



Reports of Cases

OPINION OF ADVOCATE GENERAL
BOBEK
delivered on 30 March 2017¹

Case C-111/16

Giorgio Fidenato and others

(Request for a preliminary ruling from the Tribunale di Udine (District Court, Udine, Italy))

(Request for a preliminary ruling – Agriculture – Genetically modified food and feed – Prohibition of cultivation of genetically modified maize MON 810 – Emergency measures adopted by Member States – Substantive conditions – Precautionary principle)

I. Introduction

1. Mr Fidenato and others ('the Applicants') were prosecuted for having grown genetically modified maize MON 810 in breach of a decree prohibiting its cultivation on the Italian territory. That decree was taken as an emergency measure under Article 34 of Regulation No 1829/2003 on genetically modified food or feed.²

2. In the context of criminal proceedings against the Applicants, the Tribunale di Udine (District Court, Udine, Italy) referred a number of questions to the Court. One of the questions posed by the referring court concerns the relationship between Article 34 of Regulation No 1829/2003 and the precautionary principle. Are the conditions for the adoption of emergency measures listed in Article 34 exhaustive? Or could that Article be supplemented or expanded by a parallel or even independent application of the precautionary principle?

3. The Court has already provided some guidance on the interpretation of Article 34 of Regulation No 1829/2003 in *Monsanto*.³ The relationship between the precautionary principle and that Article, which was left unexplored by the Court in *Monsanto*, is the focus of this Opinion.

¹ Original language: English.

² Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ 2003 L 268, p. 1).

³ Judgment of 8 September 2011, *Monsanto and Others* (C-58/10 to C-68/10, EU:C:2011:553).

II. Legal framework

A. EU law

1. Regulation No 1829/2003

4. Recital 3 of Regulation (EC) No 1829/2003 of 22 September 2003 on genetically modified food and feed states that ‘in order to protect human and animal health, food and feed consisting of, containing or produced from genetically modified organisms... should undergo a safety assessment through a Community procedure before being placed on the market within the Community’.

5. Article 1 sets out the objective of the Regulation:

‘The objective of this Regulation, in accordance with the general principles laid down in Regulation (EC) No 178/2002, is to:

- (a) provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food or feed, whilst ensuring the effective functioning of the internal market;
- (b) lay down Community procedures for the authorisation and supervision of genetically modified food and feed;

...’.

6. Pursuant to Article 34, entitled ‘emergency measures’:

‘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’.

2. Regulation No 178/2002

7. Recital 20 of Regulation (EC) No 178/2002 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 safety⁴ reads: ‘the precautionary principle has been invoked to ensure health protection in the Community, thereby giving rise to barriers to the free movement of food or feed. Therefore it is necessary to adopt a uniform basis throughout the Community for the use of this principle’.

8. Recital 21 states that: ‘in those specific circumstances where a risk to life or health exists but scientific uncertainty persists, the precautionary principle provides a mechanism for determining risk management measures or other actions in order to ensure the high level of health protection chosen in the Community’.

⁴ Regulation (EC) No 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 (OJ 2002 L 31, p. 1).

9. Article 4(2) sets out that ‘the principles laid down in Articles 5 to 10 shall form a general framework of a horizontal nature to be followed when measures are taken’. Section 1 of Chapter II of the Regulation follows immediately with Articles 6 and 7, and bears the title ‘general principles of food law’.

10. Article 6 is on risk analysis:

‘1. In order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis except where it is not appropriate to the circumstances or the nature of the measure.

2. Risk assessment shall be based on the available scientific evidence and undertaken in an independent, objective and transparent manner.

3. Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority referred to in Article 22 [EFSA], other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant, in order to achieve the general objectives of food law established in Article 5.’

11. Article 7 is entitled ‘precautionary principle’. It states that:

‘1. 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.

2. Measures adopted on the basis of paragraph 1 shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration. The measures shall be reviewed within a reasonable period of time, depending on the nature of the risk to life or health identified and the type of scientific information needed to clarify the scientific uncertainty and to conduct a more comprehensive risk assessment.’

12. Articles 53 and 54 regulate emergency measures for food and feed of Community origin or imported from a third country.

13. Under Article 53(1):

‘where it is evident that food or feed originating in the Community or imported from a third country is likely to constitute a serious risk to human health, animal health or the environment, and that such risk cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, acting in accordance with the procedure provided for in Article 58(2) on its own initiative or at the request of a Member State, shall immediately adopt one or more of the following measures...’

14. Pursuant to Article 54:

‘1. Where a Member State officially informs the Commission of the need to take emergency measures, and where the Commission has not acted in accordance with Article 53, the Member State may adopt interim protective measures. In this event, it shall immediately inform the other Member States and the Commission.

2. Within 10 working days, the Commission shall put the matter before the Committee set up in Article 58(1) in accordance with the procedure provided for in Article 58(2) with a view to the extension, amendment or abrogation of the national interim protective measures.

3. The Member States may maintain its national interim protective measures until the Community measures have been adopted.’

15. Article 58(1) reads as follows:

‘The Commission shall be assisted by a Standing Committee on the Food Chain and Animal Health, hereinafter referred to as the “Committee”, composed of representatives of the Member States and chaired by the representative of the Commission. The Committee shall be organised in sections to deal with all relevant matters.’

B. Italian law

16. The Decree of 12 July 2013⁵ has prohibited the cultivation of varieties of maize MON 810 coming from genetically modified seeds on the national territory until Community measures are adopted under Article 54(3) of the abovementioned Regulation and, in any event, not after 18 months from the date of the present measure. The prohibition has been further prolonged by the Decree of 22 January 2015.⁶

17. Article 4(8) of the Decree Law of 24 June 2014⁷ provides that:

‘Save where the act constitutes a more serious criminal offence, any person who fails to have regard to prohibitions banning cultivation introduced by measures adopted, including by way of precautionary measure, pursuant to Articles 53 and 54 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, shall be punished by a fine of between EUR 25 000 and EUR 50 000. The persons responsible for the offence covered by this paragraph shall also be required to remove, at his own expense and in accordance with the requirements imposed by the competent monitoring body in the performance of its criminal investigative functions, any seed crops which are prohibited and to take primary and compensatory remediation measures within the periods and in accordance with the procedures prescribed by the competent region for the territory in question.’

⁵ Decreto del 12 luglio 2013. Adozione delle misure d’urgenza ai sensi dell’art. 54 del regolamento (CE) n° 178/2002 concernente la coltivazione di varietà di mais geneticamente modificato, (GU Serie Generale n° 187 del 10 agosto 2013). (Decree of 12 July 2013 on the adoption of emergency measures within the meaning of Article 54 of Regulation (EC) No 178/2002 concerning the cultivation of varieties of genetically modified maize MON 810), (GU General Series No 187 of 10 August 2013).

⁶ Decreto del 22 gennaio 2015, (GU Serie Generale n°33 del 10 febbraio 2015). (Decree of 22 January 2015), (GU General Series No 33 of 10 February 2015).

⁷ Disposizioni urgenti per il settore agricolo, la tutela ambientale e l’efficientamento energetico dell’edilizia scolastica e universitaria, il rilancio e lo sviluppo delle imprese, il contenimento dei costi gravanti sulle tariffe elettriche, nonché per la definizione immediata di adempimenti derivanti dalla normativa europea. Decreto-Legge convertito con modificazioni dalla Legge 11 Agosto 2014, n° 116 (S.O. n° 72, relativo alla G.U. 20 Luglio 2014, n° 192). (Urgent measures for the agricultural sector, environmental protection and energy efficiency in school and university buildings, the relaunching and development of undertakings, the reduction of costs relating to electricity tariffs, and for the immediate establishment of measures ensuring compliance with EU law. Decree-Law converted, with amendments, by Law No 116 of 11 August 2014). (GU General Series No 192 of 20 August 2014, Ordinary Supplement No 72).

III. The dispute in the main proceedings and the questions referred

18. By decision of 22 April 1998,⁸ the European Commission authorised the placing on the market of genetically modified maize MON 810. In its decision, the Commission referred to the opinion delivered on 10 February 1998 by the Scientific Committee, which stated that there was no reason to believe that the placing on the market of that product would have any adverse effects on human health or the environment.

19. By a letter dated 11 April 2013, the Italian Government requested the Commission to adopt emergency measures, pursuant to Article 53 of Regulation No 178/2002, in order to ban the cultivation of genetically modified maize MON 810. In support of their request, the Italian Government submitted scientific studies carried out by the Consiglio per la ricerca e la sperimentazione in agricoltura (Agricultural Research Council, 'CRA') and by the Istituto Superiore per la Protezione e la Ricerca Ambientale (Institute for Environmental Protection and Research, 'ISPRA').

20. On 17 May 2013, the Commission replied to the Italian Government stating that, based on its preliminary assessment, no urgent need had been established for adopting measures pursuant to Articles 53 and 54 of Regulation No 178/2002.

21. In order to carry out a more detailed analysis of the scientific evidence provided by Italy, however, the Commission also indicated that it would ask the European Food Safety Authority (EFSA) to evaluate the scientific evidence that had been submitted by Italy. On 29 May 2013, the Commission asked EFSA to assess that evidence.

22. On 24 September 2013, EFSA issued Scientific Opinion No 3371, in which it concluded that '[i]n 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 and to invalidate its previous conclusions on the safety of maize MON 810 (EFSA, 2009, 2011 a, b, 2012 a, b, c, d). Therefore, the EFSA GMO Panel considers that its previous risk assessment conclusions on maize MON 810, as well as its previous recommendations for risk mitigation measures and monitoring, remain valid and applicable'.

23. In the meantime, even though the Commission had stated that no urgent need to adopt emergency measures had been shown, the Italian Government had adopted the Decree of 12 July 2013 prohibiting the cultivation of varieties of genetically modified maize MON 810 on the basis of Article 34 of Regulation No 1829/2003, in conjunction with Article 54 of Regulation No 178/2002.

24. Following the adoption of the Italian measure, the Commission did not convene the Standing Committee on the Food Chain and Animal Health pursuant to Articles 54(2) and 58(1) of Regulation N°178/2002. The Commission left the authorisation of MON 810 unchanged.

25. Mr Fidenato and others were prosecuted before the Tribunale di Udine (District Court, Udine, Italy) for having cultivated genetically modified maize MON 810 in breach of the aforementioned Decree. A penal order was issued, condemning the Applicants for having infringed Article 4(8) of Decree Law No 91/2014.

26. Mr Fidenato and others lodged an opposition against that penal order. They claimed that the Decree was unlawful, since it was issued in breach of Article 34 of Regulation No 1829/2003 and of Articles 53 and 54 of Regulation No 178/2002.

⁸ Commission Decision of 22 April 1998 concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON 810), pursuant to Council Directive 90/220/EEC (OJ 1998 L 131, p. 32).

27. By order of 10 December 2015, the Tribunale di Udine (District Court, Udine, Italy) referred the following questions to the Court:

- (a) When requested to do so by a Member State, is the Commission required, for the purposes of Article 54(1) of Regulation No 178/2002, to adopt emergency measures within the meaning of Article 53 of Regulation No 178/2002, even if in the Commission's assessment in respect of certain food or feed there is no serious, evident risk to human and animal health or to the environment?
- (b) Where the Commission notifies the Member State which had sought its assessment that its assessment is at odds with the Member State's request — an assessment which in theory precludes the need to adopt emergency measures — and where, accordingly, the Commission does not adopt such emergency measures within the meaning of Article 34 Regulation No. 1829/2003 as requested by that Member State, is the Member State which made the request authorised, pursuant to Article 53 of Regulation No 178/2002, to adopt interim emergency measures?
- (c) May considerations relating to the precautionary principle which go beyond the parameters of serious and evident risk to human or animal health or the environment in the use of food or feed justify the adoption of interim emergency measures by a Member State within the meaning of Article 34 of Regulation No 1829/2003?
- (d) Where it is clear and obvious that the European Commission has made the assessment that the substantive conditions for the adoption of emergency measures for food or feed are not met, which is later confirmed by an EFSA Scientific Opinion, and where that assessment was notified in writing to the Member State which made the request, may that Member State continue to maintain in force its existing interim emergency measures and/or extend the validity of such interim emergency measures, when the interim period for which they were put in place has expired?

28. Written observations were submitted by the Greek and Italian Governments and by the European Commission. Mr Fidenato, the Italian Government and the Commission presented oral argument at the hearing held on 9 February 2017.

IV. Assessment

29. In accordance with the request made by the Court, this Opinion focuses on the third question posed by the national court. By that question, the national court essentially asks whether emergency measures may be taken on the basis of the precautionary principle for risks that have not been explicitly foreseen by Article 34 of Regulation No 1829/2003. In other words, the national court enquires about the relationship between the precautionary principle and urgent measures under Article 34: could the precautionary principle alter or expand the conditions relating to a serious and evident risk as stated in Article 34?

30. My concise answer to that question is 'no'. The more detailed answer provided in this Opinion is structured as follows. First, I outline the precautionary principle in general terms, and as embedded in Article 7 of the Regulation No 178/2002 (Section 1). Second, I analyse Article 34 of Regulation No 1829/2003 (Section 2). Third, I examine the relationship between Article 34 and the precautionary principle and explain why, in my view, the latter may only guide the interpretation of the former without expanding its scope (Section 3). I conclude by examining the potential impact of Directive

No 2015/412⁹ (Section 4).

1. The precautionary principle

31. The precautionary principle reflects the virtue of prudence in a society which is increasingly depicted as a ‘risk society’.¹⁰ Such a society is characterised by unclear risks resulting from new technologies and, more broadly, from rapid scientific progress. In such a society, public authorities may wish to rely on a ‘rule of action in situations of uncertain risks’¹¹ that may be also translated into a duty of inaction on the part of responsible undertakings. It appears that the precautionary principle takes on such a rule.

32. The precautionary principle justifies preventive action in order to avert risks that have not yet been fully identified or understood because of scientific uncertainty. Defined in such a broad way, that principle could be construed as encompassing a wide range of risks to a variety of interests, be it the environment, health, public security, social justice, or perhaps even morality. However, if such a broader perception were to prevail, the difficulty then becomes how to determine where to draw the line so that the precautionary principle does not turn into a universal incantation to block innovation. By definition, innovation implies novelty in relation to the extant knowledge.

33. In EU law, however, it appears that the precautionary principle is understood more narrowly.¹²

34. In primary law, the precautionary principle can be found in Article 191(2) TFEU. The latter provision is applicable, however, only in the context of the Union’s environmental policy. In secondary law, other policy areas are also taken into account, such as, notably, health. As regards genetically modified organisms (GMOs) in particular, Directive No 2001/18¹³ and Regulation No 1829/2003 establish a comprehensive legal framework for the authorisation of GMOs. Regulation No 1829/2003 does not mention the precautionary principle in its text. Directive No 2001/18, on the other hand, makes several references to the precautionary principle, without, however, explicitly defining it.¹⁴

35. In the area of food law, the precautionary principle is (legislatively) defined in Article 7 of the Regulation No 178/2002. That definition could be said to contain four elements: the type of interest protected (i), the level of (un)certainty present (ii), the proportionality of the measure (iii), and the provisional nature of the measure adopted on the basis of the risk assessment.

36. First, Article 7 of the Regulation No 178/2002 spells out only one interest which may trigger the application of the precautionary principle: health. Thus, no other interest may justify the adoption of measures by virtue of Article 7. That restrictive ambit may be understood as logically connecting to the overall objective of the Regulation No 178/2002, which is to ensure a high level of protection of human life and health.¹⁵

9 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 (OJ 2015 L 68, p. 1).

10 See Beck, U., *Risikogesellschaft. Auf dem Weg in eine andere Moderne*, Suhrkamp, 1986.

11 Opinion of Advocate General Alber in *Monsanto Agricoltura Italia and Others* (C-236/01, EU:C:2003:155, point 108).

12 See, for a broad overview, the communication from the Commission on the precautionary principle (COM (2000) 1 final). For an overview of the judicial understanding of the principle, see José Luís da Cruz Vilaça, *The Precautionary Principle in EC Law*, in *EU Law and Integration: Twenty Years of Judicial Application of EU Law*, Hart Publishing, 2014, p. 321 to 354.

13 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 (OJ 2001 L 106, p. 1).

14 For instance, Recital 8 Directive 2001/18 states that ‘the precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing it’. Article 1 reads: ‘in accordance with the precautionary principle, the objective of this Directive is to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment...’. Furthermore, Article 4(1) states that ‘Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment...’.

15 See Recital 2 of Regulation No 178/2002.

37. Second, as to the level of uncertainty required to take action on the basis of the precautionary principle, the risk cannot validly be based on a purely hypothetical approach, founded on mere assumptions which have not yet been scientifically verified.¹⁶ As the Court stated, ‘a correct application of the precautionary principle presupposes, first, identification of the potentially negative consequences for health of the substances or foods concerned, and, second, a comprehensive assessment of the risk to health based on the most reliable scientific data available and the most recent results of international research’.¹⁷

38. Furthermore, ‘where it proves to be impossible to determine with certainty the existence or extent of the alleged risk because of the insufficiency, inconclusiveness or imprecision of the results of studies conducted, but the likelihood of real harm to public health persists should the risk materialise, the precautionary principle justifies the adoption of restrictive measures’.¹⁸

39. Hence, the adoption of measures based on Article 7 of the Regulation No 178/2002 is conditional upon the carrying out of the assessment of all the information available at that moment, as provided for in Article 6 of that regulation.¹⁹ That assessment must have revealed scientific uncertainty regarding the possible harmful effects on health of a food.²⁰

40. Third, a measure taken on the basis of the precautionary principle, as laid down in Article 7, must be proportionate.²¹ As held by the Court, such a measure cannot be ‘more restrictive of trade than is required to achieve the high level of health protection chosen in the Union, regard being had to technical and economic feasibility and other factors regarded as legitimate in the matter under consideration’.²² A balance must be struck between the high level of protection of health and the effective functioning of the internal market.

41. Finally, the risk management measure must be provisional. That character is intrinsic to the precautionary principle as uncertainty is inseparable from the concept of precaution.²³ Once scientific uncertainty disappears, the precautionary principle may no longer justify the preventive measures unless, potentially, new information as to the existence of a risk emerges.

42. It follows from those four different elements that, once it appears that a risk assessment, which has been as complete as possible, could not exclude the existence of a risk to health, a risk management measure that is proportionate and provisional may be adopted, despite the fact that the level of scientific knowledge does not yet allow for a firm conclusion as to the likelihood of harmful effects.

16 Judgment of 8 September 2011, *Monsanto and Others* (C-58/10 to C-68/10, EU:C:2011:553, paragraph 77).

17 See judgments of 9 September 2003, *Monsanto Agricoltura Italia and Others* (C-236/01, EU:C:2003:431, paragraph 113); of 28 January 2010, *Commission v France* (C-333/08, EU:C:2010:44, paragraph 92); and of 19 January 2017, *Queisser Pharma* (C-282/15, EU:C:2017:26, paragraph 56).

18 See judgments of 28 January 2010, *Commission v France* (C-333/08, EU:C:2010:44, paragraph 93); of 17 December 2015, *Neptune Distribution* (C-157/14, EU:C:2015:823, paragraphs 81 and 82); of 9 June 2016, *Pesce and Others* (C-78/16 and C 79/16, EU:C:2016:428, paragraph 47), and of 19 January 2017, *Queisser Pharma* (C-282/15, EU:C:2017:26, paragraph 57).

19 On the necessary connection between Article 7 and Article 6 of Regulation No 178/2002, see my Opinion in *Queisser Pharma* (C-282/15, EU:C:2016:589, points 48 to 51).

20 See judgment of 19 January 2017, *Queisser Pharma* (C-282/15, EU:C:2017:26), paragraph 57). See also my Opinion in that case (C-282/15, EU:C:2016:589, point 50).

21 See judgments of 17 October 2013, *Schaible*, C-101/12, EU:C:2013:661, paragraph 29), and of 9 June 2016, *Pesce and Others* (C-78/16 and C-79/16, EU:C:2016:428, paragraph 48).

22 Judgment of 9 January 2017, *Queisser Pharma* (C-282/15, EU:C:2017:26, paragraph 59).

23 As stated by the Court in judgment of 28 January 2010, *Commission v France*, C-333/08, EU:C:2010:44, paragraph 91), and of 19 January 2017, *Queisser Pharma* (C-282/15, EU:C:2017:26, paragraph 60).

2. Article 34 of Regulation No 1829/2003

43. Pursuant to Article 34, ‘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 ... measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation (EC) No 178/2002 [Regulation No 178/2002]’.

44. The adoption of emergency measures under Article 34 is subject to several substantive and procedural conditions.

45. First, the interests in the pursuit of which measures under Article 34 of Regulation No 1829/2003 may be taken are not confined to (human) health. They also encompass animal health and the environment. The inclusion of the protection of animal health and the environment again logically corresponds with the overall object of the Regulation.²⁴

46. Second, the level of certainty as to the materialisation of the alleged risk is relatively high: it must be ‘evident’ that the product in issue is ‘likely to constitute a serious risk’. In *Monsanto*, the Court held that ‘the expressions ‘likely’ and ‘serious risk’ must be understood as referring to *a significant risk which clearly jeopardizes* human health, animal health or the environment. That risk must be established on the basis of new evidence based on reliable scientific data’.²⁵ The Court went on to conclude that, ‘with a view to the adoption of emergency measures, Article 34 of Regulation No 1829/2003 requires the Member States to establish, in addition to urgency, the existence of a situation which is likely to constitute *a clear and serious risk* to human health, animal health or the environment’.²⁶

47. Third, by its cross-reference to Articles 53 and 54 of Regulation No 178/2002, Article 34 of Regulation No 1829/2003 also sets out a number of procedural conditions for its application. Those are, however, not important to answer the third question posed by the referring court, which is concerned with the level of (un)certainty required and by the interests protected. It is, however, clear that the measures that may be adopted by either the Member States or the Commission are by their very nature interim and limited in time.

48. Thus, it follows from Article 34 of Regulation No 1829/2003, read in conjunction with Articles 53 and 54 of the Regulation No 178/2002, that interim protective measures may be taken by the Member States where it is evident from new scientific information that a product that has already been authorised presents a significant risk which clearly endangers human health, animal health, or the environment.

3. Relationship between Article 34 of Regulation No 1829/2003 and the precautionary principle

49. By its third question, the referring court asks the Court, in essence, whether emergency measures may also be taken on the basis of risks that have not explicitly been foreseen by Article 34. That question basically aims at the first two conditions identified in the preceding sections, namely the nature of interests protected and the level of (un)certainty required for adopting such measures. As is apparent from the previous two sections, in those two aspects, Article 34 of Regulation No 1829/2003 and the precautionary principle, as captured in Article 7 of Regulation No 178/2002, differ.

²⁴ See Article 1(a) of Regulation No 1829/2003.

²⁵ Judgment of 8 September 2011, *Monsanto and Others* (C-58/10 to C-68/10, EU:C:2011:553, paragraph 76). Emphasis added.

²⁶ *Ibid.* paragraph 81. Emphasis added.

50. In its submissions to the Court, the Commission does not consider that the precautionary principle could expand the scope of Article 34. The Commission maintains that interim measures must be justified by a serious and evident risk for the health and the environment, as follows from Article 34 of Regulation No 1829/2003. Such an interim measure is legal if it is justified by emergency and also by a risk assessment, which is as full as possible, and which shows the existence of a serious and evident risk likely to endanger manifestly health and the environment. That risk should be ascertained on the basis of reliable scientific data, showing that this measure is necessary in the absence of provisions at the EU level within the meaning of Article 53 of the Regulation No 178/2002.

51. The Italian Government agrees that interim measures under Article 34 of Regulation No 1829/2003 are to be based on the existence of risks for human and animal health or for the environment. That does not, however, preclude Member States from adopting emergency measures in accordance with Article 54 of the Regulation No 178/2002 on the basis of the precautionary principle, even in cases in which the Commission has not identified any such risks.

52. The Greek Government argues that Article 34 of Regulation No 1829/2003 allows Member States to adopt emergency measures for reasons that are connected with the precautionary principle, but which do not necessarily fulfil the criteria of a serious and evident risk for the health or the environment. Risk analysis may also take into account the nature of the products; the scientific uncertainty as to the incidence of those products on human and animal health or the environment; Member States' particular methods for production or cultivation; geographical, natural and climatic conditions - and any other parameter that may have an influence over the degree of hazardousness of the product.

53. From my point of view, interim emergency measures may be adopted by the Member States if, and only if, the conditions laid down in Article 34 are fulfilled. Although the precautionary principle, as set out in Article 7 of Regulation No 178/2002, may be relied on as an interpretive tool in the context of a product covered by Regulation No 1829/2003, that principle cannot, in my opinion, be used to expand (or rather to effectively rewrite) the wording of Article 34.

54. In the following sections, I explain why the precautionary principle, as set out in Article 7 of Regulation No 178/2002, is relevant to interpret Article 34 (a), before showing that in the present case, its role indeed remains interpretive (b).

(a) The precautionary principle as a general principle of food law

55. In general, the precautionary principle set out in Article 7 of the Regulation No 178/2002 may provide guidance for the interpretation of Article 34 of Regulation No 1829/2003. The same principle might also potentially be invoked in the context of interpretative uncertainty relating to other provisions of Regulation No 1829/2003. That follows from the systemic relationship between the two regulations, which is also expressly confirmed in Article 1 of Regulation No 1829/2003.

56. On the systemic level, as their very titles indicate, Regulation No 178/2002 lays down the *general* principles and requirements of food law. Regulation No 1829/2003 governs the *specific* area of genetically modified food and feed. Thus, unless expressly excluded, the former is potentially applicable to all sectors pertaining to food, that is to 'any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested [by]

humans'.²⁷ That definition logically also includes food containing, consisting of or produced from GMOs, genetically modified food, which is a specific subset within the more general category of 'food'.²⁸

57. Within that structure of general regulation applicable to the entire area of food law, with its 'general principles of food law' (Section 1 of Chapter 2 of Regulation 178/2002), the general application of the precautionary principle amounts to 'general applicability squared'. It is further expressly singled out as being of horizontal nature, cutting across the entire area.

58. Next, further to the overall systemic argument, applicability of the 'general principles of food law' is also explicitly confirmed in Article 1 of Regulation No 1829/2003. That provision clearly states that the objective of Regulation No 1829/2003 must be read in accordance with the general principles laid down in Regulation No 178/2002. It is fair to assume that 'general principles of food law' may be included under the heading of general principles of Regulation No 178/2002.

59. Therefore, the general principles of food law, listed in Section 1 of Chapter 2 of Regulation No 178/2002, and including the precautionary principle, are also applicable to genetically modified food.

(b) The interpretive value of the precautionary principle

60. The fact, however, that the precautionary principle as set out in Article 7 of the Regulation No 178/2002 is of horizontal or intersectional application to all food law certainly does not mean that the Member States would be entitled to act directly on its basis, independently from conditions or procedures clearly and explicitly set out in relevant secondary law.

61. Article 34 of Regulation No 1829/2003 may be seen as a concrete articulation of the precautionary principle in the specific context of genetically modified food and feed in a situation of urgency.

62. The Court has already stated, with respect to the safeguard clause contained in Article 12 of Regulation No 258/97 concerning novel foods and novel food ingredients²⁹ that 'the safeguard clause must be understood as giving specific expression to the precautionary principle... [Thus] the conditions for the application of that clause must be interpreted having due regard to this principle'.³⁰

63. Article 34 of Regulation No 1829/2003 is, within that Regulation, functionally similar to Article 12 of Regulation No 258/97. Further to that, Article 34 can be also compared with another safeguard clause in the specific field of GMOs, namely the one contained in Directive 2001/18.³¹ Despite small differences in the wording, Article 23 of Directive 2001/18 and Article 34 of Regulation No 1829/2003 are comparable as they both allow Member States to adopt restrictive measures when new information or additional scientific knowledge suggests that a GMO constitutes a risk to human health or the environment.³²

²⁷ Article 2 of Regulation No 178/2002.

²⁸ For the sake of completeness, it is clear that the same reasoning does not extend to the other area governed by Regulation No 1829/2003, namely genetically modified *feed*. Feed is, however, also expressly excluded from the substantive scope of application of Regulation No 178/2002.

²⁹ Regulation (EC) No 258/97 concerning novel foods and novel food ingredients (OJ 1997 L 43, p. 1).

³⁰ See judgment of 9 September 2003, *Monsanto Agricoltura Italia and Others* (C-236/01, EU:C:2003:431, paragraph 110).

³¹ See Opinion of Advocate General Mengozzi in *Monsanto and Others* (C-58/10 to C-68/10, EU:C:2011:170, paragraphs 59 to 66).

³² That conclusion implicitly results from the answer given by the Court to the third question in the judgment of 8 September 2011, *Monsanto and Others* (C-58/10 to C-68/10, EU:C:2011:553, paragraphs 75 to 81).

64. The fact that Article 34 of Regulation No 1829/2003 is the concrete expression of the precautionary principle in the specific context it regulates does not preclude the ongoing interpretative value of Article 7 of Regulation No 178/2002. Indeed, as the Court stated in *Monsanto*, the conditions laid down by Article 34 ‘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’.³³

65. Thus, the precautionary principle is relevant for the purposes of *interpreting* Article 34. However, that role is, in my view, limited to settling potential interpretative uncertainties or vagueness. Interpretation, however, cannot be stretched as far as to effectively seek to rewrite clearly set conditions.

66. I therefore disagree with the argument advanced by the Italian Government essentially stating that Article 7 of the Regulation No 178/2002, as an expression of the precautionary principle in the area of food law, could be used to *relax* the conditions set in Article 34 of Regulation No 1829/2003.

67. It should be stressed, at the outset, that a loosening of the conditions would appear to be somewhat selective. As regards the interest protected, I note that Article 34 of Regulation No 1829/2003 includes both animal health and the environment as values on the basis of which emergency measures may be taken. In contrast, Article 7 of Regulation No 178/2002 only refers to (public, that is, human) health. Thus, in terms of the nature of the protected interests, the scope of Article 34 is actually broader. Therefore, if the argument of the Italian Government were to be followed, then a number of aims arguably pursued by the emergency measures relating to animal health and the protection of environment could potentially become illegitimate.

68. I do not think that the Italian Government would like to go down that road. I understand that the primary argument of the Italian Government is rather concerned with the level of (un)certainty required to adopt emergency measures. Indeed, the threshold set by Article 7 (namely, the *possibility* of harmful effects is *identified* but scientific *uncertainty persists*) is clearly lower than the one in Article 34 (it is *evident* that the product is likely to constitute a *serious* risk). Article 7 of Regulation No 178/2002 could therefore be relied on to effectively lower the degree of uncertainty required to adopt emergency measures.

69. This is not possible from my point of view, for at least three reasons, aside from the systemic ones already developed. They are legality, uniformity, and the differentiated procedural context in which both provisions operate.

70. First, Article 34 of Regulation No 1829/2003 has laid down the conditions that must be met in order to adopt emergency measures. The principle of legality requires that public authorities act, both at the levels of the Union and the Member States when implementing EU law, only within the confines of what was stated, without being allowed to modify those conditions. The principle of legality becomes even more relevant when, on the basis of an arguably generous reading of EU law rules, Member States start imposing criminal sanctions.

71. Second, Article 34 is a provision of a regulation. It must therefore be interpreted uniformly, irrespective of the author of the emergency measure, of the circumstances or of the Member State concerned. That requirement of uniformity not only derives from the very nature of a regulation but also from the particular aim of Regulation No 1829/2003.

³³ Judgment of 8 September 2011, *Monsanto and Others* (C-58/10 to C-68/10, EU:C:2011:553). Emphasis added.

72. Generally speaking, a regulation does not leave a margin of appreciation wider than the one that follows from the permissible interpretation of its provision within the boundaries of its text. In the present situation, the conditions of an evident and serious risk are clearly set. There might certainly be doubts as to their application in a concrete case, as is the case with any indeterminate legal notion. That is, however, very different from changing those notions altogether.

73. When it comes to Regulation No 1829/2003 in particular, it is apparent that its uniform application is of great importance in fulfilling the objective of that regulation: to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food or feed.³⁴

74. Finally, the textual difference in the level of (un)certainty required to trigger Article 34 of Regulation No 1829/2003, on the one hand, and Article 7 of the Regulation No 178/2002, on the other, is fully justified by the difference in procedural and systemic operation of both of these provisions.

75. As has been already outlined above in points 55-59 of this Opinion, Article 7 is applicable generally, to the entire area of food law, and also in relation to products that have never gone through an authorisation procedure. This fact translates into a medium level of (un)certainty that is required in order to justify the adoption of provisional measures: all currently available science was looked at, but uncertainty still persists.

76. By contrast, the products to which Article 34 applies are already ‘products authorised by or in accordance with this Regulation’. The authorisation procedure is the core of Regulation No 1829/2003.³⁵ As stated by the Court, ‘the precautionary principle... is part of such a decision-making process’.³⁶ No GMO for food or feed use, nor food or feed containing, consisting of or produced from GMOs shall be authorised unless the applicant for such authorisation has adequately and sufficiently demonstrated that it does not have adverse effects on human health, animal health or the environment.³⁷ Thus, products to which Article 34 refers have already gone through a full scientific assessment, with the involvement of the EFSA, before being placed on the market.³⁸

77. Accordingly, Article 34 and the higher threshold relating to the level of (un)certainty contained therein must be perceived in the context and against the compulsory authorisation procedure for GMOs. Because a full scientific review has already taken place, Article 34 may be triggered only if it is *evident* that there is a *serious* risk. Thus, in order to adopt emergency measures under Article 34, a higher level of evidence must be established, typically involving new risks not previously tested or assessed, in the framework of the authorisation procedure. It is also quite clear that Article 34 should not be used as a way to circumvent the authorisation or disregard the scientific assessment that was carried out at that stage.

³⁴ See Article 1 of Regulation No 1829/2003.

³⁵ See Article 1(b) of Regulation No 1829/2003.

³⁶ See judgment of 26 May 2005, *Codacons* (C-132/03; EU:C:2005:310; paragraph 63).

³⁷ Article 4(1) and Article 16(1) of Regulation No 1829/2003.

³⁸ See Recital 9, Article 6 and Article 18 of Regulation No 1829/2003. See also, under Directive 2001/18, the environmental risk assessment that must be conducted in the framework of the authorisation procedure (cf. Article 4(2), Article 6 and Annex II of that directive).

78. In sum, Article 34 of Regulation No 1829/2003 represents a specific expression of the precautionary principle in the particular context of GMOs and as far as urgent measures in that context are concerned. This dual specificity justifies the differences in its articulation, in particular as far as the level of required scientific (un)certainty is concerned. Although the precautionary principle, as encapsulated in Article 7 of the Regulation No 178/2002, remains as a general principle of food law that is also applicable to the sub-area of genetically modified food, that principle does not alter the conditions clearly set out in Article 34 of Regulation No 1829/2003.

4. Coda on Directive No 2015/412

79. In its written observations, the Italian Government recalled that Member States may, pursuant to Directive 2015/412, amending Directive 2001/18, forbid or limit the cultivation of GMOs for reasons other than those relating to health and environment. It states that the Commission has, on the basis of that Directive and following the request of the Member States, prohibited by a decision of 3 March 2016 the cultivation of genetically modified maize MON 810 on the territory of 19 Member States, including Italy.

80. The Italian Government underlines that although the result of the prohibition adopted by the Commission and that of the national decree of 12 July 2013 are for all practical purposes the same (the ban on the cultivation of MON 810), the legal bases for those two bans are completely different.

81. I agree.

82. It is clear that Directive 2015/412 considerably changed the entire legal framework applying to GMOs in the Union. This does not mean, however, that it would also alter the scope of Article 34 of Regulation No 1829/2003 for the purposes of the present case, in particular for two reasons.

83. First, Directive 2015/412 is clearly not applicable *ratione temporis* to the present case. It entered into force only in April 2015. The Italian prohibition dates back to July 2013. The act for which Mr Fidenato and others were sentenced, the planting of MON 810, apparently occurred in 2014.

84. Second, it is true that Directive 2015/412 has set out a number of grounds – such as town planning, land use, agricultural policy objectives or socio-economic impacts – in the pursuit of which Member States may adopt restrictive measures. However, those grounds are clearly limited to the procedural framework of that Directive. They cannot be invoked, be it on the basis of that directive or in the name of an all-encompassing notion of the precautionary principle, to justify the effective overriding of the wording of Article 34 of Regulation No 1829/2003. Such an approach would go against the clear letter of that provision and the legality principle articulated above.

85. Therefore, Directive 2015/412 is not relevant for the purposes of interpreting Article 34 of Regulation No 1829/2003 in the context of the present case.

V. Conclusion

86. In the light of the aforementioned considerations, I propose that the Court of Justice answer the third question posed by the Tribunale di Udine (District Court, Udine, Italy) as follows:

- Article 34 of Regulation (EC) N° 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, interpreted in the light of the precautionary principle, allows Member States to adopt emergency measures if and only if they can

establish, in addition to urgency, the existence of a situation which is likely to constitute a clear and serious risk to human health, animal health or the environment. The precautionary principle does not, however, modify the criteria listed in Article 34 of that regulation.