

Case C-442/09

Karl Heinz Bablok and Others

v

Freistaat Bayern

(Reference for a preliminary
ruling from the Bayerischer Verwaltungsgeschichtshof)

(Genetically modified food for human consumption — Regulation (EC) No 1829/2003 — Articles 2 to 4 and 12 — Directive 2001/18/EC — Article 2 — Directive 2000/13/EC — Article 6 — Regulation (EC) No 178/2002 — Article 2 — Apicultural products — Presence of pollen from genetically modified plants — Consequences — Placing on the market — Definition of ‘organism’ and ‘food for human consumption containing ingredients produced from genetically modified organisms’)

Opinion of Advocate General Bot delivered on 9 February 2011	I - 7422
Judgment of the Court (Grand Chamber), 6 September 2011	I - 7460

Summary of the Judgment

1. *Approximation of laws — Genetically modified food and feed — Regulation No 1829/2003 — Genetically modified organism — Definition*
(*European Parliament and Council Decision 1829/2003, Art. 2.5*)

2. *Approximation of laws — Genetically modified food and feed — Regulation No 1829/2003 — Scope*
(European Parliament and Council Regulations No 178/2002, Art. 2, and No 1829/2003, Art. 2.1, 2.10 and 2.13, and Art. 3(1)(c); European Parliament and Council Directive 2000/13, Art. 6(4)(a))

3. *Approximation of laws — Genetically modified food and feed — Regulation No 1829/2003 — Obligation to authorise and supervise a foodstuff*
(European Parliament and Council Regulation No 1829/2003, Arts 3(1), 4(2) and 12(2))

1. The concept of a genetically modified organism within the meaning of Article 2.5 of Regulation No 1829/2003 on genetically modified food and feed must be interpreted as meaning that a substance such as pollen derived from a variety of genetically modified maize, which has lost its ability to reproduce and is totally incapable of transferring the genetic material which it contains, no longer comes within the ambit of that concept.

(see para. 62, operative part 1)

2. Article 2.1, 2.10 and 2.13 and Article 3(1)(c) of Regulation No 1829/2003 on genetically modified food and feed, Article 2

of Regulation No 178/2002 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, and Article 6(4)(a) of Directive 2000/13 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs must be interpreted as meaning that, when a substance such as pollen containing genetically modified DNA and genetically modified proteins is not liable to be considered as a genetically modified organism, products such as honey and food supplements containing such a substance constitute food containing ingredients produced from genetically modified organisms within the

meaning of Article 3(1)(c) of Regulation No 1829/2003. That classification may be made irrespective of whether contamination by the substance in question was intentional or adventitious.

‘ingredient’ within the meaning of Article 2.13 of Regulation No 1829/2003 and Article 6(4)(a) of Directive 2000/13.

(see paras 77-79, 92, operative part 2)

Pollen is not a foreign substance or impurity in honey, but rather a normal component of it which, according to the intention of the Union legislature, 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. It must accordingly be regarded as a substance which is used in the manufacture or preparation of a foodstuff and still present in the finished product and must therefore also be classified as an

3. Articles 3(1) and 4(2) of Regulation No 1829/2003 on genetically modified food and feed must be interpreted as meaning that, when they imply an obligation to authorise and supervise a foodstuff, a tolerance threshold such as that provided for in respect of labelling in Article 12(2) of that regulation may not be applied to that obligation by analogy.

(see para. 108, operative part 3)