THE GMO AUTHORIZATION PROCEDURE IN EU: INCLUSIVITY, ACCESS TO JUSTICE AND PARTICIPATION IN DECISION-MAKING*.

by Giada Ragone**

Summary. 1. Introduction. – 2. Framing the criticisms of the GMO authorization process. – 3. Internal review and access to justice for non-governmental organisations under Title IV of the Aarhus Regulation: did it open a door for greater inclusivity in GMO authorization procedure?. – 4. A—small—novelty in EU case-law: "*TestBiotech and others v Commission*". – 4.1. A step forward or backward for NGOs' standing and participation? – 4.2. The merit of the decision and the impossibility to review the scientific basis of authorization decisions. – 5. Could the Sustainable Development debate foster greater inclusivity in the GMO authorization process in the European Union?

1. Introduction.

The present paper addresses whether the principles of inclusivity, access to justice, and participation in decision-making are adequately respected within the context of the Genetically Modified Organisms (GMO) authorization procedure put in practice by the European Union.

As it is well known, the problem with GMO authorization is deeply divisive for UE States. The European Commission complained that, in recent years, it has been often obliged to adopt several acts concerning the authorization of GMOs, despite its Member States being unable to take a shared position, either in favor of or against the decisions[1].

This comes as no surprise, since GMOs represent a sensitive issue for a number of reasons: among others, they raise huge scientific and technical questions and uncertainties, especially on potential risks for human health and the environment. As for the former, anti-GMO activists are concerned about the unpredictable effects of these organisms in terms of allergies, damages to the immune system, resistance to antibiotics and so forth; on the

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[1] See European Commission '*Comitology: Commission Proposes More Transparency and Accountability in Procedures for Implementing EU Law'*, Press Release, 14 February 2017.
Available online at: http://europa.eu/rapid/press-release_IP-17-264_en.htm.

other hand, GMO supporters consider the possibility of modifying foods, fortified with vitamins and nutrients, as an opportunity to fight malnutrition and disease, especially in developing countries.

With regard to environmental risks, the main concerns are about the maintenance of biodiversity, the risk of contamination between traditional and biotech cultures, and the unpredictable effects on the ecosystems. However, GMOs can also be seen as environmentally friendly since their plantation is capable of conserving water, soil, and energy more than the traditional farming systems. This is not the place to take a position on these different opinions; it is sufficient to point out that the scientific debate is still ongoing and it seems far from quieten.

Beyond the scientific realm, the GMO scope is controversial also because the regulation of agricultural biotechnology collides with the interests of heterogeneous stakeholders: the need for food safety and food security, the right to health, consumer rights, economic and trade interests, environmental protection, and so forth[2].

Given the relevance of the interests at stake and the divisiveness of the issue, GMO-related decisions have been defined by doctrine as "the quintessential type of decision that the public has an explicitly stated desire to participate in"[3]. In this field, more than in others, respecting the principles of inclusivity, access to justice, and participation in decision-making would increase the degree of democracy in deliberations and the opportunity for citizens to influence their own lives and future.

Being aware of these issues, European Commission has recently pointed out the need for a higher level of transparency in the procedures concerning politically sensitive matters of direct impact on citizens and businesses, especially in the field of safety of humans, animals or plants. This resulted in the proposal for a regulation that is still in the legislative process,

[2] The legal literature on these issues is huge and varied. See among the others, C. Lawson, *Intellectual property and genetically modified organisms: a convergence in laws*, Routledge, 2016; V.H. Peters, *The Health Consequence of Genetically Modified Organisms and Lack of Regulation: Genetically Engineered Food Linked to Rise in Autism Prevalence*, in *Sustainable Dev. L. & Pol'y*, 2014, pp. 21-22; S. Johnson, *Genetically Modified Food: A Golden Opportunity*, in *Sustainable Dev. L. & Pol'y*, 2014, pp. 34 and 69; H.T. Anker and M. Rosso Grossman, *Authorization of Genetically Modified Organisms: Precaution in US and EC Law*, in *European Food and Feed Law Review*, 2009, pp. 3-22; B. Koch, *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops*, Springer, 2008; C.G. Gonzalez, *Genetically Modified Organisms and Justice: The International Environmental Justice Implications of Biotechnology*, in *Geo. Int'l Envtl. L. Rev*., 19, 2007, pp. 583-.642; D. Winickoff, S. Jasanoff, L. Busch, R. Grove-Whiteand B. Wynne, *Adjudicating the GM food wars: science, risk, and democracy in world trade law*, in *The Yale Journal of International law*, 30, 2005, pp. 81-123.

[3] T. Etty, *Biotechnology*, in *The Yearbook of European Environmental Law*, 5, 2005, p. 314.

which aims at amending the decision-making procedures concerning the abovementioned areas[4].

Usually, public participation, access to judicial and administrative proceedings are considered essential to the promotion of Sustainable Development[5]. This is clearly affirmed in the Plan of implementation of the 2002 World Summit on Sustainable Development, which states that all countries should promote access to justice and inclusivity regarding legislation, regulations, activities, policies and programmes[6], and such principles are underpinned in several goals of the 2030 Agenda for Sustainable Development [7], especially SDG 16[8]. Moreover, respecting them should be prioritized in the field of environment-related decisions, as those on GMOs. To this regard, it is worth remembering that the UN Rio Declaration on Environment and Development[9], which sets the general principles for the environmental policies of XXI century, states: «Environmental issues are best handled with the participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, […]. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided»[10].

For these reasons, the GMO authorization procedure is an interesting field for the implementation of the main principles embedded in SDG 16 of the 2030 Agenda for Sustainable Development, whose realization will still take the next 10 years to happen. This paper will explore the extent to which the GMO case benefited from the approval of

[4] Proposal 2017/0035 (COD) for a Regulation of The European Parliament and of The Council amending Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers. On this point, see M. Mühlböck – J. Tosun, *Responsiveness to Different National Interests: Voting Behaviour on Genetically Modified Organisms in the Council ofthe European Union*, in JCMS, no. 2/2018, pp. 385-386.

[5] See paragraph no. 43 of the Resolution A/RES/66/288 "The Future We Want" adopted by the UN General Assembly on 27 July 2012, here available: http://www.un.org/en/development/desa/population/migration/generalassembly/docs/globalcompact/A_RES_66_288.pdf

[6] See Report of the World Summit on Sustainable Development, Johannesburg, South Africa, 26 August-4 September 2002, chapter XI, paragraphs no. 162-167.

[7] As it is well-known, the 17 Sustainable Development Goals (SDGs) of the 2030 Agenda for Sustainable Development were adopted by World leaders in September 2015 at a United Nation Summit and they officially came into force on 1 January 2016. See the Resolution adopted by the General Assembly on 25 September 2015, A/res/70/1. Transforming our world: the 2030 Agenda for Sustainable Development.

[8] SDG 16 promotes just, peaceful and inclusive societies.

[9] See annex I to the Report of the United Nations Conference on Environment and development, Rio de Janeiro, 3-14 June 1992, A/CONF.151/26 (Vol. I), here available: http://www.un.org/documents/ga/conf151/aconf15126-1annex1.htm.

[10] See Principle no. 10.

Regulation (EC) no. 1367/2006 of the European Parliament and of the Council of 6 September 2006, which implemented the Convention on access to information, public participation in decision-making, and access to justice in environmental matters (the s.c. Aarhus Convention)[11] in the European legal framework[12].

The analysis evaluates the efficacy of a binding legal instrument—the Aahrus Regulation—in pursui.ng some of the pivotal aims embedded in SDG 16, albeit just in the environmental context[13] SDG 16 is one of the most challenging goals to be achieved, as it requires «promot[ing] peaceful and inclusive societies for Sustainable Development, provid[ing] access to justice for all and build[ing] effective, accountable and inclusive institutions at all levels». In order to concretely fulfill such objectives, it is essential to adopt—at international, national, or, in the European case, supranational level—policies, binding rules and mechanisms designed for the legal background and the institutions of the relevant framework. Rules implementing SDG 16's values must be, let us say, *customized* for each different context; otherwise, these values will be confined to abstract ideals, lost in the complexity of societies and their institutional apparatuses.

Moving from this perspective, the paper proceeds as follows: first, it frames the main criticisms of the European GMO authorization procedure (par. 2). Then it explores the extent to which the adoption of Regulation no. 1367/2006 (par. 3) and the following EU case-law (par. 3) can be considered relevant towards the implementation of the principles of inclusivity, access to justice, and participation in decision-making in the GMO case. Finally, the paper addresses whether the approval of the UN Agenda 2030, and especially of Sustainable Development Goal 16, could possibly foster a greater implementation of the mentioned principles with regard to the selected case-study.

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[11] Aarhus, 25 June 1998, entered into force 30 October 2001.For further details, see, among the others, S.T. McAllister, *The Convention on Access to Information, Public Participation in Decision-Making, and Access to Justice in Environmental Matters*, in *Colo. J. Int'l Envtl. L. & Pol'y*, 1999, p. 187; M. Lee and C. Abbot, *The usual suspects? Public participation under the Aarhus Convention*, in *Modern Law Review*, 66, 2003, p. 80; M. Pallemaerts (ed.), *The Aarhus Convention at Ten: interactions and tensions between conventional international law and EU environmental law*, Europa law publishing, 2011.

[12] Before the Aarhus Regulation, the European Union adopted some Directives (2003/4/EC on public access to environmental information, repealing Council Directive 90/313/EEC; 2003/35/EC, providing for public participation in the drawing up of certain plans and programmes relating to the environment and amending with respect to public participation and access to justice Council Directives 85/337/EEC 96/61/EC) that ensure the harmonized transposition of the Aarhus Convention into the national laws of the Member States, only in relation to the first two pillars of the Convention.

[13] The rights in the Aarhus Convention are applied to an environmental context, however they are by no means confined of that context, since the rights also clearly derive from human rights law which has a more general application.

2. Framing the criticisms of the GMO authorization process.

In order to assess the current progress of the European GMO authorization procedure, it is essential to highlight the original sins of this proceeding: the lack of inclusivity in the scientific assessment, and the marginal role given to public opinion as well as the opinion of all Member States[14] in the decision-making. This last issue is even more problematic when one bears in mind the strict interpretation provided by the Court of Justice about the conditions that allow Member States to adopt emergency measures against GMOs after their approval[15]. A recent example of the high standard of proof required for such measures is provided by the *Fidenato et al* judgment of 2017[16].

According to the current EU legal framework[17], every variety of GMO must follow an

[14] The Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amended the original authorization procedure (set by Directive 2001/18/EC) in order to increase the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory. Nonetheless, as the posterior praxis and case-law show, this intervention could not be considered determined for the criticisms mentioned.

[15] On this point see E. Corcione, *Emergency Measures Against GMOs between Harmonizing and De-harmonizing Trends: The Case Fidenato et al*, in *European Papers*, 3, 2018, pp. 345-356.

[16] Court of Justice, judgment of 13 September 2017, case C-111/16, *Fidenato et al*. Under this decision, States cannot rely on the precautionary principle to exclude the cultivation of authorized GMOs within their territories, pursuant to Article 34 of Regulation 1829/2003.

[17] In the EU framework, the main legal acts regulating GMOs are: Directive 2001/18 on the deliberate release into the environment of genetically modified organisms, as modified by Directive 2015/412; Regulation 1829/2003 on genetically modified food and feed; and Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms. For a broader analysis of this legal framework within the Italian literature see, *ex multis*: L. Marini, *Principio di precauzione, sicurezza alimentare e organismi geneticamente modificati nel diritto comunitario*, in *Diritto dell'Unione Europea*, 2004, p. 7 ff.; R. Ferrara and I.M. Marino (ed.), *Gli organismi geneticamente modificati. Sicurezza alimentare e tutela dall'ambiente*, Padova, 2003; C. Casonato and M. Berti (ed.), *Il diritto degli OGM tra possibilità e scelta*, Alcione, 2006; L. Scaffardi, *Principio di precauzione e ingegneria genetica nella catena alimentare*, in R. Bifulco and A. D'Aloia (ed.), *Un diritto per il futuro*, Jovene, 2008, p. 666 ff.; A. Venturi, *Analisi del rischio e sicurezza alimentare. I fondamenti, le controversie, la regulation*, Guerini e ass., 2008; F. Rossi dal Pozzo, *Profili recenti in tema di organismi geneticamente modificati nel settore agroalimentare fra procedure di comitato e tutela giurisdizionale*, in *Diritto del Commercio Internazionale*, 2, 2014, p. 339 ff.; A. Rinella and C. Pungitore, *Organismi geneticamente modificati. Profili di diritto comparato ed europeo*, Filodiritto, 2015; L. Chieffi, *L'impiego delle biotecnologie nel campo agroalimentare tra insuperati pregiudizi e aspettative di sfruttamento economico*, in *Diritto Pubblico Europeo - Rassegna On-line*, n. 1/2015, p. 24 ff.; G. Ragone, *La disciplina degli OGM tra Unione Europea e Stati nazionali: a chi spetta il diritto all'ultima parola su questioni scientifiche controverse?*, in *BioLaw Journal*, n. 1/2015, pp. 115-130; P. Costanzo (ed.), *Organismi geneticamente modificati. Una prospettiva giuridica*, Genova University Press, 2016; G. Ragone, *L'Italia e la questione OGM alla luce della recente normativa UE*, in G. Cerina Feroni, T.E. Frosini, L. Mezzetti and P.L. Petrillo (ed.), *Ambiente, energia, alimentazione. Modelli giuridici comparati per lo sviluppo sostenibile*, Cesifin, 2016, pp. 381-391; S. Pitto, *La legittimità delle limitazioni statali agli alimenti OGM alla luce del*

application procedure to obtain authorization for cultivation, import, use, and placement on the market as food or feed. Regardless of the country where the applicant (i.e. the GMO owner) applies for such authorization, his request is processed through a centralized procedure conducted at the European level consisting of two phases: risk assessment and risk management.

The first criticism of the procedure arises at step one: the scientific (or risk) assessment. This phase is mainly conducted by the European Food Safety Authority (EFSA)[18], which is asked to give an opinion on the potential impact of each GMO product on human health, animal health, and the environment. Under Articles 6(7) and 18(7)[19] of Regulation on genetically modified food and feed[20], the public has a 30-day period to comment to the Commission on the opinion expressed by EFSA. However, these articles "appear rather symbolic, as they are typically articulated as 'soft-obligation'"[21]: indeed there are non-binding obligations for the Commission to take public comments into consideration. In some cases, depending on the content of the application submitted by the GMO owner, it happens that national risk advisors are involved in the risk assessment process to varying degrees, from consultation to carrying out an environmental risk assessment[22]. However, many national authorities perceive that, when they are involved, the Authority's risk assessments do not take their comments into adequate consideration: "although legally EFSA has not been granted a superior authority over national scientific authorities, in practice the EFSA's GMO Panel tends to assert scientific authority by overriding national safety concerns"[23].

principio di precauzione, in *DPCE Online*, n. 1/2018; G. Ragone and B. Vimercati, *La sovranità alimentare nei processi di integrazione europea: il caso degli OGM*, in A. Pérez Miras, E.C. Raffiotta G.M. Teruel Lozano and F. Vecchio (ed.), *Sovranità e rappresentanza. Stato, autonomie territoriali e processi di integrazione sopranazionale*, Editoriale Scientifica, 2018, pp. 155-172.

[18] See Regulation (EC) No 178/2002 of the European Parliament and of The Council of 28 January2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

[19] According to Articles 6(7) and 18(7), «The Authority, in conformity with Article 38(1) of Regulation (EC) No 178/2002, shall make its opinion public, after deletion of any information identified as confidential in accordance with Article 30 of this Regulation. The public may make comments to the Commission within 30 days from such publication».

[20] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.

[21] See T. Etty, *ibidem*, p. 292.

[22] Sometimes, this involvement is mandatory, in other cases, it is at the discretion of EFSA. See M. Lee, *ibidem*, 226.

[23] M. Weimer, *Risk Regulation in the Internal Market: Lessons from Agricultural Biotechnology*, Oxford University Press, 2019, p. 120.

The *de facto* superiority of EFSA's opinions over national scientific research on GMOs has also been confirmed by the European Union Courts case-law. A good example is offered by the case *Land Oberösterreich and Austria v Commission*. In two distinct judgments,[24] both the General Court and the Court of Justice declined to reverse the Commission's decision[25] to turn down the request made by the *Oberösterreich*, an Austrian region which wanted to create a GMO-free zone, banning all varieties approved at the EU level.[26] The Austrian initiative based on Article 114 (5) TFEU reads: «if, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to introduce national provisions based on *new scientific evidence relating to the protection of the environment* or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them».

According to the Austrian scientific evidences[27], considering the specific features of *Oberösterreich*'s territory, the ban was necessary to protect organic agriculture from GMO contamination, and to preserve biodiversity, as well as the environment[28]. The EFSA was then required to evaluate the Austrian report and concluded that the data failed to prove the existence of *new* scientific evidence jeopardizing the protection of the environment. Relying on the EFSA's dismissal of the Austrian evidence, the Commission declared the ban illegitimate. It is worth noting that the requirement of *new evidence* is very limiting for national authorities because it implies that their requests cannot be based upon *old* evidence

[24] See judgment of the Court of First Instance (Fourth Chamber) of 5 October 2005, *Land Oberösterreich and Republic of Austria v Commission of the European Communities*, joined cases T-366/03 and T-235/04; and, and Judgment of the Court (Third Chamber) of 13 September 2007, *Land Oberösterreich and Republic of Austria v Commission of the European Communities*, appeal, joined cases C-439/05 P and C-454/05 P.

[25] Commission Decision of 2 September 2003 relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty, (2003/653/EC): https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:230:0034:0043:EN:PDF.

[26] The national provisions on banning the use of GMOs in *Oberösterreich* was notified by Austria pursuant to Article 95(5) of the EC Treaty.

[27] Austria presented a scientific dossier "*GVO-freie Bewirtschaftungsgebiete: Konzeption und Analyse von Szenarien und Umsetzungsschritten*", also called "*Müller report*" from the name of the ecological risk researcher tasked to write it: "https://www.keine-gentechnik.de/bibliothek/zonen/studien/mueller_gvo_frei_bewirtschaftung_020428.pdf".

[28] It is worth noting that the Commission considered the Austrian concerns about the coexistence of traditionally and GM crops as an economic issue, rather than environment related. The same arises from the Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming (notified under document number C(2003) 2624).

that was not taken into account by the EFSA during its risk assessment[29].

The second point of criticism of the authorization process relates to risk management. On the basis of the EFSA's opinion, the European Commission and the Standing Committee on the Food Chain and Animal Health (SCFCAH)[30], which is composed of representatives of Member States, decide whether to authorize a product. Actually, the role of the Standing Committee has always been irrelevant in this proceeding; due to harsh political divisions among the Member States over GMOs, the Committee never reached the qualified majority required to deliver an opinion[31]. Therefore, the European Commission alone has always had the final word on authorization, cultivation, and consumption of GMOs in Europe. And despite the fact that the Commission's decision is not bound by the EFSA's opinion but must take other considerations into account, the Commission's final word has always been aligned with the Authority's opinion. Indeed, it is not so easy for the European Commission to defy EFSA's evaluation: under *Pfizer Animal Health SA v Council of the European Union*[32], "the justifications for diverging from such an opinion 'must be of a scientific level at least commensurate with that of the opinion in question', and the Commission simply does not command the resources to provide the strong scientific basis for an objection that would be legally required."[33] Therefore, "not the Commission, but rather EFSA itself may in a sense be seen as the *de facto* risk manager"[34] in the process of GMO authorization.

Also, beyond the GMO case, agencies with technical tasks and expert committees play a key role within the system of European governance, not only in terms of legislative processes, but also with respect to the judicial protection of fundamental rights. The literature has largely demonstrated how agencies and expert committees have become a key element in the EU policy-making processes and that these bodies make vital

[29] See M. Lee, *ibidem*, p. 228; On the too intensive scrutiny applied by EU Courts to scientific data produced by Member States, see M. Doherty, *The application of article 95(4)-(6) of the EC Treaty: is the emperor still unclothed?*, in *Yearbook of European Environmental Law*, 7, 2008, pp. 57-58.

[30] Known also as the Standing Committee on Plants, Animals, Food and Feed ("PAFF" Committee).

[31] See T. Christiansen and J. Polak, *Comitology between political decision-making and technocratic governance: regulating GMOs in the European Union*, in *Eipascope*, n. 1/2009, p. 6.

[32] Judgment of the Court of First Instance (Third Chamber) of 11 September 2002, *Pfizer Animal Health SA v Council of the European Union*, Case T-13/99. Par. no. 199 reads: «to the extent to which the Community institution opts to disregard the opinion [of a committee of experts], it must provide specific reasons for its findings by comparison with those made in the opinion and its statement of reasons must explain why it is disregarding the latter. The statement of reasons must be of a scientific level at least commensurate with that of the opinion in question».

[33] See T. Christiansen and J. Polak, *ibidem*, p. 8.

[34] *Ibidem*, p. 9.

contributions to the shaping of legislations[35]. Nonetheless, the described *scientification* of the GMO authorization process and the central role of the EFSA's opinions have been criticized by scholarship[36]. Indeed, the focus on the Agency's outcomes diminishes the relevance of other factors that the European Commission should take into proper account, i.e. competing evidence from Member States, environmental or consumer groups, or other legitimate factors (societal, economic, traditional, or ethical). The consideration of these factors is required by Regulation 178/2003[37], which sets forth the general principles and requirements of food law. As noted in literature[38], among the "other legitimate factors" the public's formal comments might also be included. However, "this is by no means evident, neither is, more generally, what determines the […] *legitimacy* of such other factors, which could conceivably include (widespread) public opinion"[39].

3. Internal review and access to justice for non-governmental organisations under Title IV of the Aarhus Regulation: did a door open for greater inclusivity in GMO authorization procedure?

After ratifying the Aarhus Convention in 2005[40], the European Union adopted Regulation no. 1367/2006 (the Aarhus Regulation)[41], which implemented within the EU framework the provisions and principles of the Aarhus Convention – drafted with their application to the supranational institutions and bodies of the Union in mind[42]. These institutions and

[35] Among the others, see R. Dogan, *Comitology: little procedures with big implication*, in *West European Politics*, 1997, pp. 31-60 and more recently M. Everson, C. Monda and E. Vos, *European agencies in between institutions and Member States*, Wolters Kluwer, 2014.
[36] See M. Weimer, *ibidem*; p. 116; E. Vos, *The European Court of Justice in the face of scientific uncertainty and complexity*, in M. Dawson, B. de Witte and E. Muir (ed.), *Judicial activism at the European Court of Justice*, Edward Elgar Publishing, 2013, p. 142; M. Everson and E. Vos, *Scientification of politics or politicisation of science?*, in Id. (ed.), *Uncertain risks regulated*, Routledge/Cavendish Publishing, n. 1/2009, p. 17.
[37] See Preamble 19.
[38] See T. Etty, *ibidem*, p. 292, note 34.
[39] *Ibidem*.
[40] The Decision on conclusion of the Aarhus Convention by the European Union was adopted on 17 February 2005: see Decision 2005/370/EC.
[41] Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:264:0013:0019:EN:PDF
[42] "As the provision of the Convention were drafted primarily with a view to their application to national public authorities, negotiators were aware that applying them to the supranational institutions of the Community […] might give rise to certain difficulties of a legal and institutional nature" (see M. Pallemaerts, *Access to environmental justice at EU level. Has the 'Aarhus Regulation' improved the situation?*, in Id. (ed.), *The Aarhus Convention at Ten*, 273).

bodies are thus required to make arrangements for early and effective opportunities for the public to participate in the preparation, modification, or review of acts, plans, and programs relating to the environment[43].

The two main innovations provided by the Regulation are included in Title IV; they consist of new participative instruments for environmental non-governmental organisations (NGOs), i.e. internal review and access to justice[44].

The first is a special administrative review procedure, accessible to environmental NGOs meeting given criteria[45], enabling them to make a request for internal review of administrative acts and omissions of European institutions and bodies (art. 10)[46], The institutions must consider any such request and state their reasons in a written reply as soon as possible.

The second innovation entails the possibility for NGOs to institute proceedings before the Court of Justice (art. 12). According to this provision,

«1. The non-governmental organisation which made the request for internal review pursuant to Article 10 may institute proceedings before the Court of Justice in accordance with the relevant provisions of the Treaty. 2. Where the Community institution or body fails to act in accordance with Article 10(2) or (3)[47] the non-governmental organisation

[43] Beyond the environmental context, it is worth remembering that public access to information and transparency in decision-making are EU general principles. A specific application of these principles is the "Right of access to documents", established by article 42 of the Charter of Fundamental Human Rights.

[44] See M. Pallemaerts, *ibidem*, p. 274 ff.

[45] According to Article 11 of the Regulation, «A non-governmental organisation shall be entitled to make a request for internal review in accordance with Article 10, provided that: (a) it is an independent non-profit-making legal person in accordance with a Member State's national law or practice; (b) it has the primary stated objective of promoting environmental protection in the context of environmental law; (c) it has existed for more than two years and is actively pursuing the objective referred to under (b); (d) the subject matter in respect of which the request for internal review is made is covered by its objective and activities».

[46] Article 10: «1. Any non-governmental organisation which meets the criteria set out in Article 11 is entitled to make a request for internal review to the Community institution or body that has adopted an administrative act under environmental law or, in case of an alleged administrative omission, should have adopted such an act. Such a request must be made in writing and within a time limit not exceeding six weeks after the administrative act was adopted, notified or published, whichever is the latest, or, in the case of an alleged omission, six weeks after the date when the administrative act was required. The request shall state the grounds for the review. 2. The Community institution or body referred to in paragraph 1 shall consider any such request, unless it is clearly unsubstantiated. The Community institution or body shall state its reasons in a written reply as soon as possible, but no later than 12 weeks after receipt of the request. 3. Where the Community institution or body is unable, despite exercising due diligence, to act in accordance with paragraph 2, it shall inform the non-governmental organisation which made the request as soon as possible and at the latest within the period mentioned in that paragraph, of the reasons for its failure to act and when it intends to do so. In any event, the Community institution or body shall act within 18 weeks from receipt of the request».

[47] See the previous note.

may institute proceedings before the Court of Justice in accordance with the relevant provisions of the Treaty».

Two Commission decisions further implemented the Aarhus Regulation: Decision 2008/50/EC[48] and Decision 2008/401/EC[49]. The first sets detailed rules regarding requests for the internal review of administrative acts; it specifies the evidence to be provided by NGOs, the time frame within which a reply to the application should occur, and it also highlights cooperation between European institutions and bodies. Among other innovations, Decision 2008/401/EC assigns clear responsibilities and decision-making powers to the appropriate bodies or persons within the Commission with respect to provisions of the Regulation concerning requests for internal review.

Although internal review and the possibility of access to justice for NGOs are conceived to protect the particular interests of qualified organizations concerned about specific acts (or omissions), their use can affect a more extensive number of stakeholders; indeed, "environmental interests […] are, by their very nature, collective and diffuse"[50]. And considering that NGOs are in essence representative of widespread interests, the instruments provided by the Regulation may theoretically contribute to the ideal of inclusivity, public participation, and access to justice regarding administrative acts in the environmental context, such as GMO authorizations. For these reasons, the Aahrus Regulation was welcomed by the first commentators as a "significant development in the field of environmental democracy and procedural rights to the environment"[51]. Unfortunately, despite their potential, the use and the efficacy of internal reviews and mechanisms of access to justice have been quite unsatisfactory for many years, and in some respects the situation is still unchanged today.

As for the internal review procedure, it must be noted that, "most requests for internal review filed by environmental NGOs were rejected by the EU institutions. In most instances, it is upheld that the contested acts are not of 'individual scope' and,

[48] Commission Decision of 13 December 2007 laying down detailed rules for the application of Regulation (EC) no. 1367/2006 of the European Parliament and of the Council on the Aarhus Convention as regards requests for the internal review of administrative acts.

[49] Commission Decision of 30 April 2008 amending its Rules of Procedure as regards detailed rules for the application of Regulation (EC) No 1367/2006 of the European Parliament and of the Council 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 institution and bodies.

[50] M. Pallemaerts, *Ibidem*, p. 300.

[51] T. Crossen and V. Niessen, *NGO standing in the European Court of Justice. Does the Aarhus Regulation open the door?*, in *Reciel*, 16 (3), 2007, p. 332.

consequently, they do not constitute measures for which internal review is foreseen"[52]. A step towards broader access to it was made in 2012 with the judgements *Vereniging Milieuudefensie*[53] and *Stichting Natuur en Milieu*[54]. On these occasions, the General Court ruled that restricting the measures of *individual scope* established by the Aarhus Regulation is incompatible with the Aarhus Convention[55], given that most of the environmental measures are of general application. However, this rather liberal approach of the EU case-law to the Aarhus Convention did not last long[56]. In 2015, the European Court of Justice[57] overruled the General Court, establishing that the Convention cannot be used as a benchmark for a legal review of the Aarhus Regulation.

In 2016, ten years after the Regulation was enacted, requests for internal review were lodged with the European Commission pursuant to Article 10 of Aarhus Regulation[58] in only 35 cases, six of which concerned the authorization of GMO products. Most of the time, requests not considered inadmissible were rejected following an examination of the merits[59]. One of the first applications[60] rejected on the merits came from Justice & Environment, a network of public interest environmental law organizations meeting the criteria set forth in articles 10 and 11 of the Aarhus Regulation for an NGO to be able to submit a request for internal review. Dated December 3, 2007, it concerned three Commission Decisions[61] authorizing the placing of genetically modified maize on the

[52] H. Schoukens, *Access to Justice in Environmental Cases after the Rulings of the Court of Justice of 13 January 2015: Kafka Revisited?*, in *Utrecht Journal of International and European Law*, 31(81), 2015, 47.
[53] Judgment of the General Court (Seventh Chamber) of 14 June 2012, *Vereniging Milieudefensie and Stichting Stop Luchtverontreiniging Utrecht v European Commission.*, Case T-396/09.
[54] Judgment of the General Court (Seventh Chamber), 14 June 2012, *Stichting Natuur en Milieu and Pesticide Action Network Europe v European Commission,*, Case T-338/08.
[55] And in particular with its Article 9(3), that reads: «each Party shall ensure that, where they meet the criteria, if any, laid down in its national law, members of the public have access to administrative or judicial procedures to challenge acts and omissions by private persons and public authorities which contravene provisions of its national law relating to the environment».
[56] H. Schoukens, *Articles 9(3) and 9(4) of the Aarhus Convention and access to justice before EU Courts in environmental cases: balancing on or over the edge of non-compliance?*, in *European Energy and Environmental Law Review*, 2016, p. 179.
[57] See judgment of the Court (Grand Chamber) of 13 January 2015, *Council of the European Union and European Commission v Stichting Natuur en Milieu and Pesticide Action Network Europe*, joined Cases C-404/12 P, C-405/12 P; and judgment of the Court (Grand Chamber) of 13 January 2015, *Council of the European Union and Others v Vereniging Milieudefensie and Stichting Stop Luchtverontreiniging Utrecht*, joined Cases C-401/12 P, C-403/12 P.
[58] See: http://ec.europa.eu/environment/aarhus/requests.htm
[59] See M. Pallemaerts, *ibidem*, p. 283.
[60] Here available: http://ec.europa.eu/environment/aarhus/pdf/title_iv/RIR%20J_E.pdf
[61] Commission Decision of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603xMON810 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, no. 2007/701/EC; Commission Decision of

market. The applicant argued that the labelling provisions in each of the three Decisions contradicted the labelling requirements of Regulations no. 1829/2003 and 1830/2003. The Decisions, indeed, required the products' labelling to contain the words «maize» and «not for cultivation», while the Regulations, depending on the case, required more explicit wording such as «genetically modified», «produced from genetically modified (name of the ingredient)», and so forth. According to Justice & Environment, the three Decisions thus permitted a labelling practice incapable of ensuring a high level of protection for the environment and the health of the people of the European Union. Justice & Environment asked the Commission to remedy the unlawful acts. The Commission answered with a letter[62], which recognized that the application was properly lodged under Title IV of the Aarhus Regulation but rejected the request for internal review, disagreeing with the NGO's interpretation of the Decisions. In the Commission's opinion, the Decisions' reference to the words «maize» and «not for cultivation» was not intended to replace the labelling requirements set forth in the EC Regulations; thus, the rules contained therein are to be considered mandatory in every case.

In its conclusion, the Commission affirmed that, while Justice & Environment's complaint met the conditions provided by EU procedural rules, the organisation could bring the matter before the Ombudsman or the Court of First Instance, respectively. At that time, however, it was far from clear to what extent NGOs could institute proceedings before the European Union Courts[63]. As is well-known, EU rules regulating access to European Union Courts and long-standing case-law "proved to be a formidable obstacle for public interest litigation before the Court of Justice"[64]. According to Article 263(4) TFEU, any natural or legal person may challenge the legality of an act addressed to himself or herself or an act of direct and individual concern to him or her. For NGOs, the criterion of "individual concern,

24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, no.2007/702/EC; and Commission Decision of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507xNK603 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, no. 2007/703EC.

[62] Commission Letter of 26 May 2008, SANCO/E1/CV/al D(2008) 510302. The letter is here available: http://ec.europa.eu/environment/aarhus/pdf/title_iv/Reply%20to%20J_E.pdf

[63] See T. Crossen and V. Niessen, *ibidem*, p. 332 ff.

[64] H. Schoukens, *Articles 9(3) and 9(4) of the Aarhus Convention and access to justice before EU Courts in environmental cases: balancing on or over the edge of non-compliance?*, p. 178.

«which has been strictly interpreted since the prominent *Plaumann* case of 1963[65], is very hard to meet. This was confirmed by *Greenpeace Stichting Council (Greenpeace International) v Commission* of 1998[66], when the Court stated that «an association formed for the protection of the collective interests of a category of persons could not be considered to be *directly and individually concerned*, for the purposes of the fourth paragraph of Article 173 of the Treaty, by a measure affecting the general interests of that category, and was therefore not entitled to bring an action for annulment where its members could not do so individually»[67].

Aarhus Compliance Committee, a non-judicial body tasked with overseeing the implementation of the Aarhus Convention, criticized the fact that NGOs were "practically barred from access to justice at the EU Courts"[68] in 2011[69]. According to the Committee's findings and recommendations, «this jurisprudence established by the ECJ is too strict to meet the criteria of the Convention»[70], «the Committee is also convinced that if the examined jurisprudence of the EU Courts on access to justice were to continue, unless fully compensated for by adequate administrative review procedures, the Party concerned would fail to comply with article 9, paragraph 3, of the Convention»[71]. This last provision, which provides members of the public with the right to access administrative or judicial procedures to challenge acts which contravene provisions relating to the environment, should be read in the light of the purpose reflected in the preamble of the Aahrus Convention. Under the preamble, «effective judicial mechanisms should be accessible to the public, including organizations, so that its legitimate interests are protected and the law

[65] «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». See Judgment of the Court of 15 July 1963, *Plaumann & Co. v Commission of the European Economic Community*, Case 25/62, 107 (Grounds of judgment I - On the application for annulment. Admissibility).

[66] Judgment of the Court of 2 April 1998, *Stichting Greenpeace Council (Greenpeace International) and Others v Commission of the European Communities*, Case C-321/95.

[67] Judgment *Stichting Greenpeace Council (Greenpeace International) and Others v Commission of the European Communities*, par. 14.

[68] M. Schaap, *Access to environmental justice for NGOs: reviewing the EU legal standing criteria in light of the Aarhus Convention*, in *AJV Nieuwsbief*, n. 8/2013, p. 4.

[69] See findings and recommendations of the Compliance Committee with regard to Communication ACCC/C/2008/32 (PART I) concerning compliance by the European Union adopted on 14 April 2011, especially paragraphs no. 86-88.

[70] Par. no. 87.

[71] Par. no. 88.

is enforced»[72]. However, considering what the European Court of Justice stated in 2015 about the impossibility to use the Convention as a benchmark for a legality review of the Aarhus Regulation[73], it is unlikely that the Compliance Committee's criticism[74] will trigger great changes[75].

With this background, it is not surprising that only in 2016 did some NGOs, which unsuccessfully asked for an internal review before the Commission[76], have access to judicial review for the first time. The case concerned GMO authorization and was decided in the judgment *TestBiotech and others v Commission*[77], delivered by the EU General Court on December 15, 2016[78]. The decision entails some interesting affirmations affecting inclusivity and access to justice for NGOs related to the GMO product authorization process, and it offers food for thought on the need for inclusivity in scientific assessment procedures.

[72] Par. no. 79.

[73] As already mentioned, the EU Courts held that Article 9(3) of the the Aarhus Convention on which Article 10(1) of Regulation No 1367/2006 is based, cannot be relied on in order to assess the legality of the latter provision. See judgment of the Court (Grand Chamber) of 13 January 2015, *Council of the European Union and European Commission v Stichting Natuur en Milieu and Pesticide Action Network Europe*, joined Cases C-404/12 P, C-405/12 P; and judgment of the Court (Grand Chamber) of 13 January 2015, *Council of the European Union and Others v Vereniging Milieudefensie and Stichting Stop Luchtverontreiniging Utrecht*, joined Cases C-401/12 P, C-403/12 P.

[74] See findings and recommendations of the Compliance Committee with regard to Communication ACCC/C/2008/32 (PART I) concerning compliance by the European Union adopted on 14 April 201. According to par. no. 88: "the Committee is also convinced that if the examined jurisprudence of the EU Courts on access to justice were to continue, unless fully compensated for by adequate administrative review procedures, the Party concerned would fail to comply with article 9, paragraph 3, of the Convention".

[75] A confirmation of this prediction comes from the recent Judgment of the General Court (Fifth Chamber) of 27 September 2018, *Mellifera eV, Vereinigung für wesensgemäße Bienenhaltung v European Commission*, Case T-12/17. On this occasion, once again, the EU Court has ruled that the Commission was right to reject a request for internal review from an NGO, ignoring the findings of the Aarhus Convention Compliance Committee, which explicitly state that limiting the right of challenge of NGOs to acts of individual scope is in breach of the Aarhus Convention.

[76] Thus, the NGOs were directly and individually concerned by the written reply of the Institution.

[77] Judgment of the General Court (Fifth Chamber) of 15 December 2016, *TestBioTech eV and Others v European Commission*, Case T-177/13. This judgment has been appealed and it is currently before the Court of Justice (C-82/17 P).

[78] On this case, see G. Ragone, *Il delicato ruolo del giudice tra valutazioni scientifiche e scelte politico-discrezionali in materia di OGM. Note minime a TestBiotech e a. v Commissione (T-177/13)*, in *Dpce Online*, 4, 2016, 251 ff; D. Bevilacqua, *Regolamentazione e tutela degli interessi diffusi: garanzie procedurali e vincoli tecnico-scientifici*, in *Giornale di diritto amministrativo*, n. 2/2017, p. 227 ff.

4. A—small—novelty in EU case-law: "*TestBiotech and others v Commission*".

In 2009, Monsanto Europe SA, a leading company in the field of agricultural biotechnology, submitted to the competent authority of the Netherlands an application to place foods containing a variety of genetically modified soybean on the market. The submission, compliant with Regulation no. 1829/2003, asked only for commercial authorization; it did not include requests for cultivation. Pursuant to European law, the application was forwarded to EFSA, which, in 2012, issued an overall opinion excluding the possibility that the GM soybean could be a risk to human health and the environment. On that basis, the European Commission adopted Decision 2012/347/EU, which authorized placing a Monsanto soybean variety on the market. Three environmental NGOs[79], disagreeing with the opinion that the modified soybean was as safe as its non-genetically-modified counterpart, requested the Commission to carry out an internal review of the authorization decision pursuant to Article 10 of Aarhus Regulation. The Commission rejected the NGOs' request, and thereafter, the NGOs instituted proceedings before the General Court challenging the Commission's refusal to review the authorization granted to Monsanto under Article 263 TFUE.

For the first time, the Court agreed to review a decision to reject a request for internal review made pursuant to the Aarhus Regulation, holding that the NGOs to which the decision is addressed may bring an action to annul the refusal, as provided by the fourth paragraph of Article 263 TFEU.[80] Beyond this novelty, the judgement is relevant for three main reasons.

First, the Court clarified that pleas put forth in this context are admissible, but they may allege only the Commission's lack of power to reject the request, the unlawfulness of the decision, the infringement of essential procedural requirements, and the misuse of powers or infringement of procedural rights in the adoption of the act in question. Second, the

[79] TestBiotech, European Network of Scientists for Social and Environmental Responsibility and Sambucus.
[80] According to par. no. 53 of the case: «Where there has been a decision to reject a request for internal review made pursuant to Regulation No 1367/2006 as unfounded, the non-governmental organisation to which that decision is addressed may bring an action for annulment against that decision, as provided for in the first situation covered by the fourth paragraph of Article 263 TFEU».

judgment clearly affirmed that, in this kind of proceeding, the claimant is not allowed to directly challenge the lawfulness or merits of the authorization decision of the EFSA's opinions. Third, the Court stated that although Monsanto's authorization did not cover cultivation, but only the commercialization of products, the case can be considered as an environmental law case and therefore falls within the scope of Regulation no. 1367/2006. Indeed, article 2 of the Aarhus Regulation provides a definition of "environmental law" that includes EU legislative provisions protecting human health. European rules governing the placement of GMOs on the market, aiming to ensure the movement of safe food and feed, concern the health and well-being of citizens. Therefore, those provisions should be considered part of environmental law.

4.1. A step forward or backward for NGOs' standing and participation?

The fact that the Court agreed to review the rejection of the request for internal review should be considered a *Pyrrhic victory* for NGOs. Indeed, the Court identified a very narrow range of pleas admissible in that context (the Commission's lack of power to reject the request, the unlawfulness of the rejection, and so forth), preventing NGOs' access to justice both to directly challenge both the lawfulness or merits of the authorization decision and the EFSA's scientific assessment.

The key to real progress for NGO participation is another affirmation, actually: that the environmental context includes the authorization of commercialization rules for GMO products and that such provisions fall within the scope of Regulation no. 1367/2006[81]. Such an inclusion should not be underestimated. The current text of the Aarhus Convention, at Article 6 on «Public participation in decisions on specific activities», cites decisions on whether to permit the deliberate release of GMOs into the environment (i.e. cultivation)[82]. However, it does not mention decisions on placing GMOs on the market, and this is probably one of the reasons why the progress made towards the inclusion of GMO issues in the framework of public participation and decision-making rights under the Aarhrus

[81] See paragraphs no. 61-64 of the judgment.

[82] Article 6(11) of the Convention reads: «Each Party shall, within the framework of its national law, apply, to the extent feasible and appropriate, provisions of this article to decisions on whether to permit the deliberate release of genetically modified organisms into the environment».

Convention have been considered to be only "modest"[83]. This gap was noticed soon after the Convention took force[84]. And the Lucca Guidelines[85] — a document representing a framework for good practice in the field of GMOs — tried to compensate for this gap by mentioning the need for inclusivity in decisions about placing GMOs on the market. However, the Lucca Guidelines are not a legally binding instrument. Therefore, in May 2005, an amendment to Article 6 of the Convention was introduced—the so called Almaty Amendment—which attempted to clarify the obligations of the parties with respect to public participation in decision-making on GMOs, including their placement on the market.[86] The amendment could not take force until ratified by at least three-fourths of the Parties, and as of October 2017, two ratifications were still needed[87]. So, although at the international level there is not yet a binding provision on this point, the General Court has established a higher standard of inclusivity within the European legal framework, without referring to the Lucca Guidelines, but only interpreting the Regulation which implements the Aahrus Convention.

4.2. The merit of the decision and the impossibility to review the scientific basis of authorization decisions.

Although the Court considered the plea admissible, the application for annulment was rejected on its merits. Above all, according to the Court, the applicants had not demonstrated that the Commission's authorization of the GM soybean had occurred

[83] See T. Etty, *ibidem*, pp. 287 and 314.
[84] See B. Horvathy, *New Impulses: Aarhus Convention and Genetically Modified Organisms*, in H. Müllerová (ed.), *Public participation in environmental decision-making: implementation of the Aarhus convention*, Ústav státu a práva, 2013, p. 33ff.
[85] Guidelines on access to information, public participation and access to justice with respect to Genetically Modified Organisms submitted by the Secretariat of the Convention on access to information, public participation in decision-making and access to justice in environmental matters through the Ad Hoc Working Group Of Senior Officials. The document is here available:
https://www.unece.org/fileadmin/DAM/env/pp/documents/gmoguidelinesenglish.pdf.
[86] The text of the amendment is here available:
https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32006D0957
[87] See the Council Decision of 18 December 2006 on the conclusion, on behalf of the European Community, of an amendment to the Convention on access to information, public participation in decision-making and access to justice in environmental matters (2006/957/EC). More details of ratification record are here available:
https://www.unece.org/fileadmin/DAM//env/pp/ratification.htm

without ensuring that an appropriate risk assessment of the highest possible standard had been carried out, as it is prescribed by Regulation no. 1829/2003 for genetically modified food and feed. The Court came to this conclusion specifying that judicial review should be limited to arguments regarding infringements of procedural requirements, errors in law, or manifest errors of assessment in the administrative review decision, and should not review the scientific basis of the authorization decision[88].

This raises the complex issue of the limits of judicial review in cases of techno-scientific assessments: to which extent can Courts legitimately deal with such evaluations[89]? As for EU Courts, this question was efficaciously expressed by Advocate General Maduro in his Opinion to the *Dutch Vitamin* case[90]: «must the Community judicature's review be restricted to addressing the various stages of the decision-making process, or should it assess the quality of the scientific analysis conducted or even review the latitude attributed to policy as opposed to science?». As expressed in the literature[91], the EU case-law reveals that the Courts' answer to such a question has changed over the years[92] and how the Courts should balance deferential and interventionist reviews in cases of scientific uncertainty and complexity remains a delicate dilemma. On the one hand, a Court that is immersed in the scientific merits of the case clearly oversteps its mandate[93], on the other hand, "Courts cannot hide behind a deferential standard of review and should intensively engage in scrutinizing the adequacy of the informational basis of contested measures"[94].

For our purposes, it is sufficient to suggest that if we agree that the judicial proceeding is not the proper place to contest the merits of scientific assessments provided by experts, it is pivotal that Courts "seek to ensure that decision-makers have the right type and quality of information at their disposal to make decisions"[95]. And looking at the GMO case, we should admit that this goal would not be fully achieved as long as scientific national authorities, NGOs, or other subjects representing widespread public interests, do not play a significant role in the assessment proceedings that precede (the release of) the

[88] See par. no. 74 of the judgment.
[89] An interesting answer to this question is provided in E. Vos, *The European Court of Justice in the face of scientific uncertainty and complexity*, pp. 142-166.
[90] *Commission of the European Communities v Kingdom of the Netherlands*, Case C-41/02, par. 32.
[91] E. Vos, *ibidem*, p. 145 ff.
[92] *Ibidem*, p. 144 ff.
[93] *Ibidem*, p. 165.
[94] *Ibidem*, p. 163.
[95] *Ibidem*, p. 163.

authorizations. Until then, there must be a remarkable and significant lack of inclusivity in decision-making regarding the authorization of GM products[96]. Indeed, as noted above[97], GMO authorization rules do not provide specific instruments or procedures to foster dialogue among people with different *expertise* or public participation in the assessment procedures. The most important—and perhaps the most unique—risk assessor in this context is the EFSA. This Authority has high standards of transparency: its agenda, works, opinions, and other key documents are published on its website; it regularly holds meetings of its scientific committee and panels that are open to all; it listens to the views of stakeholder groups, and so on. Nonetheless, given the underlined importance of scientific evaluation in the authorization procedure and the controversial debate over GMOs' risks to health and the environment, the Commission should act only after having considered the opinions of other risk assessors and different stakeholders. A wider participation of the public would lead to decisions which are both more scientifically reliable and more democratic: we agree that "the boundary work to distinguish expert consultations and stakeholders' consultations is far from easy"[98], and that "science is a crucial but not exclusive form of relevant knowledge […]. A plurality of perspectives is considered as enhancing both procedural legitimacy (through inclusiveness) and quality of knowledge (through extended peer review)"[99].

5. Could the Sustainable Development debate foster a major inclusivity in the GMO authorization process in the European Union?

The foregoing analysis calls for some brief observations about how the principles of inclusivity, participation in decision-making, and access to justice are indeed achieved within the context of the EU authorization procedure for GMOs.

As for decision-making processes for individual applications, we pointed out two criticisms of both the risk assessment and the risk management phases of the process. Within risk

[96] See D. Bevilacqua, *ibidem*, p. 229.
[97] Paragraph no. 2.
[98] A. Liberatore and S. Funtowicz, '*Democratising' expertise, 'expertising' democracy: what does this mean, and why bother?*, in *Science and Public Policy*, 30(3), 2003, p. 148.
[99] *Ibidem*, p. 149.

assessment, critics note a lack of inclusivity concerning national scientific experts: although, in theory, national risk advisors may be involved in the risk assessment process to varying degrees, in practice the EFSA has superior authority over national scientific research on GMOs, thus preventing a real debate over different scientific opinions from happening. Moreover, as already mentioned, the Regulation on genetically modified food and feed contains provisions that extend to the public the right to participate in risk assessment, but they are not sufficiently binding and need to be accompanied by stronger rules.

With respect to risk management, we observed that, thus far, the participation of Member States' representatives through a committee has always been irrelevant to the final decision due to the impossibility to reach a majority, needed for deliberation. Moreover, European case-law shows that it is not easy for the *de facto* unique risk management, the European Commission, to deny authorization to a product considered safe by the EFSA.

Within this framework, we highlighted that, even if in the long-term, despite a difficult evolution in praxis and case-law, the European Regulation, applying the principles and provisions of the Aarhus Convention to the European legal framework, opened the door to wider public participation in decision-making on GMOs authorizations. The Aarhus Regulation enabled NGOs to require the Commission to internally review an authorization decision, and to access judicial review if the internal review request were to be unsuccessful. This opportunity, the scope of which was not clearly expressed by the Regulation, found implementation in judgment *TestBiotech v Commission*, delivered in 2016 by the EU General Court. As noted, even if it is disputable whether that judgment represents a step forward or backward for NGOs' standing, it certainly has the merit of clearly affirming that the environmental context does include the authorization of commercialization rules for GMO products, thus making this matter fall into the scope of Regulation no. 1367/2006.

What the Aarhus Regulation—and the way it has been interpreted thus far— has not reduced is the lack of inclusivity in risk assessment procedures, most notably lack of broader scientific dialogue among different stakeholders and scientific opinions. A solution to this critical issue is necessary in order to fulfill the ideals of full inclusivity and public participation in the context here analyzed.

As it emerges from the UN Resolution *The future we want*[100], the need «to strengthen the science-policy interface» and to promote «participation and representation of men and women scientists […] in processes related to global environmental and Sustainable Development assessment and monitoring, with the purpose of enhancing national capabilities and the quality of research for policy- and decision-making processes» are pivotal ideals underlying the concept of Sustainable Development. Consequently, the hope is that the ongoing international debate on Sustainable Development and on the achievement of its goals will accelerate progress toward a wider participation and more inclusive mechanisms of decision-making in the case of GMOs and, overall, in all other expert-based EU procedures. In this perspective, a good sign comes from the Communication *Next steps for a sustainable European future. European action for sustainability* that the European Commission adopted in November 2016, outlining the European future agenda for 2030, centered on Sustainable Development Goals[101]. This agenda, which was integrated in 2017 by the key document *The new European consensus on development "Our world, our dignity, our future"*[102], deserves great attention for at least two reasons. In the first place, because the Commission presented this program as a joint commitment with Member States and many different actors, aiming to foster a more inclusive Europe[103]. Secondly, because the agenda traces an explicit link between Sustainable Development achievements and the European Better Regulation Agenda[104].

The latter consists of a package of reforms adopted in 2015[105] that could actually play a

[100] See paragraph no. 276 and 279 of the Resolution A/RES/66/288 adopted by the General Assembly on 27 July 2012.

[101] See Communication from the Commission to the European Parliament, the Council, the European economic and social Committee and the Committee of the regions, COM(2016) 739 final, *Next steps for a sustainable European future European action for sustainability*, adopted on 22 November 2016. This document was accompanied by the Commission Staff Working Document, *Key European action supporting the 2030 Agenda and the Sustainable Development Goals*, SWD (2016) 390 final.

[102] See *The New European Consensus On Development 'Our World, Our Dignity, Our Future'* Joint statement by the Council and the Representatives of the Governments of the Member States meeting within the Council, the European Parliament and the European Commission, 2017/C 210/01, of 8 June 2017.

[103] See A. Renda, *How can Sustainable Development Goals be 'mainstreamed' in the EU's Better Regulation Agenda?*, in *Ceps. Policy Insights*, n. 12/2017, p. 3.

[104] See Communication *Next steps for a sustainable European future. European action for sustainability*, 18: «The Commission will mainstream the Sustainable Development Goals into EU policies and initiatives, with Sustainable Development as an essential guiding principle for all its policies. Existing and new policies should take into account the three pillars of Sustainable Development, i.e. social, environmental and economic concerns. The Commission will to this effect ensure that its policies are sustainability-assured through its better regulation tools».

[105] The Better Regulation Agenda was adopted by the European Commission on 19 May 2015. Better Regulation's Guidelines and Toolbox are here available: https://ec.europa.eu/info/law/law-making-

pivotal role for the achievement of Sustainable Development Goals, and especially SDG 16, in European polices. Better Regulation, indeed, wishes to promote openness and transparency in the EU decision-making processes and to improve the quality of legislation through better impact assessments procedures. To this purpose, the Better Regulation Guidelines, which are part of the package, provide a new platform for consultations with both stakeholders and government representatives. Using the Commission's words, «stakeholder involvement and public consultations form an important component of the better regulation toolbox to meet the inclusiveness requirement that is at the heart of the 2030 Agenda».

For sure, it is too early to affirm that Sustainable Development Goals are fully mainstreamed in the EU Better Regulation[106]. However, it must be noted that "sustainable development is included in the better regulation toolbox as one of the impacts that should be considered in an ex ante impact assessment. [And] all the SDGs (with the obvious exception of SDG 17) are covered in one way or another by the better regulation toolbox"[107]. Therefore, although several steps are still to be made, this improved regulation should be appreciated for its ability to push the international debate on Sustainable Development into the EU framework. The European Union provided a constructive contribution to the development of the 2030 Agenda for Sustainable Development, and it is thus possible to wish that it would pursue the widest possible implementation of fundamental goals in this field (such as those embedded in SDG 16). As affirmed by the Falkenberg report of 2016, «it is a matter of credibility for the EU to deliver on implementing domestically the Sustainable Agenda that it has contributed building»[108].

process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en. See B. Vimercati, *Natura e strumenti della better regulation. Un contributo allo studio dell'integrazione tra i diversi livelli di governo*, Giappichelli, 2018, p. 119 ff.

[106] Indeed, according to A. Renda, *ibidem*, 9, "a closer look reveals a number of outstanding challenges for the better regulation agenda to really embrace to the Sustainable Development Goals. As a matter of fact, when one looks at the indicators associated with each of the SDGs, it is clear that the EU better regulation guidelines make very partial reference to similar values and benchmarks. Furthermore, what is missing in the better regulation guidelines is: i) a methodological framework that considers Sustainable Development as the framework within which to locate policy impacts, rather than one of several policy impacts; ii) a way to measure distance from SDG targets; and iii) criteria to prioritise certain impacts over others in the case of trade-offs".

[107] *Ibidem*, p. 9.

[108] See Falkenberg report EPSC Strategic Notes, 20 July 2016, here available: https://ec.europa.eu/epsc/sites/epsc/files/strategic_note_issue_18.pdf

Abstract: The present paper explores what role the principles of inclusivity, access to justice and participation in decision-making are playing in the Genetically Modified Organisms (GMO) authorization in the European Union. The introductory chapter highlights the concerns as reasons behind the delimitation of this scope: above all, the difficulties stemming from the risk regulation in agricultural biotechnology (scientific uncertainty, conflicting interests etc.) and the need to promote participation and representation of different stakeholders in processes related to global environmental and Sustainable Development assessment and decision-making. In the following pages, after having framed the main criticisms regarding the GMO authorization process, the paper will analyze the praxis and the Court of Justice of the European Union case-law after the approval of EU Regulation no. 1367/2006. This implemented the Aarhus Convention on access to information, public participation in decision-making, and access to justice in environmental matters into the European legal framework. As it will be discussed in the conclusion, neither the previously adopted Aarhus Convention nor the EU regulation have led, so far, to a satisfactory implementation of inclusivity, access to justice and participation in decision-making in the GMO field. Given that these principles echo some of the pivotal aims of Sustainable Development Goal 16 of the 2030 Agenda, the paper reflects on the possibility that the Sustainable Development debate could promote further steps towards a greater implementation of the above mentioned principles in the GMO authorization process.

Abstract: Il presente contributo indaga in che misura i principi di inclusività, accesso alla giustizia e partecipazione nei processi decisionali trovano attuazione all'interno della procedura di autorizzazione degli organismi geneticamente modificati (OGM) dell'Unione Europea. Il paragrafo introduttivo mette in luce le principali problematiche sottese allo studio di questo argomento: in particolare, le difficoltà derivanti dalla regolamentazione del rischio in relazione alle biotecnologie applicate all'agricoltura (incertezza scientifica, conflitti d'interesse etc), nonché la necessità di garantire ampia partecipazione e rappresentanza dei diversi portatori d'interessi nei processi decisionali che incidono sull'ambiente globale e sulla realizzazione dello Sviluppo Sostenibile. Nei paragrafi successivi, dopo aver illustrato le principali lacune della procedura di autorizzazione degli OGM, l'articolo analizza la prassi e la giurisprudenza della Corte GUE successive

all'approvazione del Regolamento UE n. 1367/2006. Quest'ultimo implementa a livello Europeo la Convenzione di Aarhus sull'accesso alle informazioni, la partecipazione del pubblico ai processi decisionali e l'accesso alla giustizia in materia ambientale. Come emerge dalle conclusioni, nè la sottoscrizione della Convenzione di Aarhus, prima, nè la sua implementazione tramite Regolamento, poi, hanno condotto ad oggi ad una soddisfacente attuazione dei principi di inclusività, accesso alla giustizia e partecipazione nei processi decisionali nell'ambito degli OGM. Dal momento che tali principi riecheggiano alcuni degli obiettivi stabiliti dal Goal 16 dell'Agenda 2030, l'articolo riflette da ultimo sulla possibilità che il dibattito sullo Sviluppo Sostenibile possa portare a passi ulteriori nella direzione di una maggiore implentazione dei principi menzionati nel processo di autorizzazione degli OGM in Europa.

Parole chiave: OGM – Convenzione di Aarhus – SDG 16 – giurisprudenza Corte GUE – inclusività – accesso alla giustizia – trasparenza – scienza e diritto.

Key words: GMOs – Aarhus Convention – Aarhus Regulation – SDG 16 – CJEU Case Law – inclusivity – access to justice – transparency – science and law.