



Press and Information

General Court of the European Union
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Judgment in Case T-177/13
TestBio Tech and Others v Commission

The General Court confirms the legality of the Commission decision to dismiss as unfounded a request for review of a market authorisation decision on products containing genetically modified soybeans

The parties making the request did not succeed in putting forward arguments liable to invalidate the Commission's finding that: 1) there are no significant differences between the genetically modified soybean and conventional soybean; 2) the potentially toxicological effects of the genetically modified soybean were correctly assessed; and 3) it is unlikely that the newly-expressed proteins of the genetically modified soybean are allergenic for infants

In 2009, Monsanto Europe submitted an application for the placing on the market of foods, food ingredients and feed containing genetically modified soybean.

In 2012, the European Food Safety Authority (EFSA) considered that the genetically modified soybean was, in the context of its intended uses, as safe as conventional soybean (that is to say, non-genetically modified soybean) with respect to its potential effects on human or animal health or on the environment.

On the basis of that 'favourable' opinion from EFSA, the Commission, by decision of 28 June 2012,¹ authorised the placing on the market of foods and food ingredients containing, consisting of, or produced from the modified soybean.

Three German non-governmental organisations (NGOs) opposed to the introduction of those products on the market requested the Commission to conduct an internal review of its decision on marketing authorisation.² Their criticisms of the Commission include its finding that the modified soybean is substantially equivalent to conventional soybean and that the toxicological and immunological risks had not been adequately assessed (particularly in terms of the allergenicity of the genetically modified soybean for infants). In 2013, the Commission dismissed those requests, taking the view that they were unfounded.

The three organisations asked the General Court to annul the dismissal of their request for internal review of the authorisation decision. This is the first time that the General Court has ruled on a decision adopted on its merits by the Commission further to a request for internal review under 'the Aarhus Regulation',³ which determines, among other things, the conditions for NGOs' access to justice in environmental matters.

By today's judgment, **the General Court** dismisses the action brought by the three organisations and **upholds the decision by which the Commission dismissed as unfounded a request for review of the decision on marketing authorisation.**

¹ Implementing Decision 2012/347/EU of 28 June 2012 authorising the placing on the market of products containing, consisting of, or produced from the genetically modified soybean pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ 2012 L 171, p. 13).

² European Union law in fact provides that non-governmental organisations are entitled to make a request for internal review to the EU institution or body that has adopted an administrative act under environmental law.

³ 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).

The General Court explains, first of all, that a non-governmental organisation whose request for review is dismissed may bring an action for annulment against that decision, given that it is the party to which the dismissal decision is addressed. The General Court nevertheless declares that an NGO may not put forward arguments directly challenging the lawfulness or merits of the authorisation decision; rather, it may only argue that the decision dismissing its request for review as unfounded is unlawful or unfounded. In the present case, the General Court observes that many of the arguments put forward by the three organisations allege errors of assessment by EFSA or concern only an alleged unlawfulness of the authorisation decision. The General Court therefore rejects those arguments.

The General Court confirms that the provisions on which the marketing authorisation of products containing genetically modified soybean is based form an integral part of the areas of environmental law covered by 'the Aarhus Regulation' and that that authorisation may therefore be the subject of an internal review. The General Court also rejects the arguments that the scope of its review of the lawfulness and merits of a decision, such as the one at issue in this case, should be extremely limited and be restricted to manifest errors of assessment which can be easily detected by a non-scientist. It explains that the scope of the review is the same as when an undertaking requests annulment of a marketing authorisation for its genetically modified substance.

It is in that context that the General Court explains that the organisations whose request for review was dismissed are required only to adduce substantial evidence liable to raise serious doubts as to the lawfulness of the grant of that authorisation. Although they are not required to prove that the authorisation decision is unlawful, they are nevertheless required to provide a set of material raising serious doubts as to the lawfulness of the act challenged.

As to the merits of the case, the General Court observes generally that the organisations have not succeeded in demonstrating that the Commission failed in its obligation to ensure, firstly, that an adequate risk assessment of the 'highest possible standard' was carried out and that Monsanto provided 'appropriate' data. Secondly, they have not demonstrated that the Commission infringed its obligation to ensure that food and feed that would have an adverse effect on human health, animal health or the environment must not be placed on the EU market.

By way of non-exhaustive and non-representative examples from among the numerous arguments put forward, the organisations have not succeeded in raising serious doubts liable to invalidate the Commission's findings that: 1) **there is no statistically or biologically relevant difference in the composition of the genetically modified soybean as compared to the conventional soybean**, 2) **the assessment of the potential toxicity of the modified soybean was adequate** and 3) **the allergenic risk posed by the genetically modified soybean was adequately assessed**.

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

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