INSIGHT

EMERGENCY MEASURES AGAINST GMOS BETWEEN HARMONIZING AND DE-HARMONIZING TRENDS: THE CASE *FIDENATO ET AL.*

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ABSTRACT: This *Insight* comments on the preliminary ruling in the case *Fidenato et al.* (judgment of 13 September 2017, case C-111/16), in which the Court of Justice excluded that Member States may rely on the precautionary principle enshrined in Art. 7 of Regulation 178/2002 to adopt emergency measures against the cultivation of GMOs, pursuant to Art. 34 of Regulation 1829/2003. The judgment confirms the strict interpretation of the conditions to adopt such measures, already provided by the Court of Justice in the case *Monsanto SAS* (judgment of 8 September 2011, joined cases C-58/10 and C-68/10), and the will of the EU to maintain full control over the management of scientific risk related to GMOs. At the same time, the ruling calls for some reflections on GMOs regulation in the EU, which has recently undergone some major changes in the sense of leaving much more freedom to Member States to ban the cultivation of GMOs when non-scientific risks are at stake.

KEYWORDS: precautionary principle – genetically modified food and feed – emergency measures – Regulation 1829/2003 – Regulation 178/2002 – agriculture.

I. INTRODUCTION

On 13 September 2017, the Court of Justice delivered a preliminary ruling in the case *Fidenato et al.*,[1] concerning the interpretation of EU regulations related to Genetically Modified Organisms (GMOs).[2] In particular, the case relates to the activation of an

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[1] Court of Justice, judgment of 13 September 2017, case C-111/16, *Fidenato et al.*

[2] According to Art. 2, para. 2, of the 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, "genetically modified organism" means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

emergency measure against the cultivation of genetically modified maize MON810, whose placement in the internal market was originally authorized in 1998.[3]

In 2013 Italy issued a Ministerial Decree prohibiting the cultivation of such maize pursuant to Art. 34 of Regulation 1829/2003 (hereinafter the Food and Feed Regulation).[4] The latter provision allows Member States to adopt emergency measures provided that certain substantial and procedural conditions set forth in Arts 53 and 54 of Regulation 178/2002 (hereinafter the Food Regulation)[5] are met.

Mr. Fidenato, who ran a cultivation of the prohibited maize, was prosecuted and eventually condemned by the judge for preliminary investigation pursuant to Decree Law 91/2014, which provided for criminal sanctions in case of violation of the abovementioned ban.[6] He contested the sanction before the Tribunal of Udine, challenging the lawfulness of the Decree and claiming its inconsistency with EU law.

The interpretative question raised before the Court of Justice by the Tribunal of Udine relates to the interplay between the safeguard clause provided in Art. 34 of the Food and Feed Regulation and the precautionary principle. The Court of Justice found that the precautionary principle, although being a general principle of EU food law, as enshrined in Art. 7 of the Food Regulation,[7] cannot be used to circumvent the stringent criteria for an emergency measure to be validly adopted. In fact, following the opinion of the European Food Safety Authority (EFSA),[8] the Court of Justice found that the criteria set forth in Art. 34 of the Food and Feed Regulation had not been met in the present case and the precautionary principle could not allow extensive interpretation of the safeguard clause.

[3] Commission Decision 98/294/EC of 22 April 1998 concerning the placing on the market of genetically modified maize produced by Monsanto Europe, pursuant to Directive 90/220. Following the legislative evolution in GMOs regulation, in 2004 Monsanto Europe notified the genetically modified maize MON810 as an existing product and applied for the renewal of the authorization for its placement in the internal market pursuant to Regulation 1829/2003.

[4] Regulation (EC) n. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. Art. 34 of this Regulation reads as follows: "Where it is evident that products authorised by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment, or where, in the light of an opinion of the Authority issued under Article 10 or Article 22, the need to suspend or modify urgently an authorisation arises, measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation (EC) No 178/2002".

[5] Regulation (EC) n. 178/2002 of the European Parliament and of the Council of 28 January 2002 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.

[6] Art. 4, para. 8, of Decree Law 24 June 2014 no. 91/2014.

[7] Art. 7, para. 1, of the Food Regulation provides as follows: "In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment".

[8] The European Food Safety Authority was established by the Food Regulation and it is the body in charge of carrying out the scientific evaluation of risks in GMOs authorization procedure.

The *Insight* aims at analyzing some critical aspects of the judgment. The Court of Justice reaffirmed the extremely high standards of proofs required to demonstrate the existence of a risk in the use of GMOs, making it difficult to distinguish between a risk and an already verified adverse effect. Furthermore, the judgment shows some contradictions with the evolution in the legislative framework on GMOs regulation.

II. The context: normative framework and relevant precedents

II.1. A focus on the EU normative framework on GMOs

In order to better understand the issue, it is worth to briefly outline the legislative framework related to the introduction of GMOs in the internal market.

The normative framework on GMOs in the EU has been constantly evolving.[9] One of the main cause of this evolution is the persistent opposition by some Member States to the introduction of GMOs in the EU, that has made it difficult to fully implement the harmonized authorization procedure. Furthermore, the whole GMOs regulation is aimed at striking a balance between opposing interests such as achieving the best living and health conditions and protecting the internal market, allowing the presence of safe GMOs as far as possible.

The legal framework is currently based on three main EU acts: a) the already cited Food Regulation, b) Directive 2001/18/EC (the Deliberate Release Directive)[10] now amended by Directive 2015/412/EU (hereinafter the New Deliberate Release Directive)[11] and c) the already cited Food and Feed Regulation. While the Food Regulation provides for the general framework of EU food law, both the Deliberate Release Directive and the Food and Feed Regulation concerns the specific GMOs system. In particular, the Deliberate Release Directive provides for the rules concerning the release of GMOs in the internal market and the Food and Feed Regulation regulates the placing on the market of genetically modified food and feed, i.e. food and feed containing, consisting of or produced from GMOs.

The system is based on risk regulation, achieved through a centralized prior authorization procedure to allow GMOs in the internal market. Such authorization is granted by the Commission upon the opinion of EFSA, evaluating the scientific evidence necessary to assess the risk in the introduction of the GMO in the market. Significantly

[9] For an overview and comments, M. Weimer, W*hat Price Flexibility? – The Recent Commission Proposal to Allow for National "Opt-Outs" on GMO Cultivation under the Deliberate Release Directive and the Comitology Reform Post-Lisbon*, in *European Journal of Risk Regulation*, 2010, p. 345 et seq.

[10] 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.

[11] Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.

enough, Member States have never expressed their opinion either in favor or against an authorization: all authorizations were allowed by the Commission absent an opposition of a qualified majority of Member States.[12]

The debate over the cultivation of GMOs in the EU is a long-lasting one. States have repeatedly challenged the harmonizing tendencies of the EU in this field, contesting at the same time the role of the EFSA and its decisional mechanism.[13]

A clear shift towards more flexibility in the described system has been inaugurated with the adoption of the New Deliberate Release Directive,[14] which allows Member States to ban the cultivation of authorized GMOs taking into account non-scientific factors.[15] Member States are now free to evaluate the impact and risk of GMOs on the basis of agricultural or environmental policies or socio-economic considerations, as far as there is no conflict with the environmental risk assessment. It is worth to note that, following the adoption of the New Deliberate Release Directive, the cultivation of genetically modified maize MON810 was eventually banned in the territory of nineteen Member States, including Italy.[16]

The derogation clause of the New Deliberate Release Directive also applies to GMOs for cultivation authorized under the Food and Feed Regulation; however, it does not apply to genetically modified food, food ingredients and feed. That is why, a proposal

[12] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) no 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, COM(2015) 177.

[13] S. POLI, *Scientific Advice in the GMO Area*, in A. ALEMANNO, S. GABBI (eds), *Foundations Of EU Food Law And Policy: Ten Years Of The European Food Safety Authority*, Abingdon: Routledge, 2014, p. 119 *et seq.*, in particular in relation to the criticism towards EFSA.

[14] On the process that led to the adoption of the Directive and a comment see S. POLI, *The Reform Of The EU Legislation On Gmos: A Journey To An Unknown Destination?*, in *European Journal of Risk Regulation*, 2015, p. 559 *et seq.*; M. GEELHOED, *Divided in Diversity: Reforming The EU's GMO Regime*, in *Cambridge Yearbook of European Legal Studies*, 2016, p. 20 *et seq*.

[15] The new Art. 26, lett. b), concerning cultivation of GMOs, reads as follows: "a Member State may adopt measures restricting or prohibiting the cultivation in all or part of its territory of a GMO, or of a group of GMOs defined by crop or trait, once authorised in accordance with Part C of this Directive or with Regulation (EC) No 1829/2003, provided that such measures are in conformity with Union law, reasoned, proportional and non-discriminatory and, in addition, are based on compelling grounds such as those related to: (a) environmental policy objectives; (b) town and country planning; (c) land use; (d) socio-economic impacts; (e) avoidance of GMO presence in other products without prejudice to Article 26a; (f) agricultural policy objectives; (g) public policy. Those grounds may be invoked individually or in combination, with the exception of the ground set out in point (g) which cannot be used individually, depending on the particular circumstances of the Member State, region or area in which those measures will apply, but shall, in no case, conflict with the environmental risk assessment carried out pursuant to this Directive or to Regulation (EC) No 1829/2003".

[16] Commission implementing decision (EU) 2016/321 of 3 March 2016 adjusting the geographical scope of the authorisation for cultivation of genetically modified maize (Zea mays L.) MON 810.

for amendment of the Food and Feed Regulation was issued on 22 April 2015,[17] aimed at a full recognition of non-scientific reasons to ban genetically modified food and feed. Despite the fact that it substantially mirrored the amendment approved for cultivation bans, the proposal was rejected by the European Parliament on 28 October 2015 and the procedure is currently stuck before the Council.

To some extent, the amendment proposals may be consequent to the fact that emergency measures under the Food and Feed Regulation were never authorized by the Commission, mostly because of the difficulties faced by Member States to justify mainly policy reasons on purely scientific grounds.[18] The Commission has therefore realized the need for an update of the legislative framework accordingly, substantially extending the reasoning already adopted in the New Deliberate Release Directive to products covered by Food and Feed Regulation. However, even Member States opinions are far from being unanimous on the matter, as showed by the rejection of the European Parliament.

The deep debate between the harmonizing tendency of the EU and the decentralized forces of the Member States can be further seen in the relevant previous case-law, as will be described in the next section.

II.2. Setting the (high) standard of proof: the case *Monsanto SAS*

The case *Fidenato et al.* is the last of a series of judgments adopted by the Court of Justice on GMOs regulations and the interpretation of safeguard clauses. The resistance opposed by some Member States to the introduction of GMOs in the internal market has been previously shown in several occasions, highlighting the growing need for differentiation in the field of GMOs, as opposed to the centralizing trend of the Commission.

The question arose in similar terms in the case *Monsanto SAS et al.*,[19] where the Court of Justice had the opportunity to clarify the interplay between the Deliberate Release Directive and the Food and Feed Regulation, specifically in relation to the interpretation of Arts 12 and 23 of the Deliberate Release Directive and Arts 20 and 34 of the Food and Feed Regulation, together with Arts 53 and 54 of the Food Regulation.

In particular, the Court of Justice firstly stated that when a GMO is authorized under the Food and Feed Regulation, the safeguard clause of the Deliberate Release Directive shall not apply. Secondly, the Court of Justice clarified the scope of the parameters set

[17] Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) no 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, cit.

[18] S. Poli, *The Reform of the EU Legislation on GMOs,* cit., p. 560.

[19] Court of Justice, judgment of 8 September 2011, joined cases C-58/10 and C-68/10, *Monsanto SAS et al. v Ministre de l'Agriculture et de la Pêche*. For a comment, see M. Weimer, *The Right to Adopt Post-market Restrictions of Genetically Modified Crops in the EU – A Shift from De-centralised Multilevel to Centralized Governance in the Case of GM Foods*, in *European Journal of Risk Regulation*, 2012, p. 445 *et seq*.

forth in the abovementioned Art. 34 of the Food and Feed Regulation. The Court of Justice here stated that:

> "the expressions 'likely' and 'serious risk' must be understood as referring to a significant risk which clearly jeopardises human health, animal health or the environment. That risk must be established on the basis of new evidence based on reliable scientific data.
> Protective measures adopted under Article 34 of Regulation No 1829/03 cannot validly be based on a purely hypothetical approach to the risk, founded on mere assumptions which have not yet been scientifically verified".[20]

The threshold set by the Court of Justice for the adoption of emergency measures is very high, certainly higher than the one requested under Art. 23 of the Deliberate Release Directive, that allows Member State to provisionally restrict or prohibit the use of a GMO when there are grounds for considering that a GMO constitutes a risk to the environment, but it does not qualify the risk as "serious" nor "evident".[21]

Furthermore, the Court of Justice held that the 'final word' on the assessment and management of a serious and evident risk lays on the Commission and the Council, in order to avoid "artificial disparities" in the treatment of a serious risk.[22]

In *Monsanto SAS*, the Court of Justice sheds light on the burden of proof under Art. 34 of the Food and Feed Regulation, but it did not address the possible overlap between this provision and the precautionary principle, in particular as regard as the impact of the application of such principle to derogation clauses. The Court of Justice mentioned the precautionary principle in a short passage only, where it stated that:

> "Those conditions must be interpreted not only in the light of the wording of that provision, but also in the light of the purpose of Regulation No 1829/2003 and the precautionary principle, in order to ensure a high level of protection of human life and health, whilst taking care to ensure the free movement of safe and wholesome food and feed, which is an essential aspect of the internal market".[23]

Actually, the issue was deeply analyzed by AG Mengozzi in the opinion delivered in *Monsanto SAS* case, while commenting on the divergences in the interpretation of the two clauses. The AG maintained that safeguard clauses, such as Art. 34 of the Food and Feed Regulation and Art. 23 of the Deliberate Release Directive, are expressions of the

[20] *Monsanto SAS et al,* cit., paras 76-77.

[21] The differences between the requirements under Art. 23 of the Deliberate Release Directive and Art. 34 of the Food and Feed Regulation are examined by AG Mengozzi in its opinion delivered in *Monsanto SAS et al.*, para. 75 *et seq*.

[22] *Monsanto SAS et al.*, cit., para. 78.

[23] *Ibid.*, para. 71 and case-law mentioned therein.

same principle, i.e. the precautionary principle. Therefore, they should be interpreted uniformly, despite the differences in wording.[24]

However, in *Monsanto SAS* case, the Court of Justice set a higher threshold of evidence for the adoption of emergency measures under Art. 34 of the Food and Feed Regulation in respect to other safeguard clauses, such as the one enshrined in Art. 23 of the Deliberate Release Directive.

III. The judgment

III.1. Factual background

As previously recalled, in April 2013, the Italian Government requested the Commission to adopt emergency measures to ban the cultivation of genetically modified maize MON810. The Commission rejected the request, upon negative opinion of the EFSA Panel on GMO.[25] In the report, EFSA concluded that in the documentation provided by Italy there were no elements suggesting new science-based evidence to support the adoption of the notified emergency measure to ban the cultivation of maize MON810. This notwithstanding, Italy adopted the ban on the basis of Art. 54 of the Food Regulation.

One of the question posed to the Court of Justice[26] was therefore whether States possess a more extensive power to adopt emergency measures, broadening the conditions set forth in Art. 34 of the Food and Feed Regulation, by reading them in conjunction with the precautionary principle.

III.2. AG Bobek's Opinion

"My concise answer to that question is no".[27] With this sentence the Advocate General Bobek opened its assessment of the third question, leaving no room for misunderstanding. In his opinion, he focused in particular on the relationship between the emergency measures and the precautionary principle.

[24] Opinion of AG Mengozzi delivered on 22 March 2011, *Monsanto SAS et al.*, cit., paras 62 and 64; see also Court of Justice, judgment of 9 September 2003, C-236/01, *Monsanto Agricoltura Italia S.p.A. v. Presidenza del Consiglio dei Ministri*, para. 110.

[25] Scientific Opinion on a request from the European Commission related to the emergency measure notified by Italy on genetically modified maize MON 810 according to Article 34 of Regulation (EC) No 1829/2003, in EFSA Journal 2013, available at www.efsa.europa.eu. In the opinion, EFSA concluded that "In the documentation provided by Italy in support of the current emergency measure on maize Mon 810, the EFSA GMO Panel could not identify any new science-based evidence to support the notified emergency measure".

[26] The first, second and fourth questions concerned, respectively, the duty of the Commission to adopt emergency measures when requested, the possibility for the State making the request for interim measure to adopt them in case of Commission inactivity and upon which conditions the interim emergency measures may remain in force when conditions are not met.

[27] Opinion of AG Bobek delivered on 30 March 2017, *Giorgio Fidenato et al.*, para. 30.

He first confirmed the applicability of the precautionary principle. Indeed, the principle is enshrined in Art. 7 of the Food Regulation.

The *ratio* of the principle, when applied to food security in particular, is to address the potential danger of unknown risks that stem from the use of new technologies. Therefore, the precautionary principle does not only justify, but even calls for actions where there are scientific uncertainties over a risk.[28]

Following this premise, AG Bobek provided a detailed description of the principle in EU food law, concluding in the sense that when a risk to specific interests cannot be excluded from the risk assessment, provisional measures may be adopted. However, he recalled that the relevant laws in the case at stake provide for more specific norms that, as emerges from the wording of Art. 34 of the Food and Feed Regulation, are to be read as a "concrete articulation of the precautionary principle in the specific context of genetically modified food and feed".[29] Indeed, while Art. 7 is of general application in food law, Art. 34 applies specifically to genetically modified food and feed already authorized through a process based on the precautionary principle. The evidence required to adopt emergency measures must therefore be strong enough to overcome the results of the procedure that led to the authorization of the GMO in the market.[30]

Based on the described difference, AG Bobek advised the Court of Justice that a precaution-oriented interpretation should not reach as far as to rewrite the conditions set forth in Art. 34 of Food and Feed Regulation, which are clearly different from those required by Art. 7 of the Food Regulation.[31] He eventually argued that the precautionary principle "may only guide the interpretation" of Art. 34 of the Food and Feed Regulation "without expanding its scope".[32]

III.3. The findings of the Court of Justice

The Court of Justice substantially relied on the opinion of the Advocate General, further upholding its previous case-law.[33]

The Court of Justice reiterated that the precautionary principle in EU food law has been formally enshrined in Art. 7 of the Food Regulation, in the light of which the right to adopt emergency measures shall be interpreted. The aim is to guarantee a high level of protection of human life and health, while ensuring the free movement in the internal market of safe feed and food.[34]

[28] *Ibid.*, para. 32
[29] *Ibid.*, para. 61.
[30] *Ibid.*, paras 69-78.
[31] *Ibid.*, para. 68.
[32] *Ibid.*, para. 30 and para. 49 *et seq*.
[33] *Fidenato et al.*, cit., para. 43 *et seq*.
[34] *Ibid.*, para. 47.

However, the Court of Justice clarified that the principle cannot be used to relax the substantial conditions upon which emergency measures pursuant to Art. 34 of Food and Feed Regulation can be adopted. Indeed, according to the Court of Justice, the measures to be adopted under Art. 7 of the Food Regulation and those to be adopted under Art. 34 of the Food and Feed Regulation are subject to different regimes. The former allows Member States to adopt provisional measures when risks for human health are possible, but scientific uncertainties persist; the latter asks for a higher standard of proof of the risk, requiring it to be evident and serious.[35]

Such a difference is justified in the light of the different scope of application of the recalled provisions: while the former is of general application, including to products not authorized in the internal market, the latter is to be applied to products that already passed through the authorization procedure.

In conclusion, the Court of Justice considered that the precautionary principle cannot, by itself, justify a deviation from the conditions provided by Art. 34, being anyway necessary to verify the existence of the substantial requirements thereby provided in order to adopt emergency measures.

The findings of the Court of Justice substantially recalled the opinion of AG Bobek. On such basis, the Court of Justice decided that a) the Commission is not required to adopt emergency measures pursuant to Art. 53 of the Food Regulation unless evidence of serious risk to human or animal health or environment is likely to be caused by products authorized under the Food and Feed Regulation and b) that such emergency measures cannot be adopted on the basis of the precautionary principle only, since the conditions set forth in Art. 34 of the Food and Feed Regulation must be satisfied.

IV. Comment

Formally, the findings of the Court of Justice are irreproachable. The Court of Justice has already explained in *Monsanto SAS* why the burden of proof on Member States to adopt emergency measures is set to a high standard.

Substantially, the judgment can be criticized at least in some of its parts. The high standard of evidence imposed by the Court of Justice calls for a reflection on the dividing line between risk and actual adverse effects. The standards of scientific evidence required by the Court of Justice are designed to prove a risk that has to be almost certain; certainty, however, is not a feature of "risk".

The specific question concerning the interpretation of Art. 34 in the light of the precautionary principle, which was left in the background in *Monsanto SAS*, could have led the Court of Justice to open up to more flexible interpretation of the criteria set in Art. 34.

[35] *Ibid.*, para. 51.

Indeed, while the Court of Justice was deciding on this case, the New Deliberate Release Directive was adopted, allowing Member States to restrict the cultivation of authorized GMOs on public policy grounds. On this basis, nineteenth Member States asked for the ban of the cultivation of modified maize MON810 in their territory, wholly or in part. All the requests were approved by the Commission.[36] Although the New Deliberate Release Directive was not applicable in the present case, as noted by AG Bobek,[37] the normative changes are symptomatic of a more flexible approach of the EU towards States autonomy in GMOs regulation. The New Directive seems to open the way for a potential de-harmonization process, by allowing member States to wider possibilities of derogation: the European Union felt it necessary to go back on its steps in harmonizing the matter, for the first time.[38]

In particular, with the New Deliberate Release Directive, the EU has finally acknowledged the existence and importance of non-scientific reasons behind the reluctance of States to allow GMOs in their territories. This recognition may cause a significant shift in the struggle between autonomy and harmonization in GMOs regulation.[39] Once the flexibility door has been opened through the recognition of non-scientific grounds for derogation, a different approach could have been taken in the case at stake as well, on the basis of a precautionary oriented reading of the derogation clause.[40] This could have led the Court of Justice to apply more relaxed standards of proof to the scientific evidence required for derogation or at least to require EFSA to undertake more detailed analysis and justification for the rejection of the scientific reasons provided by States.[41]

At the same time, however, the changes can also be interpreted as a confirmation by the EU of its prerogatives on risk regulation based on scientific grounds. Indeed, the ban on cultivation pursuant to the New Deliberate Release Directive can be invoked as far as non-scientific grounds for derogation are at stake. When the request for ban is grounded on a science-based risk to human health or environment, the process remains fully har-

[36] Commission implementing decision (EU) 2016/321, cit.

[37] The Directive was not applicable both *ratione temporis* and because the case falls outside the procedural framework of the New Deliberate Release Directive, see Opinion of AG Bobek, *Giorgio Fidenato et al.*, cit., para. 84.

[38] Although it is argued whether "non-environmental" or "non-health" where ever harmonized at all, M. LEE, *EU Environmental Law, Governance and Decision-Making*, Portland: Hart Publishing, 2014, p. 225.

[39] *Ibid.,* p. 235 et seq.

[40] Indeed, it is precisely the role of EU principles to be used as interpretation tools, to fill gaps and clarify general provisions. See, *ex multis*, ADAM R., TIZZANO A., *Manuale di Diritto dell'Unione Europea*, Torino: Giappichelli Editore, 2017, p. 144. On the precautionary principle, see, *ex multis*, DE SADELEER N., *The Precautionary Principle in EC Health and Environmental Law*, in *European Law Journal*, 2006, p. 144 *et seq*.

[41] For a comment on the (missing) justification of EFSA opinion see M. LEE, *Multi-Level Governance of Genetically Modified Organism in the European Union: Ambiguity and Hierarchy,* in L. BODIGUEL, M. CARDWELL (eds), *The Regulation of Genetically Modified Organism: Comparative Approaches*, New York: Oxford University Press, 2010, p. 107 *et seq*.

monized and centralized.[42] Furthermore, Art. 26, lett. B) of the New Deliberate Release Directive specifies that the grounds provided for the ban on GMOs cultivation "shall, in no case, conflict with the environmental risk assessment carried out pursuant to this Directive or to Regulation (EC) No 1829/2003", making it difficult to understand the space for derogation left to Member States when environmental concerns are at stake.

Therefore, while making a move towards Member States in recognizing non-scientific grounds for derogation, the EU is confirming once again its prerogatives on scientific-based risk regulation. Here, the EU is well aware of the relevance of the precautionary principle, which is a leading principle in the authorization process. However, even the reference to the precautionary principle has proven to be ineffective towards the absolute predominance *de facto* of EFSA evaluations of scientific proofs provided by States,[43] although the very existence of different scientific positions (i.e. uncertainty on risks) would suggest a precaution approach.

In this sense, the EU seems to be following the same mistakes of the past, fostering the absolute scientific-based approach that led to the recent reform of the normative framework on GMOs. When politically sensitive issues are at stake, it is hardly sufficient to rely on purely scientific expertise. The new approach of the EU seems to clearly separate the scientific stage from the socio-political one: however, the overall debate shows that authorization of GMOs is not a purely scientific problem. The perceived risk may vary according to different approaches at socio-political level, even before comparable scientific evidence:[44] while the assessment of risk may require a purely scientific analysis, the management of such a risk involves political discretion.

This scenario sheds a light on the ongoing struggle within the EU between harmonization and de-centralization in GMOs regulation and calls for some more general reflections. The question of the introduction and maintenance of GMOs in the internal market pertains the controversial debate between those pushing forward to overcome the limits imposed by nature and those opposing a blind faith in biotechnology. From a legal point of view, this translates in a delicate balance to be achieved between the two positions, ending in the concept of risk regulation.

The debate over the use and regulation of GMOs is, in the first place, a matter of governing the uncertain consequences of the use of GMOs over human health and en-

[42] Thus proving that the idea of a 'scientific pluralism' in relation to the evaluation of evidence in GMOs is still not fully accepted by the Commission, see E. Vos, M. Weimer, *Differentiated Integration or Uniform Regime? National Derogations from EU Internal Market Measures*, in B. De Witte, A. Ott, E. Vos (eds), *Between Flexibility and Disintegration: The Trajectory of Differentiation in EU Law*, Cheltenham: Edward Elgar Publishing, 2017, p. 329.

[43] E. Vos, M. Weimer, *Differentiated Integration or Uniform Regime?,* cit., p. 330.

[44] M. Lee, *EU Environmental Law, Governance and Decision-Making*, cit., pp. 234-236, according to whom it must be noted that non-scientific objections are especially raised by States, often masked behind scientific reasons.

vironment, a matter that pertains to the use of scientific progress.[45] It not only involves ethical questions over the manipulation of natural resources, but also the level at which such processes should be regulated. In the end, the matter pertains to the hard task of finding a balance between harmonization and respect for diversity in a sensitive topic such as the one related to the use of new technologies in agriculture. Not less important, deep economic implications are at stake in GMOs regulation, since the widespread use of GMOs may, in the long term, have an impact on small and medium traditional and organic agricultural production.[46]

In conclusion, the judgment and the legislative evolution seem to follow two parallel paths. While the New Deliberate Release Directive and the ongoing proposal for amendment of the Food and Feed Regulation are clearly following a de-harmonizing wave, the judgment reaffirms the centripetal force of the EU when scientific risk is at stake. In principle, the new derogation clauses are designed to be complementary to the authorization procedure based on scientific risk assessment. However, the judgment seems to show that authorization on scientific grounds and derogation on non-scientific grounds may overlap. This potential inconsistency is sharpened by the fact that the possibility to derogate on non-scientific grounds is left to Member States with no necessity of evidence. This choice will likely open the way for abuses by Member States and justify the unconditional opposition to GMOs that the EU has tried to fight over the last years.

The scenario is further complicated by inconsistencies at the political level as well. In the future, the centripetal approach adopted by the Court of Justice in the case at stake will be necessarily tamed by the new normative framework, which clearly indicates a flexibility path to be followed. At the same time, the procedural *impasse* in the amendment of the Food and Feed Regulation may still indicate disagreement among Member States in the choice between harmonization and de-harmonization, making any future pronunciation of the Court of Justice highly unpredictable.

[45] For an introduction to such general aspects see, among others, M. Lee, *EU Regulation of Gmos: Law and Decision Making for a New Technology*, Edward Elgar Publishing, 2008. See also N. De Sadeleer, *Marketing and Cultivation of Gmos in the EU: An Uncertain Balance between Centrifugal and Centripetal Forces*, in *European Journal of Risk Regulation*, 2015, p. 532 *et seq*.

[46] M. Lee, *EU Environmental Law, Governance and Decision-Making,* cit., p. 237.