



Press and Information

Court of Justice of the European Union

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Advocate General's Opinion in Case C-111/16
Giorgio Fidenato and others

According to Advocate General Bobek, Member States can adopt emergency measures regarding genetically modified food and feed only if they can establish, in addition to urgency, a clear and serious risk to health and the environment

In 1998¹, the European Commission authorized the placing on the market of genetically modified maize MON 810. In its decision, the Commission referred to the opinion of the Scientific Committee which stated that there was no reason to believe that that product would have any adverse effects on human health or the environment.

In 2013, the Italian Government asked the Commission to adopt emergency measures to ban the cultivation of maize MON 810 in the light of some new scientific studies carried out by two Italian research institutes. On the basis of a scientific opinion issued by the European Food Safety Authority (EFSA), the Commission concluded that there was no new science-based evidence to support the requested emergency measures and to invalidate its previous conclusions about the safety of maize MON 810. Despite this, in 2013 the Italian Government adopted a ministerial decree prohibiting the cultivation of MON 810 on Italian territory.

In 2014, Mr Giorgio Fidenato and others grew maize MON 810 in breach of the ministerial decree, for which they were later prosecuted.

In the context of criminal proceedings, the Tribunale di Udine (District Court, Udine, Italy) has notably asked the Court of Justice whether emergency measures may be taken on the basis of the precautionary principle.

In today's opinion, Advocate General Michal Bobek proposes that the Court should conclude that Member States can adopt emergency measures concerning genetically modified food and feed only if they can establish, in addition to urgency, the existence of a situation which is likely to constitute a clear and serious risk to human health, animal health and the environment, as set out in Article 34 of the EU Regulation on genetically modified food and feed².

Article 34 is, in the Advocate General's view, a concrete articulation of the precautionary principle in the specific context of genetically modified food and feed in a situation of urgency (61).

The precautionary principle laid down in food law³ allows Member States to adopt emergency measures in order to avert risks to human health that have not yet been fully identified or understood because of scientific uncertainty.

¹ Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Council Directive 90/220/EEC (OJ 1998 L 131, p. 32).

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, p. 1). Article 34 allows Member States to adopt emergency measures "where it is evident that (authorised genetically modified) products [...] are likely to constitute a serious risk to human health, animal health or the environment" (6).

³ 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, p. 1). Its Article 7, entitled "*precautionary principle*", allows Member

However, Mr. Bobek considers that this general principle does not alter the conditions clearly set out in the more specific Article 34 for several reasons. First, the principle of legality, which is even more relevant when Member States impose criminal sanctions, requires that public authorities act only within the confines of what was stated by the law. Second, a regulation is required to be interpreted and applied uniformly in all Member States. Third, the precautionary principle and Article 34 operate in different contexts since Article 34, unlike the precautionary principle, is specifically focused on genetically modified products, which have already gone through a full scientific assessment before being placed on the market.

The Advocate General adds that this conclusion is not changed by the fact that in 2015 a Directive⁴ considerably changed the legal framework applying to genetically modified organisms in the Union and that in 2016 the Commission⁵, on the basis of that Directive, banned maize MON 810 in 19 Member States, including Italy. The Advocate General remarks that the Directive entered into force after the Italian decree and focuses on different grounds.

NOTE: The Advocate General's Opinion is not binding on the Court of Justice. It is the role of the Advocates General to propose to the Court, in complete independence, a legal solution to the cases for which they are responsible. The Judges of the Court are now beginning their deliberations in this case. Judgment will be given at a later date.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

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The [full text](#) of the Opinion is published on the CURIA website on the day of delivery.

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States to adopt emergency measures “*in specific circumstances where [...] the possibility of harmful effects on health is identified but scientific uncertainty persists*”.

⁴ Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory (OJ 2015 L 68, p. 1).

⁵ Commission Implementing Decision (EU) 2016/321 of 3 March 2016 adjusting the geographical scope of the authorisation for cultivation of genetically modified maize (*Zea mays* L.) MON 810 (OJ 2016 L 60, p. 90).