

**Case C-364/24 [Dalfardo] <sup>i</sup>****Summary of the request for a preliminary ruling pursuant to Article 98(1) of the Rules of Procedure of the Court of Justice****Date lodged:**

17 May 2024

**Referring court:**

Consiglio di Stato (Italy)

**Date of the decision to refer:**

14 May 2024

**Applicant at first instance and appellant:**

PH, on his own account and as owner of the agricultural holding ‘In Trois’

**Defendant at first instance and respondent:**

Ministero dell’Agricoltura, della Sovranità Alimentare e delle Foreste

**Subject matter of the main proceedings**

Action brought against an act of the Ministero delle Politiche Agricole, Alimentari e Forestali (Ministry of Agricultural, Food and Forestry Policies) ordering the destruction of certain MON 810 genetically modified maize crops, and against the penalty resulting from the applicant’s failure to comply with that measure, claiming that the decision at issue is unlawful.

**Subject matter and legal basis of the request**

The reference for a preliminary ruling, made by the Consiglio di Stato (Council of State) pursuant to Article 267 TFEU, concerns the compatibility of Articles 26b and 26c of Directive 2001/18/EC with certain provisions of Regulation No 1829/2003, of the TEU, of the TFEU and of the Charter of Fundamental

<sup>i</sup> The name of the present case is fictitious. It does not correspond to the real name of any of the parties to the proceedings.

Rights of the European Union, and the determination of whether those articles are unlawful. In addition, if those articles are found to be unlawful, the question arises as to whether that would result in Commission Implementing Decision (EU) 2016/321, adopted on the basis of Article 26c of Directive 2001/18/EC, being invalid.

### **Questions referred for a preliminary ruling**

(1) Are Articles 26b and 26c of Directive 2001/18/EC, as amended by Directive (EU) 2015/412, compatible with Article 34 of Regulation No 1829/2003, Article 3 TEU, Articles 2, 3, 26, 34, 35 and 36 TFEU and Articles 16 and 52 of the Charter of Fundamental Rights of the European Union?

(2) If the above question is answered in the negative, may Commission Implementing Decision (EU) 2016/321 of 3 March 2016, adopted on the basis of Article 26c of Directive 2001/18/EC, be disregarded by the referring court or declared invalid on the ground that that Article 26c has been found not to comply with the higher-ranking rules of the TEU and the TFEU?

### **Provisions of European Union law and case-law relied on**

Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed; Article 34

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, Articles 22 and 23 and 26b and 26c introduced by Directive (EU) 2015/412

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;

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 (MON-ØØ81Ø-6); recitals 6 to 8

Treaty on European Union (TEU); Articles 3, 6(1) and 19(1)

Treaty on the Functioning of the European Union (TFEU); Articles 2, 3, 26, 34, 35 and 36

Charter of Fundamental Rights of the European Union; Articles 16 and 52

Judgments of the Court of Justice of 6 September 2012, *Pioneer Hi Bred Italia*, C-36/11, and of 13 September 2017, C-111/16, and order of 23 November 2017 in Case C-107/16

### **Provisions of national law relied on**

Article 35 bis of decreto legislativo 8 luglio 2003, n. 224, “Attuazione della direttiva 2001/18/CE concernente l'emissione deliberata nell'ambiente di organismi geneticamente modificati” (Legislative Decree No 224 of 8 July 2003, ‘Implementation of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms’), as introduced by decreto legislativo 14 novembre 2016, n. 227, “Attuazione della direttiva (UE) 2015/412, che modifica la direttiva 2001/18/CE per quanto concerne la possibilità per gli Stati membri di limitare o vietare la coltivazione di organismi geneticamente modificati (OGM) sul loro territorio” (Legislative Decree No 227 of 14 November 2016, ‘Implementation of Directive (EU) 2015/412 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’):

‘Penalties relating to Title III-*bis*:

Unless the acts constitute a criminal offence, an administrative fine of between EUR 25 000 and EUR 75 000 shall be imposed on any person who fails to have regard to:

(a) prohibitions banning cultivation introduced by an adjustment to the geographical scope laid down, in the cases provided for, by one of the following measures:

(1) authorisation granted by the European Commission pursuant to Articles 7 and 19 of Regulation (EC) No 1829/2003;

(2) consent issued by the competent national authority of a Member State pursuant to Articles 15, 17 and 18 of Directive 2001/18/EC;

(3) authorisation issued by the competent national authority referred to in Article 2(1) pursuant to Article 18(1) and, if the conditions are met, the decision taken by that authority pursuant to Article 18(3);

(b) prohibitions banning cultivation adopted pursuant to paragraph 6 of Article 26-*quater*;

(c) temporary prohibitions on the planting of the GMO(s) concerned provided for in paragraph 5(b) of Article 26-*quater* and paragraph 3 of Article 26-*sexies*.

2. Offenders shall be subject, pursuant to an injunction, to an ancillary administrative penalty consisting of the suspension, for up to six months, of the authorisation to cultivate GMOs conferred under the marketing measures.

3. Anyone who infringes the prohibitions laid down in paragraph 1 shall be required to destroy the GMO crops that have been unlawfully planted and to restore the areas affected to their original condition at their own expense, jointly and severally with the owner and the holders of real or personal rights of enjoyment over the area, to whom that infringement is attributable either by reason of intent or through their fault, on the basis of findings made by the persons responsible for the inspection in the course of a procedure involving the persons concerned in which they are given the opportunity to be heard. The authority referred to in paragraph 4 shall order the operations necessary for that purpose and shall lay down the period within which they are to take place, after which it shall implement the order against those involved and shall recover the sums advanced. (...)'.

#### **Succinct presentation of the facts and procedure in the main proceedings**

- 1 The applicant in the main proceedings ('the applicant') is the owner of an agricultural holding. On some of his land, he cultivated 16 rows of MON 810 GMO maize, type DKC 6729 YG and DKC 5741 YG, planted in the 2021 sowing year.
- 2 On 8 September 2021, an inspection was carried out on that land and samples were taken, which were then tested for the presence of GMOs.
- 3 By order No 511800 of 14 October 2021, appealed at first instance, the Ministry of Agriculture, Food and Forestry Policies ('the Ministry') stated that the samples taken from the applicant's land and analysed in the laboratory showed the presence of the CaMV 355 transgenic promoter, and thus the presence of GMOs in the maize crops on the land used.
- 4 Since the cultivation of MON 810 genetically modified maize is prohibited in Italy under Commission Implementing Decision (EU) 2016/321 of 3 March 2016, the Ministry imposed on the applicant the penalty provided for in Article 35-*bis* of Legislative Decree No 224 of 8 July 2003.
- 5 Pursuant to that penalty, the applicant should have destroyed the GMO crops unlawfully planted on his land and restored the areas affected to their original condition at his own expense, at the latest five days from notification of the measure at issue. The applicant was also advised that, if he did not comply with the request within the above-mentioned period, the administration would itself proceed with the destruction and would then recover from the applicant the sums advanced for that purpose.

- 6 On 19 October 2021, since the applicant had not complied with the order to destroy the GMO maize cultivated, the administration proceeded to remove it.
- 7 The applicant brought an action before the Tribunale Amministrativo Regionale per il Friuli Venezia Giulia (Regional Administrative Court, Friuli-Venezia Giulia) against the decision at issue, claiming that it was unlawful both on the ground of defects inherent in the act itself and on the ground of derived unlawfulness, in so far as it was adopted on the basis of provisions of national and EU law that were incompatible with EU law.
- 8 After the Regional Administrative Court, Friuli-Venezia Giulia had dismissed his action, the applicant brought an appeal before the referring court.

### **The essential arguments of the parties in the main proceedings**

- 9 The applicant stated that he had sown maize crops with GMOs solely for research purposes and in order for the issue of the lawfulness of Directive 412/2015/EU to be raised before the Court of Justice. In particular, he submits that Articles 26b and 26c of Directive 2001/18/EEC, introduced by Directive 2015/415, are unlawful, and that therefore Commission Implementing Decision 2016/321, adopted on the basis of Article 26c of that directive, is also unlawful.
- 10 The applicant claims that MON 810 maize was authorised for cultivation by Commission Decision 294/1998 on the basis of Article 19 of Directive 2001/18/EC and on the basis of paragraph 74 of the judgment of the Court of Justice in Case C-36/11; according to the applicant, therefore, once a GMO maize has obtained authorisation for cultivation and benefits from full and complete freedom of movement, it is for the Member State, not an individual, to justify the derogation from the free movement of those goods.
- 11 The applicant argues that Directive 2001/18/EC is contrary to Article 36 TFEU in two respects: on the one hand, it allows the introduction of a prohibition on cultivation – known as the ‘adjustment of the geographical scope’ – of a GMO authorised on the basis of a simple and unreasoned demand by the Member State to the holder of the authorisation and, on the other hand, it provides that a Member State may introduce a prohibition on cultivation on the basis of the new and different grounds referred to in Article 26b(3) and Article 26c(4) of that directive. However, Article 36 TFEU states, with regard to the free movement of goods, that prohibitions and restrictions are not to constitute a means of arbitrary discrimination or a disguised restriction on trade between Member States.
- 12 In the applicant’s view, the authorisation already granted for the cultivation of MON 810 GMO maize shows that there is no specific risk of harm to health and the environment, and therefore the issue of its legitimate economic interest should be regarded as secondary.

- 13 The applicant adds that the total or partial prohibition of GMO cultivation is a disproportionate and unreasonable instrument for the appropriate and effective pursuit of the objective of enabling the exercise of the right to engage in business. He maintains that the protection of health and the environment is ensured because there are agronomic techniques capable of preventing the unintended presence of GMOs in other products grown nearby.
- 14 According to the applicant, the measures provided for in Directive 2001/18/EC do not meet objectives of general interest recognised by the Union and are manifestly and irreparably contrary to the essence of the freedoms enshrined in the EU Treaties.

### **Succinct presentation of the reasoning in the request for a preliminary ruling**

- 15 The referring court recalls that the cultivation of MON 810 maize was prohibited in Italy as a result of Commission Implementing Decision EU 2016/321. Authorisation for the product had initially been granted to Monsanto Europe SA, which had applied for renewal of the authorisation in May 2007. In view of the Court of Justice's ruling in Case C-36/11, MON 810 maize had to be regarded as authorised in Italy on the basis of Regulation No 1829/2003, the assessment of the risks to health and the environment having thus been bypassed.
- 16 Subsequently, Directive (EU) 2015/412 introduced the possibility for a Member State to request the adjustment of the geographical scope of a cultivation authorisation already granted, so as to exclude all or part of its territory from cultivation. The Italian State submitted such a request for adjustment in respect of MON 810 maize and, by Implementing Decision 2016/321, adopted pursuant to Article 26c of Directive 2001/18, the cultivation of genetically modified maize (*Zea mays* L.) MON 810 was prohibited.
- 17 In those circumstances, the Italian authorities charged the applicant with the offence provided for in Article 35-*bis* of Legislative Decree No 224/2003, which penalises [infringements of] the cultivation bans introduced through the adjustment of the geographical scope.
- 18 The referring court examines the applicant's argument that the system established by Articles 26b and 26c of Directive 2001/18/EC has the effect of prohibiting the cultivation of certain GMO products in only some of the Member States, thus introducing conditions that could create imbalances in the internal market. Furthermore, as regards the geographical adjustment of authorisations, it is argued that this creates genuine internal barriers to the single market which impede the movement of products and lead to quantitative restrictions.
- 19 The referring court concludes that the solution adopted in Articles 26b and 26c of Directive 2001/18/EC raises doubts, in so far as the latter directive grants Member States, in essence, a change to the geographical scope of an authorisation relating

to a GMO product, without having to provide any justification or proof of the existence of any serious harm.

- 20 According to the referring court, the requirement that there must be a serious risk to human health, animal health or to the environment in order for an urgent suspension or modification of an authorisation to be ordered is also apparent from Article 34 of Regulation No 1829/2003, as interpreted by the Court of Justice in the order in Case C-107/16 and the judgment in Case C-111/16. Furthermore, citing recitals 6 to 8 in the preamble to Directive (EU) 2015/412 (which amended Directive 2001/18/EC), the referring court concludes that that directive did not seek to call into question the confidence placed in the risk assessment carried out when an authorisation for a GMO product was granted, and that the above-mentioned recitals state that the opposition of certain Member States to GMOs stems from considerations not associated with safety for health and the environment.
- 21 According to the referring court, it is clear, on the contrary, that Directive (EU) 2015/412 sought to grant the Member States an area of decision-making autonomy, but on the basis of reasoning which appears to be forced: the limitations relied on by a Member State may, in its view, increase the lack of confidence of the citizens of that State in relation to GMO products, making it more difficult for them to circulate within EU territory, despite the fact that their production and placing on the market are covered by an authorisation issued pursuant to the provisions of EU law.
- 22 In addition, the referring court states that Articles 26b and 26c of Directive 2001/18/EC conflict with Article 22 of Directive 2001/18/EC, which requires Member States not to prohibit, restrict or impede the placing on the market of GMOs, and with Article 23 of that directive, which lays down a safeguard clause under which Member States may provisionally restrict or prohibit the use of GMO products if they have detailed grounds for considering that the products constitute a risk to health or the environment on the basis of new or additional scientific knowledge. In the referring court's view, on the one hand it is reaffirmed that restrictions on the movement of GMO products that have already been authorised are permissible only if they are supported by new studies showing their danger, while, on the other hand, Member States are permitted to avoid the obligation to allow the free movement of products covered by a specific authorisation, issued after a risk assessment has been carried out.
- 23 According to the referring court, the legal basis of Articles 26b and 26c of Directive 2001/18/EC does not therefore appear capable of justifying the injury to the rights of economic operators, which is directly linked to the 'geographical adjustments' of authorisations to produce GMO products and place them on the market.

- 24 In its view, such an adverse effect is not justified and cannot therefore be regarded as consistent with the principle of proportionality; furthermore, the rules at issue are liable to affect the internal market.
- 25 Therefore, if Articles 26b and 26c of Directive 2001/18/EC, as amended by Directive (EU) 2015/412, were found to be unlawful, the question would arise as to whether Commission Implementing Decision 2016/321, which allowed the Italian State to prohibit the cultivation of MON 810 maize in Italian territory, is still valid.
- 26 A judgment by the Court of Justice is necessary because, if it were to find that Articles 26b and 26c of Directive 2001/18/EC were unlawful, that would lead to the annulment of the penalty at issue in the main proceedings.

WORKING DOCUMENT