NGOs CAN ASK THE COMMISSION TO REVIEW ITS DECISION ON GENETICALLY MODIFIED FOOD AND FEED

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The General Court decided in its decision of 14 March 2018 that non-governmental organisations ('NGOs') can ask the Commission to review its decision on authorising the placing on the market of genetically modified ('GM') food and feed.

In 2015, the Scientific Panel on Genetically Modified Organisms of the European Food Safety Authority ('EFSA') issued an opinion that products containing, consisting of, or produced from specified GM soybeans are 'as safe as their non-genetically modified counterparts with respect to potential adverse effects on human and animal health and the environment in the context of its intended uses'. In accordance with Regulation No 1829/2003 on GM food and feed,[1] the Commission subsequently authorised the placing on the market of GM soybeans that are cultivated outside the EU.[2]

After the Commission's decision to allow GM food and feed onto the European market, Testbiotech, a German NGO dedicated to banning the use and consumption of GM organisms ('GMOs'), asked the Commission to review its decision. This request was made based on the right to participate in the decision-making process provided by the international Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters ('the Aarhus Convention'),[3] as implemented at European level by Regulation No 1367/2006 ('the Aarhus Regulation').[4] Article 10 of the Aarhus Regulation provides the right for any NGO to request an internal review by the EU institution that has adopted an administrative act under 'environmental law', as defined by the Aarhus Regulation:

> *EU legislation which, irrespective of its legal basis, contributes to the pursuit of the objectives of EU policy on the environment as set out in the FEU Treaty: preserving, protecting and improving the quality of the environment, protecting human health, the prudent and rational utilisation of natural resources, and promoting measures at international level to deal with regional or worldwide environmental problems.*[5]

The EU institutions must take due account of the outcome of the public participation when adopting the final decision.[6]

The Commission, however, rejected Testbiotech's request based on Article 10 of the Aarhus Regulation, as it maintained that the decision concerned human and animal health and did not include environmental matters.[7] The request did not, according to the Commission, fall under the scope of the Aarhus Regulation. The Commissioner for Health and Food Safety found that, because the health assessment of GM food

1) 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, L268, at 1.

2) Implementing Decision (EU) No 2015/698 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybeans 305423 (DP-3Ø5423-1)pursuant to Regulation No 1829/2003, OJ 2015, L112, at 71; Implementing Decision (EU)2015/686 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybeans MON 87769 (MON-87769-7) pursuant to Regulation (EC) No 1829/2003, OJ 2015, L112, at 16; Implementing Decision (EU) 2015/696 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybeans MON 87705 (MON-877Ø5-6) pursuant to Regulation (EC) No 1829/2003, OJ 2015, L112, at 60.

3) Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, 25 June 1998, United Nations Treaty Series 1999, vol. 161, at 447.

4) 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, L264, at 13.

5) Article 2(1)(f) of the Aarhus Regulation.

6) Article 9 of the Aarhus Regulation.

7) General Court, 14 March 2018, T–33/16, ECLI:EU:T:2018:135.

and feed was not an environmental matter, the Aarhus Regulation did not apply, thereby invalidating the request for an internal review. Moreover, according to the Commissioner, the mere fact that the authorisation decisions were made under Regulation 1829/2003 on GM food and feed does not automatically create a right to review all aspects of those decisions, since they do not necessarily relate to environmental law.

After the Commission's refusal to review its decision, Testbiotech brought the case before the General Court, which concluded that Testbiotech could, based on the Aarhus Regulation, request an internal review of the Commission's decision and the court therefore annulled the Commission's rejection decision. The court ruled that, since the request for an internal review does relate to 'environmental law', the Aarhus Regulation applies. According to the court, the EU legislature intended to give a broad meaning to the concept of 'environmental law', as covered by the Regulation, not limited to matters relating to the protection of the natural environment in the strict sense.[8]

The court first analysed whether the authorisation decisions were acts adopted under environmental law within the meaning of the Aarhus Regulation and, second, whether the arguments submitted by Testbiotech in its request for an internal review fell within the scope of environmental law.

Considering the first aspect, the court concluded that the Commission's authorisation decisions were acts that fall within the scope of the area of environmental protection. The objective of Regulation 1829/2003 on GM food and feed, pursuant to which the Commission took its decision to allow the marketing of the GM soybeans, is to regulate human interventions that affect the environment when involving GM organisms liable to have effects on human and animal health. The court concluded conclusively that the authorisation decisions constitute acts adopted under environmental law within the meaning of the Aarhus Regulation.

According to the Commission, the arguments submitted by the applicant on the nutritional value, labelling and safety of GM products in food and feed were related to product safety and not to the state of the environment. The court considered, however, that if the Commission's reasoning were to be followed, the impact of GMOs on public health and on animal protection, such as the potential impact on nutritional value, would fall within the scope of environmental law only in the event that the cultivation took place within the European Union. Conversely, if the cultivation took place outside the European Union, those effects would not fall within the scope of environmental law. The court considered such a distinction artificial, which could undermine Article 10 of the Aarhus Regulation. Given that GMOs properly constitute an element of the environment, the provisions regulating the effect of GMOs on human or animal health also fall within the area of the environment.

As to whether the arguments submitted by Testbiotech in its request for an internal review fell within the scope of environmental law, the court considered that the Commission was required to examine Testbiotech's request for a review only in so far as it had claimed that the authorisation decisions contravened the provisions of environmental law within the meaning of the Aarhus Regulation.

The court stated that there is no provision in the Aarhus Regulation requiring the main focus of a request for a review to fall within the scope of environmental law. For an internal review, the Commission must examine any argument if the review applicant has claimed that the administrative act in question contravened provisions of environmental law within the meaning of the Aarhus Regulation, and an environmental law matter does not have to constitute the principal legal objective of the argument to be examined.

The court concluded that:

> *... environmental law, within the meaning of Regulation No 1367/2006, covers [...] any provision of EU legislation, concerning the regulation of genetically modified organisms, that has the objective of dealing with a risk to human or animal health, that originates in those genetically modified organisms or in environmental factors that may have effects on those organisms when they are cultivated or bred in the natural environment.*

This also applies to GMOs cultivated outside the European Union.

8) Ibid. at paragraph 44.

The court therefore interprets the scope of the Aarhus Regulation broadly. An NGO can ask the Commission or any other EU body to review every decision relating to GMOs. The involvement of the public and NGOs in the decision-making process of the authorisation of GMOs has been confirmed.

The court's decision complies with Article 6*bis* of the Aarhus Convention that was adopted in 2005, which requires states to provide for early and effective information and public participation prior to making decisions on whether to permit the deliberate release into the environment and placing on the market of GMOs. The Article has not yet entered into force (it requires two more ratifications), although some parties, such as Belgium,[9] have already implemented the Article in their national legal framework.

The decision further seems to follow the recommendations of the Aarhus Convention Compliance Committee, a body established within the framework of the Aarhus Convention. This Committee stated in its reports of 2011[10] and 2017[11] that the European Union fails to effectively implement the Aarhus Convention because neither the Aarhus Regulation nor the jurisprudence of the CJEU complies with the obligations in the Aarhus Convention. The Committee considered that the Aarhus Convention was not respected since there was no adequate administrative review procedure and no jurisprudence that would grant access to the public more easily than the EU Regulation allowed. According to the Committee, the scope of the internal review under the Aarhus Regulation is much stricter than the Aarhus Convention since it allows internal review only for decisions of 'individual concern',[12] a condition that is not required under the Aarhus Convention. This requirement allows any person to institute proceedings before the European courts only against an act addressed to that person or if the act is of direct and individual concern to them, and against a regulatory act which is of direct concern to them and does not entail implementing measures.

This concept has been interpreted strictly by the European courts,[13] ruling that the statutory aim of an environmental NGO to protect the environment is not enough to establish its 'individual concern'.[14] The court has explicitly stated that environmental NGOs that are qualified under the Aarhus Regulation to bring proceedings before the court must prove that the 'individual concern' criterion is met.[15] In the present case, however, the General Court allowed an NGO to request an internal review for a decision, without examining whether the NGO fulfilled the 'individual concern' requirement, which seems to be a step towards a less strict interpretation in line with the Compliance Committee's recommendations.

Furthermore, the European Court of Justice recently ruled[16] that organisms obtained by means of methods of mutagenesis are qualified as GMOs within the meaning of Directive 2001/18/EC on the deliberate release into the environment of GMOs[17] and must meet the obligations set out therein.

Simply put, mutagenesis involves a range of methods that can alter the genetic material of an organism without the insertion of foreign DNA. One of the mutagenesis methods is the well-known CRISPR-Cas9.[18]

9) Royal Decree of 21 February 2005 regulating the deliberate release into the environment as well as the placing on the market of genetically modified organisms or products containing them, Belgian Official Journal 24 February 2005.

10) United Nations, Economic Commission for Europe, Findings and recommendations of the Compliance committee with regard to communication ACC/C/2008/32 (Part I) concerning compliance by the European Union, 14 April 2011.

11) United Nations, Economic Commission for Europe, Findings and recommendations of the Compliance committee with regard to communication ACC/C/2008/32 (Part II) concerning compliance by the European Union, 17 March 2017.

12) Article 12(1) of the Aarhus Regulation and Article 263(4) of the Consolidated version of the Treaty on the Functioning of the European Union of 25 March 1957, OJ 2012, C–326, at 1.

13) More specifically, the 'Plaumann test' as first presented in CJEU, 15 July 1963, C–25/62, ECLI:EU:C:1963:17, where the court interpreted the 'individual concern' criterion strictly by stating that 'persons other than those to whom a decision is addressed may only claim to be individually concerned if that decision affects them by reason of certain attributes which are peculiar to them or by reason of circumstances in which they are differentiated from all other persons and by virtue of these factors distinguishes them individually just as in the case of the person addressed'.

14) CFI, 28 November 2005, Joined Cases T–236/04 and T–241/04, ECLI:EU:T:2005:426EEB; CJEU, 5 May 2009, C–355/08, ECLI:EU:C:2009:286.

15) CFI, 28 November 2005, Note 14 above. The Order of the Court of First Instance examined the Proposal of the Aarhus Regulation since, at the time of the Order, the Aarhus Regulation was not yet adopted.

16) CJEU, 25 July 2018, C–528/16, ECLI:EU:C:2018:583.

17) 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, L106, at 1.

18) Short for 'clustered regularly interspaced short palindromic repeats-associated protein 9'.

These organisms are, according to the court, subject to the regulatory framework of GMOs, including the obligations on risk assessments, traceability and labelling. The court made an exception for organisms obtained using techniques or methods of mutagenesis that have conventionally been used in a number of applications and have a long safety record.

Considering the General Court 's decision on the scope of the Aarhus Convention, the fact that the court did not assess the 'individual concern' condition and the Court of Justice's recent judgment on mutagenesis, it seems that the scope of public participation in the field of GMOs is interpreted very broadly. From now on, it is uncertain to what extent the Commission will, after a request for an internal review, change its initial decision following EFSA's risk assessment and conclusion that the GMO is 'as safe as its non-GM counterpart'. Nevertheless, the court's decision could have an unquestionable influence on the involvement of NGOs in the decision-making process on any aspect relating to GMOs. It could mean, for example, that an NGO could ask the Commission to review its decision to grant a market authorisation for the placing on the market of a medicine that contains GMOs.