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rDNA Traces in Fermentation Products Using Genetically Modified Microorganisms (GMMs)

Certain products such as amino acids, flavourings, oligosaccharides, organic acids, or vitamins are obtained by fermentation using genetically modified microorganisms (GMMs). Such fermentation products may be used as or in food and feed. Although the GMMs are separated from the fermentation products during downstream processing these products may, nevertheless, contain traces of rDNA originating from the GMMs.

The European Commission holds the view that fermentation products obtained by using GMMs are subject to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed to the extent that rDNA is still present in the fermentation product irrespective of the amount of rDNA sequences.

However, it follows from the travaux préparatoires as well as early discussions on the scope of Regulation (EC) No 1829/2003 starting immediately after its entry into force that it was neither designed nor framed to be applicable to fermentation products obtained by the use of GMMs. Accordingly, Regulation (EC) No 1829/2003 cannot be considered to be fit for purpose as regards regulation of such products.

In particular, it is clear from the regulation's wording and context that it does not apply to food or feed products obtained by fermentation using GMMs if the GMMs have been removed during downstream processing. In this case, the GMMs are mere 'processing aids' within the meaning of Recital 16, sentences 3 and 4, of Regulation (EC) No 1829/2003. Therefore, such food or feed products obtained by fermentation using GMMs are excluded from the scope of the regulation since, first, these products are not produced 'from' but produced 'with' GMMs (cf. Artt. 2(6), (7) and (10), 3(1)(c), 15(1)(c) of Regulation (EC) No 1829/2003 as construed in light of Recital 16, sentences 1, 3 and 4) and, second, the GMMs are not 'source material' of the fermentation products (cf. Art. 2(8) and (9), Art. 3(1)(a), Art. 15(1)(a) of Regulation (EC) No 1829/2003 as construed in light of Recital 16, sentences 1, 3 and 4). As GMMs are 'processing aids' within the meaning of sentences 3 and 4 of Recital 16 and the fermentation products are, therefore, produced 'with' the GMMs within the meaning of sentence 1 of Recital 16, sentence 2 of the recital has, logically, no relevance as regards the distinction between food or feed produced 'from' or 'with' GMMs.

rDNA traces in fermentation products obtained by the use of GMMs are not 'ingredients' either. Rather, they constitute mere 'residues'. Any health safety concerns related to the presence of rDNA traces are addressed by other Union legislation, e.g., on food additives, food enzymes and food flavourings or feed additives and other feed materials, respectively, or, as the case may be, on novel foods.

I. Background

In a letter dated 19 October 2016 by the European Commission (EC) to the European Food Safety Authority (EFSA) (hereinafter: 2016 Commission Letter), the EC clarified its position regarding the regulatory status of fermentation products obtained from genetically modified microorganisms (GMMs). For that purpose, the EC referred to Recital 16 of Regulation (EC) No. 1829/2003[1], more particularly to the recital's first two sentences only, though:

> *"[1]This Regulation should cover food and feed produced 'from' a GMO but not food and feed 'with' a GMO. [2]The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed."*[2]

The EC considered this criterion (i.e. "whether or not material derived from the genetically modified source material is present in the food or in the feed") to be determinative of whether Regulation (EC) No 1829/2003 applies or not. More specifically, the EC translated this criterion into the distinction whether or not recombinant DNA (rDNA) is present in the fermentation product (p. 1 of the 2016 Commission Letter):

DOI: 10.21552/stoffr/2021/3/6

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1 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, 18.10.2003, pp. 1–23.

2 Numbering of sentences added by the author.

- If rDNA is present in the fermentation product Regulation (EC) No 1829/2003 applies.
- If rDNA is not present in the fermentation product Regulation (EC) No 1829/2003 does not apply.

The EC realized that

> *"[t]here are technical challenges when making such crucial decision. These challenges relate to the actual ascertainment (detection) of the presence of the recombinant DNA itself" (p. 1 of the 2016 Commission Letter).*

In this regard, the EC acknowledged, in particular, that

> *"[w]ith the advances in DNA detection methodologies, the sensitivity of the tests is becoming extremely high. This is because the level of detection of recombinant DNA is pushed down to a few copies of varying base length (a few base pairs to longer) of DNA" (p. 1 of the 2016 Commission Letter).*

The EC added that

> *"[t]here is no established threshold/cut-off value of recombinant DNA to draw a line between 'real' and 'fortuitous' presence of recombinant DNA in fermentation products produced by GMMs" (p. 2 of the 2016 Commission Letter).*

Hence, if the EC's legal point of view was correct, any detection of whatever amount of rDNA in a fermentation product by whatever detection method would lead to the applicability of Regulation (EC) No 1829/2003 since current legislation does not stipulate a de minimis threshold for rDNA traces in fermentation products. Accordingly, the consequence of such a 'zero tolerance' approach would be that, unless the GMMs or the fermentation products obtained therefrom had been authorized in accordance with Regulation (EC) No 1829/2003, the placing on the market of fermentation products containing rDNA traces, e.g., for further use in the food and feed production chain, would not be allowed (cf. Art. 4(2) Regulation (EC) No 1829/2003).

Of course, a de minimis threshold may result, simply de facto, from available detection methods. E.g., in 2018, EFSA delivered a "Guidance on the characterisation of microorganisms used as feed additives or as production organisms" (hereinafter: 2018 EFSA Guidance)[3] and, in 2019, it issued a statement titled "Characterisation of microorganisms used for the production of food enzymes" (hereinafter: 2019 EFSA Statement)[4]. According to these documents,

> *"the applicant should investigate whether the target DNA is detected in analyses having detection threshold of 10 ng of DNA per gram or mL of product or lower"*[5].

It follows from the context of this passage, that the 'detection threshold of 10 ng of DNA per gram or mL of product or lower' is the threshold below which it is presumed that there is no or only insignificant "presence of DNA from the production strain"[6].

However, ultra-sensitive analytical methods have been developed. E.g., Sciensano, a Belgian public research institution occupied with, inter alia, food safety[7], uses real-time PCR[8] which allows for the targeting of sequence fragments which may be as small as 150 base-pairs, and rDNA sequences in the amount of 1 copy/g product, or in the amount of 10^{-15} g/g product, can be detected[9].

Such traces of rDNA, however, are unavoidable in practice, i.e. from a technological and economic point of view, avoiding the presence of such extremely low rDNA traces is unfeasible. At the same time, it is scientific consensus that rDNA traces in the amount of 10 ng per gram or mL of product, and all the more rDNA sequences in the amount of 1 copy/g product, or in the amount of 10^{-15} g/g product, do not, in themselves, constitute risks to human health or the environment.

Against this backdrop, it should stand to reason that, from a scientific point of view, fermentation products obtained from GMMs containing only minimal traces of rDNA but not the GMMs, or parts thereof, need not to be governed by Regulation (EC) No 1829/2003. This regulation would require a lengthy, unpredictable, burdensome and costly authorization procedure[10], i.e. pre-market approval requirements which are unwarranted in light of the absence of risks beyond mere so-called 'residual risks' which are inherent in any technology.

II. Legal Issue

The decisive questions as regards the regulatory status of fermentation products obtained from GMMs are whether Regulation (EC) No 1829/2003 applies to such products and whether, in this regard, the decisive criterion is the presence of traces of rDNA in the fermentation product.

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3 *EFSA Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)/Rychen* et al., Guidance on the characterisation of microorganisms used as feed additives or as production organisms, EFSA Journal 2018, https://doi.org/10.2903/j.efsa.2018.5206.

4 *EFSA CEP Panel (EFSA Panel on Food Contact Materials, Enzymes and Processing Aids)/Silano et al.*, Statement on the characterisation of microorganisms used for the production of food enzymes, EFSA Journal 2019, https://doi.org/10.2903/j.efsa.2019.5741.

5 *EFSA CEP Panel*, fn. 4, p. 11; *EFSA Panel on Additives,* fn. 3, p. 14.

6 *EFSA CEP Panel,* fn. 4, p. 10.

7 See https://www.sciensano.be/en/about-sciensano (last accessed 27 August 2021).

8 PCR: polymerase chain reaction.

9 *Fraiture et al.*, Identification of an unauthorized genetically modified bacteria in food enzyme through wholegenome sequencing, Sci Rep 2020, https://doi.org/10.1038/s41598-020-63987-5.

10 See *Nationale Akademie der Wissenschaften Leopoldina/Union der Deutschen Akademien der Wissenschaften/Deutsche Forschungsgemeinschaft*, Towards a scientifically justified, differentiated regulation of genome edited plants in the EU, 2019, pp. 59 and 63.

The problem of whether products obtained by fermentation using GMMs are governed by Regulation (EC) No 1829/2003 was discussed both during the legislative procedure[11] and immediately after promulgation of Regulation (EC) No 1829/2003[12]. From the beginning, this discussion focussed on the distinction between products 'produced from' GMOs covered by the regulation and products 'produced with' GMOs not covered by the regulation[13]. In addition, it always was common view that this distinction is informed by Recital 16 of Regulation (EC) No. 1829/2003[14] which reads, in full, as follows:

> *"[1]This Regulation should cover food and feed produced 'from' a GMO but not food and feed 'with' a GMO. [2]The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. [3]Processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore, are not included in the scope of this Regulation. [4]Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation. [5]Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation."*[15]

Concerning the distinction between 'produced from' and 'produced with' a GMO, it is of note and importance that the EC, in the early stages[16], did not rely on "whether or not material derived from the genetically modified source material is present in the food or in the feed" (Recital 16, sentence 2, of Regulation (EC) No 1829/2003) but rather on whether the relevant GMM is used as a 'processing aid' within the meaning of Recital 16, sentences 3 and 4, of Regulation (EC) No 1829/2003.

In any case, as early debates on the European Union (EU) level[17] and in legal literature[18] show, this recital was not considered to be substantially helpful in answering the aforementioned problems. To the contrary, at least in legal literature[19], the recital was looked upon as rather clouding than clarifying the issue of whether, and under which circumstances, Regulation (EC) No 1829/2003 applies to food and feed obtained by fermentation using GMMs.

What is more, discussions on the Community level as early as 2004, i.e. just about five months after Regulation (EC) No 1829/2003 became applicable[20], reveal that the regulation was, obviously, not considered to be applicable to food and feed obtained by fermentation using GMMs at all. In fact, during the legislative procedure, the Council and the EC had agreed that

> *"the status of food produced by fermentation using genetically modified micro-organisms not present in the final product (would) need to be clarified, at the latest in the context of the report to be presented by the Commission as foreseen by Article 48 of the Regulation"*[21].

The Chair of the Standing Committee for the Food Chain and Animal Health correctly concluded in 2004 that this agreement, which the European Parliament had been informed of,

> *"clearly suggested that Council did not intend the scope of Regulation No 1829/2003 to include food produced by fermentation using GMMs because if Council had intended to include these foods in the scope, there would have been no reason for Council to turn down this request, or to record the aforementioned statement."*[22]

Hence, even if Regulation (EC) No 1829/2003 was interpreted as covering fermentation products obtained by the use of GMMs, it could hardly be considered to be fit for purpose because the regulation was neither designed nor framed to be applicable to such products.

Against this background, the Chair of the Standing Committee for the Food Chain and Animal Health proposed a 'pragmatic approach' which met with consensus by the Member State representatives. According to this 'pragmatic approach', only

> *"[f]ood and feed (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using a genetically modified micro-organism (GMM) which is present in the final product, totally or par-*

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11 Cf. *Standing Committee on the Food Chain and Animal Health, Section on Genetically Modified Food and Feed and Environmental Risk*, Summary Record of the 3rd Meeting – 24 September 2004, p. 1; Report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed, COM(2006), 626 final, pp. 23–24.

12 *Standing Committee*, fn. 11, pp. 1–2; Report from the Commission, fn. 11, pp. 23–26.

13 E.g., *Standing Committee,* fn.11, pp. 1–2; *Girnau,* Die neuen Regelungen zur Kennzeichnung und Rückverfolgbarkeit von gentechnisch veränderten Lebensmitteln (Verordnungen (EG) Nr. 1829/2003 und 1830/2003), ZLR 2004, p. 349–352; *Werner/Kniel/Berg*, Die Neue Gentechnik-Kennzeichnung und -Rückverfolgbarkeit – Sind diese Regelungen in der Praxis anwendbar?, DLR 2004, p. 167–168.

14 E.g., Report from the Commission, fn. 11, p. 24; *Girnau*, fn. 13, p. 350; *Werner/Kniel/Berg,* fn. 13, p. 167.

15 Numbering of sentences added by the author.

16 Report from the Commission, fn. 11, p. 24.

17 E.g., *Standing Committee*, fn. 11, pp. 1–2; Report from the Commission, fn. 11, pp. 23–26.

18 *Girnau*, fn. 13, p. 350; *Werner/Kniel/Berg,* fn. 13, p. 167–168.

19 *Girnau*, fn. 13, p. 350; *Werner/Kniel/Berg,* fn. 13, p. 167–168.

20 Regulation (EC) No 1829/2003 entered into force on 7 November 2003 and became applicable on 18 April 2004 (cf. Art. 49 of Regulation (EC) No 1829/2003).

21 *Standing Committee*, fn. 11, p. 1.

22 *Standing Committee*, fn. 11, p. 1.

tially, whether alive or not, are included in the scope of Regulation (EC) No 1829/2003, in regard of both authorisation and labelling"[23].

This approach might be, and might have been, understood as including fermentation products containing traces of rDNA in the scope of Regulation (EC) No 1829/2003 since one might claim that in such cases, in which rDNA originating from the GMMs is present in the fermentation product, the GMM is still "present in the final product ... partially".

However, any such purely 'pragmatic approach' could not, and cannot, become a legally binding rule. Whether Regulation (EC) No 1829/2003 covers fermentation products obtained by the use of GMMs and containing traces of the GMMs' rDNA is to be deduced solely from the regulation itself through solid interpretation of its operative provisions (i.e. Artt. 1 et seqq.) and, as the case may be, in light of its preamble (Recitals 1 et seqq.).

III. Legal Analysis

1. Introductory Remarks

What has to be clarified right from the beginning of the legal analysis is that the answer to the question whether fermentation products obtained from GMMs are governed by Regulation (EC) No 1829/2003 has to be derived from the legally binding norms of the regulation, i.e. its Artt. 1 et seqq. The preamble, especially Recital 16, of Regulation (EC) No 1829/2003 is only an auxiliary means for the purpose of interpreting the regulation's norms. It is well-established jurisprudence of the European Court of Justice (ECJ)

"that the preamble to a [Union] act has no binding legal force and cannot be relied on as a ground for derogating from the actual provisions of the act in question"[24].

The preamble, i.e. the recitals, of an EU legislative act only forms part of the context of the act's provisions and informs about the object and purpose of the act. Hence, the recitals play a role in the systematic and teleological method of interpretation of EU law.

2. Factual Bases

The legal issue is whether Regulation (EC) No 1829/2003 applies to food or feed obtained by fermentation using GMMs, and whether, in this regard, a decisive criterion is the presence of rDNA in the fermentation product. The factual bases of this issue can be illustrated as follows:

Certain products may be obtained by fermentation using GMMs. Such fermentation products may be enzymes, but also, e.g., amino acids, flavourings, oligosaccharides, organic acids, or vitamins used in food or feed. In the course of downstream processing, the GMMs are separated from the fermentation product. Downstream processing also removes DNA, including rDNA, of the GMMs. Nevertheless, the fermentation product may still contain traces of rDNA originating from the GMMs. At present, even slightest traces of rDNA can be detected by ultra-sensitive analytical methods. The presence of such rDNA traces in the fermentation product is technically unavoidable, i.e. even most technologically advanced purification methods cannot guarantee the complete absence of such rDNA traces. What is more, avoiding rDNA traces above currently attainable detection thresholds (e.g., 1 DNA copy/g product or 10^{-15} g of DNA/g product) would be economically unfeasible and would not contribute to any meaningful minimization of risk since, from a scientific perspective, even the presence of rDNA traces in the amount of 10 ng per gram or mL of product is not per se a safety risk.

3. Scope of Application of Regulation (EC) No. 1829/2003

Whether Regulation (EC) No 1829/2003 applies to products obtained by fermentation using GMMs depends on the scope of application of the regulation. As regards authorization and supervision, the pertinent provisions are Art. 3(1) and Art. 15(1) of Regulation (EC) No 1829/2003, and as regards labelling, the pertinent provisions are Art. 12(1) and Art. 24(1) of Regulation (EC) No 1829/2003.

According to Art. 3(1) of Regulation (EC) No 1829/2003, the regulation's provisions on authorization and supervision apply to:

"(a) GMOs for food use;
(b) food containing or consisting of GMOs;
(c) food produced from or containing ingredients produced from GMOs."

In a similar fashion, Art. 15(1) of regulation (EC) No 1829/2003 lays down that, as regards authorization and supervision with a view to feed, the regulation applies to:

"(a) GMOs for feed use;
(b) feed containing or consisting of GMOs;
(c) feed produced from GMOs."

Any GMO for food or feed use and any food or feed referred to in Art. 3(1) or Art. 15(1), respectively, of Regulation (EC) No 1829/2003 must not be placed on the market unless on the basis of an authorisation granted in accordance with the regulation (Art. 4(2), 16(2) of Regulation (EC) No 1829/2003).

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23 *Standing Committee*, fn. 11, p. 2.

24 ECJ, C-162/97, Nilsson and Others, ECLI:EU:C:1998:554, para. 54.

Similar rules apply concerning the scope of application of the regulation's section on labelling. According to Art. 12(1) of Regulation (EC) No 1829/2003, the labelling provisions apply to foods which

"(a) contain or consist of GMOs; or
(b) are produced from or contain ingredients produced from GMOs."

As regards labelling of feed, Art. 24(1) of Regulation (EC) No 1829/2003 defines the scope of applicability of the feed labelling provisions (i.e. Artt. 24–26) simply by reference to Art. 15(1) of the regulation.

The scope of application of the food labelling provisions, i.e. Artt. 12–14 of Regulation (EC) No 1829/2003, is further narrowed by the provision that it relates to "foods which are to be delivered as such to the final consumer or mass caterers" only (Art. 12(1) of Regulation (EC) No 1829/2003). Fermentation products are, at least as a rule, not delivered as such to final consumers or mass caterers, though.

Hence, this legal analysis will be limited to the scope of application as defined by Art. 3(1) and Art. 15(1), respectively, of Regulation (EC) No 1829/2003. Therefore, the following questions need to be answered: is the fermentation product

(1) a 'food' or 'feed' 'containing or consisting of GMOs', Art. 3(1)(b), 15(1)(b) of Regulation (EC) No 1829/2003 (question 1), or
(2) a 'food' or 'feed' 'produced from GMOs', Art. 3(1)(c), 15(1)(c) of Regulation (EC) No 1829/2003 (question 2), or
(3) a 'food containing ingredients produced from GMOs', Art. 3(1)(c) of Regulation (EC) No 1829/2003 (question 3), or

is the GMM a

(4) 'GMO' for 'food use' or 'feed use', Art. 3(1)(a), 15(1)(a) of Regulation (EC) No 1829/2003 (question 4)?

If fermentation products do neither form 'food' nor constitute 'feed' within the meaning of the law, they are not subject to Regulation (EC) No 1829/2003 anyway. E.g., numerous fermentation products are used as mere processing aids which, in the end, do not form part of the food or feed product intended for human or animal consumption respectively.

4. Question 1: Are Fermentation Products 'Food' or 'Feed' 'Containing or Consisting of GMOs', Art. 3(1)(b), 15(1)(b) of Regulation (EC) No 1829/2003?

A fermentation product is a 'food' or 'feed' 'containing or consisting of GMOs' within the meaning of Art. 3(1)(b), 15(1) of Regulation (EC) No 1829/2003 if it is a 'food' or 'feed' (a.) which 'contains or consists of GMOs' (b.).

a. Are Fermentation Products 'Food' or 'Feed'?

aa. Are Fermentation Products 'Food'?

The term 'food' is legally defined by Art. 2(1) of Regulation (EC) No 1829/2003 in conjunction with Art. 2 of Regulation (EC) No 178/2002[25]. Accordingly, a 'food' is

> *"any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans" (Art. 2(1) of Regulation (EC) No 178/2002).*

For further clarity, Art. 2(2)-(3) of Regulation (EC) No 178/2002 lays down that

> *"'Food' includes ... any substance ... intentionally incorporated into the food during its manufacture, preparation or treatment. ...*
> *'Food' shall not include:*
> *...*
> *(h) residues and contaminants."*

It follows from these definitions that some, or even most, fermentation products are 'food' within the meaning of Art. 2(1) of Regulation (EC) No 1829/2003 in conjunction with Art. 2 Regulation (EC) No 178/2002. Specifically with regard to 'food enzymes' within the meaning of Art. 3(2)(a) of Regulation (EC) No 1332/2008[26], Recital 18 of that regulation clarifies that "[f]ood enzymes are covered by the definition of food in Regulation (EC) No 178/2002". Hence, in this case, the Union legislature itself classified 'food enzymes' within the meaning of Regulation (EC) No 1332/2008 as food within the meaning of Regulation (EC) No 178/2002. Obviously, the Union legislature is of the opinion that 'food enzymes' are 'substances ... reasonably expected to be ingested by humans' (Art. 2(1) of Regulation (EC) No 178/2002) or 'intentionally incorporated into the food during its manufacture' (Art. 2(2) of Regulation (EC) No 178/2002) without being mere 'residues or contaminants' (Art. 2(3)(h) of Regulation (EC) No 178/2002). Accordingly, and generally speaking, depending on their function and purpose, fermentation products may fall under the definition of 'food'.

bb. Are Fermentation Products 'Feed'?

The term 'feed' is legally defined by Art. 2(1) of Regulation (EC) No 1829/2003 in conjunction with Art. 3(4) of Regulation (EC) No 178/2002. Accordingly, a 'feed' is

25 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1–24.

26 Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97, OJ L 354, 31.12.2008, pp. 7–15.

"any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals" (Art. 3(4) of Regulation (EC) No 178/2002).

Accordingly, whether a fermentation product is a 'feed' depends, essentially, on whether it is 'intended to be used for oral feeding to animals'. Again, the purpose and function of the individual fermentation product is decisive. E.g., amino acids resulting from fermentation using GMMs are used as feed additives to be ingested by animals[27].

b. Are Fermentation Products Food or Feed 'Containing or Consisting of GMOs'?

The fermentation product, be it a food or feed, may contain rDNA, but not the GMMs as such, since they have been removed during downstream processing. Accordingly, at this point, the question does not arise whether GMMs are 'GMOs', i.e. 'genetically modified organisms' (on this question see infra sub III.5.b.aa.).

Rather, the question is whether rDNA constitutes a 'GMO'. The term 'GMO' is legally defined by Art. 2(5) of Regulation (EC) No 1829/2003 in conjunction with Art. 2(2), Annex I B of Directive 2001/18/EC[28].

Art. 2(2) of Directive 2001/18/EC defines the term 'GMO' as follows:

"'genetically modified organism (GMO)' means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination".

Accordingly, the first issue is whether rDNA, or DNA, is an 'organism'. The term 'organism' is defined in Art. 2(1) of Directive 2001/18/EC. The definition of 'organism' reads as follows:

"biological entity capable of replication or of transferring genetic material".

It is a commonly held view from the very beginning of GMO legislation in the EU in 1990[29] that chemical substances such as 'naked' DNA molecules do not form a 'biological entity' and are, thus, not 'organisms' within the meaning of Art. 2(1) of Directive 2001/18/EC[30]. In order to be classified a 'biological entity' within the meaning of Art. 2(1) of Directive 2001/18/EC, chemical substances such as molecules, e.g., DNA sequences, need to be organized in such a manner as to enable the entity to replicate or to transfer its own genetic material[31]. In fact, as the ECJ held, the terms 'biological entity capable of replication or of transferring genetic material' as laid down in Art. 2(1) of Directive 2001/18/EC "necessarily imply that the genetic information ... is capable of being transferred specifically to a suitable recipient for the purposes of recombination"[32]. An entity which contributes "merely [to] a transfer of DNA which is no longer capable of playing a role in reproduction"[33] does not form a 'biological entity' within the meaning of Art. 2(1) of Directive 2001/18/EC. Consequently, a fortiori, 'naked' DNA as such, especially the 'naked' rDNA traces in fermentation products, do not constitute 'organisms' because such 'naked' rDNA traces do not play a role in reproduction and, therefore, do not possess the required capability of transferring genetic material within the meaning of Art. 2(1) of Directive 2001/18/EC. Since rDNA is not an 'organism', it is not a 'GMO' within the meaning of Art. 2(2), Annex I B of Directive 2001/18/EC either.

c. Conclusion

Fermentation products containing rDNA traces are not food or feed 'containing or consisting of GMOs' within the meaning of Art. 3(1)(b), 15(1)(b) of Regulation (EC) No 1829/2003.

5. Question 2: Are Fermentation Products 'Food' or 'Feed' 'Produced from GMOs', Art. 3(1)(c), 15(1)(c) of Regulation (EC) No 1829/2003?

A fermentation product is a 'food' or 'feed' 'produced from GMOs' within the meaning of Art. 3(1)(c), 15(1)(c)of Regulation (EC) No 1829/2003 if the fermentation product is a 'food' or 'feed' (a.) which is 'produced from GMOs' (b.).

a. Are Fermentation Products 'Food' or 'Feed'?

Fermentation products may constitute 'food' or 'feed' within the meaning of Art. 2(1) of Regulation (EC) No 1829/2003 in conjunction with Art. 2, 3(4) Regulation (EC) No 178/2002 (cf. supra sub III.4.a.).

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27 See https://www.transgen.de/lebensmittel/1050.zusatzstoffe-vitamine-aminosaeuren-gentechnisch-veraenderte-mikroorganismen.html (last accessed 27 August 2021).

28 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106, 17.4.2001, pp. 1–39.

29 See *Commission of the European Communities*, Handbook for the Implementation of the Directive 90/220/EEC on the Deliberate Release of Genetically Modified Organisms to the Environment, Vol. 1, 1992, p. 17.

30 *Herdegen/Dederer*, EG-Recht/Erläuterungen, 1. Richtlinie 2009/41/EG, para. 9, in: Herdegen/Dederer (eds.), Internationales Biotechnologierecht – Gentechnik, Biopatente, genetische Ressourcen, 2020; *Palme*, Einleitung 90/219/EWG, para. 17, in: Eberbach/Lange/Ronellenfitsch (eds.), Recht der Gentechnik und Biomedizin, 2021.

31 Cf. also ECJ, C-442/09, Bablok and Others, ECLI:EU:C:2011:541, para. 62.

32 ECJ, C-442/09, Bablok and Others, ECLI:EU:C:2011:541, para. 55.

33 ECJ, C-442/09, Bablok and Others, ECLI:EU:C:2011:541, para. 55.

b. Are Fermentation Products 'Produced from GMOs'?

The fermentation product is obtained by fermentation using GMMs. Therefore, the fermentation product might be 'produced from GMOs'. Hence, the question is whether the GMMs are 'GMOs' at all (aa.) and, if so, whether the fermentation product is 'produced from' such GMOs (bb.).

aa. Are the GMMs 'GMOs'?

The legal definition of 'GMO' is laid down in Art. 2(5) of Regulation (EC) No 1829/2003 in conjunction with Art. 2(2), Annex I B Directive 2001/18/EC. Art. 2(2) Directive 2001/18/EC, in turn, refers to the definition of 'organism' in Art. 2(1) Directive 2001/18/EC. It is beyond doubt that a 'microorganism' is a 'biological entity capable of replication or of transferring genetic material' and, therefore, an 'organism' within the meaning of Art. 2(1) of Directive 2001/18/EC.

Whether a 'microorganism' is a 'GMO', i.e. a 'genetically modified organism' (cf. Art. 2(2) of Directive 2001/18/EC) depends on the use of certain genetic modification techniques. According to the general definition of 'GMO', a 'GMO' is an organism

> *"in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;*
> *Within the terms of this definition:*
> *(a) genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;*
> *(b) the techniques listed in Annex I A, part 2, are not considered to result in genetic modification".*

Hence, if the genetic modification technique used to modify the microorganism is listed in Annex I A, part 1 of Directive 2001/18/EC or if the genetic modification technique used to modify the microorganism is neither listed in Annex I A, part 1[34] nor listed in Annex I A, part 2[35] of Directive 2001/18/EC but, still, satisfies the criteria of the general GMO definition (i.e. 'the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination'), the microorganism is a 'GMO'.

However, even if the microorganism is a 'GMO' in accordance with the aforementioned definition, it may still be exempted from the scope of application of Regulation (EC) No 1829/2003 if the microorganism has been "obtained through the techniques of genetic modification listed in Annex I B to Directive 2001/18/EC"[36] (Art. 2(5) of Regulation (EC) No 1829/2003). This may be the case if the method of genetic modification used is a so-called 'mutagenesis' technique (Annex I B No 1 to Directive 2001/18/EC).

In this regard, the ECJ clarified that all "organisms obtained by means of techniques/methods of mutagenesis constitute GMOs within the meaning of [Art. 2(2) of Directive 2001/18/EC]"[37]. In addition, the Court held that "only organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of that directive"[38] according to Art. 3(1), Annex I B No 1 of Directive 2001/18/EC. It follows from the Court's reasoning that "new techniques/methods of mutagenesis which have appeared or have been mostly developed since Directive 2001/18 was adopted" (i.e. on 12 March 2001) do not belong to those mutagenesis techniques which have such a long history of safe use[39]. It can be further deduced from the judgment that among these non-exempted new mutagenesis techniques are "techniques/methods of directed mutagenesis involving the use of genetic engineering which have appeared or have been mostly developed since Directive 2001/18 was adopted"[40]. According to the submissions of the referring French court underlying the ECJ's judgment, these directed mutagenesis techniques include, at least, "oligonucleotide-directed mutagenesis or directed nuclease mutagenesis"[41].

Therefore, as far as GMMs used for the purpose of obtaining fermentation products are developed through classic genetic engineering techniques (e.g., those techniques which are mentioned in Annex I A part 1 No 1 and 2 to Directive 2001/18/EC) or through novel genome editing techniques (i.e. ODM[42] or SDN[43]), such GMMs constitute 'GMOs' within the meaning of Art. 2(5) of Regulation (EC) No 1829/2003 in conjunction with Art. 2(2), Annex I B Directive 2001/18/EC.

bb. Are Fermentation Products 'Produced from' GMMs?

The term 'produced from GMOs' is legally defined as "derived, in whole or in part, from GMOs, but not containing or consisting of GMOs" (Art. 2(10) of Regulation (EC) No 1829/2003).

It follows that food or feed 'produced from GMOs' may be food or feed that neither contains GMOs nor consists of GMOs. Hence, food or feed 'produced from GMOs' may contain neither the GMO as such nor living cells of the GMO. Examples of such foods include oil produced from genetically modified (GM) soybean or sugar produced from GM

34 Which is a non-exhaustive list, see ECJ, C-528/16, Confédération paysanne and Others, ECLI:EU:C:2018:583, para. 35.

35 Which is an exhaustive list, see ECJ, C-528/16, Confédération paysanne and Others, ECLI:EU:C:2018:583, para. 36.

36 Which is an exhaustive list, too.

37 ECJ, C-528/16, Confédération paysanne and Others, ECLI:EU:C:2018:583, para. 54.

38 ECJ, C-528/16, Confédération paysanne and Others, ECLI:EU:C:2018:583, para. 54.

39 ECJ, C-528/16, Confédération paysanne and Others, ECLI:EU:C:2018:583, para. 51.

40 ECJ, C-528/16, Confédération paysanne and Others, ECLI:EU:C:2018:583, para. 47.

41 ECJ, C-528/16, Confédération paysanne and Others, ECLI:EU:C:2018:583, para. 23.

42 Oligonucleotide-directed mutagenesis.

43 Site-directed nuclease mutagenesis.

sugar beet. These foods, i.e. oil and sugar produced from GM soybean or GM sugar beet, respectively, may not even contain DNA or rDNA. The manufacture of oil requires refinement which is a multiple-stage process necessary to obtain highly purified oil and which destroys, degrades or removes proteins and DNA alike[44], whereas crystalline sugar is an ultrapure substance the composition of which does not differ depending on whether its source material (e.g., sugar beet or sugarcane) has been genetically modified or not[45]. These products, i.e. oil from GM soybean and sugar from GM sugar beet, need to be authorized according to Art. 4(2) in conjunction with Art. 3(1)(c) of Regulation (EC) No 1829/2003, and labelled according to Art. 13(1) in conjunction with Art. 12(1)(b) of Regulation (EC) No 1829/2003, even in the absence of rDNA.

Therefore, it stands to reason that the presence of rDNA is not decisive as regards the applicability of Regulation (EC) No 1829/2003. To the contrary, foods or feed may be covered by Regulation (EC) No 1829/2003 as foods or feed 'produced from GMOs' even in the absence of GMOs or rDNA. In other words, foods or feed may contain no living cells of GMOs and rDNA but may, nevertheless, be considered 'produced from' GMOs and, therefore, covered by Regulation (EC) No 1829/2003.

Consequently, the distinction drawn by the EC (supra sub I.), i.e. the distinction that

– if rDNA is present in the fermentation product Regulation (EC) No 1829/2003 applies,
– if rDNA is not present in the fermentation product Regulation (EC) No 1829/2003 does not apply,

has no legal bases in Regulation (EC) No 1829/2003 since the presence or absence of rDNA is in no way determinative as to whether food is governed by Regulation (EC) No 1829/2003 or not.

Hence, as regards the problem of whether products obtained by fermentation using GMMs are food or feed 'produced from' GMOs, the actual question is whether they are 'derived from GMOs' within the meaning of Art. 2(10) of Regulation (EC) No 1829/2003.

It can be deduced from the wording of that provision that products obtained by fermentation using GMMs are not 'derived from GMOs' (German: 'aus GVO abgeleitet'; French: 'issu d'OGM'; Italian: 'derivato da tali organismi'; Spanish: 'derivado de OMG'). For a food or feed to be 'derived' from an organism, the food or feed must be a derivative of the organism. A food or feed is 'derived' from, i.e. is a derivative of, an organism only if the organism itself is processed during the manufacturing into the food or feed product (such as soybean is processed into oil and sugar beet is processed into sugar). This means that the resultant food or feed contains, or consists of, substance which corresponds to substance of the source organism. Hence, the food's or feed's substance must be a continuation of the organism's substance obtained by mere processing of the organism. In other words, and in brief, the organism as such is processed into the food or feed respectively.

This is not the case with products obtained by fermentation using GMMs. The GMMs as such are not processed into the fermentation product. The fermentation products do not consist of substance which is a processed continuation of the GMMs' substance. Rather, the fermentation products are proteins, amino acids or complex molecules which are, in turn, cellular products produced within, and then isolated from, the GMMs. Hence, the GMMs as such are not, in themselves, processed into fermentation products.

Consequently, products obtained by fermentation using GMMs are not 'produced from' GMOs but are 'produced with' GMOs. The GMMs are production entities producing fermentation products, not source material further processed as such into these products.

This interpretation of Art. 3(1)(c), 15(1)(c) in conjunction with Art. 2(10) Regulation (EC) No 1829/2003 is in line with Recital 16 of the regulation. This recital informs the meaning of the terms 'produced from GMOs' enshrined in Art. 2(10) of Regulation (EC) No 1829/2003. Recital 16 is framed as follows:

> *"[1]This Regulation should cover food and feed produced 'from' a GMO but not food and feed 'with' a GMO. [2]The determining criterion is whether or not material derived from the genetically modified source material is present in the food or in the feed. [3]Processing aids which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore, are not included in the scope of this Regulation. [4]Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation. [5]Thus, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation."*[46]

In light of this recital, products obtained by fermentation using GMMs are not 'produced from' but 'produced with' GMOs for the following reasons:

According to Recital 16 of Regulation (EC) No 1829/2003, the distinction whether food or feed fermentation products are 'produced from' or 'produced with' GMOs (Recital 16, sentence 1) depends on "whether or not material derived from the genetically modified source material is present in the food" (Recital 16, sentence 2). In any case, however, fermentation products are not included in the scope of the reg-

44 Cf. https://www.transgen.de/datenbank/zutaten/2072.sojaoel.html (last accessed 27 August 2021).

45 https://www.transgen.de/datenbank/zutaten/2089.zucker.html (last accessed 27 August 2021).

46 Numbering of sentences added by the author.

ulation, if they constitute "food [or] feed which are manufactured with the help of a genetically modified processing aid" (Recital 16, sentence 4). According to the legislature's will as expressed in Recital 16, such food or feed is not covered by the regulation. It follows logically that such food or feed cannot be considered to be food or feed 'produced from' GMO within the meaning of sentence 1 of Recital 16, since food or feed that is not included in the regulation's scope according to Recital 16, sentence 4 cannot be at the same time food or feed covered by the regulation according to Recital 16, sentence 1. Hence, sentence 4 of Recital 16 also clarifies that, if a GMM is a GM processing aid, traces of rDNA from that GMM are not to be considered "material derived from ... genetically modified source material" within the meaning of sentence 2 of Recital 16. Otherwise, the product containing such rDNA traces would be food or feed covered by the regulation according to Recital 16, sentences 1 and 2, which would be inconsistent with Recital 16, sentence 4 according to which the product is not included in the regulation's scope.

In brief: what is out of the regulation's scope in accordance with Recital 16, sentence 4 cannot be within the scope of the regulation according to Recital 16, sentences 1 and 2. In other words, if food or feed products obtained by fermentation using GMMs are excluded from the scope of Regulation (EC) No 1829/2003 as a matter of Recital 16, sentences 3 and 4, these food or feed products are 'produced with' GMOs within the meaning of Recital 16 sentence 1 which is why it is immaterial whether rDNA traces in the food enzymes are 'material derived from the GM source material' within the meaning of Recital 16, sentence 2. To put it differently: sentence 2 of Recital 16 becomes obsolete if sentences 3 and 4 of the recital apply.

It follows that whether food or feed products obtained by fermentation using GMMs are covered by Regulation (EC) No 1829/2003 in light of its Recital 16 depends on whether the GMMs are mere GM 'processing aids' within the meaning of sentences 3 and 4 of the recital.

In fact, the EC was of the very same opinion in its report to the Council and the European Parliament on the implementation of Regulation (EC) No 1829/2003 of 2006 (hereinafter: 2006 Commission Report). In this report, the EC stated that

> *"[w]hen the GM micro-organism is used as a processing aid, the food and the feed resulting from such production process [is] not to be considered as falling under the scope of the Regulation [sc. (EC) No 1829/2003]"*[47].

Similarly, the EC held that

> *"[f]ood or feed produced using genetically modified micro-organisms as processing aids [is] not falling under the scope of the Regulation [sc. (EC) No 1829/2003]"*[48].

The term 'processing aid' is defined in Art. 3(2)(b) of Regulation (EC) No 1333/2008[49]:

> *"'processing aid' shall mean any substance which: (i) is not consumed as a food by itself; (ii) is intentionally used in the processing of raw materials, foods or their ingredients, to fulfil a certain technological purpose during treatment or processing; and (iii) may result in the unintentional but technically unavoidable presence in the final product of residues of the substance or its derivatives provided they do not present any health risk and do not have any technological effect on the final product".*

In the 2006 Commission Report[50], the EC referred to the earlier but congruent definition of 'processing aid' in Art. 1 of Directive 89/107/EEC[51]. According to the EC, with a view to products obtained by fermentation using GMMs, the GMM is a processing aid "when the micro-organisms are removed after the fermentation and ... the produced food is further purified in the production process"[52].

As regards feed, the term 'processing aid' is defined in Art. 2(2)(h) of Regulation (EC) No 1831/2003[53] as follows:

> *"'processing aids' means any substance not consumed as a feeding stuff by itself, intentionally used in the processing of feeding stuffs or feed materials to fulfil a technological purpose during treatment or processing which may result in the unintentional but technologically unavoidable presence of residues of the substance or its derivatives in the final product, provided that these residues do not have an adverse effect on animal health, human health or the environment and do not have any technological effects on the finished feed".*

Again, in the 2016 Commission Report, the EC clarified that "[w]hen the GM micro-organisms are present in the feed or when they are not removed during the production process, they are not used as processing aids"[54] which implies, e contrario, that when the GMMs are removed during downstream processing they can be considered processing aids.

The EC's Guidance Document on Criteria for Categorisation of Food Enzymes of 2014 (hereinafter: 2014 Commission Guidance) endorsed this view:

47 Report from the Commission, fn. 11, p. 24.

48 Report from the Commission, fn. 11, p. 26.

49 Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, OJ L 354, 31.12.2008, pp. 16–33.

50 Report from the Commission, fn. 11, p. 24.

51 Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorized for use in foodstuffs intended for human consumption, OJ L 40, 11.2.1989, pp. 27–33.

52 Report from the Commission, fn. 11, p. 24.

53 Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition, OJ L 268, 18.10.2003, p. 29–43.

54 Report from the Commission, fn. 11, p. 25.

"when the GM micro-organism is used as a processing aid (the GMM is removed during the downstream processing), the food and feed resulting from such production process [is] not to be considered as falling under the scope of the Regulation [sc. (EC) No 1829/2003]"[55].

As has been outlined earlier (supra sub III.2.), after fermentation the GMMs are removed in the course of downstream processing separating the fermentation products from the GMMs. Hence, the GMMs are, indeed, mere processing aids within the meaning of Art. 3(2)(b)(i) of Regulation (EC) No 1333/2008 and Art. 2(2)(h) of Regulation (EC) No 1831/2003 respectively. Accordingly, such products obtained by fermentation using GMMs are not 'produced from' but 'produced with' GMOs within the meaning of Recital 16 and Art. 3(1)(c) in conjunction with Art. 2(19) of Regulation (EC) No 1829/2003.

This result is also in line with the distinction between 'produced from GMOs' and 'produced by GMOs' under Regulation (EC) No 834/2007[56] concerning organic products. The term 'produced from GMOs' is defined exactly in parallel with Art. 2(10) of Regulation (EC) No 1829/2003 (i.e. as 'derived in whole or in part from GMOs but not containing or consisting of GMOs'; Art. 2(u) of Regulation No 834/2007), whereas the term 'produced by GMOs' is defined as 'derived by using a GMO as the last living organism in the production process, but not containing or consisting of GMOs nor produced from GMOs' (Art. 2(v) of Regulation (EC) No 834/2007). The 2014 Commission Guidance construes 'produced by GMOs' as "with the aid of a GMO, such as enzymes produced with the aid of a GMM"[57]. Indeed, within the process of fermentation using the GMMs and due to subsequent purification removing the GMMs during the downstream processing, the GMMs have been used as the last living organism in the production process. Hence, the distinction 'produced from' GMOs and 'produced with' GMOs in Regulation (EC) No 1829/2003 is exactly mirrored by the distinction between 'produced from' GMOs and 'produced by' GMOs in Regulation (EC) No 834/2007.

The conclusion that food or feed products obtained by fermentation using GMMs are not food or feed 'produced from' GMOs within the meaning of Art. 3(1)(c), 15(1)(c) in conjunction with Art. 2(10) of Regulation (EC) No 1829/2003 cannot be refuted by reference to the 2011 ECJ Bablok case[58]. In this judgment, the Court held that pollen from GM maize is a GMO unless it "has lost its ability to reproduce and is totally incapable of transferring the genetic material which it contains"[59]. In this case, GM pollen "no longer comes within the scope of th[e] concept [of a GMO within the meaning of Article 2(5) of Regulation (EC) No 1829/2003]"[60] since it is not an 'organism' within the meaning of Art. 2(5) of Regulation (EC) No 1829/2003 in conjunction with Art. 2(2) in conjunction with Art. 2(1) of Directive 2001/18/EC any more. However, "when it [therefore] can no longer be classified as a GMO", "pollen must be regarded as being 'produced from GMOs' within the meaning of Article 2.10 of Regulation No 1829/2003"[61], i.e. 'produced from' the GM maize[62].

This reasoning cannot be applied to food or feed products obtained by fermentation using GMMs, though, i.e. the ECJ Bablok case does not call for considering fermentation products to be 'produced from' the GMMs. The facts of the 2011 ECJ Bablok case are significantly distinct from the facts of the case at hand. At its origins, pollen is an 'organism' within the meaning of the aforementioned provisions. Hence, GM pollen is a GMO which, in addition, is not derived by using, e.g., the GM maize as the last living organisms in a production process but which is derived directly from the GM maize as the plant's reproductive material. In contrast, fermentation products are proteins, amino acids or other complex molecules. Like 'naked' DNA also proteins, amino acids and other complex molecules do not form 'organisms' within the meaning of Art. 2(5) of Regulation (EC) No 1829/2003 in conjunction with Art. 2(2) in conjunction with Art. 2(1) of Directive 2001/18/EC because they can neither replicate themselves nor transfer genetic material[63]. Unlike pollen which is a male gamete necessary for sexual reproduction of (certain) plants[64], the aforementioned fermentation products are, in themselves, not capable of transferring genetic material. Even if the fermentation products contain rDNA traces which may be transferred horizontally to other (micro-)organisms, such transfer of genetic material is not owed to an inherent transfer capability of these products because they are, unlike pollen or other gametes, not carriers of genetic material for purposes of reproduction. In addition, rDNA traces in fermentation products do not play a role in reproduction[65].Therefore, also the presence of rDNA traces does not transform fermentation products into 'GMOs' within the meaning of Art. 2(5) of Regulation (EC) No 1829/2003 in conjunction with Art. 2(2), Annex I B of Directive 2001/18/EC. In conclusion, the case at hand has to be distinguished from the ECJ Bablok case for reasons of decisive factual discrepancies between the two cases.

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55 Guidance Document on Criteria for Categorisation of Food Enzymes, 24 February 2014, p. 8.

56 Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91, OJ L 189, 20.7.2007, pp. 1–23.

57 Commission Guidance, fn. 55, p. 9.

58 ECJ, C-442/09, Bablok and Others, ECLI:EU:C:2011:541.

59 ECJ, C-442/09, Bablok and Others, ECLI:EU:C:2011:541, para. 62.

60 ECJ, C-442/09, Bablok and Others, ECLI:EU:C:2011:541, para. 62.

61 ECJ, C-442/09, Bablok and Others, ECLI:EU:C:2011:541, para. 71.

62 Cf. ECJ, C-442/09, Bablok and Others, ECLI:EU:C:2011:541, para. 70.

63 *Herdegen/Dederer*, fn. 30, para. 9; *Palme*, fn. 30, para. 17.

64 ECJ, C-442/09, Bablok and Others, ECLI:EU:C:2011:541, para. 50.

65 On this requirement see ECJ, C-442/09, Bablok and Others, ECLI:EU:C:2011:541, para. 55.

c. Conclusion

Fermentation products are not food or feed 'produced from GMOs' within the meaning of Art. 3(1)(c), 15(1)(c) of Regulation (EC) No 1829/2003.

6. Question 3: Are Fermentation Products 'Food Containing Ingredients Produced from GMOs', Art. 3(1)(c) of Regulation (EC) No 1829/2003?

A fermentation product is a 'food containing ingredients produced from GMOs' within the meaning of Art. 3(1)(c) of Regulation (EC) No 1829/2003 if the product is a 'food' (a.) which contains 'ingredients produced from GMOs' (b.).

a. Are Fermentation Products 'Food'?

Fermentation products may constitute 'food' within the meaning Art. 2(1) of Regulation (EC) No 1829/2003 in conjunction with Art. 2 Regulation (EC) No 178/2002 (cf. supra sub III.4.a.).

b. Are Fermentation Products Food 'Containing Ingredients Produced from GMOs'?

Fermentation products may contain traces of rDNA. The preliminary issue is whether such rDNA traces are 'ingredients' within the meaning of Art. 3(1)(c) of Regulation (EC) No 1829/2003.

The term 'ingredient' is defined in Art. 2(13) of Regulation (EC) No 1829/2003 by reference to Art. 6(4) of Directive 2000/13/EC[66]. This directive was repealed by Regulation (EU) No 1169/2011[67] (Art. 53(1) of Regulation (EU) No 1169/2011). According to Art. 53(2) of Regulation (EU) No 1169/2011, references to Directive 2000/13/EC shall be construed as references to Regulation (EC) No. 1169/2011. Consequently, Art. 2(13) of Regulation (EC) No 1829/2003 is to be understood as referring to the definition of 'ingredient' in Art. 2(2)(f) of Regulation (EU) No. 1169/2011. This provision defines 'ingredient' as

> *"any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as 'ingredients'".*

With a view to this definition, rDNA is a 'substance' but it is not 'used in the manufacture' of the fermentation product. The product is 'produced with' GMMs as GM 'processing aids' (cf. III.5.b.bb.). Accordingly, it is the GMMs, but not the rDNA sequences, which are 'used in the manufacture' of the fermentation product. It stands to reason that rDNA traces are also not an 'altered form' of the GMM. Hence, if, in the course of manufacture of the fermentation product, the GMMs are processing aids only, any substances which are components of these processing aids can only be considered a 'residue'. Therefore, the traces of rDNA present in fermentation products and originating from the GMMs are 'residues' remaining of the downstream processing.

This conclusion is again in conformity with the 2011 ECJ Bablok case[68]. In this case, the Court held that GM pollen is an 'ingredient' of honey[69]. By reference to Directive 2001/110/EC[70], the Court classified pollen as a "natural component" of honey and, at the same time, as a component, "which, according to the intention of the European Union legislature, cannot in principle be removed from it"[71]. The ECJ concluded that, therefore, pollen "must be regarded as a substance which is 'used in the manufacture or preparation of a foodstuff and still present in the finished product'"[72], i.e. pollen is, by definition, an 'ingredient' of honey. In contrast, unlike pollen in honey, rDNA traces do not come within the legal definition of any fermentation product. E.g., according to the legal definitions of 'food enzymes' or 'food enzyme preparations' as laid down in Art. 3(2) Regulation (EC) No 1332/2008, rDNA is not, by definition, a 'normal component' of 'food enzymes' or 'food enzyme preparations' which, as a rule, must not be removed from these products according to the explicit will of the EU legislature.

rDNA is also not to be considered an 'ingredient' with a view to Recital 16, sentence 2 of Regulation (EC) No 1829/2003, i.e. Recital 16, sentence 2, does not require to construe the term 'ingredient' as covering rDNA originating from the GMMs. rDNA is not 'material derived from ... genetically modified source material ... present in the food or in the feed' within the meaning of Recital 16, sentence 2. Within the context of Recital 16, sentence, 2, 'genetically modified source material' means the source material of the 'food' or 'feed'. However, the GMMs are not the GM source

66 Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs, OJ L 109, 6.5.2000, p. 29–42.

67 Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004, OJ L 304, 22.11.2011, p. 18–63.

68 ECJ, C-442/09, Bablok and Others, ECLI:EU:C:2011:541.

69 ECJ, C-442/09, Bablok and Others, ECLI:EU:C:2011:541, para. 79.

70 Council Directive 2001/110/EC of 20 December 2001 relating to honey, OJ L 10, 12.1.2002, p. 47–52.

71 ECJ, C-442/09, Bablok and Others, ECLI:EU:C:2011:541, para. 77.

72 ECJ, C-442/09, Bablok and Others, ECLI:EU:C:2011:541, para. 78.

material of the fermentation products. Rather, the GMMs are 'processing aids' within the meaning of Recital 16, sentence 3 and 4 of Regulation (EC) No 1829/2003 (supra sub III.5.b.bb.). Therefore, logically, they cannot be at the same time 'genetically modified source material' of the fermentation products within the meaning of Recital 16, sentence 2 of the regulation. By definition, a (GM) processing aid cannot be a (GM) source material at the same time. If the fermentation products are not included in the regulation's scope in light of its Recital 16, sentence 4, they cannot be captured by sentence 2 of the recital. For that reason, also rDNA traces in the fermentation products cannot be considered 'material derived from the genetically modified source material' within the meaning of Recital 16, sentence 2 of Regulation (EC) No 1829/2003. Hence, Recital 16, sentence 2, has no bearing on the interpretation of the term 'ingredient' as regards rDNA traces originating from the GMMs used for manufacturing of fermentation products.

In addition, object and purpose of Regulation (EC) No 1829/2003 do not require to include fermentation products with residues of rDNA in the regulation's scope. Among the several objectives of Regulation (EC) No 1829/2003, one important objective is to ensure "a high level of protection of human life and health ... in relation to genetically modified food" (Art. 1(a) of Regulation (EC) No 1829/2003). Even if rDNA traces in fermentation products should be of concern to human health, the presence of such rDNA traces does not call for the applicability of the regulation. Rather, the safety of fermentation products, whether they contain rDNA traces or not, is assessed under Regulations (EC) No 1331/2008[73], No 1332/2008, No 1333/2008 and No 1334/2008[74]. This conclusion is in line with the 2006 Commission Report[75]. In this report, the EC "underlined that an extended range of food produced using GM microorganisms as processing aids are already subject to requirements consisting in a safety assessment and a pre-market approval, or will be subject to such requirements by the way of new proposed legislation in the near future"[76]. Part of this "new proposed legislation" are the aforementioned regulations, i.e. Regulations (EC) No 1331/2008, No 1332/2008, No 1333/2008 and No 1334/2008.

c. Conclusion

Fermentation products are not 'food containing ingredients produced from GMOs' within the meaning of Art. 3(1)(c) of Regulation (EC) No 1829/2003.

7. Question 4: Are the GMMs 'GMOs for Food Use', Art. 3(1)(a) of Regulation (EC) No 1829/2003, or 'GMOs for Feed Use', Art. 15(1)(a) of Regulation (EC) No 1829/2003?

The GMMs are 'GMOs for food use' within the meaning of Art. 3(1)(a) of Regulation (EC) No 1829/2003 or 'GMOs for feed use' within the meaning of Art. 15(1)(a) of Regulation (EC) No 1829/2003 if the GMMs are 'GMOs' (a.) 'for food use' or 'for feed use' (b.).

a. Are the GMMs 'GMOs'?

GMMs constitute 'GMOs' within the meaning Art. 2(5) of Regulation (EC) No 1829/2003 (supra sub III.5.b.aa.).

b. Are the GMMs GMOs 'for Food Use' or 'for Feed Use'?

The term 'GMOs for food use' is defined in Art. 2(8) of Regulation (EC) No 1829/2003 as follows:

> *"'genetically modified organism for food use' means a GMO that may be used as food or as a source material for the production of food".*

The term 'GMOs for feed use' is, mutatis mutandis, defined in the same fashion as follows:

> *"'genetically modified organism for feed use' means a GMO that may be used as feed or as a source material for the production of feed" (Art. 2(9) of Regulation (EC) No 1829/2003).*

In case of products obtained by fermentation using GMMs, the GMMs are not 'used as food' or 'used as feed' within the meaning of the aforementioned definitions. Rather, the GMMs are processing aids which are removed during downstream processing (supra sub III.5.b.bb.). Accordingly, the GMMs do not form part of the fermentation products.

The actual issue, therefore, is whether the GMMs are a 'source material for the production of food or feed' within the meaning of Art. 2(8), (9) of Regulation (EC) No 1829/2003.

It has been already pointed out that the GMMs are processing aids and, thus, not 'source material' of the fermentation products (supra sub III.5.b.bb., III.6.b.). An organism is 'source material' for the production of food or feed only if the organism is processed during the manufacturing process into the food or feed (such as soybean is, e.g., processed into soy oil or sugar beet is processed into crystalline sugar). This means that the organism is processed into the food

73 Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, OJ L 354, 31.12.2008, p. 1–6.

74 Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC, OJ L 354, 31.12.2008, p. 34–50.

75 Likewise, *Standing Committee*, fn. 11, p. 2.

76 Report from the Commission, fn. 11, p. 25.

or feed in such a way that the food's or feed's substance is a processed continuation of the organism's substance. This does not apply to food or feed products obtained by fermentation using GMMs, though. The GMMs are not processed into the food or feed fermentation products. These products are proteins, amino acids or other complex molecules which do not constitute substances that are a continuation of the GMMs' substance obtained by mere processing.

c. Conclusion

The GMMs are neither 'GMOs for food use' nor 'GMOs for feed use' within the meaning of Art. 3(1)(a), 15(1)(a) of Regulation (EC) No 1829/2003.

IV. Overall Conclusions

1. Regulation (EC) No 1829/2003 was neither designed nor framed to be applicable to fermentation products obtained by the use of GMMs. Accordingly, it cannot be considered to be fit for purpose as regards regulation of such products.
2. Regulation (EC) No 1829/2003 does not apply to food or feed obtained by fermentation using GMMs if the GMMs have been removed during downstream processing.
3. The presence or absence of rDNA is in no way determinative as to whether fermentation products obtained by the use of GMMs are governed by Regulation (EC) No 1829/2003 or not.
4. The GMMs are 'processing aids' within the meaning of Recital 16, sentences 3 and 4, of Regulation (EC) No 1829/2003. Therefore, food or feed obtained by fermentation using the GMMs are excluded from the scope of the regulation. It follows logically that food or feed obtained by fermentation using GMMs is 'produced with' GMOs within the meaning of Recital 16 sentence 1 of the regulation. For that reason, sentence 2 of Recital 16 of Regulation (EC) No 1829/2003, which lays down a criterion to distinguish between food or feed 'produced from' GMOs and food or feed 'produced with' GMOs, has no relevance. Rather, sentence 2 of Recital 16 is not applicable at all in case of GMMs used as processing aids for the manufacture of fermentation products. Therefore, it is also immaterial whether rDNA traces in the fermentation products are 'material derived from the genetically modified source material ... present in the food or in the feed' within the meaning of Recital 16, sentence 2.
5. rDNA traces in fermentation products obtained by the use of GMMs are mere 'residues'.
6. Even if such traces of rDNA should raise health safety concerns, any such concerns are addressed, as regards food additives, food enzymes or food flavourings, under Regulations (EC) No 1331/2008, 1332/2008, 1333/2008 and 1334/2008; and, as regards feed additives or other feed materials, under Regulations (EC) No 1831/2003 and No 767/2009[77]. As regards food fermentation products not covered by Regulations (EC) No 1331/2008, 1332/2008, 1333/2008 and 1334/2008, the Novel Foods Regulation[78] may apply.

77 Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC, OJ L 229, 1.9.2009, p. 1–28.

78 Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001, OJ L 327, 11.12.2015, p. 1–22. See Report from the Commission, fn. 11, p. 25.