JUDGMENT OF THE [GENERAL COURT] (Fourth Chamber)

5 October 2005

(Approximation of laws – National provisions derogating from a harmonisation measure – Ban on the use of genetically modified organisms in Upper Austria – Conditions for application of [Article 114(5) TFEU])

In Joined Cases T-366/03 and T-235/04,

Land Oberösterreich, represented by F. Mittendorfer, lawyer,

Republic of Austria, represented by H. Hauer and H. Dossi, acting as Agents, with an address for service in Luxembourg,

applicants,

v

Commission of the European [Union], represented by M. Patakia and U. Wölker, acting as Agents, with an address for service in Luxembourg,

defendant,

APPLICATIONS for annulment of Commission Decision 2003/653/EC of 2 September 2003 relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to [Article 114(5) TFEU] (OJ 2003 L 230, p. 34),

[THE GENERAL COURT]

(Fourth Chamber),

composed of H. Legal, President, P. Lindh and V. Vadapalas, Judges,

Registrar: C. Kristensen, Administrator,

having regard to the written procedure and further to the hearing on 17 March 2005,

gives the following

Judgment

Legal context

[Article 114 TFEU]

1 [Article 114(4) to (7) TFEU] provides:

'4. If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in [Article 36 TFEU], or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.

5. Moreover, without prejudice to paragraph 4, if, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.

6. The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.

When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.

7. When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.'

Directive 90/220

2 According to Article 1(1) of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ 1990 L 117, p. 15), the objective of that directive was to approximate the laws, regulations and administrative provisions of the Member States and to protect human health and the environment as regards the deliberate release of genetically modified organisms ('GMOs') into the

environment and the placing on the market of products containing, or consisting of, GMOs intended for subsequent deliberate release into the environment.

3 Article 4 of Directive 90/220 required the Member States to take all appropriate measures to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs.

4 Part C of Directive 90/220 (Articles 10 to 18) contained specific provisions concerning the placing on the market of products containing GMOs. Under Article 11(5) of the directive, read in conjunction with Article 11(1), no product containing GMOs could be released into the environment before the competent authority of the Member State in which the product was to be placed on the market for the first time had given its written consent following a notification to that authority by the manufacturer or the importer into the [Union]. Article 11(1) to (3) of the directive specified the information to be contained in that notification, which had, in particular, to enable the national authority to carry out the risk assessment required by Article 10(1). The risk assessment had to precede any consent.

5 Article 16 of Directive 90/220 stated:

'1. Where a Member State has justifiable reasons to consider that a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, it may provisionally restrict or prohibit the use and/or sale of that product on its territory. It shall immediately inform the Commission and the other Member States of such action and give reasons for its decision.

2. A decision shall be taken on the matter within three months in accordance with the procedure laid down in Article 21.'

Directive 2001/18

6 Following several amendments, Directive 90/220 was repealed and replaced by 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 Directive 90/220 (OJ 2001 L 106, p. 1). It pursues the same objectives.

7 The deliberate release or placing on the market of a GMO is subject to an authorisation regime. Any person wishing to obtain a consent must first carry out a health and environmental risk assessment. Article 4(3) of Directive 2001/18 provides:

'Member States and where appropriate the Commission shall ensure that potential adverse effects on human health and the environment, which may occur directly or indirectly through gene transfer from GMOs to other organisms, are accurately assessed on a case-by-case basis. This assessment shall be conducted in accordance with Annex II taking into account the environmental impact according to the nature of the organism introduced and the receiving environment.'

8 Directive 2001/18 establishes two separate sets of rules for the placing on the market of a GMO as or in a product and for its deliberate release for any purpose other than being placed on the market.

9 Consents granted before 17 October 2002 under Directive 90/220 for the placing on the market of a GMO as or in a product may be renewed before 17 October 2006, in accordance with the simplified procedure set out in Article 17(2) to (9) of Directive 2001/18.

10 Article 23 of Directive 2001/18, headed 'Safeguard clause', reads as follows:

'1. Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory.

The Member State shall ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public.

The Member State shall immediately inform the Commission and the other Member States of actions taken under this Article and give reasons for its decision, supplying its review of the environmental risk assessment, indicating whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.

2. A decision shall be taken on the matter within 60 days in accordance with the procedure laid down in Article 30(2) …'

Background to the dispute

11 On 13 March 2003, the Republic of Austria notified the Commission of the Oberösterreichisches Gentechnik-Verbotsgesetz 2002, a draft law of the Land Oberösterreich (Province of Upper Austria) banning genetic engineering ('the notified measure'). The notified measure was intended to prohibit the cultivation of seed and planting material composed of or containing GMOs and the breeding and release, for the purposes of hunting and fishing, of transgenic animals. The notification was intended to secure, on the basis of [Article 114(5) TFEU], a derogation from Directive 2001/18. The notification relied on a report entitled 'GVO-freie Bewirtschaftungsgebiete: Konzeption und Analyse von Szenarien und Umsetzungsschritten' (GMO-free areas of farming: conception and analysis of scenarios and steps for realisation).

12 The Commission requested the European Food Safety Authority (EFSA) to issue an opinion, in accordance with Article 29(1) and Article 22(5)(c) of 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), on the probative value of the scientific information relied on by the Republic of Austria.

13 In its opinion of 4 July 2003 ('the EFSA opinion'), EFSA essentially reached the conclusion that that information did not contain any new scientific evidence which could justify banning GMOs in the Land Oberösterreich.

14 Those were the circumstances in which the Commission adopted Decision 2003/653/EC of 2 September 2003 relating to national provisions on banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to [Article 114(5) TFEU] (OJ 2003 L 230, p. 34, 'the contested decision').

15 According to the contested decision, the Republic of Austria failed to provide new scientific evidence or demonstrate that a specific problem in the Land Oberösterreich arose following the adoption of Directive 2001/18 which made it necessary to introduce the notified

measure. Since the conditions set out in [Article 114(5) TFEU] were not satisfied, the Commission rejected the Republic of Austria's request for derogation.

Procedure and forms of order sought

16 By application lodged at the Registry of the [General Court] on 3 November 2003, the Land Oberösterreich brought the action registered under case number T-366/03.

17 By application lodged at the Registry of the Court of Justice on 13 November 2003, the Republic of Austria brought an action allocated case number C-492/03.

18 By order of the Court of Justice of 8 June 2004, that case was referred to the [General Court], pursuant to Article 2 of Council Decision 2004/407/EC, Euratom of 26 April 2004 amending Articles 51 and 54 of the Protocol on the Statute of the Court of Justice (OJ 2004 L 132, p. 5). It was registered under case number T-235/04.

19 By decision of the President of the Fourth Chamber of the [General Court] of 22 February 2005, after the parties had been heard, Cases T-366/03 and T-235/04 were joined for the purposes of the oral procedure and the judgment, in accordance with Article 50 of the Rules of Procedure of the [General Court].

20 Upon hearing the report of the Judge-Rapporteur, the Court (Fourth Chamber) decided to open the oral procedure and, as measures of organisation of procedure provided for in Article 64 of the Rules of Procedure, put questions in writing to the Republic of Austria and the Commission.

21 The parties presented oral argument and answered the questions put by the Court at the hearing on 17 March 2005.

22 In Case T-366/03, the Land Oberösterreich claims that the Court should:

– annul the contested decision;

– order the Commission to pay the costs.

23 In Case T-235/04, the Republic of Austria claims that the Court should:

– annul the contested decision;

– order the Commission to pay the costs.

24 In Cases T-366/03 and T-235/04, the Commission claims that the Court should:

– dismiss the actions;

– order the applicants to pay the costs.

The admissibility of the action brought by the Land Oberösterreich

25 Although the Commission has not contested the admissibility of the action brought by the Land Oberösterreich, it should be noted that the contested decision was addressed to the Republic of Austria. In order to assess whether the action in Case T-366/03 is admissible, the Court

considers it appropriate to verify of its own motion whether the contested decision is of direct and individual concern to the Land Oberösterreich, within the meaning of the fourth paragraph of [Article 263 TFEU].

26 The Land Oberösterreich submits that it has a specific legal interest in bringing proceedings, separate from that of the Republic of Austria. It contends in that regard that, constitutionally, the notified measure falls within its exclusive competence. In addition, it asserts that it is directly and individually concerned by the contested decision, and therefore the action in Case T-366/03 is admissible. As regards more specifically its individual interest, the Land Oberösterreich claims that the contested decision prejudices its autonomous legislative powers, notwithstanding the fact that the notified measure was in draft form.

27 In accordance with settled case-law, persons other than those to whom a decision is addressed may claim to be individually concerned within the meaning of the fourth paragraph of [Article 263 TFEU] only if that decision affects them by reason of certain attributes which are peculiar to them, or by reason of circumstances in which they are differentiated from all other persons, and by virtue of these factors distinguishes them individually just as the addressee of that decision may be so distinguished (Case 25/62 *Plaumann v Commission* [1963] ECR 95 at 107, and Case 169/84 *COFAZ and Others v Commission* [1986] ECR 391, paragraph 22). The purpose of that provision is to ensure that legal protection is also available to a person who, whilst not the person to whom the contested measure is addressed, is in fact affected by it as if he were the addressee (Case 222/83 *Municipality of Differdange and Others v Commission* [1984] ECR 2889, paragraph 9).

28 In the present case, the Land Oberösterreich is the author of a draft law falling within its own competence and in respect of which the Republic of Austria sought a derogation under [Article 114(5) TFEU]. The contested decision therefore not only affects a measure of which the Land Oberösterreich is the author, but also prevents it from exercising, as it sees fit, its own powers conferred on it under the Austrian constitutional system. It follows that the Land Oberösterreich is individually concerned by the contested decision for the purposes of the fourth paragraph of [Article 263 TFEU] (see, to that effect, Case T-214/95 *Vlaamse Gewest v Commission* [1998] ECR II-717, paragraph 29 et seq., and Joined Cases T-346/99, T-347/99 and T-348/99 *Diputación Foral de Alava and Others v Commission* [2002] ECR II-4259, paragraph 37).

29 Furthermore, although the contested decision was addressed to the Republic of Austria, the latter did not exercise any discretion when communicating it to the Land Oberösterreich, which therefore is also directly concerned by the contested decision for the purposes of the fourth paragraph of [Article 263 TFEU] (see, to that effect, Joined Cases 41/70 to 44/70 *International Fruit Company and Others v Commission* [1971] ECR 411, paragraphs 25 to 28).

30 It follows that the Land Oberösterreich has standing to seek the annulment of the contested decision.

The substance

31 The applicants raise four pleas in law alleging (i) infringement of the right to be heard, (ii) breach of the obligation to state reasons, (iii) infringement of [Article 114(5) TFEU] and (iv) breach of the precautionary principle.

The first plea: infringement of the right to be heard

Arguments of the parties

32 The applicants complain that the Commission did not give them the opportunity to state their views before adopting the contested decision.

33 Although the Court of Justice has ruled that the right to be heard does not apply to the procedure laid down in [Article 114 TFEU] (Case C-3/00 *Denmark v Commission* [2003] ECR I-2643), the applicants assert that the circumstances of this case call for a different answer.

34 First, *Denmark v Commission* concerned a request for derogation under [Article 114(4) TFEU] relating to a national measure in force at that time. In the present case, since the notified measure was still in draft form, the Commission could, without prejudicing the functioning of the internal market or the interests of the applicant Member State, have continued the procedure in accordance with the third subparagraph of [Article 114(6) TFEU], in order to give the applicants the opportunity to state their views.

35 Second, contrary to its approach in the case which gave rise to the judgment in *Denmark v Commission*, the Commission did not confine itself, in the present case, to ruling on the notification, but sought an expert report from EFSA, on which the contested decision is based. The Commission should therefore have given the applicants the opportunity to state their views on the EFSA opinion before adopting the contested decision. Had they been given that opportunity, they could have rebutted that opinion and enabled the Commission to take a different decision.

36 The Commission disputes those arguments. It states that the Land Oberösterreich cannot rely on the right to be given the opportunity to state its views because it was not a party to the procedure in question, which concerned solely the Republic of Austria. It submits, moreover, that the right to be heard does not apply to the procedure in [Article 114(5) TFEU] (*Denmark v Commission*, paragraph 50).

Findings of the Court

37 The Court of Justice has ruled that the right to be heard does not apply to the procedure laid down in [Article 114(4) TFEU] (*Denmark v Commission*, paragraph 50). It should be examined whether, as the applicants claim, the procedure laid down in [Article 114(5) TFEU] is subject to a different rule.

38 In *Denmark v Commission*, the Court of Justice relied on the fact that the procedure laid down in [Article 114(4) TFEU] was initiated not by a [Union] institution but by a Member State, the decision of the [Union] institution being adopted merely in response to that initiative. Under that procedure, approval is sought for national provisions derogating from a harmonisation measure adopted at [Union] level. In its request, the Member State is at liberty to comment on the decision it asks to have adopted, as is quite clear from [Article 114(4) TFEU], which requires that State to indicate the grounds for maintaining the national provisions in question. The Commission in turn must be able, within the prescribed period, to obtain the information which proves to be necessary without being required once more to hear the applicant Member State (*Denmark v Commission*, paragraphs 47 and 48).

39 According to *Denmark v Commission* (paragraph 49), those factors are reinforced, first, by the second subparagraph of [Article 114(6) TFEU], according to which the derogating national provisions are deemed to have been approved if the Commission does not take a decision within a certain period. In addition, under the third subparagraph of [Article 114(6) TFEU], no extension of that period is allowed where there is a danger for human health. The Court concluded therefrom that the authors of the Treaty intended, in the interest of both the applicant Member State and the proper functioning of the internal market, that the procedure laid down in [Article 114(4) TFEU] should be speedily concluded. The Court

ruled that that objective would be difficult to reconcile with a requirement for prolonged exchanges of information and observations (*Denmark v Commission*, paragraph 49).

40 This Court considers that that reasoning may be applied to the procedure laid down in [Article 114(5) TFEU]. Like the procedure referred to in [Article 114(4) TFEU], the procedure in [Article 114(5) TFEU] is commenced at the request of a Member State seeking the approval of national provisions derogating from a harmonisation measure adopted at [Union] level. In both cases, the procedure is initiated by the notifying Member State, which is at liberty to comment on the decision it asks to have adopted. Likewise, both procedures must, in the interest of the applicant Member State and the proper functioning of the internal market, be concluded rapidly.

41 Contrary to what the applicants claim, the fact that the procedure in [Article 114(5) TFEU] relates to national measures which are still in draft form does not mean that it can be distinguished from the procedure laid down in [Article 114(4) TFEU] to an extent that the right to be heard can be held to apply to it. The applicants cannot properly argue that the requirement for speed is less great when examining a national measure which has not yet entered into force, so that the Commission could easily extend the six-month deadline laid down in [Article 114(6) TFEU] in order to have an exchange of arguments.

42 First, the applicants' argument is contrary to the letter of [Article 114(6) TFEU]. That provision applies without distinction to requests for derogation concerning national measures in force, referred to in [Article 114(4) TFEU], and to requests concerning measures in draft form, to which [Article 114(5) TFEU] is applicable. Also, the Commission may exercise the option, provided for in the third subparagraph of [Article 114(6) TFEU], of extending the six-month deadline for making a decision only if the complexity of the matter makes it necessary and in the absence of danger for human health. It is apparent therefore that the third subparagraph of [Article 114(6) TFEU] does not allow the Commission to defer the end of the six-month period for making a decision only so that the Member State which has submitted a request for derogation under [Article 114(5) TFEU] to it can be given the opportunity to state its views.

43 Second, the applicants' argument runs counter to the scheme of [Article 114(5) TFEU]. The fact that that provision relates to a national measure which is not yet in force does not diminish the interest in having the Commission rule quickly on the request for derogation which has been submitted to it. The authors of the Treaty intended that that procedure should be speedily concluded in order to safeguard the applicant Member State's interest in being certain of the applicable rules, and in the interest of the proper functioning of the internal market.

44 On that latter point, it should be pointed out that, in order to avoid prejudicing the binding nature and uniform application of [Union] law, the procedures laid down in [Article 114(4) and (5) TFEU] are both intended to ensure that no Member State applies national rules derogating from the harmonised legislation without obtaining prior approval from the Commission. In that respect, the rules applicable to national measures notified under [Article 114(4) TFEU] do not differ significantly from those which apply to national measures still in draft form notified under [Article 114(5) TFEU]. Under both procedures, the measures in question are inapplicable as long as the Commission has not adopted its decision on whether to grant a derogation. Under [Article 114(5) TFEU], that situation arises from the very nature of the measures in question, which are still in draft form. As regards [Article 114(4) TFEU], that situation arises from the subject-matter of the procedure which it lays down. The Court of Justice has pointed out that measures for the approximation of the laws, regulations and administrative provisions of the Member States which concern the establishment and functioning of the internal market would be rendered ineffective if Member States retained the right unilaterally to apply national rules derogating from those measures. A Member State

is not, therefore, authorised to apply the national provisions notified by it under [Article 114(4) TFEU] until after it has obtained a decision from the Commission approving them (see, by analogy with the procedure under [Article 114(4) TFEU], Case C-41/93 *France v Commission* [1994] ECR I-1829, paragraphs 29 and 30, and Case C-319/97 *Kortas* [1999] ECR I-3143, paragraph 28).

45 Finally, it is necessary to reject the applicants' argument that the circumstances of this case differ from those which gave rise to the judgment in *Commission v Denmark*, in that the Commission did not confine itself to ruling on the basis of information submitted by the Republic of Austria, but asked EFSA to produce an expert report, on which the contested decision is based. Since the right to be heard does not apply to the procedure in question, that argument is irrelevant.

46 Moreover, it should be observed that the fact that the right to be heard is not applicable does not mean that the Commission is obliged to come to a decision solely on the basis of the information provided in support of the request for derogation. On the contrary, it is clear from *Denmark v Commission* (paragraph 48) that the Commission must be able, within the prescribed period, to obtain the information which proves to be necessary without being required once more to hear the applicant Member State.

47 It follows that the first plea must be dismissed as misplaced, without it being necessary to rule on the specific point of whether the Land Oberösterreich, although not a party to the administrative procedure, was able to rely on infringement of the right to be heard.

The second plea: breach of the obligation to state reasons

Arguments of the parties

48 According to the applicants, the contested decision fails to satisfy the requirements of [Article 296 TFEU]. It does not contain a view on the duration of the notified measure, which is limited to three years. That question is, however, crucial for assessing whether the measure is proportionate. Consents granted on the basis of Directive 90/220 must be renewed in the light of the stricter criteria of Directive 2001/18, before 17 October 2006. The applicants argue that the period of validity of the notified measure was only three years so as to coincide with that expiry date and to prevent GMOs which fail to satisfy the environmental protection requirements of Directive 2001/18 from being used in the Land Oberösterreich before the expiry of the moratorium agreed on by the Council in 1999. The Commission should have responded to the arguments in the notification that the level of environmental protection resulting from Directive 2001/18 was insufficient.

49 The Commission disputes that it infringed [Article 296 TFEU]. It takes the view that it was not necessary to comment in detail on the limited duration of the notified measure, since that factor was irrelevant in the light of the conditions under [Article 114(5) TFEU].

Findings of the Court

50 According to settled case-law, the statement of reasons required by [Article 296 TFEU] must be appropriate to the measure at issue and must disclose in a clear and unequivocal fashion the reasoning followed by the institution which adopted the measure in such a way as to enable the persons concerned to ascertain the reasons for the measure and to enable the [Union] judicature to exercise its power of review (Case C-367/95 P *Commission v Sytraval and Brink's France* [1998] ECR I-1719, paragraph 63, and Case C-159/01 *Netherlands v Commission* [2004] ECR I-4461, paragraph 65).

51 The question whether the statement of reasons meets the requirements of [Article 296 TFEU] must be assessed with regard not only to its wording but also to its context and to all the legal rules governing the matter in question (Case C-350/88 *Delacre and Others v Commission* [1990] ECR I-395, paragraphs 15 and 16, and Case C-114/00 *Spain v Commission* [2002] ECR I-7657, paragraphs 62 and 63).

52 Although the Commission is obliged to state the reasons on which its decisions are based, mentioning the matters of fact and law which provide the legal basis for the measure in question and the considerations which have led it to adopt its decision, it is not required to discuss all the issues of fact and of law raised during the administrative procedure (Case T-290/94 *Kaysersberg v Commission* [1997] ECR II-2137, paragraph 150).

53 In order to comply with the obligation to state reasons laid down in [Article 296 TFEU], a decision adopted by the Commission on the basis of [Article 114(5) TFEU] must contain a sufficient and relevant indication of the factors taken into consideration in determining whether the conditions laid down by that article for the grant of a derogation are met.

54 [Article 114(5) TFEU] requires that the introduction of national provisions derogating from a harmonisation measure be based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to the Member State concerned arising after the adoption of the harmonisation measure, and that the proposed provisions as well as the grounds for introducing them be notified to the Commission. Since the conditions are clearly cumulative, they must all be satisfied if the request for derogation is not to be rejected by the Commission (Case C-512/99 *Germany v Commission* [2003] ECR I-845, paragraphs 80 and 81).

55 In the present case, the Commission has set out its arguments in a detailed and comprehensive manner, enabling the addressee of the contested decision to be aware of its factual and legal grounds and the Court to review the lawfulness of the decision.

56 The Commission relied on three main factors in order to reject the Republic of Austria's request. First of all, it found that that Member State had failed to demonstrate that the notified measure was justified in the light of new scientific evidence concerning protection of the environment (recitals 63 to 68 of the contested decision). Moreover, the Commission considered that the notified measure was not justified by a problem specific to the Republic of Austria (recitals 70 and 71 of the contested decision). Finally, the Commission rejected the arguments of the Austrian authorities seeking to justify the national measures by recourse to the precautionary principle, taking the view that those arguments were too general and lacked substance (recitals 72 and 73 of the contested decision).

57 As regards the question whether the Commission infringed [Article 296 TFEU] by failing to express a view on the arguments put forward by the Republic of Austria in which it claimed, in essence, that the notified measure was justified by an insufficient level of environmental protection until the expiry of the period laid down by Article 17(1)(b) of Directive 2001/18 for the renewal of consents granted before 17 October 2002 under Directive 90/220 for the placing on the market of a GMO as or in a product, it should be noted that the contested decision does not expressly deal with that point. However, that lacuna is attributable not to a lack of reasoning, but to the nature of the reasoning followed by the Commission in setting out the factual and legal grounds which justify the contested decision. Since the Commission set out why it considered that the notification failed to meet the requirements of [Article 114(5) TFEU] concerning the existence of new scientific evidence relating to protection of the environment and of a problem specific to the Member State concerned, it was not required to respond to the arguments of the Republic of Austria as regards the level of environmental protection achieved by Directive 2001/18 until 17 October 2006.

58 Consequently, this plea must be dismissed as unfounded.

The third plea: infringement of [Article 114(5) TFEU]

Arguments of the parties

59 The applicants submit that the Commission should have granted the Republic of Austria's request, since the requirements of [Article 114(5) TFEU] were satisfied. They claim that the notified measure was intended to protect the environment, that it was based on new scientific evidence, that it was justified by a problem specific to Austria and that it complied with the principle of proportionality.

60 The Commission criticises those arguments.

Findings of the Court

61 [Article 114 TFEU], distinguishes between notified provisions according to whether they are national provisions which existed prior to harmonisation or national provisions which the Member State concerned wishes to introduce. In the first case, provided for in [Article 114(4) TFEU], the maintenance of existing national provisions must be justified on grounds of major needs referred to in [Article 36 TFEU] or relating to the protection of the environment or the working environment. In the second case, provided for in [Article 114(5) TFEU], the introduction of new national provisions must be based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure.

62 The difference between the two situations envisaged in [Article 114 TFEU] is due to the existence, in the first, of national provisions predating the harmonisation measure. They are thus known to the [Union] legislature, which cannot or does not seek to be guided by them for the purpose of harmonisation. It is therefore considered acceptable for the Member State to request that its own rules remain in force. To that end, the [FEU] Treaty requires that such national provisions must be justified on grounds of major needs referred to in [Article 36 TFEU] or relating to the protection of the environment or the working environment. By contrast, in the second situation, the adoption of new national legislation is more likely to jeopardise harmonisation. The [Union] institutions could not, by definition, have taken account of the national provisions when drawing up the harmonisation measure. In that case, the needs referred to in [Article 36 TFEU] are not taken into account, and only grounds relating to protection of the environment or the working environment are accepted, on condition that the Member State provides new scientific evidence and that the need to introduce new national provisions results from a problem which is specific to the Member State concerned and subsequent to the adoption of the harmonisation measure (*Germany v Commission*, paragraphs 40 and 41, and *Denmark v Commission*, paragraphs 56 to 58).

63 It is for the Member State which invokes [Article 114(5) TFEU] to prove that the conditions for application of that provision have been met (Opinion of Advocate General Tizzano in *Germany v Commission*, point 71; see also, by analogy with [Article 114(4) TFEU], *Denmark v Commission*, paragraph 84).

64 Under [Article 114(5) TFEU], in the present case it was for the Republic of Austria to demonstrate, on the basis of new scientific evidence, that the level of environmental protection afforded by Directive 2001/18 was not acceptable having regard to a problem specific to that Member State which arose after the adoption of Directive 2001/18. It is therefore necessary to examine at the outset whether the Commission erred in finding that

the Republic of Austria had failed to demonstrate the existence of a specific problem which arose after the adoption of Directive 2001/18.

65 In the contested decision, the Commission rejected the arguments of the Republic of Austria by which it sought to demonstrate that there was a specific problem within the meaning of [Article 114(5) TFEU], on the ground that it was clear from the notification that the small size of farms, far from being specific to the Land Oberösterreich, was a common characteristic, to be found in all the Member States. The Commission also adopted the conclusions of EFSA, in particular those according to which, first, 'the scientific evidence presented contained no new or uniquely local scientific information on the environmental or human health impacts of existing or future GM crops or animals' and, second, 'no scientific evidence was presented which showed that this area of Austria had unusual or unique ecosystems that required separate risk assessments from those conducted for Austria as a whole or for other similar areas of Europe' (recitals 70 and 71 of the contested decision).

66 It must be stated that the applicants have failed to provide convincing evidence such as to cast doubt on the merits of those assessments as to the existence of a specific problem, but have confined themselves to drawing attention to the small size of farms and the importance of organic production in the Land Oberösterreich.

67 In particular, the applicants have not put forward evidence to rebut EFSA's conclusions that the Republic of Austria failed to establish that the territory of the Land Oberösterreich contained unusual or unique ecosystems that required separate risk assessments from those conducted for Austria as a whole or in other similar areas of Europe. When requested at the hearing to comment on the scale of the problem posed by GMOs in the Land Oberösterreich, the applicants were not able to state whether the presence of such organisms had even been recorded. The Land Oberösterreich stated that the adoption of the notified measure was prompted by the fear of having to face the presence of GMOs because of the announced expiry of an agreement pursuant to which the Member States had temporarily committed themselves no longer to issue consents for those organisms. Such considerations, by their general nature, are not capable of invalidating the concrete findings set out in the contested decision.

68 Consequently, the arguments by which the applicants have disputed the findings made by the Commission on the condition relating to the existence of a problem specific to the notifying Member State must be rejected.

69 Since the conditions required by [Article 114(5) TFEU] are cumulative, it is sufficient that only one of those conditions is not satisfied for the request for derogation to be rejected (*Germany v Commission*, paragraph 81). Since the applicants have failed to demonstrate that one of the conditions required by [Article 114(5) TFEU] was satisfied, the third plea must be dismissed as unfounded, without it being necessary to rule on the other complaints and arguments.

The fourth plea: breach of the precautionary principle

70 The applicants criticise the Commission for ignoring the fact that the notified measure was a measure of preventive action within the meaning of [Article 191(2) TFEU], justified by the precautionary principle; the Commission disputes that.

71 This Court finds that this plea is irrelevant. A request had been submitted to the Commission under [Article 114(5) TFEU]. It decided that the conditions for application of that article were not met. This Court has found, following examination of the third plea, that the contested decision was not incorrect. The Commission therefore had no option in any event but to reject the application which was submitted to it.

72 The fourth plea must therefore be dismissed.

73 In the light of all the foregoing, the actions must be dismissed in their entirety.

Costs

74 Under Article 87(2) of the Rules of Procedure, the unsuccessful party is to be ordered to pay the costs if they have been applied for in the successful party's pleadings.

75 In the present case, since the applicants have been unsuccessful, they must be ordered to pay the costs of the action incurred by the Commission, in accordance with the form of order sought by the Commission.

On those grounds,

THE [GENERAL COURT] (Fourth Chamber)

hereby:

1. Dismisses the actions;

2. Orders the applicants to pay the costs.

Legal Lindh Vadapalas

Delivered in open court in Luxembourg on 5 October 2005.

H.Jung H. Legal

Registrar President