General Court of the European Union
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Press and Information

Judgment in Case T-240/10
Hungary v Commission

The General Court has annulled the Commission's decisions concerning authorisation to place on the market the genetically modified potato Amflora

The Commission infringed the procedural rules of the systems for authorising GMOs in the European Union

In the territory of the European Union, genetically modified organisms (GMOs) may be released into the environment or placed on the market only if consent has been given, subject to specific conditions and granted with a view to specified uses, after a scientific assessment of the risks.

The authorisation system consists of two different procedures which are applied depending on the intended use of the GMOs. The aim of the first procedure, whose rules are laid down by Directive 2001/18/EC[1], is to authorise GMOs with a view to their deliberate release into the environment. Within the framework of that procedure, it is in principle for the Member State with which an undertaking has lodged an application for this purpose to issue consent. However, the other Member States, and also the Commission, may raise objections vis-à-vis the intended consent decision.

The second authorisation procedure, set up by Regulation 1829/2003[2], concerns genetically modified food and feed. In that case, the application for consent is assessed at EU level.

Where, in the context of the first procedure, an objection has been raised or, in the context of the second procedure, an application for consent has been submitted, the final decision on the authorisation is taken by the Commission or by the Council on the basis of the scientific opinions of the European Food Safety Authority (EFSA).

In those situations, the Commission is assisted by two committees[3] made up of representatives from the Member States who express their respective opinions with knowledge of the opinions of the EFSA. If the opinion of the competent committee is in favour of the authorisation of the GMO, the Commission will grant consent. If that is not the case, or if no opinion has been given, the Commission will submit a proposal for authorisation to the Council, which may grant or oppose it. If the Council does not adopt a decision, the Commission will grant the consent.

The company BASF Plant Science GmbH first asked the Swedish authorities, through a subsidiary, to authorise the placing on the market of the genetically modified potato Amflora with a view to its cultivation and use for industrial purposes. Several Member States having made observations regarding that application, the taking of the final decision was entrusted to the EU authorities.

Secondly, the company BASF directly initiated an authorisation procedure before the EU authorities with a view to the production of animal feed based on that potato. That latter application

[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] The present case involves the Regulatory Committee on the Release into the Environment of Genetically Modified Organisms, established by Directive 2001/18/EC, and the Standing Committee on the Food Chain and Animal Health, referred to in Regulation (EC) No 1829/2003.

also covered the situation of the adventitious presence of GMO traces in food for human or animal consumption.

After receiving favourable opinions from the EFSA in 2005, the Commission submitted the proposals for authorisation to the committees then, receiving no opinion from them, to the Council, which did not adopt a decision. In consequence, the Commission could have granted the authorisations applied for at that stage. However, having received, during the authorisation procedures, information concerning inconsistencies between different scientific opinions of the EFSA, the Commission did not grant the authorisations but decided to consult that authority again so that the latter could explain its opinions. In June 2009, the EFSA adopted a consolidated scientific opinion in which it (there being minority opinions conflicting with its conclusions) confirmed that the Amflora potato did not present a risk to human health or to the environment. Following that opinion, no new draft decisions were put before the competent committees by the Commission, which granted the two authorisations applied for by decisions of 2 March 2010[4].

Taking the view, however, that the Amflora potato presents a risk to human and animal health and also to the environment, Hungary brought an action for annulment of the Commission's authorisation decisions. France, Luxembourg, Austria and Poland intervened in the proceedings in support of Hungary.

In its judgment delivered today, the General Court has found, first of all, that the Commission, before adopting the contested decisions, did not submit the amended drafts of those decisions, together with the EFSA's consolidated opinion of 2009 and the minority opinions, to the competent committees. Whereas the enacting terms of the contested decisions are identical to those of the draft decisions initially submitted to the competent committees and to the Council, that is not the case with the scientific foundation used by the Commission in order to adopt those decisions. In consequence, the General Court finds that, by having decided to request a consolidated opinion from the EFSA, and by basing the contested decisions on, inter alia, that opinion without allowing the competent committees to comment on the opinion or on the amended draft decisions, **the Commission departed from the rules of the authorisation procedures.**

In that respect, the General Court takes the view that, **if the Commission had complied with those rules, the result of the procedure or the content of the contested decisions could have been substantially different.** As the votes on the previous drafts within the committees were very divided, and as the conclusions of the EFSA's consolidated opinion of 2009, coupled with the minority opinions, expressed more uncertainties than the previous opinions of the EFSA, it was therefore possible that the members of the committees might review their position and decide for or against the authorisations applied for. Furthermore, if there had been an unfavourable opinion or if there had been no opinion from the committees, the Commission would have been obliged to submit the proposals for authorisation to the Council, which could have decided for or against the authorisations in question. It was only at the end of that procedure, when there is no decision by the Council, that the Commission could have adopted its decisions.

In that regard, the General Court finds that the addition in the drafts of the contested decisions of a statement of reasons referring to a new opinion of the EFSA by way of scientific foundation constitutes a substantial alteration to those drafts in relation to their previous version. As a consequence, **those decisions cannot be considered to be identical to the previous drafts and proposals.** In addition, the consolidated opinion of 2009, which includes major differences in relation to the previous opinions of the EFSA, must be treated as a new substantive assessment and not as a simple, purely formal confirmation of the assessments of the risks contained in the previous opinions.

[4] Commission Decision 2010/135/EU of 2 March 2010 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a potato product (Solanum tuberosum L. line EH92-527-1) genetically modified for enhanced content of the amylopectin component of starch (OJ 2010 L 53, p. 11) and Commission Decision 2010/136/EU of 2 March 2010 authorising the placing on the market of feed produced from the genetically modified potato EH92-527-1 (BPS-25271-9) and the adventitious or technically unavoidable presence of the potato in food and other feed products under [Regulation No 1829/2003] (OJ 2010 L 53, p. 15).

In those circumstances, **because the Commission significantly failed to fulfil its procedural obligations, the General Court has annulled the contested decisions.**

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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