



Press and Information

Court of Justice of the European Union

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Judgment in Joined Cases C-58/10 to C-68/10
Monsanto SAS and Others

The Court rules on the conditions under which the French authorities could introduce a provisional prohibition on the cultivation of MON 810 maize

In the present cases, emergency measures could be adopted under the conditions set out in the legislation governing human food and animal feed

The deliberate release of genetically modified organisms (GMOs) – whether through field experiments or the cultivation of GMO plant varieties – is governed by EU legislation which is centred, in particular, around two schemes: on the one hand, that of Directive 2001/18/EC¹, which is applicable to the release of all GMOs and, on the other, that of Regulation No 1829/2003², which may also apply with regard to GMOs intended for human or animal consumption. In keeping with the precautionary principle, that legislation seeks to ensure a high level of protection of human life and health, whilst safeguarding the free movement of human food and animal feed.

By decision of 22 April 1998³, the European Commission authorised the placing on the market of genetically modified MON 810 maize, at the request of Monsanto Europe, on the basis of Directive 90/220/EEC on the deliberate release into the environment of GMOs, which was then in force. Pursuant to that decision, France gave its written consent to that placing on the market. MON 810 maize, which was developed by the American group Monsanto, is used in the European Union as animal feed and is particularly resistant to certain parasites.

On 11 July 2004, Monsanto Europe notified MON 810 maize to the Commission as an ‘existing product’, not under Directive 2001/18/EC, but on the basis of Regulation No 1829/2003 on genetically modified food and feed, as having been lawfully placed on the market before the date of application of that regulation (18 April 2004)⁴. On 4 May 2007, Monsanto Europe applied for renewal of the authorisation to place that GMO on the market on the basis of that same regulation.

In 2007 France adopted, by way of emergency measures, an order suspending the transfer and use, within its national territory, of MON 810 maize seed, and subsequently, in 2008, two orders prohibiting the planting of MON 810 maize seed.

Actions for annulment of those measures have been brought by Monsanto and a number of seed producers before the French Conseil d’État (Council of State). In the course of those actions the question has arisen as to whether emergency measures could be adopted by France on the basis of Directive 2001/18/EC, which allows for the adoption of such measures by a Member State directly and on its own initiative, or whether they ought to have been adopted on the basis of Regulations No 1829/2003 and No 178/2002, which allow a Member State to adopt emergency measures only when it has informed the Commission officially of the need to adopt such measures and the Commission has failed to act.

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 and repealing Council Directive 90/220/EEC (OJ 2001 L 106, p. 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, p. 1).

³ Decision 98/294/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Directive 90/220 (OJ 1998 L 131, p. 32).

⁴ Pursuant to Regulation No 1829/2003 (Article 20(1)(a)).

In that context, the Conseil d'État decided to submit questions to the Court of Justice concerning the rules applicable to emergency measures governing the marketing authorisations for the GMO products at issue.

The Court observes, as a preliminary point, that the answers given in the present cases are without prejudice to the application of Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species⁵, which applies to seeds derived from maize varieties such as MON 810, although the French authorities did not rely on its provisions which allow a Member State, on request, to be authorised, by the Commission or the Council, to adopt prohibition measures.

Next, the Court notes that, in the present cases, MON 810 maize, which was authorised as, *inter alia*, seed for purposes of planting under Directive 90/220/EEC on the deliberate release into the environment of GMOs (repealed by Directive 2001/18/EC), was notified as an 'existing product' pursuant to Regulation No 1829/2003, and was subsequently the subject of a pending application for renewal of authorisation under that regulation. The Court finds that, in such circumstances, a Member State **may not have recourse to the safeguard clause provided for in Directive 2001/18/EC in order to adopt measures provisionally suspending and then prohibiting the use or placing on the market of a GMO such as MON 810 maize.**

It notes that such emergency measures may, however, be adopted under Regulation No 1829/2003.

The Court states in that regard that, **when a Member State is minded to adopt emergency measures under the latter regulation, it must comply not only with the substantive conditions laid down in Regulation No 1829/2003 but also with the procedural conditions set out in Regulation No 178/2002⁶, the former regulation referring to the latter on this point.** The Member State must therefore inform the Commission 'officially' of the need to take emergency measures. If the Commission fails to act, the Member State must inform it and the other Member States 'immediately' of the content of the interim measures which it has adopted. Thus, explains the Court, the Member State must inform the Commission 'as quickly as possible' and – as, moreover, in the context of the safeguard clause introduced by Directive 2001/18/EC – that information must, in the event of an emergency, be forwarded to the Commission no later than the time at which the emergency measures are adopted by the Member State concerned.

The Court further holds, with regard to the substantive conditions governing emergency measures adopted under Regulation No 1829/2003, that that regulation **requires the Member States to 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 or the environment.** Notwithstanding their temporary and preventive nature, **those measures may be adopted only if they are based on a risk assessment which is as complete as possible in view of the particular circumstances of the individual case, which indicate that measures are necessary.**

The Court observes, lastly, that, in the light of the overall scheme provided for by Regulation No 1829/2003 and its objective of avoiding artificial disparities, the assessment and management of a serious and obvious risk ultimately come under the sole responsibility of the Commission and the Council, subject to review by the EU Courts. It adds that, at the stage of adoption and implementation of emergency measures by the Member States, as long as no decision has been adopted at EU level, the national courts before which proceedings have been brought to test the lawfulness of such national measures have jurisdiction to assess the lawfulness of those measures, having regard to the substantive and procedural conditions set out in Regulations No 1829/2003 and No 178/2002. By contrast, where a decision has been adopted at EU level, the factual and legal assessments contained in that decision are binding on all bodies of the Member

⁵ Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ 2002 L 193, p. 1), as amended by Regulation No 1829/2003.

⁶ 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).



State to which such a decision is addressed, including its courts which are called on to assess the lawfulness of the measures adopted at national level.

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 judgment is published on the CURIA website on the day of delivery.

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