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GROUNDS AND PRINCIPLE FOR THE REVIEW OF ADMINISTRATIVE ACTS IN ENVIRONMENTAL LAW MATTERS UNDER REGULATION NO. 1367/2006

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Judgment of the Court of Justice (Third Chamber) of 12 September 2019, — *TestBioTech eV, European Network of Scientists for Social and Environmental Responsibility eV, Sambucus eV v European Commission, Monsanto Europe, Monsanto Company, United Kingdom of Great Britain and Northern Ireland, European Food Safety Authority (EFSA),* C-82/17 P, ECLI:EU:C:2019:719

The proceedings instituted before the EU judicature against a decision rejecting the request for internal review of an administrative act cannot be founded on new grounds or on evidence not appearing in the request for review, as otherwise the requirement, in Regulation No. 1367/2006, relating to the statement of grounds for such a request would be made redundant and the object of the procedure initiated by the request would be altered.

In order to state in the manner required the grounds for conducting the review, a party requesting the internal review of an administrative act under environmental law is required to put forward the facts or legal arguments of sufficient substance to give rise to serious doubts as to the assessment made in that act by the EU institution or body.

With regard to genetically modified products (GMOs), the appeal for the annulment of the judgment of the General Court of the European Union of 15 December 2016, TestBioTech and Others v Commission (T-177/13, not published, EU:T:2016:736) - by which the General Court dismissed an action for annulment of the European Commission decision of 8 January 2013 on the internal review of the Commission Implementing Decision 2012/347/EU of 28 June 2012 authorizing the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87701 × MON 89788 (MON-877Ø1-2 × MON-89788-1) pursuant to Regulation (EC) no. 1829/2003 of the European Parliament and of the Council - is dismissed.

TestBioTech eV, the European Network of Scientists for Social and Environmental Responsibility eV and Sambucus eV are ordered to bear their own costs and to pay those incurred by the European Commission. Monsanto Europe and Monsanto Company are ordered to bear their own costs.

The case at issue concerns the Commission Implementing Decision 2012/347/EU of 28 June 2012, by which the European Commission granted Monsanto Europe with an authorization for the marketing of food, food ingredients and feed containing, consisting of, or produced from, a genetically modified soybean (MON 87701 x MON 89788).
The authorization procedure followed the rules set forth under Regulation no. 1829/2003 on genetically modified food and feed [1].

Following the authorization given to Monsanto, the appellants, TestBiotech and two others non-profit environmental organizations, submitted a request to the European Commission under Regulation No. 1367/2006 (so-called "Aarhus Regulation") on access to justice in environmental matters[2], to perform an internal review of said authorization decision.
The Commission rejected the request, considering that the authorization decision complied with Regulation No. 1829/2003.
In particular, in authorizing the place on the market of the modified soybean, the Commission considered the opinion issued by the European Food Safety Authority (EFSA), which concluded that the modified soybean was as safe as its non-genetically modified counterpart as for the potential effects on human and animal health or the environment.
In light of the Commission's decision, the appellants brought an action for annulment before the General Court. In the application for the annulment, the appellants put forward four pleas in law, alleging*: "(i) an absence of substantial equivalence between the modified soybean and its conventional counterpart; (ii) a failure to assess synergistic/combinatorial effects and toxicity; (iii) an absence of exhaustive immunological assessment; and (iv) an absence of post-market-authorisation monitoring of consumption of products containing the modified soybean*".
Thr General Court confirmed the legality of the measure contested by the appellants.
First, the General Court found that certain arguments were inadmissible on the grounds that they were not in the request for internal review. The General Court observed, in this regard, that under Regulation No. 1367/2006 a request for internal review of an administrative act made to an institution that adopted it under environmental law "*must specify which act is being challenged and state the grounds for conducting the review*". Furthermore, a third party challenging an administrative act is required to bring to the attention of the EU body which granted it, any facts or legal arguments raising serious doubts about the assessment made and substantial evidence as to the lawfulness of the measure itself.
On the other side, working on the practical application of the precautionary principle in the case at issue, the General Court held the following milestones on the scope and standard for the internal review of administrative act in environmental matters.
1. So far as concerns the scope of the judicial review of a decision rejecting a request for internal review of an administrative act as unfounded, the General Court held that, despite the review carried out by the court in respect of a discretionary measure may face limitations - due to the fact that the Court's role is not to substitute the assessment of the institution which adopted the decision – the Court is nevertheless bound by the fundamental principles of the EU legal order in administrative procedure, in addition to the precautionary principle in the Aarhus Convention, which imposes far more attention and respect of the party's guaranteed rights.
2. In the light of the precautionary principle, on the evidentiary rules the Court highlighted that, contrary to the Commission's assertions in its Implementing Decision, a party cannot be required *'[to] prove that the [authorisation] decision is in breach of Regulation (EC) No 1829/2003'; rather, it must provide a set of material raising serious doubts as to the lawfulness of the authorisation decision*". This way the Court confirmed the remit of the Commission in the internal review procedure, where it is required to examine all relevant information and not only the evidence provided by the party requesting the review.
3. It follows from the above that, before granting a marketing authorization, the Commission shall make use of its discretion to identify where the conditions laid down in Regulation No. 1829/2003 have been met, taking into account the EFSA's opinion, but without being bound by it in adopting its decision, as the responsibility for determining the level of risks deemed as acceptable lies with the institution responsible for the political choice, which shall be bound by the general principles of EU law, including the precautionary principle, to ensure a high level of human health protection (note: not the highest level technically possible!).
4. As a result, the guidance documents provided for by EFSA does not bind the Commission, "*although it is certainly possible that it may opt to apply them as an assessment framework in the cases brought before it*." Therefore, a party can neither rely on the infringement of the documents transmitted by EFSA to the Commission, nor rely on the expectation that EFSA will act in accordance with its own guidance issued pursuant to Regulation No. 1829/2003.

Coming after, as regards the toxicity assessment of the product at issue, the Court held that it had not been demonstrated that the Commission made a manifest error, nor it had been explained when a toxicity assessment shall be considered "appropriate" and on which grounds, so to allow a scrutiny of the action of the Commission.
Finally, as regards the potential application of Regulation No. 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin, the Court stated that "*tests and adjustments made to establish maximum residue levels for the modified soybean (…) should be done as part of an examination under that regulation and not under Regulation No 1829/2003*."
Taking into considerations the above, the General Court examined the various pleas in law, finding that the action must be rejected as partly ineffective and partly inadmissible and, for the remainder, as unfounded[3].
An appeal was brought before the Court of Justice against the decision of the General Court.
The appellants contended that the General Court erred in dismissing the applicants' arguments and evidence as inadmissible, because they were not contained in the request for review, as well as in applying an impossible burden of proof on them, in failing to recognize that the guidance documents issued by EFSA had given rise to a legitimate expectation; in not requiring compliance with the safety assessment required by Regulation No. 1829/2003, and in dismissing their complaint (on the grounds of Regulation No. 396/2005) that the Commission did not require neither a full examination of the toxicity of the soybean, nor a monitoring of its impact after the issue of the authorization.
By the judgement at issue, the Court first stated that a proceedings brought before a EU Court against a decision rejecting a request for internal review cannot be found on new grounds or evidence not appearing in the request for review - contrary to the applicants' arguments - otherwise the requirements set forth in Regulation No. 1367/2006 would be redundant and the object of the procedure would be altered.
Next, the Court faced a number of alternative arguments brought forward by the appellants against the decision of the General Court not to take into account the evidence in support of their pleas on the basis that certain items of evidence were vague, unclear, or not coherently and intelligibly stated.
As for the second ground of appeal, regarding the burden of proof on a party in requesting the internal review of an administrative act, the Court of Justice explained, that "*it is inherent in the system of review that the party requesting the review provides concrete and precise grounds which might be able to call into question the assessments on which the authorization decision is based.*"
Accordingly, the General Court was correct in holding that, "*a party requesting the internal review of an administrative act under environmental law is required to put forward the facts or legal arguments of sufficient substance to give rise to serious doubts as to the assessment made in that act by the EU institution or body*".
On the third ground of appeal, concerning whether a party may rely on EFSA's guidance in a request for review under Regulation no. 1367/2006, the Court of Justice highlighted that the General Court correctly drew its conclusion on the basis that the guidance to be provided by EFSA is conceived to assist the applicant in the preparation of the application, being "*aimed at structuring the pieces of information that an applicant is required to provide*" and "*not to confer on a third party, such as TestBioTech, a right to require that certain information be provided at that time*".
As per the fourth ground of appeal, by which the appellants alleged errors of law relating to the safety assessment provided for under Regulation No. 1829/2003, the Court of Justice remarked that "*whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself, since* [it] *does not preclude the scope of the toxicity assessment from being determined on a case-by-case basis*". Nor the approach of the General Court is contrary to the law, according to which the application shall be accompanied by "*either an analysis, supported by appropriate information and data, showing that the characteristics of the food are not different from those of its conventional counterpart, having regard to the accepted limits of natural variations for such characteristics (…) or a proposal for labelling*".
Eventually, the Court found also the fifth ground of appeal unfounded. Indeed, despite acknowledging that Regulation No. 1829/2003 provides that genetically modified feed must not

have adverse health effects, the Court underlined that no provision of that regulation requires the effects connected with any pesticide use to be examined in the course of the procedure for authorizing a GMO.
As none of the grounds of appeal has been upheld, the appeal was dismissed in its entirety.
The judgment under exam leaves a number of open issues on the practical implications for non-governmental organizations in judicial proceedings following a rejection of a request for internal review under Regulation No. 1367/2006.
Indeed, it is clear that the Court of Justice requires – at least - that (i) judicial proceedings are not instituted on grounds or evidence not included in the request for internal review, and that (ii) an applicant is required to put forward facts or legal arguments of sufficient substance to give rise to serious doubts as to the assessment made by the EU institution.
However, based on the conclusions drew by the Court with respect to the burden of proof that the NGOs should have met, what the Court of Justice may effectively consider "*of sufficient substance to give rise to serious doubts as to the assessment made in that act by the EU institution*" remain vague.

[1] 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 L 268, 18.10.2003, p. 1–23).
[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 L 268, 18.10.2003, p. 1–23).
[3] On the substance, in a nutshell the Court stated that it had not been demonstrated that the Commission had confirmed the authorisation of the modified soybean without ensuring that an appropriate risk assessment of the 'highest possible standard' had been carried out. Secondly, nor that the Commission had infringed its obligation, to ensure that food and feed that would have an adverse effect on human and animal health or the environment must not be placed on the market; that it had not fulfilled the obligation to take into account any relevant provisions of EU law; that it had not observed its obligation to ensure a high level of protection for human health; and that it had failed to meet the legitimate expectations of the applicants.