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**ECJ Ruling on Mutagenesis:
Effects on “ohne Gentechnik” labelling**

In its ruling dated 25 July 2018, the European Court of Justice (ECJ) stated that organisms obtained by mutagenesis constitute genetically modified organisms (GMOs) within the meaning of Directive 2001/18/EC on the deliberate release of GMO. This Directive’s scope of application only excludes organisms obtained through techniques of mutagenesis which have conventionally been used in a number of applications and have a long safety record.¹

New genetic engineering methods therefore fall under the genetic engineering law of Directive 2001/18/EC, even if mutagenesis methods are involved. This is true in particular for oligonucleotide-directed mutagenesis (ODM), a method used, for example, to produce the rapeseed of the company Cibus, which was to be marketed a few years ago in the EU. According to the ECJ ruling, it has been determined that such rapeseed may be marketed only after authorisation under genetic engineering law and that products containing such organisms or produced therefrom must be labelled as GMO.

However, techniques of conventional random mutagenesis through chemical mutagens or radiation are excluded from Directive 2001/18/EC. Although the resulting organisms are in fact GMO within the meaning of Directive 2001/18/EC, they are exempt from the GMO definition in food law and are therefore not GMO within the meaning of food legislation.

For the “ohne Gentechnik” label, that means that organisms obtained with new mutagenesis methods are subject to the same restrictions as GMO that were produced with conventional genetic engineering methods and fall under genetic engineering law (see 1. for further details). In contrast, products from plants or animals that were cultivated using conventional mutagenesis may continue to be used for “ohne Gentechnik” food (2.).

1. New mutagenesis methods

The ECJ ruling dated 25 July 2018 clarifies that genetic engineering law is equally applicable to new molecular biology methods that are known as mutagenesis techniques.

¹ ECJ, judgement of 25 July 2018, Case C-528/16, Confédération Paysanne, ECLI:EU:C:2018:583, published at <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:62016CJ0528&qid=1541691902286>.

They do not fall under the mutagenesis exemption in Art. 3 (1) in conjunction with Annex I B No. 1 of Directive 2001/18/EC. According to these provisions, this Directive does not apply to organisms obtained through mutagenesis. Pursuant to the ECJ ruling and Recital 17 of Directive 2001/18/EC, this includes only mutagenesis methods which have conventionally been used in a number of applications and have a long safety record. Thus, the exemption applies only to conventional mutagenesis methods.

Accordingly, the genetic engineering law of Directive 2001/18/EC applies equally to new mutagenesis methods and current genetic engineering methods. This means that all regulations concerning the “ohne Gentechnik” label for organisms that were obtained with conventional genetic engineering methods are applicable to new mutagenesis methods.

With regard to new mutagenesis methods, difficulties arise from the fact that the legal situation clarified by the ECJ for the EU may be different in third countries outside the EU. Organisms that were produced with new mutagenesis techniques may not be subject to genetic engineering law in third countries, may not be called GMO there, and may not be identifiable as GMO without detailed tracing of their origin. For this reason, it must be clarified for all plant or animal products that come from such third countries whether they are subject to genetic engineering law in the EU.

This is a particular challenge for all importers of food, food additives and their raw materials of plant or animal origin, since organisms produced with new mutagenesis methods and products containing them may only be imported if they are authorised under genetic engineering laws in the EU. Otherwise, they cannot be placed on the market. Once authorisation has been granted, they must be labelled according to general genetic engineering law with a reference to GMO if the corresponding labelling thresholds are exceeded.

This challenge therefore not only affects producers of “ohne Gentechnik” foods, but all food companies. The requirement that products obtained by new mutagenesis techniques be authorised under genetic engineering law and labelled with a reference to GMO applies to all foods and not just to “ohne Gentechnik” food.

By the same token, it can be generally presumed that all ingredients acquired within the EU comply with the requirements of “ohne Gentechnik” labelling if the supplier submits a non-GMO certificate for the product according to the current template and there are no indications that this certificate is inaccurate.

2. Conventional mutagenesis

On the other hand, products from plants or animals that were cultivated with conventional mutagenesis may continue to be used without limitation for “ohne Gentechnik” food.

Although the ECJ stated that organisms obtained through conventional mutagenesis represent GMOs within the meaning of the definition of the term in Art. 2 (2) of Directive 2001/18/EC, the ruling also determined that organisms produced through conventional mutagenesis are excluded from the directive’s scope of application based on the mutagenesis exemption in Art. 3 (1) in conjunction with Annex I B No. 1 of Directive 2001/18/EC.

With regard to the food law, the consequence of this exemption is that organisms produced through conventional mutagenesis are not GMO at all. These laws apply a narrower definition of GMO than Directive 2001/18/EC. Regulation (EC) No. 1829/2003 on genetically modified food and feed in Art. 2 (5) defines the term “GMO” for the purposes of that regulation as

- GMO within the meaning of Directive 2001/18/EC
- excluding organisms obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC.

Organisms that fall under the mutagenesis exemption in Annex I B of the Directive are therefore not GMO within the meaning of this Regulation. The same is true for the term GMO in Art. 3 (1) of Regulation (EC) 1830/2003 concerning the traceability and labelling of GMO.

Organisms obtained through conventional mutagenesis are therefore defined as GMOs in the GMO Directive, but not in food law. Accordingly, they are subject to neither the authorisation nor the labelling requirements for GMO.

Only the narrow GMO definition of food law, which does not include conventional mutagenesis, is relevant for the "ohne Gentechnik" label.

The requirements for "ohne Gentechnik" labelling in Sec. 3a of the EC Genetic Engineering Implementation Act (EGGenTDurchfG) explicitly stipulate that only GMO that fall under the scope of Regulations 1829/2003 or 1830/2003 may not be used.² Furthermore, the relevance of the narrower definition of GMO of these regulations results from the fact that the EGGenTDurchfG as a whole serves for the implementation of these regulations.

The "ohne Gentechnik" label also does not contravene general prohibitions of consumer deception under food or competition law if substances that come from plants or animal types cultivated through conventional mutagenesis are used.

While food law prohibits misleading information practices with respect to food characteristics, in particular as to its method of manufacture or production (Art. 7 (1) (a) of Regulation (EU) 1169/2011 on the provision of food information to consumers), such misleading information is also a prohibited unfair commercial practice within the meaning of competition law (Art. 6 (1) (b) of Directive 2005/29/EC concerning unfair business-to-consumer commercial practices).

Based on established case law, the term misleading information is to be interpreted to mean that the use of a legally defined description as such does not constitute misleading information.³ This is recognised for both organic products⁴ and for "ohne Gentechnik" food.⁵

² Cf. § 3a Par. 2 No. 1 and 2, Par. 3 and Par. 4 No. 1 and 2 EGGenTDurchfG.

³ Fed. Admin. Court (BVerwG), judgment of 23 February 1992, 3 C 33.98, Fed. Admin. Court Decisions (BVerwGE) 89, 320 = NVwZ 1992, 781 (becel Diät-Wurst) with reference to European Court Reports (ECR) 1988, 4489 ("Joghurt-Fall"); ECR I 1990, 4695 ("Sucrandel"/"synthetischer Süßstoff").

⁴ Higher Regional Court (OLG) Karlsruhe, judgment of 15 Oct. 1993, 2 pp. 78/93, LMRR 1993, p. 36, according to which, despite pesticide residues in organic apples, there is no misleading information, if production followed the requirements of the EU Regulation on organic production and the residues result from an adjoining orchard; Rathke, in: Zipfel/Rathke, Lebensmittelrecht, 170. EL 2018, LMIV, Art. 7 marginal no. 227 with additional evidence; Grube, in: Voit/Grube, LMIV, 2nd ed. 2016, Art. 7 marginal no. 121,140. Bornkamm/Feddersen, in: Köhler/Bornkamm/Feddersen, UWG, 36th ed. 2018, Sec. 5 marginal no. 2.79. Cf. also BVerfG [Fed. Const. Court], decision of 30 January 2002, 1 BvR 1542/00, NJW 2002, 1486, (biobronch) according to which the more detailed statutory regulation of the conditions for labelling content takes precedence over an interpretation based on general rules of interpretation.

Likewise, correctly, Grube, in: Voit/Grube, LMIV, 2nd ed. 2016, Art. 7 marginal no. 140, even if individual opinions in the literature classify statutory regulation as legally authorised consumer deception. Cf. also on the permissibility of the designation "non-alcoholic" for beverages with up to 0.5 volume percent alcohol, Sec. 47 Par. 1 and 3 of the Wine Regulation and Rathke/Sosnitzer, in: Zipfel/Rathke, Lebensmittelrecht, 170. EL 2018, Beer Regulation, Introductory notes, marginal no. 17 f. on non-alcoholic beer.

As a result, legally-relevant misleading information may only occur if there is a violation of the relevant statutory requirements. On the opposite, it is irrelevant whether consumers expect a food that is labelled in compliance with the law to have a property other than the factual one,⁶ e.g. because they do not know the details of the legal provisions.

This is also true if the term used in the relevant labelling law is legally defined in a manner differing from other statutory regulations.

Therefore, it does not contravene the use of the “ohne Gentechnik” label if food contains substances from plants or animals that were cultivated with conventional mutagenesis. Although organisms obtained by conventional mutagenesis, according to the ECJ ruling dated 25 July 2018, represent GMOs within the meaning of Directive 2001/18/EC, they do not fall within the scope of its application because they are explicitly excluded therefrom. The organisms developed with such techniques were therefore a priori excluded from the concept of GMO in food law.

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⁶ Explicitly so, Rathke, in: Zipfel/Rathke, Lebensmittelrecht, 170. EL 2018, LMIV, Art. 7 marginal no. 227 and Grube, in: Voit/Grube, LMIV, 2nd ed. 2016, Art. 7 marginal nos. 121,140.