II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

DECISIONS

COMMISSION

COMMISSION DECISION

of 12 October 2007

relating to Articles 111 and 172 of the Polish Draft Act on Genetically Modified Organisms, notified by the Republic of Poland pursuant to Article 95(5) of the EC Treaty as derogations from the provisions of Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms

(notified under document number C(2007) 4697)

(Only the Polish text is authentic)

(Text with EEA relevance)

(2008/62/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:

1. PROCEDURE

(1) 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.
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> 6. The Commission shall, within six months of the notifications 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 on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.'

(2) In a letter dated 13 April 2007, the Polish Permanent Representation to the European Union notified the Commission, in accordance with Article 95(5) of the EC Treaty, of Articles 111 and 172 of a draft Act on Genetically Modified Organisms, in derogation of the provisions of Directive 2001/18/EC of the European Parliament and the Council [1] on the deliberate release into the environment of genetically modified organisms (hereinafter: Directive 2001/18/EC).

(3) By a letter of 9 July 2007, the Commission informed the Polish 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.

(4) The Commission published a notice regarding the request in the *Official Journal of the European Union* [2] to inform the other parties concerned of the draft national measures that Poland intended to adopt [3].

[1] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Regulation (EC) No 1830/2003 (OJ L 268, 18.10.2003, p. 24).
[2] OJ C 173, 26.7.2007, p. 8.
[3] The observations were issued from Lithuania, EuropaBio, the European Seed Association and Greenpeace. Observations were also made by individuals, professional associations and Polish institutions.

2. RELEVANT COMMUNITY LEGISLATION

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

(5) 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.

(6) 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. 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. 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, the Directive does provide for this possibility. 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 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'. 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 procedure foreseen under Article 30(2) of Directive 2001/18/EC.

2.2. Regulation (EC) No 1829/2003 on genetically modified food and feed

(7) According to its Article 1, Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [1] (hereinafter 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 authorisation and supervision of genetically modified food and feed and (c) in laying down provisions for the labeling of genetically modified food and feed. Taken into account these different objectives, this Regulation is based on Article 37, 95 and 152(4)(b), of the EC Treaty. This Regulation applies to GMOs for food and feed use, food or feed containing or consisting of GMOs and food or feed produced from or containing ingredients produced from GMOs. As recalled in recital 11 of the Regulation, authorisation may also be granted to a GMO to be used as a source material for production of food and feed.

(8) Regulation (EC) No 1829/2003 establishes a centralised system for the authorisation of GMOs (Articles 3 to 7 for genetically modified food and Article 15 to 19 for genetically modified feed). Every application shall be accompanied by a dossier supplying the information required by Annexes III and IV to Directive 2001/18/EC and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC (Articles 5(5)(a) and 17(5)(a)). The European Food Safety Authority (EFSA) prepares an opinion on each authorisation (Articles 6 and 18). In case of GMOs to be used as seeds or other plant-propagating materials falling within the scope of the Regulation, Articles 6(3)(c) and 18(3)(c) requires EFSA to delegate the environmental risk assessment to a national competent authority. Article 8 of the Regulation lays down rules applicable to 'existing products' defined as food products placed on the market

[1] OJ L 268, 18.10.2003, p. 1. Regulation as amended by Commission Regulation (EC) No 1981/2006 (OJ L 368, 23.12.2006, p. 99).

under Council Directive 90/220/EEC [1] before the entry into force of Regulation (EC) No 258/97 of the European Parliament and of the Council [2] or in accordance with the provisions referred to in Regulation (EC) No 258/97 or other products which have been lawfully placed on the market before the date of application of this Regulation, and for which operators responsible of the placing on the market have notified to the Commission within six months of the date of application of this Regulation that the products were placed on the market in the Community before the date of the application of this Regulation. According to the same Article 8, these products may continue to be placed on the market, used and processed under certain conditions. Article 20 of the Regulation sets out the same procedure for feed products which have been authorised under Directives 90/220/EEC or 2001/18/EC, including use as feed, under Directive 82/471/EEC [3], which are produced from GMO, or under Council Directive 70/524/EEC [4], which contain, consist or are produced from GMOs. Within one year from the date of application of the Regulation, and after verification that all the information required has been submitted and examined, the products concerned entered the Community Register of genetically modified food and feed (The Register).

3. NATIONAL PROVISIONS NOTIFIED

3.1. Scope of the national provisions notified.

(9) Poland has attached to its notification all the provisions of the draft Act. Nevertheless, according to the explanatory note submitted by Poland, the derogation to Directive 2001/18/EC would concern only points 5 and 6 of Article 111(2) of Part IV of the draft Act, which concerns the deliberate release of GMOs for experimental purposes, and its Article 172. Accordingly, the assessment in the present decision will be limited to those provisions, without prejudice to other official procedures which will eventually assess the conformity of the rest of the Act — including the other provisions of Article 111 — with Community legislation.

3.1.1. *Article 111 (deliberate releases for experimental purposes)*

(10) Article 111 lays down the content of an application for the issuing of a decision for the deliberate release of a GMO.

According to Article 111(1): 'An application for the issuing of a decision in the matter of deliberate release should contain':

According to Article 111(2): 'The following shall accompany an application for the issuing of a decision in the matter of a deliberate release':

1. a risk assessment prepared for the genetically modified organisms being released (…);

2. documentation relating to the preparation of the risk assessment (…);

3. technical documentation of the deliberate release;

4. a programme of action in the case of a risk to the health of persons or animals or the safety of the environment associated with the deliberate release;

5. certification from the mayor of the municipality, town or city that in the local spatial development plan, with regard to the need to protect local environment, nature and cultural landscape of the area in question, provision is made for the possibility of deliberate release;

6. written declarations from the holders of farms neighboring the location of the deliberate release that they do not object to the release;

7. notarised copy of the contract for the conduct of the deliberate release (…);

8. summary of the application.

3.1.2. *Article 172 (establishment of special zones for the cultivation of GMOs)*

(11) Article 172 stipulates:

'1. It shall be prohibited to cultivate genetically modified plants, subject to the provisions of paragraph 2.

[1] OJ L 117, 8.5.1990, p. 15. Directive as repealed by Directive 2001/18/EC.
[2] OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).
[3] OJ L 213, 21.7.1982, p. 8. Directive as last amended by Commission Directive 2004/116/EC (OJ L 379, 24.12.2004, p. 81).
[4] OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 1800/2004 (OJ L 317, 16.10.2004, p. 37).

2. The Minister with responsibility for agriculture, in consultation with the Minister with responsibility for the environment and after seeking the opinion of the council of the municipality (*gmina*) in which the genetically modified plants are to be cultivated, shall issue a decision concerning the creation of a zone designated for the cultivation of genetically modified plants in a specified area situated within the territory of the municipality (zone designated for the cultivation of genetically modified plants), following the submission by the applicant mentioned in Article 4(21)(f) of an application for the issue of a decision concerning a zone designated for the cultivation of genetically modified plants.

3. An application for the issue of a decision concerning the creation of a zone designated for the cultivation of genetically modified plants should contain:

1. the forename and surname or name and registered office and the address of the applicant mentioned in Article 4(21)(f);

2. the species and variety of genetically modified plant, the properties obtained as a result of the genetic modification and the unique identifier;

3. the number of the cadastral parcel containing the agricultural parcel within the meaning of the regulations on the national system for keeping records of producers, records of farms and records of applications for the award of payments, the area of the agricultural parcel in hectares, the location of the agricultural parcel within the cadastral parcel, the sheet number of the cadastral map for that cadastral parcel, the name of the cadastral region and the name of the municipality and voivodship.

4. The application shall be submitted in writing and in electronic form.

5. The application mentioned in paragraph 3 shall be accompanied by written declarations from the holders of land within the area of spatial isolation from the land on which it is planned to cultivate genetically modified plants that they do not object to the intention to create a zone designated for the cultivation of genetically modified plants.

6. A copy of the application for the issue of a decision concerning a zone designated for the cultivation of genetically modified plants shall be sent, in writing and in electronic form, within five days following the date on which the application is submitted, by the Minister with responsibility for agriculture to:

1. the Minister with responsibility for the environment;

2. the council of the municipality within which the genetically modified plants are to be cultivated;

and these, within 45 days following the date of delivery to them of a copy of the application mentioned in paragraph 3, shall convey their position in the matter, indicating the reasons therefore, to the Minister with responsibility for agriculture.

7. The Minister with responsibility for the environment shall convey to the Minister with responsibility for agriculture the position mentioned in paragraph 6(1) after seeking the opinion of the Team mentioned in Article 26(4) and the opinion of the Committee mentioned in Article 25.

8. The council of the municipality mentioned in paragraph 6(2) shall, immediately after receiving the application, make the information contained therein publicly known in the town or village in which the zone is to be created, in the manner customarily adopted in the area in question.'

(12) Poland has notified to the Commission all provisions of Article 172. Without prejudice to other official procedures which will assess the conformity of the rest of the Act with Community legislation, the Commission considers that all provisions of Article 172 derogate from Directive 2001/18/EC.

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

3.2.1. *Impact of points 5 and 6 of Article 111(2)*

(13) The scope of the latter provisions, in conjunction with the explanation of the explanatory note, implies that it will primarily impact on the release of GMOs for any other purpose than for placing on the market (primarily for field trials) under Part B (Articles 5 to 11) of Directive 2001/18/EC.

3.2.2. *Impact of Article 172*

(14) The scope of Article 172(1) of the draft Act implies that it will primarily impact on:

— the cultivation of genetically modified seed varieties authorised under the provisions of part C (Articles 12 to 24) of Directive 2001/18/EC,

— the cultivation of genetically modified seed varieties already approved under the provisions of Directive 90/220/EEC and now notified as existing products under Articles 8 and 20 of Regulation (EC) No 1829/2003,

— the cultivation of genetically modified seed varieties authorised under the provisions of Regulation (EC) No 1829/2003.

4. JUSTIFICATION PUT FORWARD BY POLAND

(15) Information for the draft Act, offering interpretation about the Act's impact on and conformity with Community legislation, is provided in the submitted explanatory note on the draft Act (pages 12 and 16 and 17) and the text of the notification (pages 3 to 5).

4.1. **Justifications put forward for points 5 and 6 of Article 111(2)**

(16) According to the Polish notification (pages 3 and 4) and explanatory note (page 12), following arguments support the existence of 'elements related to specific conditions' in the sense of Article 95(5) EC Treaty.

(17) In the drafting of the rules governing the deliberate release of genetically modified organisms into the environment for experimental purposes, the principle adopted was that a set of arrangements as strict as possible should be created for assessing the safety of a given field experiment in the context of its safety for the environment. This is especially important because release is the first stage of research where the new genetically modified organism comes into contact with the environment and the experiment is conducted without such effective protective measures as are applied in closed systems.

(18) The effect of such an organism on the environment is unknown and may be potentially harmful (this applies particularly to organisms other than genetically modified higher plants). Such action therefore requires special conditions of safety to be maintained, which is in accordance with the precautionary principle that applies in EU Member States. In view of the richness of biodiversity in Poland, the introduction of genetically modified organisms into the environment may cause serious disturbances to its functioning.

(19) The overriding principle was therefore adopted that there should be as strict as possible an assessment of all component elements of a given field experiment. Particular emphasis was placed on the environmental conditions (soil composition, fauna, flora, presence of protected species, climatic conditions, etc.).

(20) These proposals (namely, to condition the release to the consent of the neighbouring owners of farm parcels and the provisions of local spatial plans) place additional obligations on applicants, but they do not exclude the carrying out of work involving the deliberate release of GMOs into the environment. The restrictive approach to the question of release is also linked to the structure of Polish agriculture, which is among the most fragmented in the Community. This poses a serious problem not only for commercial growing of GM plants, but also for the safe location of field experiments.

(21) The Polish authorities make no reference to any new scientific evidence *since the Directive has been adopted* relating to the protection of the environment.

4.2. **Justifications put forward for Article 172**

(22) According to the Polish notification (pages 4 and 5) and explanatory note (16 and 17), the rules on commercial cultivation in the national provisions are based to a large extent on Commission Recommendation 2003/556/EC of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming [1].

(23) The idea of creating zones designated for the cultivation of genetically modified plants is a development of paragraph 3.3 of the aforementioned Recommendation, which concerns cooperation between neighbouring farms. Account was also taken of paragraph 2 and paragraph 3.3.2 (coordinated management measures), which speaks of the voluntary clustering of fields of different farms for the cultivation of similar crop varieties (GM, conventional or organic) in a particular area, as well as subparagraph 3.3.3 concerning voluntary agreements among farmers on zones of a single production type.

(24) According to the draft act, cultivation of genetically modified plants should be limited to areas which do not contain elements of value from a nature conservation standpoint and whose agrarian structure enables safe cultivation of transgenic plants, without damaging the operations of other farmers.

[1] OJ L 189, 29.7.2003, p. 36.

(25) The regulations proposed in the draft act permit minimisation of the risk associated with the mixing of reproductive material or crossing of genetically modified plants with unmodified plants, and make it possible to inspect genetically modified crops.

(26) A ground for the introduction of derogations in the national provisions as regards the restriction of the cultivation of transgenic plants, is the need to fulfil the expectations of Polish society. Provisions restricting the cultivation of GM plants have the purpose of preventing the possible damage which may result should transgenes cross over into conventional crops. Concerns relating to the cultivation of GM plants are associated mainly with the impossibility of eliminating the risk of contamination of crops due to possible crossing. This results from the fact that Polish agriculture is fragmented to a very high degree. Poland has almost two million farms, and the average area of a farm is less than 8 ha. Polish agriculture is characterised by a conventional production system, and there is also increasing interest in organic production. Given this high level of fragmentation, it is not possible to isolate GM crops from conventional and organic crops, and this may also pose a serious threat to Poland's developing organic farming. In this situation, the uncontrolled introduction of transgenic plants into cultivation may inflict losses on farmers.

(27) The reluctance of Polish farmers is also increased by the absence of provisions on compensation for agricultural losses resulting from the uncontrolled crossing of varieties. At present, there are no national provisions relating to the coexistence of the three forms of agriculture — conventional, organic and using transgenic plants — the draft provisions are the first attempt to regulate this matter.

(28) The Polish authorities make no reference to any new scientific evidence since the Directive has been adopted relating to the protection of the environment.

5. LEGAL ASSESSMENT

(29) 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.

(30) 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.

(31) The notification submitted by the Polish authorities on 13 April 2007 is intended to obtain approval for the introduction of the new Article 111(2) points 5 and 6 and Article 172 of the Act which Poland considers to be a derogation to Directive 2001/18/EC.

(32) Poland submitted this notification as derogation to Directive 2001/18/EC only. Therefore, the legal assessment contained in this Decision will focus only on Directive 2001/18/EC.

(33) Directive 2001/18/EC harmonises at Community level the rules with regards to the 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 into the environment of GMOs in the European Union, notably since authorisations in accordance with the legislation for genetically modified food and feed (Regulation (EC) No 1829/2003) are carried out also in line with its governing principles.

(34) 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:

— in accordance with the provisions of Part B of the Directive 2001/18/EC, experimental releases of GMOs are not subject to the consent of any third parties (such as neighbouring farmers, as stipulated by the Polish draft Act) and any authorities other than the Competent Authorities designated under Article 4(4) of the Directive (such as local municipalities, as stipulated by the Polish draft Act),

— Directive 2001/18/EC, enables free circulation of genetically modified seeds approved at Community. Articles 13-18 of the Directive establish an authorisation procedure which includes the assessment of each individual notification for GMO(s) by the competent authorities and, under circumstances, the authorisation through the Committee procedure of Articles 5 and 7 of Council Decision 1999/468/EC [1]. In accordance with Article 19 of the Directive ('Consent'), '(…) only if a written consent has been given for the placing on the market of a GMO as or in a product may that product be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to.' Moreover, Article 22 of the Directive (Free circulation) stipulates that 'without prejudice to Article 23, Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive'.

(35) In view of the above, if a GMO receives a consent for cultivation in the EU under the procedure provided for by Directive 2001/18/EC, Member States cannot introduce any additional restrictions to its cultivation. However the Polish Act prohibits their cultivation unless designated in specific zones, even if no such restriction is established by the written consent given under the Directive.

(36) Directive 2001/18/EC is affected, in so far as the draft act restricts the cultivation of all GMOs in Poland, whereas the Directive (Articles 13-18) foresees a procedure providing at a EC level a case-by-case risk analysis prior to the authorisation of the placing on the market of a GMO.

(37) The proposed restrictions of the cultivation of genetically modified seeds in Poland also create 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.

(38) Article 111(2)(5, 6) of the draft Polish Act seeks to restrict the cultivation of genetically modified seeds for experimental releases. Experimental releases of genetically modified seeds are regulated under Directive 2001/18/EC although at a national rather than Community level. In accordance with Article 6(1) of the Directive (Standard authorisation procedure), the notification for each experimental release of GMOs is submitted to the Competent Authority of the Member State within whose territory the release is to take place. In accordance with Article 6(8), the notifier may proceed with the release only when he has received the written consent of the competent authority, and in conformity with any conditions required in the consent. Therefore, the provisions of the notified draft Act which establish additional administrative requirements for the authorisation of such releases, such as mayors' certifications and written declarations for the neighboring farmers that they do not object to the releases, irrespective of any potential risk, have to be considered in contradiction with the Directive.

(39) Article 172(1) prohibits the cultivation of genetically modified plants, subject to the provisions of paragraph 2, namely the designation of specific zones by the Ministry of Agriculture. This general ban is in breach of Article 19 of Directive 2001/18/EC, which stipulates that if a written consent has been given for the placing on the market of a GMO as or in a product, that product may be used without further notification throughout the Community in so far as the specific conditions of use and the environments and/or geographical areas stipulated in these conditions are strictly adhered to. Furthermore, the general ban of the draft Polish Act is in breach of Article 22 of the Directive, which stipulates that Member States may not prohibit, restrict or impede the placing on the market of GMOs, as or in products, which comply with the requirements of this Directive.

(40) 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. This provision indicates that the cultivation of a GMO can be prohibited only on a case-by-case basis and upon particular conditions (new information made available since the date of consent), without providing the basis to any Member State to adopt a general ban of the cultivation or any other use of GMOs.

[1] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

(41) It results from the above that, as the Polish authorities explained in their notification, point 5 and 6 of Article 111(2) and Article 172 are not compatible with Directive 2001/18/EC. Under these circumstances, there is no need to further examine them under other Community legislation and in particular under Regulation 1829/2003/EC in the context of this Decision. Nevertheless, the assessment under Directive 2001/18/EC will not prejudice the assessment on the compliance of the notified draft Act with other parts of Community law, and especially Regulation (EC) No 1829/2003 in the context of other EC procedures.

(42) 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. 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. Therefore, the exception provided for by Article 95(5) of the EC Treaty must be interpreted in such a way that its scope is not extended beyond the cases for which it formally provides.

(43) 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.

(44) Moreover, and given the exceptional character of the national measure concerned, the burden of proof for the existence of the requirements justifying the adoption of such a measure in accordance with Article 95(5) of the EC Treaty, lies with the Member State which notifies the measure.

(45) 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 shall be justified on the following cumulative conditions ([1]):

— 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.

(46) Therefore, under the abovementioned Article, the introduction of national measures which are incompatible with a Community harmonisation measure first of all needs to be justified by new scientific evidence concerning the protection of the environment or the working environment.

(47) As it results from paragraph 45 of this Decision, it is 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.

(48) The justifications put forward by Poland (text of notification, pages 3-5) are that:

— the uncertainty surrounding the first stage of research where the new genetically modified organism comes into contact with the environment, where the effect of such a genetically modified organism on the environment is unknown and potentially harmful,

— the need to limit the cultivation of genetically modified plants to areas which do not contain elements of value from a nature conservation standpoint and whose agrarian structure enables safe cultivation of transgenic plants, without damaging the operations of other farmers,

— the need to fulfil the expectations of Polish society, while concerns relating to the cultivation of genetically modified plants are associated mainly with the impossibility of eliminating the risk of contamination of crops due to possible crossing,

— a high level of fragmentation of Polish agriculture, where it is not possible to isolate GM crops from conventional and organic crops, thus posing the uncontrolled introduction of transgenic plants into cultivation may inflict losses on farmers,

([1]) ECR, C-439/05 P and C-454/05 P, points 56-58.

— the reluctance of Polish farmers towards the cultivation of GMOs which is increased by the absence of provisions on compensation for agricultural losses resulting from the uncontrolled crossing of varieties, while at present there are no national provisions relating to the coexistence of the three forms of agriculture (conventional, organic and transgenic plants).

(49) It results from the justifications put forward by Poland that Polish authorities make no reference to any new information related to the protection of the environment in their notification or in the accompanying explanatory note. Their justifications concern broader issues such as the uncertainty surrounding the first stage of research, the conservation of nature and the matter of liability. There is no reference to any new scientific studies, researches, literature or any other possible findings emerged after the adoption of Directive 2001/18/EC and indicating new evidence concerning the protection of the environment or working environment.

(50) Under those circumstances, in the absence of new scientific element the Commission did not have any reason to submit, the notification to the European Food Safety Authority EFSA and ask its opinion, in accordance with Article 28(2) of Directive 2001/18/EC.

(51) Given the fact that the submission of new scientific evidence constitutes a cumulative condition for the fulfillment of the requirements of Article 95(5) EC Treaty, their absence has as consequence the rejection of the notification without the need to further examine the fulfillment of other conditions.

6. **CONCLUSION**

(52) 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 environment or the working environment, there must be a problem specific to the Member State making the request, and the problem must have arisen after the adoption of the harmonisation measure.

(53) The Polish notification does not provide any new scientific evidence relating to the protection of the environment or the working environment, which could 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.

(54) Consequently, the request from Poland for introducing Articles 111(2)(5, 6) and 172 aimed at derogating from the provisions of Directive 2001/18/EC concerning the experimental release and cultivation of GMOs in Poland does not fulfill the conditions set out in Article 95(5).

(55) 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 our above, the Commission considers that Poland's request for introducing national provisions derogating from Directive 2001/18/EC, submitted on 13 April 2007, does not fulfill the conditions set out in Article 95(5) of the EC Treaty, as Poland did not provide new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to Poland.

(56) The Commission therefore considers that the national provisions notified cannot be approved in accordance with Article 95(6) of the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

Points 5 and 6 of Article 111(2) and Article 172 of the draft Law on Genetically Modified Organisms notified by Poland pursuant to Article 95(5) of the EC Treaty, are rejected.

Article 2

This Decision is addressed to the Republic of Poland.

Done at Brussels, 12 October 2007.

For the Commission
Stavros DIMAS
Member of the Commission