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Court/Tribunal: European Court of Justice
Case: Joined Cases C-58/10 to C-69/10, Monsanto SAS and Others
Date: September 8, 2011
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Summary of Ruling:

The use or sale of Genetically Modified Organisms (“GMOs”), such as MON 810 maize, whose renewal application is pending may not be suspended and subsequently prohibited by provisional national measures of a Member State when the GMO was initially approved for use under Directive 90/220/EEC, notified as existing products according to the conditions under Regulation No 1829/2003 Article 20.

Background:

MON 810 is a genetically modified variety of maize developed by Monsanto SAS (“Monsanto”) that is used as animal feed in the territory of the European Union. Monsanto received the required authorization for use of MON 810 in the European Community in 1998 under Directive 90/220/EEC. In 2001, Directive 90/220/EEC was repealed and replaced by Directive 2001/18/EC. The latter directive added a provision that limited the authorization of “the release into the environment of [Genetically Modified Organisms] (“GMO’s”) at the Community level,” but also simplified the process for renewing authorizations already granted under Directive 90/220/EEC. In 2007, the French Republic prohibited the transfer and use of MON 810 maize and in 2008, a new order imposed a general prohibition on the cultivation of MON 810 maize.

The prohibition on the cultivation of MON 810 maize was contested in various proceedings before the Conseil d’Etat, which stayed the proceedings and referred the following set of questions to the Court of Justice of the European Union (“Court”) for a preliminary ruling:

1. For GMO’s containing feed that were authorized for market use prior to the enactment of Regulation No. 1829/2003, and where authorization would be maintained pursuant to Article 20, must the feed be regarded as among the products to which Directive 2001/18/EC Article 12 refers? And if so, regarding the emergency measures that may be adopted after the market-use authorization, is the feed subject to Regulation No. 1829/2003 Article 34? Or may measures be adopted by a Member State pursuant to Directive 2001/18/EC Article 23 and the relevant national provisions?
2. Assuming the emergency measures may be adopted only under Regulation No. 1829/2003 Article 34, may the Member State adopt risk-containment measures pursuant to Regulation No. 178/2002 Article 53 or interim protective measures pursuant to Article 54 of the same regulation, as referred to by Regulation No. 1829/2003 Article 34, and under what circumstances?

3. Assuming that authorities may intervene pursuant to Directive 2001/18/EC Article 23, Regulation No. 1829/2003 Article 34, or both, what degree of requirement, accounting for the precautionary principle, may be imposed? With respect to identifying the risk, assessing its probability, and evaluating the nature of its effects, Article 23 of the Directive specifies that adoption of emergency measures is subject to the condition that the Member State must have on “detailed grounds for considering that a GMO ... constitutes a risk to ... the environment,” whereas Article 34 of the Regulation specifies that adoption of emergency measures is subject to the condition that it be “evident” that the feed is “likely to constitute a serious risk to ... the environment.”

Analysis:

First Question:

The first question addressed whether the power to adopt emergency measures lies with the Member States per Directive 2001/18/EC Article 23, or with the European Commission per Regulation No. 1829/2003 Article 34. Article 12 precludes the applicability of some provisions in the Directive, including Article 23, to GMO’s that satisfy the following key requirements: (1) the GMO’s must be authorized by European Community legislation; (2) the legislation must provide for an environmental risk assessment; and (3) the legislation must impose obligations at least equivalent to those of the Directive regarding labeling and information to the public.

The Court reasoned that because Directive 2001/18/EC directly replaced Directive 90/220/EEC, the authorization was granted on the basis of the requirements. Monsanto sought to subject MON 810 maize only to Regulation No. 1829/2003, and MON 810 maize was never notified under Directive 2001/18/EC; therefore, Article 23 of that Directive does not apply. Thus, any emergency measures may be adopted only on the basis of the Regulation, specifically Article 34 therein.

Second Question:

The second question addressed whether Member States could adopt unilateral measures if only the emergency measures referred to in Regulation No. 1829/2003 Article 34 could be implemented. Regulation No. 1829/2003 Article 34 refers to Regulation No. 178/2002 Articles 53-54 with respect to the adoption of emergency measures that grant the European Commission priority to adopt emergency measures. Only if the Commission does not act may Member States adopt their own emergency measures. In the initial proceedings, the Commission and Monsanto used Articles 53-54 as the basis for arguing that the French Government did not have the authority to prohibit the use of MON 801, as it had not previously asked the Commission to act. The opposing parties, however, submitted that the wording of Article 53 actually provides for the Commission to adopt environmental measures only when the Member States have not acted satisfactorily.

The Court noted that per Article 53, the Commission’s right to act is contingent on instances where the Member States did not act satisfactorily. However, the article does not deal with GMO’s specifically. Further, the Court noted that Regulation No.

1829/2003 refers only to the “procedures” provided for in Articles 53-54, which consist of the Commission taking action to adopt emergency measures (Article 53), or if the Commission does not respond, the Member States taking interim action (Article 54). Accordingly, the Court held that pursuant to Regulation No. 1829/2003 Article 34, Member States may adopt unilateral measures only on an interim basis, and only when the Commission has not acted expediently.

Third Question:

Here, the Court detailed the conditions that would justify the adoption of emergency measures under Directive 2001/18/EC Article 23 and Regulation No. 1829/2003 Article 34. First, the Court noted that the French Government did not have the power to adopt unilateral emergency measures because it did not notify the Commission prior to adoption. The conditions required to justify adoption were not relevant to the proceedings. Regardless, the Court addressed the question. As part of its deliberation, the Court noted that the conditions that justify adoption of emergency measures differ between Article 23 and Article 34. Although both justifications for adoption regard human health as the main component, Article 23 requires “detailed grounds for considering that a GMO . . . constitutes risk to human health,” whereas Article 34 requires it to be “evident that [the GMO’s] are likely to constitute a serious risk to human health . . .” Taking these two Articles together, irrespective of which Article is chosen, there must be a real and substantial risk to human health and the environment, not just a hypothetical one. Further, it is impossible and unnecessary to define exactly what level of risk is required for the adoption of emergency measures. Rather, it will be determined on a case-by-case basis.

Holdings:

1. GMO’s, such as MON 810 maize, that were initially approved for use under Directive 90/220/EEC and notified as existing products according to the conditions under Regulation No 1829/2003 Article 20, and whose renewal application is still pending, may not have their use or sale provisionally suspended or prohibited by a Member State under Directive 2001/18/EC Article 23. However, such emergency measures may be adopted pursuant to Regulation No. 1829/2003 Article 34.
2. Adoption of emergency measures by a Member State pursuant to Regulation No. 1829/2003 Article 34 is authorized only in accordance with the procedural conditions set forth in Regulation No. 178/2002 of the European Parliament and of the Council of 28 January 2002. These established the general principles and requirements of food law and the procedures in matters of food safety. The national court is responsible for determining if the Member States are in compliance.
3. Adoption of emergency measures by a Member State pursuant to Regulation No. 1829/2003 Article 34 requires establishment, in addition to urgency, that there exists a serious and clear risk to human health, animal health, or the environment.