Shackles for Bees? The ECJ's Judgment on GMO-Contaminated Honey

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Case C-442/09, Bablok and Others (not yet reported)

An old German proverb says: What the farmer doesn't know he doesn't eat. In the case of the Bablok decision delivered by the European Court of Justice on 6 September 2011, it is not the farmers, but the judges who seem to be wary about the unknown. According to their judgement, substances derived from genetically modified plants require market authorisation to be placed on the market as food, even if the substance itself is not fertile anymore. Since the Court takes the view that pollen is an ingredient of honey rather than a natural component, honey contaminated with pollen from genetically modified organisms will fall within the classification of foodstuffs requiring marketing authorisation. So whenever a bee collects pollen from a genetically modified plant, this can make the entire honey harvest unmarketable. Not even the slightest contamination will be tolerated, irrespective of whether it was intentional. Because the prohibition to put unauthorised honey on the market applies abstractly, regardless of whether there is a concrete risk for the health of consumers, the judgement will have considerable impact on the coexistence of conventional, ecological and genetically-modified farming.

I. Background of the case

The Bablok revolves around two acts of secondary Union law: As per Directive 2001/18[1], genetically modified organisms (GMOs) may be released deliberately into the environment or placed on the market only when prior authorisation has been given. Regulation No 1829/2003[2] builds on the rule of the Directive and provides that GMOs for food use, foodstuffs containing or consisting of GMOs, or foodstuffs produced from ingredients produced using or containing GMOs must be authorised before being placed on the market.

In 1988, Monsanto obtained authorisation to place MON 810 maize on the German market. At that time, it was one of the first genetically modified plants to be allowed for cultivation in the European Community. The MON 810 strain of maize contains a gene from a bacterium that expresses a toxin (Bt toxin) poisonous to some parasitic insects. This leads to an increased harvest certainty. In subsequent years, a number of food products derived from this strain were authorised under Regulation No 258/97.[3] In 2007, Monsanto applied for its authorisations to be renewed.[4] The application is still under consideration. However, the cultivation of MON 810 maize was prohibited in Germany by a decision of 17 April 2009 of the Federal Office for Consumer Protection and Food Safety, which ordered the provisional suspension of the marketing authorisation.[5]

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1 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, OJ 2001, L 106/1.

2 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ 2003, L 268/1.

3 Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients, OJ 1997, L 43/1.

4 See <http://ec.europa.eu/food/dyna/gm_register/index_en.cfm> (last accessed on 18 January 2012).

5 See SpiegelOnline International, "Germany Bans Cultivation of GM Corn", 14 April 2009, available on the Internet at <http://www.spiegel.de/international/germany/0,1518,618913,00.html> (last accessed 18 January 2012).

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The case before the ECJ arose from a dispute between Karl-Heinz Bablok, an amateur beekeeper, and the Land of Bavaria ("Freistaat Bayern"), which owns various plots of land on which MON 810 maize has been cultivated for research purposes. In the vicinity of these plots (about 500 metres distance), Bablok produces honey both for sale and for his own personal consumption. Up to 2005, he also produced pollen for sale as a foodstuff in the form of a food supplement. In the same year, traces of MON 810 maize DNA were detected in the maize pollen harvested by Bablok and in a number of samples of his honey. Bablok brought proceedings against the Land of Bavaria on the basis that residues of genetically modified MON 810 maize rendered his products unsuitable for marketing and consumption.

In the main proceedings, the Bavarian Administrative Court of Augsburg had to decide, inter alia, whether, as a result of the presence of pollen from MON 810 maize, the honey and the pollen have been subject to "material interference" within the meaning of § 36a of the German Genetic Engineering Act, in conjunction with § 906(2) of the German Civil Code and whether, as a result, they have indeed been rendered unsuitable for marketing or consumption. According to § 36a of the Genetic Engineering Act, the transfer of properties of an organism based on genetic engineering or other releases of genetically modified organisms constitute a significant impairment within the meaning of § 906 of the Civil Code, if the products affected may no longer be placed on the market (cf. § 36a(1) no. 1) or their intended marketing is possible only with restrictions or is excluded by reason of the applicable provisions on the labelling of products (cf. § 36a(1) nos. 2 and 3). According to § 906(2) of the German Civil Code, where the owner of a plot of land is obliged to tolerate an influence emanating from another plot of land, he may require from the user of the other plot of land reasonable compensation in money if the influence impairs a use of the owner's plot of land that is customary in the location or its income beyond the degree that the owner can be expected to tolerate.

At first instance, the Administrative Court held in its judgement of 30 May 2008 that as a result of contamination by MON 810 maize pollen, the honey and pollen-based food supplements produced by Bablok required authorisation under Article 4(2) of Regulation No 1829/2003. All parties appealed against the judgement to the Bavarian Higher Administrative Court. Before that court, the parties argued that the Regulation is not applicable to pollen from the MON 810 strain of maize found in honey or used as a food supplement, since the effects of low-level, natural contamination of foodstuffs were examined, and thus authorised, when the pollen was authorised for release into the environment pursuant to Directive 2001/18. They further argued that pollen found in honey or used as a food supplement is not a GMO for the purposes of Regulation No 1829/2003 because, at the time when it finds its way into honey or is designated for use as a foodstuff, it no longer possesses any specific and individual capacity to reproduce. In addition, according to the parties, the Regulation is not applicable to foodstuff of animal origin, such as honey. If at all, the rules for authorisation contained in the Regulation need to be interpreted restrictively, meaning that in the event of an adventitious contamination a market authorisation should only be required where a threshold of 0,9 % (such as that laid down with respect to labelling in Article 12(2) of the Regulation) is exceeded.

The question of material interference, which is central to the outcome of the dispute in the main proceedings, turns on the issue whether contaminated products may no longer be placed on the market without authorisation as required by Article 4(2) of Regulation No 1829/2003 or whether, at any rate, they may be so placed only on condition that they are labelled as having been genetically modified. Both consequences could trigger recompensation claims pursuant to § 906(2) of the German Civil Code.

The Higher Administrative Court observed that its judgement depends, first of all, on whether pollen from maize, such as that in issue in the main proceedings, is an "organism" within the meaning of Regulation No 1829/2003, even though it cannot be considered a functional living organism. In this regard, the referring court seems to have been torn between legal semantics and the objective of the regulations on market authorisation. On one hand, maize pollen very rapidly loses its reproductive capacity, with the result that it no longer constitutes a functional living organism throughout the honey's ripening period, from the moment at which the honey in which it is deposited and sealed in the combs. On the other hand, such an interpretation may be contrary to the objective of protecting human and animal health pursued by the Regulation, which, according to recitals 1 to 3 and 9 in the Preamble thereto, seeks to ensure that only safe and wholesome food and feed of the highest possible standard

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is placed on the market. To exclude from the scope of the Regulation food containing unlimited amounts of genetically modified DNA or proteins might be incompatible with that objective.

Eventually, the Higher Administrative Court decided to stay the proceedings and to refer to the European Court of Justice for a preliminary ruling in November 2009. The referring questions, in essence, relate to Article 3(1) of Regulation No 1829/2003, which defines its scope of application. Under this provision, the marketing authorisation and supervision scheme covers: (a) GMOs for food use, (b) food containing or consisting of GMOs and (c) food produced from or containing ingredients produced from GMOs.

II. Judgment of the European Court of Justice

1. The concept of "genetically modified organisms"

The first question of the preliminary ruling asks whether the term GMO must be interpreted as meaning that it includes also material from genetically modified plants which at the time of entering a food or designation for use as a food/food supplement does not possess (or no longer possesses) a specific and individual capacity to reproduce. In other words, the court seeks clarification as to whether fertility is a prerequisite for the classification of a genetically modified substance (in this case, pollen) as a GMO.

An organism within the meaning of Directive 2001/18 and the Regulation No 1829/2003 means any biological entity capable of replication or of transferring genetic material. An organism is "genetically modified" if its genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.[6] These definitions necessarily imply that the genetic information included in the GMO is capable of being transferred specifically to a suitable recipient for the purposes of recombination. This endorses "conclusively two criteria which go together, namely viability and fertility".[7] Thus, the answer to the first question of the referring court is that a substance derived from a genetically modified plant is considered a GMO only as long as it retains its ability to reproduce and is capable of transferring the genetic material which it contains. As soon as the substance at issue loses one or both of these characteristics, it does no longer come within the scope of GMOs.[8] Since it is common ground that the substance at issue (pollen) has lost all specific and individual ability to reproduce, it boils down to the question whether it is still capable of "transferring genetic material". This is left for the referring court to decide, which has to take due account of the scientific data available and consider all forms of scientifically-established transfer of genetic material.[9]

However, even if it is found that the pollen is not, or is no longer, capable of transferring genetic material, with the result that it cannot be categorised as an organism and therefore does not come within the concept of a GMO, that will not necessarily mean that it does not come within the scope of Regulation No 1829/2003.[10] After all, the objective pursued by the Regulation is the protection of human health,[11] and this is less related to the reproductive ability of GMOs than to the actual presence of genetically modified material in the food. Accordingly, the authorisation scheme provided for in the Regulation does not only apply to "GMOs for food use" (cf. Article 3(1)(a) of the Regulation) and to "food containing or consisting of GMOs" (cf. Article 3(1)(b) of the Regulation), but also to "food produced from or containing ingredients produced from GMOs" (cf. Article 3(1)(c) of the Regulation). In fact, this possibility has been considered by the referring court in its second question.

2. The concept of "ingredients"

By its second question, the referring court seeks clarification as to whether the presence of infertile residues of GMOs triggers the need for market authorisation. Accordingly, the court asks two questions: Firstly, whether food supplements (such as honey) containing genetically modified material which is neither fertile nor viable anymore – and is therefore not a GMO within the meaning of Regulation No 1829/2003 – must nevertheless be regarded as "food

6 See Article 2(1) and (2) of Directive 2001/18 and Articles 2.4 and 2.5 of Regulation No 1829/2003, which refer to the definition given in the Directive.

7 ECJ C-442/09, *Bablok and Others*, para. 55.

8 *Ibid.*, para. 62.

9 *Ibid.*, para. 60.

10 *Ibid.*, para. 61.

11 *Ibid.*, para. 56.

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produced from or containing ingredients produced from GMOs" within the meaning of Article 3(1)(c) of the Regulation. If that is answered in the affirmative, the court asks, secondly, whether that classification may be made irrespective of whether the contamination by the genetically modified substance in question was unintentional and adventitious.

In the case at issue, which concerns products "containing" pollen derived from a GMO, the scope of Article 3(1)(c) of Regulation No 1829/2003 depends on the concept of "food" as defined in Article 2.1 thereof, by reference to Article 2 of Regulation No 178/2002[12], and also on the concept of "ingredient", as defined in Article 2.13 of Regulation No 1829/2003, by reference to Article 6(4)(a) of Directive 2000/13[13], and that of "produced from GMOs", as defined in Article 2.10 of Regulation No 1829/2003.

The pollen at issue in the main proceedings is derived from MON 810 maize, that is to say, from a GMO. The ECJ regards that pollen as being "produced from GMOs" when it can no longer be classified as a GMO since it no longer consists of a GMO and no longer contains a GMO.[14] Whether pollen derived from MON 810 maize falls within the scope of the Regulation No 1829/2003 thus primarily depends on its classification as an "ingredient". According to the Article 2.13 of the Regulation, which refers to Article 6(4)(a) of Directive 2001/13, an ingredient means "any substance used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form". As regards to pollen contained in honey, Annex II to Directive 2001/110[15] contains a clarification: "Honey consists essentially of different sugars, predominantly fructose and glucose as well as other substances such as organic acids, enzymes and solid particles derived from honey collection." Pollens are solid particles actually derived from honey collection, partly due to bees but mainly due to the centrifugation carried out by the beekeeper. Hence, they are not a foreign substance or impurity in honey, but rather a normal component of it which cannot in principle be removed from it, even if the frequency with which it is incorporated and the quantities in which it is present in honey are attributable to certain random factors arising during production.[16] Even so, the Court takes the view that pollen contained in pollen-based food supplements must be classified as an ingredient within the meaning of Article 6(4)(a) of Directive 2000/13 and, consequently, within the meaning of Article 3(1)(c) of Regulation No 1829/2003, since it is introduced into those products in the course of their manufacture or production and is still present in the finished product.[17]

On this point, the Commission disagrees with the Court. According to the Commission, a distinction must be drawn between the concept of "ingredient" and that of "natural component". In its submission, pollen is considered a natural component of honey, not an ingredient, with the result that honey containing pollen should not come within the scope of Article 3(1)(c) of Regulation No 1829/2003.[18]

In contrast, the Court notes that the distinction as put forward by the Commission does not take account "of the particular conditions under which pollen is incorporated into honey or of the voluntary maintenance of that pollen in the composition of the end product".[19] The Commission's interpretation would "undermine the objective of protecting human health, since a foodstuff such as honey would escape any safety checks, even though it might contain significant quantities of genetically modified material", and "disregard the determining criterion for the application of Regulation No 1829/2003, [...] namely that as to 'whether or not material derived from the genetically modified source material is present in the food'".[20]

By the same token, the Court rebuts Monsanto's suggestion to restrict Article 3(1)(c) of Regulation No 1829/2003 to substances that have been inten-

12 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 2002, L 31/1

13 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 2000, L 109/29.

14 ECJ C-442/09, *Bablok and Others*, para. 71.

15 Council Directive 2001/110/EC of 20 December 2001 relating to honey, OJ 2002, L 10/47.

16 ECJ C-442/09, *Bablok and Others*, paras. 76–77.

17 *Ibid.*, paras. 74 and 78.

18 *Ibid.*, para. 80. The Commission substantiates this conclusion by referring to recital 16 of the Preamble to the Regulation, according to which "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 the Regulation". The Commission infers from this that foods of animal origin may be considered to be produced from a GMO only if the animal itself has been genetically modified.

19 *Ibid.*, para. 81.

20 *Ibid.*, paras. 82–83.

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tionally introduced into the food. According to the ECJ, intention "cannot be made into a condition for the application of the authorisation scheme provided for by the Regulation, since the risk to human health which that Regulation is intended to prevent is independent of whether the substance in question is introduced intentionally or adventitiously".[21]

3. Zero tolerance for unauthorised ingredients

By its third question, the referring court asks whether a tolerance threshold, such as that provided in respect of labeling requirements, may be applicable to marketing authorisation mutatis mutandis. This would mean that contaminated food and food supplements could still be placed on the market if the proportion of "ingredients produced from GMOs" did not exceed 0.9 %, as laid down in Article 12(2) of Regulation No 1829/2003.

Monsanto and the Polish Government take the view that the risk of contamination of foodstuffs with weak traces of MON 810 maize has already been taken into consideration when it was authorised for intentional release into the environment under Directive 2001/18.[22] The ECJ rejects this argument by stressing the different goals of Directive 2001/18 and Regulation No 1829/2003. While the former was drafted primarily from the angle of environmental considerations, the latter more specifically emphasises the protection of human health which is linked to the specific fact that that food is, by definition, intended for human consumption.[23] Accordingly, the Regulation "introduces an additional level of control".[24] Both authorisation schemes are independent from each other in the sense that an authorising decision under Directive 2001/18 does not cover all subsequent risks to human health that Regulation No 1829/2003 is sought to control.[25]

The Court furthermore rejects an analogous application of a tolerance threshold such as that provided for in respect of labelling in Article 12(2) of Regulation No 1829/2003, since this would, inter alia, run counter to the objective of ensuring "a high level of protection of human life and health".[26] As a result, where the conditions set out in Article 3(1) of the Regulation are fulfilled, the authorisation and supervision obligation exists irrespective of the proportion of genetically modified material contained in the product in question.[27]

III. Comment and outlook

According to the Court, substances can no longer be considered a GMO when they have lost their ability to reproduce and are incapable of transferring genetic material. This will however not necessarily mean that food or food supplements containing such substances are exempt from the need of market authorisation. After all, the authorisation scheme provided for in Regulation No 1829/2003 does not only apply to "GMOs for food use" and to "food containing or consisting of GMOs", but also to "food produced from or containing ingredients produced from GMOs". Honey is certainly not "produced from GMOs", but it may contain "ingredients produced from GMOs". The decisive question therefore is whether the pollen contained in honey may be classified as such an "ingredient".

The Grand Chamber approached this question from a technical standpoint but ended up giving a political answer. According to the Courts own analysis, pollen is not a foreign substance or impurity of honey, but rather a normal component of it. Honey is produced from the nectar of plants, which the bees collect, transform by combining with specific substances of their own, deposit, dehydrate, store and leave in honeycombs to ripen and mature (cf. Annex I of Directive 2001/110). When a worker honey bee moves past the anthers of a flower to collect nectar, pollen gets trapped by her body hairs. This pollen is stored in the nest and is used as food for the larvae. It may find its way into honey either by natural contamination, through the action of bees during honey production, or as a result of a technical process, when honeycombs are centrifuged by the beekeeper in the harvesting of the honey, which may result in the extraction of the content not only of cells filled with honey, but also of neighbouring cells intended for the storage of pollen. Even where pollen cells are separated from honey cells and are therefore not centrifuged

21 *Ibid.*, paras. 87 to 89.

22 *Ibid.*, para. 94

23 *Ibid.*, paras. 95 to 100.

24 *Ibid.*, para. 101.

25 *Ibid.*, para. 102.

26 *Ibid.*, paras. 107 and 108.

27 *Ibid.*, para. 103.

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together – as good apicultural practice suggests –,[28] the extracted honey will almost inevitably contain traces of pollen.[29] What is more, pursuant to Annex II of Directive 2001/110 the beekeeper is not even allowed to remove pollen from the honey: Without prejudice to filtered honey, "no pollen or constituent particular to honey may be removed except where this is unavoidable in the removal of foreign inorganic or organic matter". Against this background, one could infer that pollen is indeed rather a natural component or even a residue than an ingredient of honey and therefore should not come within the scope of Article 3(1)(c) of Regulation No 1829/2003.[30] Such interpretation could also be supported by secondary Union law.[31] As a result, honey containing contaminated pollen would be subject neither to the authorisation requirements nor to the labelling requirements referred to in the Regulation.

Despite this insight, the Court decided differently. It held that pollen must be regarded as both a component of honey and an ingredient with the consequence that, firstly, jars of honey will have to be relabelled to show that they contain pollen (unless it is exempt under the 0.9 % threshold for the adventitious presence of authorised genetically modified substances),[32] and secondly, honey containing pollen derived from GMOs will require authorisation under Regulation No 1829/2003 prior to being put on the market. This may be the case even where the pollen comes from a GMO that is authorised for intentional release into the environment; as long as it has not been explicitly authorised as food or food supplement, it cannot be put on the market for consumption. Furthermore, contrary to the prevailing view in literature,[33] the classification of a substance as an ingredient is considered independent of whether it has been added intentionally and actively during the manufacture or preparation of the respective foodstuff. According to the Court, the only thing that matters is the actual presence of genetically modified material in the end product.

One may like this conclusion or not, but it is a clear policy statement. It stresses the link between the requirement of market authorisation for genetically modified or contaminated food and the protection of human health. The tenor of the decision is very simple: As long as the long term effects of genetical modification remain unclear, the European legislator will rather be hesitant. What the judge doesn't know he doesn't approve. Although the conclusion of the Court is not entirely consistent with the concept of "ingredient" pursuant to secondary Union law and partly brakes with the previous legal practice in the field of green genetical engineering,[34] it has its rationale. At the end of the day, it falls within the discretion of the ECJ to balance the different objectives and principles enshrined in European law. This does however not mean that the Court has ignored European law, as one commentator puts it.[35] Sometimes it is necessary to go beyond the limits of literal interpretation in order to reconcile statutory law with legal policy. If the Court finds that the protection of human health prevails over the interests of industry, it is free to do so, even if this requires an interpretation of the law that goes beyond its literal meaning. It must however be kept in mind that this will not remain without consequences.

In the short term, the judgement will have considerable impact on the coexistence of conventional, ecological and genetically-modified farming (which is principally left to the Member States) and the marketability of honey within the European Union. Bees collect nectar within a radius of about 10 kilometres from their hives. When choosing a blossom, they will take into account the colour, the scent, the number of anthers and other factors. However, they could not

28 See Bund für Lebensmittelrecht und Lebensmittelkunde e.V., „Stellungnahme zur Anwendbarkeit der VO (EG) Nr. 1829/2003 auf Honig", *ZLR* (2011), at p. 515; Waldemar Ternes, Alfred Täufel, Liselotte Tunger and Martin Zobel, *Lebensmittelrecht-Lexikon 2008* (Hamburg: Behr's 2008), at p. 804; Josef Lipp, *Handbuch der Bienenkunde* (Stuttgart: Ulmer 1994), at p. 46; Tobias Teufer, „Honig, Pollen und der Anwendungsbereich der Verordnung (EG) Nr. 1829/2003", *ZLR* (2011), at p. 198.

29 See Gudrun Beckh and Gregor Camps, „Neue Spezifikationen für Trachthonige", *Deutsche Lebensmittelrundschau* (2009), at p. 107; Tobias Teufer, „Honig, Pollen und der Anwendungsbereich der Verordnung (EG) Nr. 1829/2003", *ZLR* (2011), at p. 198.

30 Annex II of Directive 2001/110 also seems to differentiate between solid particles derived from honey collection, such as pollens, and food ingredients.

31 See Moritz Hagenmeyer, „Case Note – ECJ ignores EU Law in Honey/Pollen Case", 6 *EFFL* (2011), p. 292 *et sqq.*; Tobias Teufer, "Honig, Pollen und der Anwendungsbereich der Verordnung (EG) Nr. 1829/2003", *ZLR* (2011), p. 196 *et sqq.*

32 See Stefan Leible, „Die Kennzeichnung von mit Hilfe gentechnischer Verfahren hergestellter Lebensmittel", *ZLR* (2011), p. 13 *et sqq.*

33 See for instance Walter Zipfel and Kurt-Dietrich Rathke, *Lebensmittelrecht* (München: Beck 2011), C 110, § 5 LMKV, para. 3; Moritz Hagenmeyer, *LMKV-Kommentar* (München: Beck 2006), § 5 LMKV, para. 4.

34 See Bund für Lebensmittelrecht und Lebensmittelkunde e.V., „Stellungnahme zur Anwendbarkeit der VO (EG) Nr. 1829/2003 auf Honig", *ZLR* (2011), p. 513 *et sqq.*

35 Moritz Hagenmeyer, "Case Note – ECJ ignores EU Law in Honey/Pollen Case", 5 *EFFL* (2011), at p. 291.

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care less about whether the plant is conventional, ecological or genetically modified. Whenever a bee choses to pick up pollen from a genetically modified plant, this can make the entire honey harvest unmarketable. Unless the plant is covered by a specific authorisation for being placed on the market as food, honey produced from that nectar cannot be sold; even the slightest contamination with genetically modified pollen will prevent it from being marketed. For manufacturers, importers and distributors of honey, this creates a considerable burden and risks that partly go beyond their sphere of influence. Since only about 50 % of the European demand for honey can be satisfied from within the common market, the judgement could lead to trade disputes with exporting countries such as Argentina and China who will certainly be affected by the zero tolerance philosophy.[36] Furthermore, biotechnology companies that produce genetically modified seed are faced with liability risks and food control authorities will incur increasing costs. All this could hinder the progress of green gene technology in Europe. These factors will need to be balanced against the potential risk to human health inherent in the consumption of genetically modified food which the European legislator is sought to control under the authorisation regime.

In the long term however, the decision is likely to have limited importance due to the recent replacement of Directive 2000/13 by Regulation No 1169/2011,[37] which establishes a legal framework to regulate information appearing on foodstuffs and alcoholic beverages and contains a statutory definition of "ingredient". According to Article 2(2)(f) of this Regulation, "ingredient means any substance or product 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". Whether this will have any influence on the legal classification of pollen and other "components" of similar type remains to be seen. Considering the influence of the biotechnological industry in Europe and the fragile legal argumentation on which the Bablok decision rests, chances are good that the Court will take a step backwards.

All in all, the ECJ might have been better advised to take a more flexible standpoint from the very beginning. Even though the stringent criteria set out in the Bablok decision are based on legitimate policy grounds, it might have been more reasonable and proportionate to resort to a tolerance threshold. This would have relativized the safety concerns arising from genetical contamination without displeasing major stakeholders. On the other hand, the long-term effects of genetical engineering are largely unknown. Skeptics are worried about the environmental hazards and claim that genetically modified food is to blame for rising food allergies. In turn, biotechnology companies dispute negative effects and highlight the advantages of genetically "optimized" food. In the absence of reliable evidence in favor of one or the other position, we might just recall another German proverb: Caution is the mother of wisdom.

36 See Bund für Lebensmittelrecht und Lebensmittelkunde e.V., „Stellungnahme zur Anwendbarkeit der VO (EG) Nr. 1829/2003 auf Honig", *ZLR* (2011), at p. 513; Tobias Teufer, „Honig, Pollen und der Anwendungsbereich der Verordnung (EG) Nr. 1829/2003", *ZLR* (2011), at p. 200.

37 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, OJ 2011, L 304/18.

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