

COMMISSION DECISION**of 3 November 2009****relating to the draft Regional Legislative Decree declaring the Autonomous Region of Madeira to be an Area Free of Genetically Modified Organisms, notified by the Republic of Portugal pursuant to Article 95(5) of the EC Treaty***(notified under document C(2009) 8438)***(Only the Portuguese text is authentic)****(Text with EEA relevance)**

(2009/828/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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

Whereas:

the other parties concerned of the draft national measure that Portugal intended to adopt. Bulgaria, Czech Republic, Denmark, France, Latvia, Malta and Romania submitted their comments.

COMMUNITY LEGISLATION

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

PROCEDURE

- (1) In a letter dated 5 May 2009, the Portuguese Permanent Representation to the European Union notified the Commission, in accordance with Article 95(5) of the EC Treaty, a draft Regional Legislative Decree (hereinafter: 'the draft decree') declaring the Autonomous Region of Madeira to be an Area Free of Genetically Modified Organisms (GMOs). The draft decree was accompanied by an explanatory statement and a document setting out the arguments reasoning and justifying the declaration of the Autonomous Region of Madeira as an Area Free from GMOs.
- (2) By a letter of 26 June 2009, the Commission informed the Portuguese 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 following this notification. The Portuguese notification contained no scientific literature, studies, or any other scientific information that would support the respective argumentation. Therefore the Commission asked Portugal by that letter to complement its notification with more concrete information in the form of relevant scientific literature which would indicate the evidence relating to the protection of the environment or the working environment on grounds of a problem specific to the region of Madeiras. Portugal submitted complementary information on 31 July 2009.
- (3) The Commission published a notice regarding the request in the *Official Journal of the European Union* ⁽¹⁾ to inform

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 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.'

(1) OJ C 139, 19.6.2009, p. 2.

NATIONAL DRAFT PROVISIONS NOTIFIED

Scope of the national draft provisions notified

- (5) In accordance with Article 1 of the draft decree, the Autonomous Region of Madeira is declared to be an area free of the cultivation of varieties of genetically modified organisms (GMOs). In accordance with Article 2, the introduction of plant or seed propagating material containing GMOs into the territory of the Autonomous Region of Madeira and also its use in agriculture would be prohibited. Article 3 would define the infringement of the provisions of the above article as administrative offence and Article 4 would lay down additional penalties. Article 5 would establish provisions for the investigation, prosecution and decision of the administrative offenses and Article 6 would stipulate the use of the proceeds from fines.

Impact on Community legislation of the national draft provisions notified

- (6) The scope of the latter draft provisions, in conjunction with the explanation of the explanatory note, implies that it will primarily impact on:

- the cultivation of genetically modified seed varieties authorised under the provisions of part C (Articles 12 – 24) of 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⁽¹⁾ (hereinafter ‘Directive 2001/18/EC’),
- the cultivation of genetically modified seed varieties already approved under the provisions of Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms⁽²⁾ and now notified as existing products under Articles 8 and 20 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed⁽³⁾ (hereinafter ‘Regulation (EC) No 1829/2003’),
- the cultivation of genetically modified seed varieties authorised under the provisions of Regulation (EC) No 1829/2003.

- (7) Directive 2001/18/EC is based on Article 95 of the EC Treaty. It aims at approximating legislation and procedures in Member States for the authorisation of

GMOs intended for deliberate release into the environment. In accordance with its Article 34, Member States were required to transpose it into national law by 17 October 2002.

- (8) According to its Article 1, Regulation (EC) No 1829/2003 aims at (a) providing 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 food and feed, whilst ensuring the effecting functioning of the internal market; (b) in laying down Community procedures for the authorization and supervision of genetically modified food and feed and (c) in laying down provisions for the labeling of genetically modified food and feed.

JUSTIFICATION PUT FORWARD BY PORTUGAL

- (9) Information for the draft Act, offering interpretation about the Act’s impact on and conformity with Community legislation, is provided in:

- The document submitted together with the notification of 5 May 2009 and titled ‘Establishment of the Autonomous Region of Madeira (RAM) as an “Area Free of Genetically Modified Organisms (GMOs)” — Arguments’,
- The additional information submitted on 31 July 2009 titled ‘Establishment of the Autonomous Region of Madeira as an Area Free of Genetically Modified Organisms (GMOs) — Additional information’.

- (10) In its justification, Portugal points to agricultural and natural reasons.

- (11) The agricultural reasons refer to the impossibility of co-existence between GM crops and conventional and/or organic crops in the Autonomous Area of Madeira. They particularly invoke aspects such as the distance between fields, border strips, sowing of varieties with different growth cycles, refuge areas, installation of pollen traps or barriers to prevent pollen dispersion, crops rotation systems, crop production cycles, reduction of the size of the seed banks through adequate soil tillage, management of populations in field borders, choosing of optimal sowing dates, handling of seeds to avoid mixing or the prevention of seed spillage when travelling to and from the field and on field boundaries.

⁽¹⁾ OJ L 106, 17.4.2001, p. 1.

⁽²⁾ OJ L 117, 8.5.1990, p. 15.

⁽³⁾ OJ L 268, 18.10.2003, p. 1.

- (12) The natural reasons claim that the effects of introducing GMOs into nature (in the case of the RAM, the natural Madeiran forest) have not been adequately studied, although many articles have been published in which concerns are raised with regard to the consequences of deliberately releasing GMOs into nature and to the resulting environmental effects which might be expected. However there may be other potential risks which are not covered by these scientific studies.
- (13) The natural reasons further refer to:
- (a) preliminary tests carried out using GM varieties;
 - (b) model showing the invasive capacity of GM varieties;
 - (c) interaction of the model to the use of plants containing GMOs;
 - (d) capacity of transgenic plants to cross-pollinate;
 - (e) parallel effects with other species;
 - (f) production of toxins;
 - (g) collateral interactions;
 - (h) effects connected with genetic alterations;
 - (i) implications in poor agricultural practices;
 - (j) gene transfer;
 - (k) effects on the food chain.
- (14) Portugal concludes that on the basis of the above, the introduction of genetically modified material into the RAM could have extremely dangerous consequences for the Madeiran environment in general (it would be pointless to distinguish between agricultural and forest areas). Although there are no solid theories on the matter, research and experiments, as well as all the theoretical parallels, suggest that the risk to nature presented by the deliberate release of GMOs is so dangerous and poses such a threat to the environmental and ecological health of Madeira, that it is not worthwhile risking their use, either directly in the agricultural sector or even on an experimental basis.

LEGAL ASSESSMENT

- (15) Article 95(5) of the EC Treaty applies to new national measures 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.
- (16) 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.
- (17) Nevertheless, under the same provision, 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.
- (18) The notification submitted by the Portuguese authorities on 5 May 2009 is intended to obtain approval for the introduction of the draft decree.
- (19) Portugal did not specify the European Community act which the draft decree derogates from. Cultivation of GMOs is to a large extent regulated by Directive 2001/18/EC, and Regulation (EC) No 1829/2003.
- (20) Article 95(5) of the Treaty requires that when a Member State deems it necessary to introduce national provisions derogating from a harmonisation measure, those provisions could be justified on the following cumulative conditions ⁽¹⁾:
- 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.

⁽¹⁾ ECJ, C-439/05 P and C-454/05 P, para. 56-58.

- (21) The justifications put forward by Portugal make extensive reference to the potential effects of the cultivation of GM varieties on the environment. The notification contains an analysis of extended and complicated issues such as preliminary tests carried out using GM varieties, model showing the invasive capacity of GM varieties, interaction of the model to the use of plants containing GMOs, capacity of transgenic plants to cross-pollinate, parallel effects with other species, production of toxins, collateral interactions, effects connected with genetic alterations, implications in poor agricultural practices, gene transfer and effects on the food chain.
- (22) It results from these justifications that a thorough scientific risk assessment is necessary to indicate whether the submitted scientific evidence relates to the protection of the environment or the working environment on grounds of a problem specific to the Autonomous Region of Madeira arising after the adoption of Directive 2001/18/EC and Regulation (EC) No 1829/2003 or other relevant EC provisions. This assessment should be carried out by the European Food Safety Authority (EFSA) which, in accordance with Article 22(2) 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⁽¹⁾, is competent to provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety, and shall provide independent information on all matters within these fields and communicate on risks. Moreover, in accordance with Article 29 of that Regulation, EFSA shall issue a scientific opinion at the request of the Commission, in respect of any matter within its mission, and in all cases where Community legislation makes provision for the Authority to be consulted.
- (23) For this reason the Commission sent on 23 September 2009 a mandate to the European Food Safety Authority (EFSA) asking it to assess, on the basis of the new evidence provided by Portugal and in the light of the requirements of Article 95(5) of EC Treaty, whether the particular evidence relates to the protection of the environment on grounds of a problem specific to the concerned area, namely the Autonomous Region of Madeira.
- (24) Under those circumstances, the adoption of the EFSA Opinion is necessary before the adoption of a decision on the Portuguese notification. In view of the extended scope of the potential adverse environmental effects indicated by the Portuguese notification and the complexity of the scientific aspects related to the cultivation of GMOs in the Autonomous Region of Madeira, it is necessary that EFSA is granted a reasonable period of time before adopting its Opinion. For this reason, the Commission asked EFSA to deliver its Opinion by 31 January 2010.
- (25) The justifications put forward by Portugal make no specific reference to danger for human health, which would be caused by the cultivation of GMOs in the Autonomous Region of Madeira. While they specifically refer to risks for the environment and 'ecological health', no evidence has been presented with regards to identified or potential effects on human health. All scientific arguments have focused solely on agricultural aspects and the protection of biodiversity in Madeira.
- (26) In view of the above, the adoption of a decision within the deadline of six months, namely by 4 November 2009, which is laid down by Article 95(6)(1) of EC Treaty, would lack the essential scientific support on such a complex matter. Therefore, taking into consideration the complexity of the matter and the absence of danger for human health, the Commission, in accordance with Article 95(6)(3) of EC Treaty, should extend the period to decide on the Portuguese notification to another six months, namely until 4 May 2010.

HAS ADOPTED THIS DECISION:

Article 1

The period to approve or reject the draft Regional Legislative Decree declaring the Autonomous Region of Madeira to be an Area Free of Genetically Modified Organisms, notified by the Republic of Portugal pursuant to Article 95(5) of the EC Treaty, is extended to 4 May 2010.

Article 2

This Decision is addressed to the Republic of Portugal.

Done at Brussels, 3 November 2009.

For the Commission

Stavros DIMAS

Member of the Commission

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.