Genetically modified organisms and coexistence measures: the role of domestic courts in the evaluation of national limitations

di Simone Pitto

Title: Organismi geneticamente modificati e misure di coesistenza: il ruolo dei giudici interni nella valutazione delle limitazioni nazionali

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1. – The case here commented represents the last chapter in a group of judgements of the European Court of Justice (hereinafter also "ECJ") related to Italian limitations to the cultivation of genetically modified seeds.

With this ruling, the ECJ Court provided key clarifications regarding the legitimacy of national measures deemed to regulate the coexistence between mutagenic crops and organic or traditional crops. The core of the ruling concerns the evaluation of the compliance with EU law of national provisions adopted by an Italian region to prohibit the cultivation of GMOs in certain areas in order to avert the unintended presence of GMOs within organic and conventional GMO-free crops. In this evaluation, a role of paramount importance seems to be reserved by the Court to the judicial authorities of the Member states.

2. – The case originates from a fine imposed in 2015 on a farmer ("PH") by the Italian Region Friuli Venezia Giulia (hereinafter "FVG"). PH was charged for having cultivated transgenic corn type MON810 in his farm. The cultivation of this variety of corn in the area had been prohibited within the entire territory of the FVG Region by Regional Statute Law No. 5 of April 8, 2011. Article 2 of the Statute based the ban on the purpose of avoiding the unintended presence of GMOs in conventional and organic corn crops in the regional territory. In fact, such territory was considered to be particularly affected by the risk of commixture in view of the local production patterns and the structure of farms.

The farmer challenged the fine before the Court of Pordenone, deeming it illegitimate. In the related case a request for a preliminary interpretative ruling was raised to the Court of Justice. The Italian court firstly pointed out that the dispute did not concern the possibility of freely marketing genetically modified corn but rather the power of a national authority to prohibit its cultivation. The difference between relevant applicable regulation had already been clarified by the Court of Justice *inter alia* in the *Confédération paysanne and Others v Premier ministre and Ministre de l'agriculture* case back in 2018 (ECJ, July 25, 2018, C-528/16 with case comment by E. Spiller, *Tecniche "nuove", obblighi "nuovi"? La CGUE in «riscrittura giudiziaria» della direttiva n. 18/2001 CE Nota a Confédération paysanne*

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v. Ministre de l'Agriculture (C-528/16), in *BioLaw Journal*, 1, 2019, 513-523). On that occasion, the Court held that the marketing of products obtained by mutagenic techniques must be considered subject to the ordinary provisions on GMOs unless they are found to be obtained by mutagenesis techniques already used conventionally and with a long tradition of safety.

The Court of Pordenone also recalled the precedent decided by the Court of Justice in *Fidenato et. a. v. Italy* and, in particular, the first ruling of May 2013, (ECJ, May 8, 2013, C-542/12). On that occasion, the Court had interpreted Article 26b of Directive 2001/18 in the part related to national coexistence measures. According to the Court, the aforementioned provision must be interpreted as meaning that it does not allow a member state to prohibit the cultivation of GMOs as MON810 in its territory on the ground that obtaining a national authorization would constitute a coexistence measure aimed at avoiding the unintended presence of GMOs in other crops. The decision also pointed out that the ban on the cultivation of mutagenic corn MON810 in the entire Italian territory had been established by Commission Implementing Decision no. 2016/321 of March 3, 2016 by which the geographical scope of the authorization had been modified.

Based on this precedent, in the case at hand the Court of Pordenone submits two questions to the Court of Justice for a preliminary ruling. On the one hand, the Italian judge wonders whether the cultivation ban of the FVG statute law could be considered as compatible with EU law and in particular with the Directive 2001/18EC and the Regulation 1829/2003EC.

On the other hand, the Court of Pordenone questioned whether such a ban could be construed as a measure having an equivalent effect prohibited by Articles 34, 35, and 36 TFEU.

3. – In order to understand the context in which the decision is set, it seems appropriate to briefly outline the Italian approach to the regulation of GMOs crops and the difficult process of implementation of EU law under Italian legislation.

The relevant EU framework was originally contained under Directives 90/219/EEC on the use of transgenic microorganisms and 90/220/EEC, on the deliberate release of genetically modified organisms. Both directives enacted a process of preliminary authorization for the release of GMOs on the market and in the environment. The authorization was to be delivered by the European Commission at the end of a verification procedure aimed at ascertaining the absence of possible risks from the products. The current regulation is now contained in Directives 2001/18/EC and 2009/41EC which replaced and modified the previous relevant legal framework. According to Article 2 of the Directive 2001/18/EC a genetically modified organism is defined as 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».

The European way of regulating transgenic organisms through prior authorization differs from the legal paradigm adopted in other jurisdictions. Diametrically divergent is the model chosen by the United States. U.S. food law opted for a substantial equivalence of the process used in determining the final characteristics of a product. In other words, the U.S. approach is finalized to a regulation of the *product* instead of the *process* to obtain such a product (F. Bruno, *Il Diritto alimentare*, Padova, 2022, 155 ss.).

Applied to GMO, this entails that similar products (e.g. GMO and non-GMO crops) present the same risks under a regulatory point of view (see *amplius* P. Borghi, *La disciplina comunitaria degli organismi geneticamente modificati e la sua applicazione italiana*, in A. Germanò (a cura di), *Diritto agrario comunitario e*

nazionale, Catanzaro, 2013, 197 ss.). GMO are then considered as «like-products», and consequently any limitation to their use in the lack of a scientific evidence consists in a discrimination prohibited by international commerce law.

On the contrary the European approach to the GMOs is focused on the different process required to obtain GM products so that a special risk assessment is considered as justified. This has an impact especially on the different requirements established for the information on food and ingredients to be provided to the consumers. Under the U.S. food law, producers are not bound to inform customers about the GMO nature of a product. Instead, as the present judgment of the ECJ suggests, according to EU law the need to allow the consumers to express a free and informed choice with respect to genetically modified products is a central objective of the Directive 18/2011 EC. The same need is set as a justification for the coexistence measures envisaged by Article 26b of the Directive.

Notably the need of a precise information of the consumers is faced through a specific set of rules concerning GMOs special labelling (see and J. Bovay, J.M. Alston, *GMO food labels in the United States: Economic implications of the new law*, in *Food Policy*, 78, 2018, 14-25). Products consisting of, containing or derived from GMOs (both food and animal feed) are subject to the labelling and traceability requirements set forth under Regulations no. 1829/2003 EC and no. 1830/2003 EC. The former establishes special labels and sets tolerance thresholds for the unintentional or technically unavoidable presence of GMOs in conventional food. However, according to Article 12 of the Regulation no. 1829/2003 EC, said requirements do not apply to foods containing authorized GMOs in a proportion inferior to 0.9%.

The presence of a tolerance threshold stems from the impossibility of preventing the adventitious or technically unavoidable presence of GMOs in conventional products. Finally, under Regulation (EC) No. 1830/2003 GM foods are subject to further traceability requirements so that GMOs can be individuated at all stages of the production and distribution chain.

4. – Coming to the European legal framework, it is possible to note that the transposition of the directives under Italian law has been rather difficult and has faced a quite enduring resistance. This is testified by the introduction of several bans on the cultivation of GMO seeds including MON810 despite the prior authorization of the European Commission (see for instance the so-called "Amato Decree" of August 4, 2000).

In this first phase of the entry of GMOs into the Italian context, the Court of Justice intervened on different occasions recognizing the contrast between Italian national and regional legislation and the EU law (see *Monsanto v. Italy*, ECJ, 9th September 2003, C-236/01, with case review by L. Marini, *La "sostanziale equivalenza" dei prodotti alimentari geneticamente modificati alla luce della sentenza Monsanto e degli sviluppi della normativa comunitaria*, in *Diritto del commercio internazionale*, 4, 2033, 854 - 863).

On the domestic front, however, Italian measures have often been "saved" by the jurisprudence of national courts on the basis of a broad interpretation of the precautionary principle (see *amplius* on the extent of the principle H. Bergkamp, L. Hanekamp, *European Food Law and the Precautionary Principle: Paradoxical Effects of the EU's Precautionary Food Policies*, in H. Bremmers, K. Purnhagen (eds), *Regulating and Managing Food Safety in the EU. Economic Analysis of Law in European Legal Scholarship*, Cham, 2018, 217-244 and A. Anyshchenko, *The precautionary principle in EU regulation of GMOs: socio-economic considerations*

and ethical implications of biotechnology, in *Journal of Agricultural and Environmental Ethics*, 5, 2019, 855-872).

In 2015, the Italian Council of State ruled that the national ban on the cultivation of MON210 was legitimate despite the previous authorization issued by the EU Commission (*inter alias* Cons. Stato, sec. III, 6th February 2015 no. 605; see *amplius* F. Albissini, *Diritto agroalimentare innanzi alle sfide dell'innovazione*, in *BioLaw Journal*, 2, 2020, 25-27).

On the other hand, the ECJ showed a quiet different approach toward Italian prohibitions to the GMO cultivations. In *Pioneer Hi Bread*, the Court ruled that the Italian authorities were not entitled to condition the cultivation of GMO crops to a national authorization in case they have been previously authorized according to EU law (see ECJ 6th September 2012, C-36/11, *Pioneer Hi Bread Italia SpA v. Italy*).

In *Fidenato v. Italy* (a case quite similar to the present), the ECJ added that Article 34 of Regulation no. 1829/2003 EC does not authorize member states to adopt emergency measures including bans to specific cultivations based on the reference to the precautionary principle alone (see ECJ 13th September 2017, C-111/16, *Giorgio Fidenato and Others v. Italy* with case review by S. Pitto, *La legittimità delle limitazioni statali agli alimenti OGM alla luce del principio di precauzione*, in *DPCE online*, 1, 2018, 245-253). Instead, such bans may be compatible with EU law only in case of evidence of a serious risk to human health, animal health or the environment.

Member States are then bound to provide precise scientific evidence to ground national limitations while similar evidence was lacking under the Italian ministerial decrees. In the light of such omission and considering the previous authorization issued by the EU Commission, according to the ECJ Member states are not allowed to adopt national bans to GMO invoking the precautionary principles.

The *Fidenato* decision seems to suggest a different approach to the precautionary principle between the ECJ and Italian courts: the latter are keen on relying on a broad interpretation of the principle extending its application to risks that might be just potential. On the other hand, the ECJ conclusion is based on a strict interpretation of the requirements of article 34 of the EU regulation no. 1829/2003 EC, especially with regards to the "*serious risk to human health, animal health or the environment*".

With respect to the precautionary principle, the Court's precedent supports a strict scrutiny of the scientific uncertainty needed to justify an exemption to the EU Regulation. Such an exemption cannot be granted based on a simple supposition but just on a solid identification of potential adverse effects that may jeopardize human health in view of the most reliable scientific data (see *ex multis* ECJ 28th January 2010, *Commission v. France* and ECJ 17th December 2015, *Neptune Distribution*, C-157/14).

The contrast has scaled down after the Directive no. 2015/412 has entered in force. According to the consolidated version of the Directive no. 2001/18/ EU as amended by the former, Member States are entitled to ban the cultivation of transgenic seeds on their territory even in case an authorization of the European Commission has been approved. In the light of such an amendment, Member states may limit the cultivation of GMO crops non just in view of risks for the environment or the health but with a much broader margin of discretion (e.g., land use regulation, socio-economic impacts, public order). Some scholars have raised criticism with respect to such amendments arguing that they may leave the ground to cultivation bans merely guided by ideological rather than scientific based concerns (F. Albissini, cit., 29).

Currently, Italy has opted for the introduction of bans to the cultivation of different genetically modified seed varieties through Legislative Decree No.

227/2016 and in accordance with Commission Implementing Decision (EU)2016/321 of March 3, 2016. The latter modifies the geographic scope of the authorization for the cultivation of genetically modified crops by excluding the Italian territory. The current domestic regulation, however, allows the import and marketing of GM products. Apart from the ban on cultivation, the use and marketing of genetically modified crops is widespread in Italy especially for animal feed (see 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*, 1, 2015, 2).

Italy however is not alone among the EU Member States still sceptical with respect to the cultivation of GMOs. After having invoked in 2008 the safeguard clause to establish a ban on the cultivation of MON810, the French Republic confirmed in 2014 the generalized ban to the cultivation of GM corn enacting an opt-out national provision (see *Arrêté du 14 mars 2014 interdisant la commercialisation, l'utilisation et la culture des variétés de semences de maïs génétiquement modifié*, in *Journal officiel de la Republique Francais*, Mar, 15, 2014, p. 5340). Germany as well prohibited the cultivation of GM crops as of 2009 and similar provisions may be appreciated in Greece, Austria and Luxemburg.

5. – After 2015, the cultivation of GM crops came to the fore mainly with regard to so-called coexistence measures between GMO and GMO-free crops. Among the reasons that are suitable to justify national limitations to the cultivation of GM plants, article 26b of the Directive 2001/18 CE envisaged the «avoidance of GMO presence in other products». The measure is deemed to regulate the coexistence of GMO and GMO-free products in the same territory, a matter which is addressed in the judgement of the EJC here commented.

The fundamental concern for the EU legislator in such respect is to avoid accidental contamination in order to maintain the different characteristics of each variety of products. This shall allow the consumers to express their potential choice to avoid products derived by genetically modified crops. In this respect, Article 26b of the Directive 2001/18 allowed Member States to adopt measures deemed to avoid the involuntary presence of GMOs in other crops even before the adoption of the Directive 2015/412 EU. Further to such amendments, the EU Commission adopted a Recommendation in 2003 with the purpose of providing guidance to the implementation of coexistence policies by the Member state.

The EU Commission Recommendation of 13th July 2010 allows Member States to establish GMO free zones within their territory in compliance with the principle of proportionality and pursuant to the scopes of EU law. As noted by the ECJ in the case here commented, coexistence measures must avoid unnecessary burdens on farmers, seed producers, cooperatives, and other stakeholders and should consider regional and local constraints and characteristics, such as the shape and size of fields in a given region and the agricultural management practices.

Italian authorities implemented the recommendation with the decree-law no. 279 of 22th November 2004, converted in law with statute law no. 5/2005, which represents the national legal framework for the coexistence measures (see M.C. Errigo, *Diritto e OGM. Una storia complicata*, in *BioLaw Journal*, 1, 2020, 273-275).

Pursuant to section 4 of the decree-law, the core of the relevant provisions is contained in the coexistence plans to be approved by the Italian regional authorities. The plans shall include the technical guidelines to carry out the coexistence with GM free crops. Stakeholders such as private and corporate bodies and NGO are entitled to participate in the process of approval. Section 8 of the decree-law also establishes that until the regional plans are approved, the cultivation of GM crops is forbidden with the only exception of the cultivation of GM crops authorized for research and experimental purposes.

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6. – It is within this context that the queries addressed to the Court of Justice by the Court of Pordenone are answered. The Court considered as a premise that the FVG region by regional law 8.4.2011 no. 5 adopted a regional plan on the use of GM organisms in agriculture. According to the regional authorities, FVG is characterized by models of production and farm structures that realize a marked risk in case of coexistence of transgenic and non-transgenic cultivation. The region then opted for a complete ban on the cultivation of GMO corn throughout the regional territory. The measure, based on Article 2.4. of the European Commission's July 13, 2010 recommendation, also envisaged a penalty between E. 5,000 and E. 50,000 in case of violation of the ban.

The Court of Pordenone held that the question does not concern the possibility of freely marketing MON810 in the Union's territory but the legality of the provision of a ban to cultivation extended to the entire regional territory.

It is also asked whether the regional ban may be construed as a measure with equivalent effect contrary to Articles 34, 35 and 36 TFEU. According to ECJ case law «All trading rules enacted by member states which are capable of hindering, directly or indirectly, actually or potentially, intra-community trade are to be considered as measures having an effect equivalent to quantitative restrictions» (see ECJ 11th July 1974, C-8/74 and 15th November 2005, C-320/03). As per the *Cassis de Dijon* case, any product lawfully manufactured and marketed in a Member state in accordance with the regulations and traditional manufacturing processes of that country, shall be admitted to the market of any other member state (see ECJ, 20th February 1979, C-120/78).

After rejecting the Italian government's preliminary objections, the Court addresses the first question in the merits. The Luxembourg court held that under Directive 2001/18 the release of GMOs into the environment is subject to prior authorization procedures involving an assessment and monitoring of risks to human health and the environment. Such an authorization is to be provided in accordance with principles and procedures subject to harmonization within the EU.

MON810 had been authorized by the Commission with the Commission's Decision 98/293/EC, dated April 22, 1998, which was in force on the date the penalty was imposed to PH in the case pending before the Court of Pordenone. In the Court's opinion, however, Member states are allowed to adopt coexistence measures under Article 26a of Directive 2001/18 even in the case of GMOs that have already been authorized (as stated in *Pioneer Hi Bred Italia*, C-36/11, cited above).

According to the Court, there are three requirements that national measures must meet. A first limitation concerns the purpose of the measures. Article 26b only allows measures aimed at averting the unintended presence of GMOs in conventional organic or GMO-free crops while it does not justify limitations motivated by health and environmental protection concerns. This is because these objectives are pursued through the Commission's harmonized EU-wide authorization procedure. In the *Fidenato case* the Court had then excluded that a coexistence measure could be justified by the presence of a national authorization procedure for GMO cultivation (see ECJ 8th May 2013, *Fidenato* v. *Italy*, C-542/12, point 33).

The measures considered by Article 26b have a different *ratio*: on the one hand, the protection of biodiversity and the plurality of crops as well as the need to preserve the particularities of GMO-free and organic seeds. Certain characteristics of genetically modified crops may actually grant a higher level of diffusion of the plants and ultimately make it difficult to separate one product from another. On the other hand, Article 26b pursues the interest in ensuring that consumers make an informed choice of the food product they intend to purchase.

The second requirement according to the Court is that the national measures shall be appropriate in the terms of Article 26b. In light of the principle

of proportionality the Court considers appropriate those measures that effectively achieve the goal of avoiding the unintended presence of GMOs in other products, preserve consumers' right to choose and sacrifice to the least possible extent the objectives of the EU law.

Finally, Member States are required to take in account the guidelines annexed to the European Commission's Recommendation of 13th July 2010, including general principles for national coexistence measures. While the guidelines are not strictly binding, in the Court's view, they must be considered by the judicial authorities of Member States when deciding disputes brought in relation to coexistence measures.

In essence, the Court invites the referring court (and in general the courts of the Member states) to be the "guardian" of the requirements of the directive and to assess the legitimacy of the ban imposed by the FVG region. To carry out this evaluation, the national court must take into consideration the compatibility between the domestic measure and the objective pursued. In addition, the Court must also determine whether the ban is necessary or proportionate to pursue said objective. In the decalogue of criteria available suggested to the domestic courts, the ECJ includes factors such as the evaluation of the optimal levels of admixture pursued by the measures, the local special characteristics and needs (biological, climatic, etc.) and the actual likelihood of the risk of admixture between crops. The purity levels of GMO-free crops should also be considered in light of the economic incidence of admixture with various types of crops, which is evidently higher in organic crops.

On the first issue, therefore, the Court ruled that Article 26a of Directive 2001/18 does not preclude national prohibition measures provided that these, upon assessment by the national court, are necessary to achieve the objective and proportionate, allowing choice over the product to be consumed by consumers.

7. – The second question, is answered rather briefly by the Court of Justice. With it, the Pordenone Tribunal questioned whether a national ban on GMOs could be construed as or result in a measure with equivalent effect prohibited by EU law. The Luxembourg Court in this regard qualified the question in different terms: according to the European judge, in an area subject to complete harmonization such as GMOs regulation, a national measure must be assessed in the light of the act of harmonization and not by virtue of primary law (see paragraph 61 of the case commented).

The Court is convinced that the pre-distribution authorization of the GMO provided for in EC Directive 2001/18 EC and Regulation No. 1829/2003 EC establishes a harmonized legal framework in the territory of the EU. Therefore, in the absence of an authorization in accordance with these EU provisions, GMO products cannot be distributed in the common market. Although Article 22 of the directive prohibits the re-discussion within national legal systems of an already authorized authorization for the distribution of GMOs, the Court notes that the coexistence measures in Article 26a provide a common exemption throughout the EU. Therefore, the Court concludes that any national measure restricting the cultivation or marketing of GMOs should be subject to a review of legality under the Directive itself and/or Regulation 1829/2003 but not under Articles 34-36 TFEU.

8. – The Court of Justice takes the opportunity of this reference for a preliminary ruling to clarify the limits of the review on the coexistence measures adopted by Member states in order to avoid the unintended presence of GM food.

A first element concerns the role of national courts with respect to the evaluation of domestic policies introducing restrictions to the cultivation of GM

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crops in the territory of the EU. Although according to the Court the Italian ban on a product such as MON810 already authorized by the Commission cannot be considered *prima facie* contrary to Union law, national courts are required to assess compliance with the requirements set forth in Article 26b of Directive 2001/18 EC and verify that the «measures are in conformity with Union law, reasoned, proportional and non-discriminatory» as well as founded on the compelling interests indicated (see L. Galizia, *La Corte di Giustizia sugli OGM friulani*, in www.lexfood.it, 26.7.2022, last view on the 18th November 2022).

The Court's emphasis on highlighting the limits on national policies seems appreciable in the face of the extensive list of compelling grounds for coexistence measures under Article 26b. The aforementioned reasons often relate to a wide political discretion not always conveyed by actual scientific justifications related to the implementation of the precautionary principle or to other interests deserving of protection under EU law (e.g. "public policy" envisaged by Article 26b section 3, g), see F. Albissini, cit., 31). This may be particularly appreciated in a system such as the Italian one that has historically been hostile to the spread of GMO crops and characterized by an enduring struggle between the need to promote technological innovation in food market and concerns for the protection of food safety (cf. A. Stazi, *Genetically Modified Organisms and Sustainable Development: circulation of models, access to resources and traceability*, in L. Scaffardi, V.Z. Zencovich (eds.), *Food and Law. A comparative perspective*, Rome, 2020, Vol. II, 555-557, available at https:/romatrepress.uniroma3.it/libro/cibo-e-diritto-una-prospettiva-comparata).

Quiet surprisingly, however, a question that remains unanswered in the judgement is whether a provision related to "coexistence" is to be deemed *prima facie* compatible with a generalized ban on cultivation of GM crops as the one established by FVG regional statute. In this context, it is possible to argue that the coexistence would remain only theoretical.

Finally, it may be noted that the ECJ does not clarify in the judgment whether the scrutiny on the national measure may be extended to the assessment of the proportionality of the fine imposed on PH. Instead, the clarification would have represented a quite useful support to the national courts. In such regards, it is necessary to consider that ECJ has recently recognized the authority of the national courts to disapply sanctions established by domestic law in case they result unproportionate (see ECJ 8th March 2022, C-205/20). Just as in the aforementioned precedent, in the case here commented it is possible to note that Directive 2001/18 EC stipulates that sanctions adopted by Member States to censure violations of national transposition measures must be proportionate (namely «effective, proportionate and dissuasive»; see Article 33 of the Directive 18/2001EC).

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