a sec. 4 GenTG, established case-law of the Federal Court of Justice contains comparable principles under the general provisions of the law relating to neighbours (cf. BGHZ 101, 106 <108>).

The liable owners and users of land were also those who cause the interference; the removal of the interference depends on their will and they enjoy the advantages arising from the interfering use. The landowner's responsibility for the situation results from the physical control of the property and the advantages, but does also carry burdens associated with it. Just like under current law, advantages of private use of property accrue to the owner even if they arise without the owner's involvement, so the owner must, in other cases, bear the burden of the property even if danger was not caused by the owner (cf. BVerfGE 102, 1 <19>).

- (cc) In particular, it protects ownership and occupational freedom, human life, health and the environment, all of which are interests of constitutional status, that would be otherwise endangered, to strive for a balancing of interests between neighbouring owners and users of land, to secure the coexistence of various agricultural crops, and to protect and take precautions against the dangers of genetic engineering. Other important public interests also recognised under European law, such as the protection of consumers, are strengthened. If one includes these constitutionally protected rights in the balancing of the rights and interests affected, the balancing by the legislature is unobjectionable.
- c) § 36a GenTG interferes with the freedom to practice an occupation or a profession under Art. 12 289 sec. 1 GG, but this is constitutionally justified.
- aa) The business use for profit of a plot of land from which interference emanates is protected by 290 Art. 12 sec. 1 GG. The situations governed by § 36a GenTG relate, not exclusively but typically, to occupation-related conduct protected by Art. 12 sec. 1 GG. § 36a GenTG defines the basic legal and economic conditions for individual occupational activity using GMOs, and also serves as a preventive

instrument for the legislature to promote the development, use and implementation of good professional practice in dealing with these organisms. In this respect, § 36a GenTG differs from § 906 BGB, which covers both occupational and private use of land.

§ 36a GenTG must therefore be measured in light of Art. 12 sec. 1 GG as well as Art. 14 sec. 1 GG. 291

bb) § 36a GenTG does not contain a direct interference with these rights. However, the protection of fundamental rights is not restricted to direct interference. Art. 12 sec. 1 GG also protects against provisions or acts which, although they do not relate directly to an occupation, nevertheless have an objective tendency to regulate an occupation or profession (cf. BVerfGE 95, 267 <302>; 97, 228 <254>; 111, 191 <213>; established case-law).

The supplementation and specification of private law relating to neighbours in § 36a GenTG is suitable to influence and restrict the free practice of an occupation or profession. This applies, in the first instance, to the economic consequences of an event that induces liability, consequences that may have substantial effects on individual users of genetic engineering and be of decisive significance for their later occupational activity. In addition, persons who use land for profit are given an incentive to avoid liability by complying with good professional practice (§ 16b GenTG) and to assess all costs that incur from their decisions within the framework of the exercise of their occupation or profession and their participation in the market. This may influence the choice of means, scope and specific organisation of an activity in the same way as decisions on the nature, quality and price of goods produced for the market. The supplementation and specification of provisions of the law relating to neighbours here typically include for-profit use of land protected by Art. 12 sec. 1 GG, and in doing so create basic conditions for the practice of an occupation or a profession. The legislature uses liability not only to balance the conflicting interests of neighbouring owners and users of land, but also as a preventive instrument to promote the development, use and implementation of good professional practice in dealing with GMOs, and to guarantee the coexistence of different forms of agricultural cultivation.

The situation would be no different if one were to regard § 36a GenTG as a mere specification of what would in any case have applied under § 906 BGB and the case-law of the Federal Court of Justice. Admittedly, the general rules of the law relating to neighbours are basic conditions for the practice of an occupation or a profession that happen to apply. But in contrast to § 906 BGB, § 36a GenTG regulates the practice of an occupation or profession as an independent aim, not merely incidentally. In § 36a secs. 1 to 3 GenTG, the legislature gave precise shape to central elements of liability under the law relating to neighbours, as in §§ 1004, 906 BGB, by introducing mandatory interpretation rules; in this respect, it deprived the courts of the possibility of interpretation and application of the law on a case-by-case basis. This occurs specifically in relation to situations typically based on the occupational or professional use of land. The provision in § 36a sec. 4 GenTG, which serves to overcome difficulties in proving causality, is binding wherever and for whoever genetic engineering law applies, whereas the Civil Code has no provision to this effect in addition to the provisions in § 830 sec. 1 sentence 2 BGB and § 287 ZPO, which are applied in case-law by analogy.

- cc) The indirect interference with occupational freedom is constitutionally justified.
- (1) There are no constitutional objections to § 36a GenTG from the point of view of the 296 protection of public confidence, conveyed by an authorisation of placing on the market. In the case of commercial cultivation of genetically modified plants, the holder of the authorisation is, in any case, generally likely to be not the farmer who is liable under §§ 1004, 906 BGB, § 36a GenTG, but the producer of the seed permitted to be placed on the market. In any event, the holder of an authorisation may not, by reason of the public-law authorisation, rely on the authorised use causing no interference or harm in relation to third parties.

The authorisation has no effect on civil liability. With the exception of the express bar on defensive claims in § 23 sentence 1 GenTG, it does not transfer any responsibility for interference to the state, and it does not create any ground for trust that would prevent liability later. Accordingly, Art. 7 sec. 7 and Art. 19 sec. 7 of Regulation (EC) No 1829/2003 provide that the grant of authorisation does not restrict general civil and criminal liability of food and feed enterprises with regard to the food or feed in question. Nor is it relevant whether the holder of an authorisation under genetic engineering law was subject to public-law requirements and whether these were satisfied. Such public-law duties are

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intended to keep the risks of the alteration of genetic material as small as possible, in the interest of the public. However, they do not serve the function of exempting an originator of nuisance or a damaging party from responsibility under civil law.

298 (2) § 36a GenTG is a provision governing the practice of an occupation or profession which is not disproportionate.

For the same reasons for which the provision is to be seen as a permissible provision determining 299 the content and limits of ownership for the use of real property, it also, regarding the regulation of the exercise of an occupation or a profession, serves legitimate aims of public interest and is suitable, necessary and appropriate to pursue these.

dd) Insofar as the freedom to engage in business activities of persons not covered by Art. 12 sec. 1 300 GG can be restricted, this constitutes an interference with the general right to freedom of action (Art. 2 sec. 1 GG), which is justified for the same reasons.

d) The right to academic freedom guaranteed by Art. 5 sec. 3 sentence 1 GG is also not violated.

aa) The supplementation and specification of private law relating to neighbours in § 36a GenTG is qualified to influence and restrict an otherwise free practice of scholarship. The provision defines the conditions for civil-law responsibility of scholars and thus changes the basic conditions of free research. The concrete risk of liability, the consequences of a case of liability and the expenses incurred for precautionary measures are factors which can be of decisive importance for the decision on how to formulate questions, define the scope and practically implement a research project. Through strict no-fault liability, research can be guided in such a way that risks are considered at an early stage and experiments are organised and carried out in such a way that the introduction of GMOs on other plots of land and associated disadvantages for third parties and the general public are avoided or reduced to a minimum.

bb) This interference with academic freedom is justified.

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In the area of land use for research with GMOs, a number of fundamental rights and constitutionally protected interests confront each other. The constitutional foundation of the aims pursued in § 36a GenTG is, in particular, to be found in Art. 2 sec. 2 sentence 1, Art. 12 sec. 1, Art. 14 sec. 1 GG, and in the constitutional mandate for the state to protect natural resources, in Art. 20a GG. These are constitutional values that also justify the restriction of academic freedom.

The legislature endeavoured to find a balance between conflicting legal positions. This concern is evident not only in the public-interest aims pursued by § 36a GenTG, but also in the reasons for the Federal Government bill on the Genetic Engineering Amendment Act 2008. It states that the provisions of genetic engineering law were to be drafted so that they promote research into and application of genetic engineering in Germany. But at the same time, the protection of human beings and the environment were to remain the highest aim of genetic engineering law, pursuant to the precautionary principle. Also, freedom of choice of farmers and consumers and the coexistence of different types of agricultural crops were to be guaranteed, as before (BTDrucks 16/6814, p. 10).

In accordance with these objectives, and in addition to the basic acceptance of the release and cultivation of genetically modified crops, it is particularly the alleviations of procedure that help the legislature to advance research in the field of "green" genetic engineering. On the other hand, the legislature uses strict civil-law liability to impose limits on research where third-party rights are endangered or interfered with.

The solution chosen by the legislature takes sufficient account of the constitutionally protected legal 307 interests involved and complies with constitutional requirements.

It is true that § 36a GenTG, in order to protect conflicting legal interests, subjects free scholarship 308 and research to the same strict liability as the use of GMOs for other purposes. If organisms not permitted to be placed on the market are released for research purposes, introductions at the limit of detection may already result in a substantial interference and ensue in no-fault liability under the law relating to neighbours (§ 36a sec. 1 no. 1 GenTG). If GMOs permitted to be placed on the market are examined and tested, the methods of good professional practice must be observed (§ 16b secs. 2 and 3 GenTG). Under § 36a sec. 2 GenTG, these are held to be financially reasonable. Research is not

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exempted from liability either where a substantial interference cannot be prevented in advance by protective measures and good professional practice. In the area of research, the risk of a certain degree of gene transfer, which may possibly be unavoidable in cultivation on open fields, is also borne by users of the land from which the interference emanates. Therefore, they must take particular care in selecting suitable locations for an experimental introduction of GMOs into the environment. But despite this strict liability, the legislature assumes that it can implement the purpose promoted by § 1 no. 3 GenTG and contribute to secure Germany as a research location. Its assumption that it can promote research while at the same time protecting humans and the environment and maintaining coexistence is defensible.

In the balancing of the opposing interests, it must be taken into account in favour of academic freedom that it is precisely scholarship freed from considerations of utility for society and political expedience that ultimately serves the state and society best (cf. BVerfGE 47, 327 <369-370>). Research in the field of "green" genetic engineering, whether it be research on potential risks involved, development research or accompanying research, is also of great importance for the public good and, as a general rule, serves to protect essential concerns such as human health and the environment. The deliberate release of GMOs is, in most cases, a necessary step on the way to developing new products that are derived from such organisms or contain them (cf. Recital no. 23 of Directive 2001/18/EC). With the "step by step" principle, the containment of such organisms may only be reduced step by step and the scale of their release be increased if the evaluation of the previous step, in terms of protection of human health and the environment, indicates that the next step can be taken (cf. Recital no. 24 of Directive 2001/18/EC). No GMOs, as or in products, may be considered for placing on the market without first being subjected to satisfactory field testing at the research and development stage in ecosystems that could be affected by their use (cf. Recital no. 25 of Directive 2001/18/EC). After their placement on the market, there is surveillance and monitoring during marketing. New or additional scientific knowledge of dangers to human health or the environment may authorise a European Member State to temporarily restrict or prohibit the use and sale of a GMO as or in a product. Research using GMOs permitted to be placed on the market may further the coexistence of the various agricultural crops by providing the foundations for the development of good professional practice. Finally, the interaction of the GMO introduced into the environment with a surrounding ecosystem is not a merely unintended incidental consequence, but the essential focus of the examination. This may be the case when, in connection with scientific projects, basic data on the coexistence of forms of cultivation with or without genetic engineering are to be collected, evaluated and converted into recommendations for practice. In development research and research on the potential risks involved too, the spread of the GMO in the environment may be a necessary part of an experiment.

For the benefit of the conflicting legal interests of constitutional status – ownership and occupational 310 freedom, human life, health and the environment - the balancing must also take account of the fact that research into GMOs may endanger these interests. In particular, research on the potential risks involved and development research before approving a GMO for the market may have a high degree of potential risk, since it may still be unclear how this organism functions and what harm it causes to humans, plants, animals and biodiversity. The experimental cultivation of GMOs permitted to be placed on the market may, on the one hand, encourage the amicable coexistence of various agricultural crops by obtaining data on coexistence, but it may also, on the other hand, interfere with conflicting interests (in particular Art. 12 sec. 1, Art. 14 sec. 1, Art. 20a GG) through cross-pollination or other introductions of these organisms on neighbouring land. It is true for every area of research that it may not be possible to recover organisms once they are deliberately introduced or accidentally released into the environment, and interference with or harm to third-party legal interests or the environment may therefore be irreversible.

If these aspects are included in the consideration, the balancing undertaken by the legislature in § 36a GenTG for the benefit of the conflicting public-interest concerns is unobjectionable. Even for the owners or users of land who act for research purposes, limit of reasonableness are not exceeded.

e) § 36a GenTG does not violate the principle of equality before the law.

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The general principle of equality (Art. 3 sec. 1 GG) demands that all people be treated equally before the law. However, this does not prohibit the legislature from all discrimination. Depending on the area of regulation and the distinguishing elements, the legislature is confronted with different limits, reaching from the mere prohibition of arbitrariness to a strict requirement of proportionality.

In § 36a secs. 1, 2 and 4 GenTG, the persons who use a plot of land and employ genetic 314 engineering and therefore fall under the provisions that put into precise terms and supplement the private law relating to neighbours are not given equal treatment in comparison with other persons responsible for interference, who are liable under general civil law relating to neighbours. Although liability provisions always relate to different groups of persons, the concern here is the different treatment of different factual situations, that is, the use of GMOs in contrast to other use of land. The legislature is therefore bound only by the standard of arbitrariness.

The legislature based this discrimination on pragmatic criteria. § 36a sec. 1 nos. 1 to 3 GenTG links the unequal treatment to a legal position which applies to the persons affected who are entitled to use when introducing GMOs, and to disadvantages arising from this. There are at present no comparable duties of authorisation and labelling for genetically modified products that could be triggered by introductions from conventional or organic production. In § 36a sec. 2 GenTG, unequal treatment is tied to a particular legal situation which applies only to those who deal with GMOs permitted to be placed on the market. § 36a sec. 4 GenTG is based on the desire to legislate, in the area of genetic engineering, the principles developed in case-law for other persons responsible for interference, as part of a general liability of originators of nuisance.

By discriminating along these lines, the legislature pursues the legitimate public-interest aims set 316 out above and enshrined in constitutional law. These are so important that they justify not only the interference with Art. 12 sec. 1, Art. 14 sec. 1 and Art. 5 sec. 3 sentence 1 GG, but that they do also justify unequal treatment of various groups of persons responsible for an interference, and all the more an unequal treatment of factual situations.

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> Application for judicial review in the matter of the Genetic Engineering Act is unsuccessful

Application for judicial review in the matter of the Genetic Engineering Act is unsuccessful

Press Release No. 108/2010 of 24 November 2010

Judgment of 24 November 2010 1 BvF 2/05

The First Senate of the Federal Constitutional Court today pronounced its judgment in the proceedings on an abstract judicial review brought by the government of the *Land* Saxony-Anhalt against provisions of the federal Genetic Engineering Act (*Gesetz zur Regelung der Gentechnik* - GenTG) on

- the definitions "genetically modified organism" and "placing on the market" (§ 3 nos. 3 and 6 GenTG),
- genetically modified organisms location register (below: location register; § 16a GenTG),
- the treatment of products placed on the market (§ 16b GenTG) and
- · claims in the case of interference with use (§ 36a GenTG)

and held that § 3 nos. 3 and 6, § 16a.1 to 16a.5, § 16b.1 to 16b.4 and § 36a of the Genetic Engineering Act as most recently amended by Article 1 of the Act to Amend the Genetic Engineering Act, to Amend the Law on Implementing EU Genetic Engineering Legislation and to Amend the Novel Foods and Novel Food Ingredients Ordinance (Gesetz zur Änderung des Gentechnikgesetzes, zur Änderung des EG-Gentechnik-Durchführungsgesetzes und zur Änderung der Neuartige Lebensmittel- und Lebensmittelzutatenverordnung) of 1 April 2008 (Federal Law Gazette (Bundesgesetzblatt - BGBl. I p. 499) are compatible with the Basic Law (Grundgesetz - GG).

Information on the application for judicial review is given in <u>Press Release no. 29/2010</u> of 5 May 2010. It can be accessed on the Federal Constitutional Court's website (in German).

In essence, the decision is based on the following considerations:

The challenged provisions are procedurally and substantially constitutional.

- 1. The legislative competence of the Federal legislature is based on Article 74.1 no. 26 second alternative of the Basic Law, which gives the Federal legislature comprehensive competence to make law on genetic engineering, which includes human genetic engineering and animal and plant genetic engineering.
- 2. Where the challenged provisions encroach upon the fundamental right to informational self-determination (Article 2.1 in conjunction with Article 1.1 GG), the freedom of science and research (Article 5.3 sentence 1 GG), occupational freedom (Article 12.1 GG) and the fundamental right to property (Article 14.1 GG), this is justified.
- a) In the challenged provisions, the legislature pursues legitimate aims of public interest, in the realisation of which it must be accorded a broad discretion, particularly against the background of the broad social and scientific debate on the use of genetic engineering and appropriate government regulation.

In its possibility of deliberately creating changes in genetic makeup, genetic engineering intervenes in the elementary structures of life. It is extremely difficult or impossible to reverse the consequences of such intervention. Once genetically modified material has been released into the environment, it is difficult or impossible to restrict its spread. The legislature has a particular duty of care in view of the fact that the state of scientific knowledge has not yet been finally established when assessing the long-term consequences of the use of genetic engineering. In making law, it must not only

balance the constitutionally protected interests affected by the use of genetic engineering on the one hand and their regulation on the other hand, but must similarly comply with the duty contained in Article 20a GG to also protect natural resources with responsibility for future generations.

The intended protection in particular of humans, the environment and the property of others against harmful effects of genetically modified organisms and providing against such dangers coming into existence (see § 1 no. 1 GenTG), ensuring the coexistence of a variety of agricultural forms of production (see § 1 no. 2 GenTG) and the balancing of interests between adjoining landowners protects in particular human life, health and the environment, and also the fundamental right to property and occupational freedom, as interests with constitutional status which would otherwise be jeopardised. Other important public interests which are also recognised under European law, such as the protection of consumers and informing the public, are strengthened. In this respect, the creation of transparency with regard to the deliberate release of genetically modified organisms into the environment, which is intended to follow from the establishment of the location register, makes an important contribution to the formation of public opinion and constitutes an independent and legitimate purpose of legislation. In order to create such transparency, it is permissible to make particular data generally accessible to the public, without further connection to particular purposes. The right to informational self-determination does not in principle exclude the creation of data generally accessible to the public, even if they are of a personal nature.

- b) The provisions challenged are suitable and necessary to achieve these objects. They are also appropriate.
- aa) In amending the definitions of "genetically modified organism" and "placing on the market" (§ 3 nos. 3 and 6 GenTG), the legislature ensured that approved experimental release into the environment and its unintended consequences are also subject to the state's powers of supervision and intervention under the Genetic Engineering Act. The fact that these are unintended or technically unavoidable events does not decrease the risk entailed by the release of genetically modified organisms into the environment and the marketing of genetically modified products of undesired or harmful, possibly irreversible effects, a risk which is to be controlled in the sense of the greatest possible precautions. In addition, the legislature would risk not complying with its responsibility to protect natural resources.
- bb) The location register contains details on the experimental release and cultivation of genetically modified organisms for the whole territory of the Federal Republic of Germany, in order to make it possible to surveil and monitor any effects of these organisms, in particular on humans, on the environment and on conventional and organic farming and to inform the public. In dividing the location register (§ 16a GenTG) into a section accessible to the public and a section not accessible to the public, the legislature created a workable and constitutionally unobjectionable compromise between the state's and the public's interest in freely available information on the one hand and the interest in confidentiality of the persons involved on the other hand. It may in particular not be raised as an objection to the statutory provisions that the location register increases the likelihood of wilful destruction of genetically modified cultures. Even before it was introduced, there were repeated obstructions of the release and cultivation of genetically modified organisms; these must be dealt with by the means of police law and criminal law.
- cc) The challenged provisions on the treatment of products placed on the market in § 16b GenTG leave the authorities and non-constitutional courts enough latitude to comply proportionately with their precautionary duty, with best practice standards and with the requirements of suitability of persons and equipment in the individual case. This relates in particular to the question of what in the individual case constitutes precautionary duty and professional practice standards. The requirements, which are broadly defined here, make it possible for the de facto basic conditions of treatment of genetically modified organisms to be appropriately taken into account and for the scope of the duties to be restricted to the degree which is necessary in the individual case to avoid substantial interference with the protected interests of § 1 nos. 1 and 2 GenTG.
- dd) § 36a GenTG does not create a new type of special liability for the use of genetically modified organisms, but supplements and puts into concrete terms the existing strict liability of originators of nuisance in the private law relating to neighbours (§§ 1004, 906 of the German Civil Code); the provision is integrated in the structure of this. This supplementation and concretisation of private law relating to neighbours achieves an appropriate and well-balanced adjustment of the conflicting interests by contributing to an amicable coexistence of conventional, organic and genetically modified-crop production and a genuine freedom of choice for producers and consumers.
- ee) Taken as a whole, the weighting made by the legislature in each case in favour of the aims of public interest pursued is unobjectionable, in particular against the background of the fact that the effects of genetic engineering have not yet been finally established, and the limit of reasonableness is not exceeded for the persons who are addressed by the statute even where they act for the purpose of research.

Bundesverfassungsgericht - Press - Application for judicial review in the matter of t... Seite 3 von 3 3. The principle of equality before the law of Article 3. 1 GG is also not violated. Where fact situations are treated unequally, this is based on special factual and legal features of the use of genetic engineering and is justified by the public interest aims of the legislature. This press release is also available in the original [Link auf: german version.]