

## II

(Acts whose publication is not obligatory)

## COMMISSION

## COMMISSION DECISION

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 95(5) of the EC Treaty**

(notified under document number C(2003) 3117)

(Only the German text is authentic)

(Text with EEA relevance)

(2003/653/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 95(5) and (6) thereof,

Whereas:

#### I. FACTS

- (1) In a letter dated 13 March 2003, the Austrian Permanent Representation to the European Union notified the Commission, in accordance with Article 95(5) of the EC Treaty of a draft Upper Austrian Act on the prohibition of genetic engineering 2002 banning the use of genetically modified organisms in the region of Upper Austria (hereinafter national provisions) in derogation of the provisions of Directive 2001/18/EC of the European Parliament and of the Council <sup>(1)</sup>.

#### 1. Article 95(5) and (6) of the EC Treaty

- (2) Article 95(5) and (6) of the Treaty provides:

'5. (...) 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 notification as referred to in paragraphs (...) 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 to 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 (...) 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.'

#### 2. Relevant Community legislation

2.1. *Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms*

- (3) The deliberate release of genetically modified organisms (GMOs) into the environment is governed by Directive 2001/18/EC as of 17 October 2002, on which date Member States are required to have implemented the relevant national measures. This Directive is based on Article 95 of the Treaty establishing the European Community and aims at approximating legislation and procedures in Member States for the authorisation of GMOs intended for deliberate release into the environment.

<sup>(1)</sup> OJ L 106, 17.4.2001, p. 1.

- (4) Directive 2001/18/EC puts in place a step-by-step approval process on a case-by-case assessment of the risks to human health and the environment before any GMO or product consisting of or containing GMOs or genetically modified micro-organisms (GMMs) can be released into the environment or placed on the market.
- (5) The Directive provides for two different procedures, for experimental releases (referred to as part B releases) and for placing on the market releases (referred to as part C releases). Part B releases require an authorisation at national level, whereas part C releases are subject to a Community procedure, with an eventual decision being valid throughout the European Union.
- (6) At the current time, authorisation for placing on the market of genetically modified seeds for the purpose of cultivation is exclusively provided for by Directive 2001/18/EC. To date, no genetically modified seeds have been authorised under this Directive although 22 applications are pending authorisation some of which include uses that include cultivation.
- (7) 18 authorisations for the placing on the market of GMOs were granted under the previous Council Directive 90/220/EEC<sup>(1)</sup>, which was repealed by Directive 2001/18/EC on 17 October 2002. Of these products, seeds from three genetically modified maize varieties, three genetically modified oilseed rape varieties and a chicory variety have been authorised for the placing on the market to include cultivation as a use. In addition, approval has also been granted for cultivation of two genetically modified carnation varieties.
- (8) Directive 2001/18/EC provides for the placing on the market and experimental release into the environment of transgenic animals on the basis that they are classified as GMOs. Whilst no transgenic animals or fish have as yet been approved for these purposes, or applications for such submitted for approval, the Directive does provide for this possibility.
- (9) In addition to the above provisions regarding the authorisation procedures, Article 23 of Directive 2001/18/EC contains a 'safeguard clause'. The provisions of this Article mainly foresee that, '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 Direc-

tive 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'. Furthermore, in the event of a severe risk, Member States may take emergency measures, such as the suspension or termination of the placing on the market of a GMO and must inform the Commission of the decision taken on the basis of Article 23, as well as the reasons for having made such a decision. On this basis, a decision shall be taken at Community level on the invoked safeguard clause, in accordance with the comitology procedure foreseen under Article 30(2) of Directive 2001/18/EC.

- (10) Directive 2001/18/EC has not yet been transposed into the Austrian legal order, in contradiction with the provisions of its Article 34, which requires Member States to bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 17 October 2002.

## 2.2. Council Directive 90/219/EEC (as amended by Directive 98/81/EC)

- (11) Directive 90/219/EEC<sup>(2)</sup>, as amended by Directive 98/81/EC<sup>(3)</sup>, governs the contained use of genetically modified micro-organisms (GMMs). Austria, as well as 11 other Member States, has transposed this Directive in order to also cover other GMOs, including transgenic animals and fish, and not just GMM. This is admissible under the contained use Directive. Progeny have already been bred from transgenic animals and fish in certain Member States under the contained use conditions of Directive 90/219/EC as transposed into their national law. However, consents for such activities are issued on a national basis, under the provisions of the Directive, with no associated Community procedure.

## 2.3. Seeds legislation

- (12) The seeds legislation comprises Council Directives 66/401/EEC<sup>(4)</sup>, 66/402/EEC<sup>(5)</sup>, 2002/54/EC<sup>(6)</sup>, 2002/55/EC<sup>(7)</sup>, 2002/56/EC<sup>(8)</sup> and 2002/57/EC<sup>(9)</sup>, as last amended by Directive 2003/61/EC<sup>(10)</sup>. These Directives foresee that a seed variety can circulate freely within the Community provided that:

- the variety has passed with success tests proving that it is distinct, stable and sufficiently homogenous. Furthermore, it must have a satisfactory use and cultivation value,

<sup>(2)</sup> OJ L 117, 8.5.1990, p. 1.

<sup>(3)</sup> OJ L 330, 5.12.1998, p. 13.

<sup>(4)</sup> OJ 125, 11.7.1966, p. 2298/66.

<sup>(5)</sup> OJ 125, 11.7.1966, p. 2309/66.

<sup>(6)</sup> OJ L 193, 20.7.2002, p. 12.

<sup>(7)</sup> OJ L 193, 20.7.2002, p. 33.

<sup>(8)</sup> OJ L 193, 20.7.2002, p. 60.

<sup>(9)</sup> OJ L 193, 20.7.2002, p. 74.

<sup>(10)</sup> OJ L 165, 3.7.2003, p. 23.

<sup>(1)</sup> OJ L 117, 8.5.1990, p. 15.

- if the seeds of this variety have been, at a later stage, officially examined with regard to their qualities and certified as basic seeds or certified seeds or, for some species, officially examined and admitted as commercial seeds.
- (13) These directives have therefore an agronomic and botanical objective, and only aim at GMO as seeds, which have to fulfil the same criteria as conventional seeds under the same Directives.
- (14) To be placed on the market and allowed to move freely throughout the Community, a genetically modified seed has to pass successively two separate stages:
- its genetic modification has to receive prior authorisation according to part C of Directive 2001/18/EC,
  - its characteristic as a variety has to have been subject to tests foreseen by Community legislation on seeds.
- (15) If results are positive, Member States register this variety in the corresponding national catalogue of seeds, which allows the seeds of this variety to circulate freely on the Member State territory and be admitted for commercial cultivation (once officially examined and certified). It is only once it has been registered in the Community catalogue of varieties that the seeds of this variety can benefit from freedom of movement throughout the Community territory (also only once officially examined and certified).
- (16) Therefore, there is not only one Directive regulating in a specific and global manner the issue of transgenic seeds, but two Directives (Directive 2001/18/EC and the relevant seeds Directive applying to the GMO at stake) which apply jointly and regulate two separate aspects of the genetically modified variety.

#### 2.4. Regulation (EC) No 258/97 of the European Parliament and of the Council on novel foods

- (17) Regulation (EC) No 258/97<sup>(1)</sup> sets out rules for authorisation and labelling of novel foods including food products containing, consisting of or produced from GMOs. This Regulation notably foresees that risks to the environment may be associated with novel foods or novel food ingredients, which contain or consist of genetically modified organisms. Therefore, it establishes a link with Directive 2001/18/EC, which stipulates that,

for such products, an environmental risk assessment must always be undertaken to ensure environmental safety. The Regulation therefore imposes a specific environmental risk assessment similar to that laid down in Directive 2001/18/EC, but must also include the assessment of the suitability of the product to be used as a food or food ingredient.

### 3. National provisions notified

#### 3.1. Scope of the national provisions notified

- (18) The draft Act<sup>(2)</sup> is primarily concerned with the protection of GMO-free (organic) production systems in the province of Upper Austria. Protection of nature and the environment as well as natural biodiversity are also cited as objectives.
- (19) In its first page, the Report of the Committee on National Economic Affairs<sup>(3)</sup>, hereinafter 'the Committee Report' gives a summary of the grounds for and content of the draft Act:
- 'The use of genetically modified organisms (GMOs) in agriculture and forestry, and in crop farming in particular, is not, according to current scientific knowledge, free from risk with respect to either the maintenance of GMO-free agricultural production (coexistence) or the conservation of the natural environment (biodiversity).
- The aim of this Act is to safeguard organic farming as well as traditional agricultural crop and animal products from GMO contamination (hybridisation). In addition, natural biodiversity, particularly in sensitive ecological areas, as well as genetic resources in nature, including those of hunting and fishing, are to be protected from GMO contamination.'
- (20) On this basis, the draft Act primarily seeks to ban the use of genetically modified seeds (including those with Community authorisation) in the province of Upper Austria as a means to (i) safeguard organic and traditional farming (coexistence) and (ii) protect natural biodiversity, particularly in sensitive ecological areas, as well as genetic resources from 'contamination' of GMOs. It does, however, accept adventitious traces of genetically modified seeds in conventional stocks to a level of 0,1 % (apparently both authorised and non-authorised genetically modified seed).

<sup>(2)</sup> Provincial Act, prohibiting the cultivation of genetically modified seed and planting material and the use of transgenic animals for breeding purposes as well as the release of transgenic animals especially for the purposes of hunting and fishing (Upper Austrian Act prohibiting genetic engineering 2002).

<sup>(3)</sup> Report of the Committee on National Economic Affairs concerning the Provincial Act prohibiting the cultivation of genetically modified seed and planting material and the use of transgenic animals for breeding purposes as well as the release of transgenic animals especially for the purposes of hunting and fishing (Upper Austrian Act prohibiting genetic engineering 2002).

<sup>(1)</sup> OJ L 43, 14.2.1997, p. 1.

(21) It also seeks to ban the use of transgenic animals for breeding and in particular their release for hunting and fishing.

(22) It requires that Upper Austria will provide compensation to persons for monetary losses due to the presence of GMOs in conventional products.

(23) The Act is a temporary measure, applicable for three years after its adoption.

### 3.2. *Impact on Community legislation of the national provisions notified*

(24) The scope of the draft Upper Austrian Act implies that it will primarily impact on:

— experimental releases of GMOs in accordance with the provisions of part B of Directive 2001/18/EC,

— the cultivation of genetically modified seed varieties authorised under the provisions of part C of Directive 2001/18/EC,

— the cultivation of genetically modified seed varieties already approved under the provisions of Directive 90/220/EEC as now governed by Directive 2001/18/EC. The consents for these products will have to be renewed under Directive 2001/18/EC but not until the year 2006,

— contained use activities involving the breeding of transgenic animals and fish. However, this would not be in contradiction of the Directive per se, given that the provisions of Directive 90/219/EEC as amended by Directive 98/81/EC (as opposed to those of national laws) do not explicitly extend to such GMOs,

— placing on the market and experimental release into the environment of transgenic animals on the basis that they are classified as GMOs, if such approvals were to be granted (which is not the case for the time being) in accordance with Directive 2001/18/EC.

(25) In this context it is also important to mention that during second reading of the Commission Proposal for a Regulation on genetically modified food and feed, the European Parliament adopted an amendment aiming to introduce a new Article 26a in Directive 2001/18/EC. Following agreement from the Council on 22 July 2003, this Article will be inserted into the Directive on the entry into force of the new Regulation. The Article reads:

'Member States may take appropriate measures to avoid the unintended presence of GMOs in other products.

The Commission shall gather and coordinate information based on studies at Community and national level, observe the developments regarding coexistence in the Member States and, based on the information and observations, develop guidelines on the coexistence of genetically modified, conventional and organic crops.'

(26) On the other hand, the draft Act is unlikely to impact on the novel food Regulation. This Regulation addresses food or food ingredients containing or consisting of a GMO, which are not to be used as seed or planting material. Therefore, the novel food Regulation shall be considered as out of the scope of the draft Act.

(27) Regarding the horizontal issue of coexistence, the Commission adopted, on 23 July 2003, a Recommendation with guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming <sup>(1)</sup>. The Recommendation states that:

'It is important to make a clear distinction between the economic aspects of coexistence and the environmental and health aspects dealt with under Directive 2001/18/EC on the deliberate release of GMOs into the environment.

According to the procedure laid down in Directive 2001/18/EC, the authorisation to release GMOs into the environment is subject to a comprehensive health and environmental risk assessment. The outcome of the risk assessment can be one of the following:

— a risk of an adverse effect to the environment or health that cannot be managed is identified, in which case authorisation is refused,

— no risk of adverse effects on the environment or health is identified, in which case authorisation is granted without requiring any additional management measures other than those specifically prescribed in the legislation,

— risks are identified, but they can be managed with appropriate measures (e.g. physical separation and/or monitoring); in this case the authorisation will carry the obligation to implement environmental risk management measures.

If a risk to the environment or health is identified after the authorisation has been granted, a procedure for the withdrawal of the authorisation or for modifying the conditions of consent can be initiated under the safeguard clause set out in Article 23 of the Directive.

<sup>(1)</sup> OJ L 189, 29.7.2003, p. 36.

Since only authorised GMOs can be cultivated in the European Union, and the environmental and health aspects are already covered by Directive 2001/18/EC, the pending issues still to be addressed in the context of coexistence concern the economic aspects associated with the admixture of genetically modified and non-genetically modified crops.'

- (28) Concerning territorial measures, the Recommendation states:

'While considering all the options available, priority should be given to farm-specific management measures and to measures aimed at coordination between neighbouring farms.

Measures of a regional dimension could be considered. Such measures should apply only to specific crops whose cultivation would be incompatible with ensuring coexistence, and their geographical scale should be as limited as possible. Region-wide measures should only be considered if sufficient levels of purity cannot be achieved by other means. They will need to be justified for each crop and product type (e.g. seed versus crop production) separately.'

- (29) From the above considerations, it clearly appears that the main Community legislation potentially affected by the Austrian notification is Directive 2001/18/EC. In fact, this horizontal piece of legislation can be seen as the cornerstone of any deliberate release of GMOs in the European Union, notably since authorisations under seeds and novel foods legislation are carried out in line with its governing principle. This interpretation is accepted in the assessment carried out by the Austrian authorities in their Committee Report that states:

'The national legislator's room to manoeuvre with regards to authorised GMOs is therefore determined in accordance with the specific primary law stipulations relating to the "Release Directive" <sup>(1)</sup> or in accordance with the safeguard clause of the same Directive.'

- (30) For these reasons, the legal assessment contained in this Decision will focus on Directive 2001/18/EC and will not touch upon other pieces of legislation covering biotechnology, since their importance is minor in the present context.

#### 4. Justifications put forward by Austria

- (31) Justification for the draft Act is provided by the Committee report and a recent study on coexistence commissioned by the province of Upper Austria and the Federal Ministry of Social Security and Generations, hereinafter 'the Müller Study' <sup>(2)</sup>.

<sup>(1)</sup> The "Release Directive" being defined prior in the Committee Report as Directive 2001/18/EC.

<sup>(2)</sup> 'Genetically modified-free areas of farming: conception and analysis of scenarios and steps for realisation', Werner Müller, 28 April 2002 (carried out on behalf of the department for environment of the region of Upper Austria and of the Federal Ministry for social security and generations).

- (32) The basis for the Act, as detailed in the report, is that the use of GMOs is not free from risk with respect to either the maintenance of genetically modified-free agricultural production (coexistence) or the conservation of the natural environment (biodiversity). The Müller study produces a broad compilation of generic information on GM crops and coexistence, together with scientific data on causes and contexts of GMOs contamination.

- (33) The Müller study purportedly confirms long-term negative effects on genetically modified-free agricultural production and naturally occurring crop formations cannot be ruled out.

- (34) The study suggests that it is practically impossible for organic and conventional production to coexist alongside a large GMO cultivation, with a feared long-term damage to the environment. The above justification, in terms of biodiversity and coexistence, is applied to transgenic animals in a similar manner as to genetically modified seeds. Along this line, the Müller study considers that:

'The danger as far as the (Upper) Austrian environment is concerned lies in the fact that recombinated genes may harm conventional genetically modified-free and organic agricultural crop production. If genetically modified varieties of seed or planting material are cultivated extensively, genetically modified-free agricultural crop production would no longer be possible in future. Since the danger facing this type of production appears to relate to all products that are permitted as seed and planting material, all these products are covered by the cultivation ban contained in the draft. The same applies to transgenic animals used for breeding purposes and, to the release of transgenic animals especially for the purposes of hunting and fishing. In the long run, these animals reproduce and threaten the existence of the naturally occurring animal.'

- (35) On this basis, the Müller study concludes that:

'Genetically modified-free areas represented the only approach, which could ensure long-term security in relation to the problems of coexistence within the small-structured Austrian agricultural sector. Given that the proportion of organic farmers is particularly high in Upper Austria (around 7%), hardly any areas would be available for a GMO cultivation if the intention was to safeguard the organic production of agricultural products by establishing protection zones with a 4 km radius from sources of foreign contamination.'

(36) The specificity to the province of Upper Austria is founded on the fact that production in this region is based on a small-structured farming system and that management measures to control the presence of GMOs in organic/conventional production systems is not possible. The Committee Report therefore concludes:

'(...) it must be emphasised in Austria's case that in accordance with the study mentioned, "genetically modified-free areas" represent the only approach which can ensure the long-term security of coexistence within Austria's "small-structured agricultural sector". In relation to the province of Upper Austria, it arises from this study that hardly any areas would be available for a GMO cultivation if the intention is to safeguard the organic production of agricultural products by establishing protection zones with a 4 km radius from the foreign contamination source. In this regard, particular reference is made to the high proportion of organic farmers (in the case of Upper Austria) who are distributed over the province as a whole and whose existence would be threatened.'

## II. PROCEDURE

(37) In a letter dated 13 March 2003, the Austrian Permanent Representation to the European Union notified the Commission, in accordance with Article 95(5) of the EC Treaty, of a draft Upper Austrian Act on the prohibition of genetic engineering 2002 banning the use of genetically modified organisms in the region of Upper Austria in derogation of the provisions of Directive 2001/18/EC.

(38) By a letter dated 25 March 2003, the Commission informed the Austrian authorities that it had received the notification under Article 95(5) of the EC Treaty and that the six-month period for its examination pursuant to Article 95(6) had begun on 14 March 2003, the day after the notification was received.

(39) By a letter dated 6 May 2003, the Commission informed the other Member States of the request received from the Austrian Republic. The Commission also published a notice regarding the request in the *Official Journal of the European Union* <sup>(1)</sup> to inform the other parties concerned of the draft national measures that Austria intended to adopt <sup>(2)</sup>.

## III. LEGAL ASSESSMENT

### 1. Consideration of admissibility

(40) Article 95(5) of the Treaty reads as follows: '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.'

(41) The notification submitted by the Austrian authorities on 14 March 2003 is intended to obtain approval for the introduction of new national provisions which are deemed to be incompatible with Directive 2001/18/EC, a Community measure concerning the approximation of the laws, regulations and administrative provisions of the Member States, aiming at the establishment and operation of the Internal Market.

(42) Directive 2001/18/EC harmonises at Community level the rules with regards to deliberate release of GMOs, for experimental release or for placing on the market. This horizontal piece of legislation can be seen as the cornerstone of any deliberate release of GMOs in the European Union, notably since authorisations under seeds and novel foods legislation are carried out in line with its governing principle. Therefore, and for the reasons developed in detail under point III.2, the legal assessment contained in this Decision will focus on Directive 2001/18/EC and will not touch upon other pieces of legislation covering biotechnology, which importance is minor in the present context.

(43) As required by Article 95(5) of the EC Treaty, Austria notified the Commission of the exact wording of the draft provisions, which are incompatible with those set out namely in Directive 2001/18/EC, as well as of an explanation of the reasons which, in its opinion, justifies the introduction of those provisions.

(44) When comparing the provisions of Directive 2001/18/EC and the national measures notified, it emerges that the latter are more restrictive than those contained in the Directive, notably in the following aspects:

— the governing principle of Directive 2001/18/EC is a case-by-case risk analysis, whereas the Austrian Act foresees a 'blanket' ban,

— Directive 2001/18/EC, in combination with the seeds Directives, enable free circulation of genetically modified seeds approved at Community level, whereas the Austrian Act foresees prohibition of all genetically modified seeds, irrelevant whether they have been approved or not.

(45) The justifications put forward by Austria are mainly that:

— the Müller study commissioned by the Region of Upper Austria has brought to light new scientific evidence showing a danger for the (Upper) Austrian environment,

<sup>(1)</sup> OJ C 126, 28.5.2003, p. 4.

<sup>(2)</sup> Comments were received from Italy, the Netherlands and Euro-pabio.

- the same study has also demonstrated that the Upper Austrian agricultural structure was specific (notably since based on small-scale farms, with a substantial proportion of organic farming),
  - the Müller study was published after the adoption of Directive 2001/18/EC and according to Austria, the issue of coexistence, which is not tackled by this Directive, is still considered as unsolved.
- (46) In the light of the foregoing, the Commission considers that the notification submitted by Austria in order to obtain approval for the introduction of national provisions derogating from the provisions of Directive 2001/18/EC is therefore to be considered admissible under Article 95(5) of the EC Treaty.

## 2. Assessment of merits

- (47) In accordance with Article 95(6) of the Treaty, the Commission must ensure that all the conditions enabling a Member State to avail itself of the possibilities of derogation provided for in this Article are fulfilled:

'6. The Commission shall, within six months of the notification as referred to in paragraphs (...) 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 to 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 (...) 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.'

- (48) The Commission must therefore assess whether the conditions provided for by Article 95(5) of the Treaty are met. This Article requires that when a Member State deems it necessary to introduce national provisions derogating from a harmonisation measure, that Member State should base the introduction on:
- new scientific evidence relating to the protection of the environment or the working environment,
  - grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure.

- (49) Article 95(5) of the EC Treaty applies to new national measures, which introduce incompatible requirements with those of a Community harmonisation measure on

the basis of 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, and which are justified by new scientific evidence.

- (50) Furthermore, under Article 95(6) of the EC Treaty, the Commission is either to approve or reject the draft national provisions in question after verifying 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.

- (51) Therefore, the national provisions notified and the reasons given by the Member State are examined in light of the Community harmonisation measure from which they derogate, in this case, the provisions of Directive 2001/18/EC on the deliberate release into the environment of GMOs. Again, for the reasons developed in detail under point 1.3.2, the legal assessment contained in this Decision will focus on Directive 2001/18/EC and will not touch upon other pieces of legislation covering biotechnology, which are of minor importance in the present context.

- (52) This specific Directive is affected, in so far as the draft act bans the use of all GMOs in the region of Upper Austria, whereas the Directive foresees a case-by-case risk analysis prior to the authorisation of a GMO.

- (53) The proposed ban on the cultivation of genetically modified seeds in the province of Upper Austria also creates an obstacle to the placing on the market of genetically modified seeds that would have been authorised for this purpose under Directive 2001/18/EC. The draft Act would, therefore, have implications for genetically modified seeds already approved for the placing on the market under existing Community legislation as well as future approvals.

- (54) Whilst the Act does not seek to ban genetically modified seeds for experimental releases, this is only on the proviso that these activities are effected in closed systems. Experimental releases of genetically modified seeds are regulated under Directive 2001/18/EC although at a national rather than Community level. National authorities have the jurisdiction to include 'containment type measures', such as isolation distances and barriers, in consents issued for experimental releases on the basis of potential risk to human health or the environment<sup>(1)</sup>. However, to put in place national measures requiring that such releases have to be conducted under 'closed systems', irrespective of any potential risk, has to be considered in contradiction with the Directive.

<sup>(1)</sup> In this context it is also important to mention that the seeds Directives stipulate the adoption of such measures to ensure a high level of purity for basic and certified seeds. However, no distinction is made regarding admixture between conventional and genetically modified varieties.

(55) In addition to this, Directive 2001/18/EC does not contain any (*de minimis*) thresholds for the adventitious or technically unavoidable presence of non-authorised GMOs in seeds. Consequently, Member States do not have discretion in judging which quantities of GMOs are dangerous, and subsequently introduce such thresholds.

(56) Finally, in accordance with Article 23 of Directive 2001/18/EC, if on the basis of new information, made available since the date of consent, a Member State has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under Directive 2001/18/EC 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 Committee Report shows that Austria is fully aware of this possibility, but considers it inappropriate to meet its objective, which is a total ban of GMOs in the province of Upper Austria:

'The Upper Austrian Act prohibiting genetic engineering 2002 is not only to apply to individual GMOs (that have already been authorised) but also makes provision for a general ban on all GMOs as or in a product that are already presently approved and those still to be approved in future.

(...)

It does appear somewhat impractical, however, to carry out a procedure in accordance with Article 23 of the "Release Directive" following every approval procedure conducted in relation to a GMO.'

(57) In accordance with the Court's case law, any exception to the principle of the uniform application of Community law and of the unity of the internal market must be strictly interpreted. Article 95(5) of the EC Treaty provides an exception to the principles of uniform application of Community law and the unity of the market. Therefore, it must be interpreted in such a way that its scope is not extended beyond the cases for which it formally provides.

(58) In the light of the time-frame established by Article 95(6) of the EC Treaty, the Commission, when examining whether the draft national measures notified under Article 95(5) are justified, has to take as a basis 'the grounds' put forward by the Member State. This means that, under the Treaty, the responsibility of proving that these measures are justified lies with the Member State

making the request. Given the procedural framework established by Article 95 of the EC Treaty, including in particular a strict deadline for a Decision to be adopted, the Commission normally has to restrict itself to examining the relevance of the elements which are submitted by the requesting Member State, without having to seek possible justifications itself.

(59) The introduction of national measures which are incompatible with a Community harmonisation measure needs to be justified by new scientific evidence concerning the protection of the environment or the working environment. Of course, whether the scientific evidence is new must be judged in light of developments in scientific knowledge.

(60) It is therefore up to the Member State, which has requested that there is a need for a derogation, to provide new scientific evidence, in support of the measures notified.

(61) The Austrian authorities argue that 'the extensive use of genetically modified seed and planting material in crop production would at first interfere with and then, in the long-term, displace organic and conventional genetically modified-free production, resulting in an expansion of the GMO cultivation'.

(62) The Austrian authorities have commissioned the 'Müller study', on which the Committee Report is based, and which demonstrates, according to Austria, that 'new scientific evidence has now come to light which justifies an Upper Austrian Act prohibiting genetic engineering 2002 in the form proposed'. Furthermore, this study is also supposed to demonstrate that 'genetically modified-free areas' represent the only approach which can ensure the long-term security of coexistence within Austria's 'small-structured agricultural sector'.

(63) The Commission has sent the full Austrian notification <sup>(1)</sup> to the European Food Safety Authority (hereinafter the EFSA) and requested it in a mandate <sup>(2)</sup>, under Article 29(1) and in accordance with Article 22(5)(c) of Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>(3)</sup>, to provide a scientific opinion as to whether:

— the information provided by Austria in the Report entitled GMO-free agricultural areas — Design and analysis of scenarios and implementational measures provides any new scientific evidence, in terms of risk

<sup>(1)</sup> These documents are: Letter dated 13 February 2003 Ref: Verf-5-130000/37-GM; 'Notification to the Commission concerning the introduction of a national provision (draft Committee Report) prohibiting the cultivation of genetically modified seeds and propagating material, the use of transgenic animals for breeding purposes and the release of transgenic animals, in particular for hunting and fishing purposes (Upper Austria Genetic Engineering Prohibition Act 2002. (Oö: GTVG 2002)), in accordance with Article 95(5) of the EC Treaty'; 'Report of the Committee on National Economic Affairs concerning the Provincial Act prohibiting the cultivation of genetically modified seed and planting material and the use of transgenic animals for breeding purposes as well as the release of transgenic animals especially for the purpose of hunting and fishing (Upper Austrian Act prohibiting genetic engineering 2002)'; 'GMO-free agricultural areas: Design and analysis of scenarios and implementation measures', study by Engineer Werner Müller; 'Green Report 2001, Report on the economic and social situation of Upper Austrian agriculture and forestry in 2001'; and 'Report on the Implementation of NATURA 2000 in Upper Austria over the next five years'.

<sup>(2)</sup> Question No EFSA-Q-2003-001.

<sup>(3)</sup> OJ L 31, 1.2.2002, p. 1.

to human health and the environment, that would justify the banning of cultivation of genetically modified seeds and propagating material, the use of transgenic animals for breeding purposes and the release of transgenic animals, authorised for these purposes under Directive 90/220/EEC or Directive 2001/18/EC,

— in particular, EFSA is requested to comment as to whether the scientific information presented in the report provides new data that would invalidate the provisions for the environmental risk assessment under the above legislation.'

(64) The EFSA concluded, on 4 July <sup>(1)</sup>, that: The Scientific Panel on Genetically Modified Organisms is of the opinion that

— the scientific information presented in the report provided no new data that would invalidate the provisions for the environmental risk assessment established under Directive 90/220/EEC or Directive 2001/18/EC,

— the scientific information presented in the report provided no new scientific evidence, in terms of risk to human health and the environment, that would justify a general prohibition of cultivation of genetically modified seeds and propagating material, the use of transgenic animals for breeding purposes and the release of transgenic animals, authorised for these purposes under Directive 90/220/EEC or Directive 2001/18/EC in this region of Austria.'

(65) With regard to the 'new' scientific information, the Commission considers that the Müller Report contains data, which were for a large part available prior to the adoption of Directive 2001/18/EC on 12 March 2001. This assessment is confirmed by the EFSA. In addition to this, Austria relies on the fact that the Müller Study was released on 28 April 2002, about a year after the date of adoption of Directive 2001/18/EC (12 March 2001). However, the vast majority of the sources referred to in the bibliography were published prior to the adoption of Directive 2001/18/EC. Therefore, the core of the study appears more as a validation of previous works than like new material identifying specific problems arising after the adoption of Directive 2001/18/EC.

(66) Moreover, the Austrian authorities have not provided any new scientific evidence, which specifically concerns the protection of the environment or the working environment.

(67) It therefore appears that Austrian concerns about coexistence relate more to a socio-economic problem than to the protection of the environment or the working environment. Again, this assessment is confirmed by the EFSA, which opinion states:

'No evidence was presented in the report to show that coexistence is an environmental or human health risk issue. EFSA was not asked by the Commission to comment on the management of coexistence of genetically modified and non-genetically modified crops, but the Panel recognised that it is an important agricultural issue.'

(68) On this basis, and in line with the definition of coexistence contained in its Recommendation on the issue <sup>(2)</sup>, the Commission therefore considers that the concerns relating to coexistence raised by Austria cannot be specifically regarded as protection of the environment or the working environment within the meaning of Article 95(5) of the EC Treaty.

(69) The Commission also considers that any measure for coexistence, to be introduced on a regional basis, in the context of economic risk should be proportionate. In accordance with the new Article 26(a) of Directive 2001/18/EC and the Commission Recommendation of coexistence, such measures would have to take account of (i) specific crop-type, (ii) specific crop use and (iii) if sufficient levels of purity cannot be achieved by other means.

(70) Furthermore, in light of the documentation provided by Austria, particularly the excerpts from the Müller study included with the notification, it is clear that small-structured farming systems are certainly not specific to this region and exist in all Member States. The acceptance of the Act with regard to Article 95(5) of the Treaty cannot, therefore, be founded on such justification.

(71) There again, the EFSA opinion does not corroborate the Austrian justification:

'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. 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. No specific cases were presented of impacts of GMOs on biodiversity, either directly or through changes in agricultural practices.'

<sup>(1)</sup> Opinion of the Scientific Panel on Genetically Modified Organisms on a question from the Commission related to the Austrian notification of national legislation governing GMOs under Article 95(5) of the Treaty, The EFSA Journal (2003) 1, 1-5.

<sup>(2)</sup> See recital 27.

- (72) As for the arguments, which, in the view of the Austrian authorities, justify recourse to the precautionary principle, the Commission must point out that 'recourse to the precautionary principle presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined with sufficient certainty' <sup>(1)</sup>. Indeed, it follows from the Community courts' interpretation of the precautionary principle <sup>(2)</sup> that a preventive measure may be taken only if the risk, although the reality and extent thereof have not been 'fully' demonstrated by conclusive scientific evidence, appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken. A preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture, which has not yet been scientifically verified.
- (73) The Commission considers that the allegations being made for recourse to the precautionary principle are too general and lack substance. Furthermore, the EFSA has not identified a risk that would justify taking action on the basis of the precautionary principle at Community or national level. As a result, in this case, there is no justification for applying the precautionary principle.

#### IV. CONCLUSION

- (74) Article 95(5) of the EC Treaty requires that, if a Member State deems it necessary to introduce national provisions in derogation from Community harmonisation measures, the national provisions must be justified by new scientific evidence relating to the protection of the environment or the working environment, there must be a problem specific to the State making the request, and the problem must have arisen after the adoption of the harmonisation measure.
- (75) In this case, after having examined the Austrian request, the Commission considers that Austria has not provided new scientific evidence relating to the protection of the environment or the working environment, and has not demonstrated that there is a specific problem within the territory of Upper Austria, which arose following the adoption of Directive 2001/18/EC on the deliberate release into the environment of GMOs, and which makes it necessary to introduce the notified national measures.
- (76) Consequently, the request from Austria for introducing national measures aimed at prohibiting the use of GMOs in Upper Austria does not fulfil the conditions set out in Article 95(5).
- (77) Under Article 95(6) of the EC Treaty, the Commission is either to approve or reject the draft national provisions in question after verifying 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.
- (78) Since the request made by Austria does not fulfil the basic conditions set out in Article 95(5), there is no need for the Commission to verify whether or not the notified national provisions are a means of arbitrary discrimination or disguised restriction on trade between Member States, and whether or not they constitute an obstacle to the functioning of the internal market.
- (79) In light of the elements which it had available to assess the merits of the justifications put forward for the national measures notified, and in light of the considerations set out above, the Commission considers that Austria's request for introducing national provisions derogating from Directive 2001/18/EC, submitted on 13 March 2003:
- is admissible,
  - does not fulfil the conditions set out in Article 95(5) of the EC Treaty, as Austria did not provide new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to Upper Austria.
- (80) The Commission therefore has grounds to consider that the national provisions notified cannot be approved in accordance with Article 95(6) of the Treaty,

HAS ADOPTED THIS DECISION:

#### *Article 1*

The national provisions on banning the use of GMOs in Upper Austria notified by Austria pursuant to Article 95(5) of the EC Treaty are rejected.

#### *Article 2*

This Decision is addressed to the Republic of Austria.

Done at Brussels, 2 September 2003.

*For the Commission*  
Margot WALLSTRÖM  
*Member of the Commission*

<sup>(1)</sup> See the Commission Communication on recourse to the precautionary principle (COM(2000)1 final, 2.2.2000).

<sup>(2)</sup> See in particular judgments in cases T-13/99 and T-70/99 of the Court of First Instance, (2002) ECR-II, p. 3305.