General Court of the European Union
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Press and Information

Judgment in Case T-33/16
TestBio Tech v Commission

The General Court annuls the decision whereby the Commission rejected an application for review of the marketing authorisation granted to products containing genetically modified soybeans

The effects of GMOs on human or animal health may fall within the area of the environment, so that non-governmental organisations may refer to those aspects within an application for review based on the Aarhus Regulation

Between 2007 and 2010 the companies Pioneer Overseas and Monsanto Europe sought authorisation to place on the market foods, food ingredients and feed containing genetically modified soybeans.

In each case, the European Food Safety Authority (EFSA) considered, in essence, that the genetically modified soybean was, in the context of its intended uses, as safe as non-genetically modified soybean with respect to potential effects on human and animal health or on the environment.

On the basis of the EFSA opinion, the Commission, by means of decisions of 24 April 2015,[1] authorised the placing on the market of the products concerned.

TestBioTech, an NGO opposed to the introduction of those products on the market, asked the Commission, on the basis of an EU regulation that enables NGOs to participate in the decision-making process in environmental matters ('the Aarhus Regulation'[2]), to carry out an internal review of the authorisation decisions of 24 April 2015.[3] By decision of 16 November 2015, the Commission rejected the greater part of the application for review, holding, in essence, that the aspects relating to the health assessment of genetically modified food and feed cannot be examined in the light of the Aarhus Regulation, because those aspects are not concerned with environmental risk assessment, but instead the area of health.

TestBioTech brought an action before the General Court seeking the annulment of the Commission's rejection decision. According to TestBioTech, the application for internal review is in fact linked to issues that fall within the scope of the Aarhus Regulation. In that regard, TestBioTech claims that the marketing authorisation decisions, adopted on the basis of the EU regulation on genetically modified food and feed,[4] constitute acts adopted under environmental law within the

[1] Implementing Decision (EU) No 2015/698 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 (DP-3Ø5423-1) pursuant to Regulation No 1829/2003 (OJ 2015 L 112, p. 71); Implementing Decision (EU) 2015/686 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87769 (MON-87769-7) pursuant to Regulation (EC) No 1829/2003 (OJ 2015 L 112, p. 16); Implementing Decision (EU) 2015/696 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87705 (MON-877Ø5-6) pursuant to Regulation (EC) No 1829/2003 (OJ 2015 L 112, p. 60).

[2] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ 2006 L 264, p. 13).

[3] EU law provides that NGOs may submit an application for internal review to the EU institution which has adopted an administrative act in matters of the environment.

[4] 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).

meaning of the Aarhus Regulation, and that the impact of genetically modified organisms on the state of human health is a health issue that is related to the state of the environment.

By today's judgment, **the General Court annuls the Commission's decision**.

The General Court recalls first that the regulation on genetically modified food and feed, on which the authorisations of 24 April 2015 are based, is an integral part of the matters of environmental law covered by the Aarhus Regulation and that such authorisations can therefore be the subject of internal review.

As regards whether the arguments raised by TestBioTech in its application for review do fall within the scope of the area of environmental law within the meaning of the Aarhus Regulation,[5] the General Court observes, inter alia, that any GMO must be cultivated before it can be processed into food or feed. **When being cultivated, GMOs are part, as a general rule, of the natural environment** and therefore properly constitute an element of the environment. It follows that **the provisions of the rules on the labelling of GMOs whose objective is to regulate the effect on human or animal health of GMOs also fall within the area of the environment**.

The General Court concludes that **environmental law within the meaning of the Aarhus Regulation covers any provision of EU legislation concerning the regulation of GMOs that has the objective of dealing with a risk to human or animal health, that originates in those GMOs** or in environmental factors that may have effects on GMOs when they are cultivated or bred in the natural environment. That finding is no less applicable in situations where the genetically modified organisms have not been cultivated within the EU.

The General Court holds that the complaints made by TestBioTech in its application for review fall wholly within the area of environmental law within the meaning of the Aarhus Regulation. The Commission therefore erred in concluding that those complaints could not be examined within the framework of that regulation. The General Court consequently annuls the Commission's rejection decision, which entails that the Commission will have to make a further decision on TestBioTech's application.

NOTE: An appeal, limited to points of law only, may be brought before the Court of Justice against the decision of the General Court within two months of notification of the decision.

NOTE: An action for annulment seeks the annulment of acts of the institutions of the European Union that are contrary to European Union law. The Member States, the European institutions and individuals may, under certain conditions, bring an action for annulment before the Court of Justice or the General Court. If the action is well founded, the act is annulled. The institution concerned must fill any legal vacuum created by the annulment of the act.

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[5] In its application for internal review, TestBioTech claimed that (1) there was a lack of guidance from EFSA concerning the health impact of genetically modified seed with significantly altered nutritional content; (2) the lack of guidance resulted in an inadequate and inconsistent assessment of nutritional risks which does not meet legal requirements; (3) the lack of guidance resulted in infringement of the provisions on labelling ; (4) the lack of guidance resulted in inadequate and inconsistent post-marketing monitoring proposals, 5) there was a failure to consider herbicide residues when examining the impact of the consumption of genetically modified food and feed on health as regards soybeans MON 87705 and 305423 and 6) as regards soybean MON 87705, the assessment of the unintended effects of ribonucleic acid interference was inadequate.