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**A5-0154/2003**

6 May 2003

**\*\*\*II**

## **RECOMMENDATION FOR SECOND READING**

on the Council common position for adopting a European Parliament and Council regulation on transboundary movements of genetically modified organisms

(15546/1/2002 – C5-0081/2003 – 2002/0046(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Jonas Sjöstedt

***Symbols for procedures***

- \* Consultation procedure  
*majority of the votes cast*
- \*\*I Cooperation procedure (first reading)  
*majority of the votes cast*
- \*\*II Cooperation procedure (second reading)  
*majority of the votes cast, to approve the common position  
majority of Parliament's component Members, to reject or amend  
the common position*
- \*\*\* Assent procedure  
*majority of Parliament's component Members except in cases  
covered by Articles 105, 107, 161 and 300 of the EC Treaty and  
Article 7 of the EU Treaty*
- \*\*\*I Codecision procedure (first reading)  
*majority of the votes cast*
- \*\*\*II Codecision procedure (second reading)  
*majority of the votes cast, to approve the common position  
majority of Parliament's component Members, to reject or amend  
the common position*
- \*\*\*III Codecision procedure (third reading)  
*majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission)

***Amendments to a legislative text***

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

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## PROCEDURAL PAGE

At the sitting of 24 September 2002 Parliament adopted its position at first reading on the proposal for a European Parliament and Council regulation on transboundary movements of genetically modified organisms (COM(2002) 85 – 2002/0046 (COD)).

At the sitting of 13 March 2003 the President of Parliament announced that the common position had been received and referred to the Committee on the Environment, Public Health and Consumer Policy (15546/1/2002 – C5-0081/2003).

The committee had appointed Jonas Sjöstedt rapporteur at its meeting of 27 March 2002.

The committee considered the common position and draft recommendation for second reading at its meetings of 25 March 2003 and 30 April 2003.

At the latter meeting it adopted the draft legislative resolution by 20 votes to 2, with 8 abstentions.

The following were present for the vote: Caroline F. Jackson, chairman; Mauro Nobilia and Guido Sacconi, vice-chairmen; Jonas Sjöstedt, rapporteur; and Hans Blokland, John Bowis, Dorette Corbey, Chris Davies, Véronique de Keyser (for David Robert Bowe), Karl-Heinz Florenz, Robert Goodwill, Françoise Grossetête, Hans Kronberger, Bernd Lange, Caroline Lucas (for Alexander de Roo), Torben Lund, Albert Jan Maat (for Peter Liese), Jules Maaten, Minerva Melpomeni Malliori, Patricia McKenna, Riitta Myller, Ria G.H.C. Oomen-Ruijten, Neil Parish (for Avril Doyle), Marit Paulsen, Dagmar Roth-Behrendt, Horst Schnellhardt, Inger Schörling, Renate Sommer (for Eija-Riitta Anneli Korhola), Bart Staes (for Marie Anne Isler Béguin) and Phillip Whitehead.

The recommendation for second reading was tabled on 6 May 2003.

## DRAFT LEGISLATIVE RESOLUTION

### **European Parliament legislative resolution on the Council common position for adopting a European Parliament and Council regulation on transboundary movements of genetically modified organisms (15546/1/2002 – C5-0081/2003 – 2002/0046(COD))**

#### **(Codecision procedure: second reading)**

*The European Parliament,*

- having regard to the Council common position (15546/1/2002 – C5-0081/2003),
  - having regard to its position at first reading<sup>1</sup> on the Commission proposal to Parliament and the Council (COM(2002) 85<sup>2</sup>),
  - having regard to the amended proposal (COM(2002) 578<sup>3</sup>),
  - having regard to Article 251(2) of the EC Treaty,
  - having regard to Rule 80 of its Rules of Procedure,
  - having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Consumer Policy (A5-0154/2003),
1. Amends the common position as follows;
  2. Instructs its President to forward its position to the Council and Commission.

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<sup>1</sup> TA (2002) 0432.

<sup>2</sup> OJ C 151 E, 25.6.2002, p. 121.

<sup>3</sup> OJ C not yet published.

Amendment 1  
Recital 6

(6) Exports of GMOs ***intended for deliberate release into the environment*** should be notified to the Party or non-Party of import, allowing it to make an informed decision, based on a risk assessment carried out in a scientifically sound manner.

(6) Exports of GMOs should be notified to the Party or non-Party of import, allowing it to make an informed decision, based on a risk assessment carried out in a scientifically sound manner ***and taking into account the precautionary principle.***

*(Reflects Am. 3 at first reading, adopted on 24th September 2002)*

*Justification*

*The amendment reflects first reading amendment 3.*

Amendment 2  
Recital 8

(8) Exporters should await the express consent of the Party or non-Party of import before proceeding with ***the first*** transboundary movement of a GMO intended for deliberate release into the environment.

(8) Exporters should await the express consent of the Party or non-Party of import before proceeding with ***a*** transboundary movement of a GMO intended for deliberate release into the environment. This obligation should not apply where ***the Party or non-Party of import has given notice in writing that subsequent transboundary movements of the GMO will no longer require an approval.***

*(Reflects Am. 60 at first reading, adopted on 24th September 2002)*

*Justification*

*Recital 8 of the common position offers new text. The amendment reflects first reading amendment 60 which also deleted the word "first".*

Amendment 3  
CHAPTER I  
Article 1

In accordance with the precautionary principle, and without prejudice to the provisions of Directive 2001/18/EC, the objectives of this Regulation are to establish a common system of notification and information for transboundary movements of genetically modified organisms (GMOs) and to ensure coherent implementation of the provisions of the Protocol on behalf of the Community in order to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

In accordance with the precautionary principle, and without prejudice to the provisions of Directive 2001/18/EC, the objectives of this Regulation are to establish a common system of notification and information for transboundary movements of genetically modified organisms (GMOs) and to ensure coherent implementation of the provisions of the Protocol on behalf of the Community in order to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, ***and, to ensure, in accordance with the Protocol, respect for the regulatory framework of the importing country in relation to such GMOs.***

*(Reflects Am. 9 at first reading, adopted on 24th September 2002)*

*Justification*

*The amendment reflects first reading amendment 9. The Council rejected amendment 9 arguing that the concept of “facilitation” is “diffuse”. The term “facilitate” is therefore replaced by “ensure”.*

Amendment 4  
CHAPTER I  
Article 2 (2)

2. Pharmaceuticals for humans that are addressed by other relevant international agreements or organisations are excluded from the scope of this Regulation.

2. Pharmaceuticals for humans that are addressed by other relevant international agreements ***to which the Community or the relevant Member State is party*** or organisations ***of which the Community or the relevant***

*Member State is a member* are excluded from the scope of this Regulation.

#### *Justification*

*Without the additional wording, which reflects Amendment 10 adopted in first reading, this paragraph would be open to abuse and would not be in line with Art. 5 of the Biosafety Protocol.*

#### Amendment 5 CHAPTER II Article 4

The exporter shall ensure notification, in writing, to the competent authority of the Party or non-Party of import prior to the **first** intentional transboundary movement of a GMO intended for deliberate release into the environment and destined for the use specified in accordance with Annex I, point (i). The notification shall contain, as a minimum, the information specified in Annex I. The exporter shall ensure the accuracy of the information contained in the notification.

The exporter shall ensure notification, in writing, to the competent authority of the Party or non-Party of import prior to the intentional transboundary movement of a GMO intended **directly or indirectly** for deliberate release into the environment and destined for the use specified in accordance with Annex I, point (i). The notification shall contain, as a minimum, the information specified in Annex I. The exporter shall ensure the accuracy of the information contained in the notification. ***If the Party or non-Party of import has, before or after the first transboundary movement of the GMO, given notice in writing that subsequent transboundary movements of the GMO will no longer require an approval, this article shall not apply to such subsequent transboundary movements.***

*(Partially reinstates Ams. 60 and 50 first reading, adopted on 24 September 2002)*

#### *Justification*

*Partial representation of first reading amendments 60 and 50. The second part is intended to clarify the procedures necessary as a result of the removal of the blanket qualification implied by the word removed in the first part of the amendment. Whilst it would plainly be absurd for every shipment of every GMO to require separate express consent, to apply this requirement*



*only to first movements is too restrictive. To the extent the Biosafety Protocol allows this, the amendment also aims to accommodate the idea of amendment 50.*

Amendment 6  
CHAPTER II  
Article 5, paragraph 1

1. A failure by the Party of import to acknowledge receipt of a notification or to communicate its decision shall not imply its consent to an intentional transboundary movement. No first intentional transboundary movement may be made without **express** consent of the Party or, where appropriate, non-Party of import.

1. A failure by the Party of import to acknowledge receipt of a notification or to communicate its decision shall not imply its consent to an intentional transboundary movement. No first intentional transboundary movement may be made without **prior written** consent of the Party or, where appropriate, non-Party of import.

*(Partially reflects Am 60 at first reading, adopted on 24th September 2002)*

*Justification*

*The amendment partially reflects first reading amendment 60.*

Amendment 7  
CHAPTER II  
Article 5 (3)

3. The exporter shall not proceed with the first intentional transboundary movement of a GMO intended for deliberate release unless the procedures determined by the Party of import in accordance with Articles 9 and 10 of the Protocol or, where appropriate, equivalent procedures required by a non-Party of import have been followed.

3. ***Without prejudice to the requirements laid out in Article 5.1***, the exporter shall not proceed with the first intentional transboundary movement of a GMO intended for deliberate release unless the procedures determined by the Party of import in accordance with Articles 9 and 10 of the Protocol or, where appropriate, equivalent procedures required by a non-Party of import have been followed.

### *Justification*

*It is important to clarify that, even where the procedures determined by the Party of import in accordance with Articles 9 and 10 of the Protocol or equivalent procedures required by a non-Party of import have been followed, transboundary movement should not occur without that Party or non-Party's express consent. The words are added to avoid possible conflicts of interpretation between Article 5.1 (and various other references to "express consent") and Article 5.3. Without this, there remains a danger that national authorities, particularly in developing countries, might be persuaded, perhaps through external pressure, to adopt procedures which do not include a clear requirement for "express consent". This amendment reflects the spirit and intentions of first reading Amendment 60.*

### Amendment 8 CHAPTER II Article 5, paragraph 4

4. Paragraphs 1, 2 and 3 shall not apply to cases of transboundary movements covered by simplified procedures or bilateral, regional and multilateral agreements or arrangements entered into in accordance with Article **13 and** 14 of the Protocol.

4. Paragraphs 1, 2 and 3 shall not apply to cases of transboundary movements covered by simplified procedures, ***notified in accordance with Article 13 of the Protocol, or by*** bilateral, regional and multilateral agreements or arrangements entered into in accordance with Article 14 of the Protocol, ***provided these agreements and arrangements do not result in a lower level of protection than that provided by the Protocol and this Regulation.***

### *Justification*

*The amendment proposes to amend a part of the text of the common position which was not included in the proposal submitted in first reading. The amendment shall clarify that bilateral, regional or multilateral agreements the Community enters into should not result in a lower level of protection than provided for by the Protocol and by this regulation.*

### Amendment 9 CHAPTER II Article 6

The exporter shall for a period of a minimum of five years keep a record of the notification referred to in Article 4 and the acknowledgement of receipt and the decision of the Party or, where appropriate, non-Party of import and send a copy of these documents to the competent authority of the Member State from which the GMO is exported and to the Commission.

The exporter shall for a period of a minimum of five years keep a record of the notification referred to in Article 4 and the acknowledgement of receipt and the decision of the Party or, where appropriate, non-Party of import and send a copy of these documents to the competent authority of the Member State from which the GMO is exported and to the Commission. ***While taking into account Article 16, the Commission shall make available to the public the notification referred to in Article 4.***

*(Partially reflects Am. 23 at first reading, adopted on 24th September 2002)*

#### *Justification*

*The amendment reflects first reading amendment 23 and takes into account the new Article 16 of the common position.*

#### Amendment 10 CHAPTER II Article 9 (1)

1. The Commission on behalf of the Community ***or, where appropriate, the Member State, which made the decision,*** shall inform the BCH and other Parties through the BCH of any final decision regarding use, including placing on the market, within the Community or use within a Member State, of a GMO that may be subject to transboundary movements for direct use as food or feed or for processing. This information shall be sent to the BCH within fifteen days of the adoption of that decision.

1. The Commission on behalf of the Community shall inform the BCH and other Parties through the BCH of any final decision regarding use, including placing on the market, within the Community or use within a Member State, of a GMO that may be subject to transboundary movements for direct use as food or feed or for processing. This information shall be sent to the BCH within fifteen days of the adoption of that decision.

*Justification*

*Article 9 paragraph 1 confuses responsibilities. While the Commission's proposal (see Art. 8.1) required the Commission to inform the BCH, the common position foresees two alternative information chains. Art. 9.1 does not define in which cases the Commission and in which cases the Member States shall inform BCH*

Amendment 11  
CHAPTER II  
Article 10 (2)

- |   |   |    |  |
|---|---|----|--|
| 2 | If a developing country Party or non-Party of Import or a Party or non-Party with an economy in transition has declared through the BCH that it will take a decision prior to an import of a specific GMO intended for direct use as food or feed, or for processing, according to Article 11.6 of the Protocol, the exporter shall not proceed with the first export of such GMO unless the process provided for under that provision has been followed. | 2. | If a developing country Party or non-Party of Import or a Party or non-Party with an economy in transition has declared through the BCH that it will take a decision prior to an import of a specific GMO intended for direct use as food or feed, or for processing, according to Article 11.6 of the Protocol, the exporter shall not proceed with the first export of such GMO unless the process provided for under that provision has been followed. <b><i>In cases of non-decision Article 5 shall apply mutatis mutandis.</i></b> |
|---|---|----|--|

*Justification*

*The amendment reflects the second sentence of amendment 29, adopted in 1st reading.*

Amendment 12  
CHAPTER II  
Article 10 (3)

Parties' and non-Parties' national decisions on import

- |   |  |
|---|--|
| 3. Failure by the Party or non-Party of Import to acknowledge receipt of a notification or to communicate its decision according to | 3. Failure by the Party or non-Party of Import to acknowledge receipt of a notification or to communicate its decision |
|---|--|

paragraph 2 shall not imply its consent or refusal to the import of a GMO intended for direct use as food or feed, or for processing. No GMO that may be subject to transboundary movements for direct use as food or feed or for processing may be exported, unless it is authorised within the Community *or the competent authority of a third country has expressly agreed to its import as required under Article 12 of Regulation (EC) No 178/2002.*

according to paragraph 2 shall not imply its consent or refusal to the import of a GMO intended for direct use as food or feed, or for processing. No GMO that may be subject to transboundary movements for direct use as food or feed or for processing may be exported, unless it is authorised within the Community.

#### *Justification*

*By deleting this text this amendment places the proposed Regulation in conformity with the requirements of the Cartagena Protocol on Biosafety.*

#### Amendment 13

#### CHAPTER II

#### Section 3 a (new), Article 11 (a) (new)

#### *Section 3a (new)*

#### *Food and feed produced from or with the aid of GMOs*

#### *Article 11a (new)*

*Where a Party or non-Party of import requires under its domestic regulatory framework, the notification of imports of food or feed produced from or with the aid of GMOs but not containing GMOs, the exporter shall comply with the laws and rules of the Party or non-Party of import in accordance with the Protocol.*

*(Partially reflects Am. 30 at first reading, adopted on 24th September 2002)*

*Justification*

*The amendment partially reflects first reading amendment 30. While the Council agreed to address in some more detail GMOs destined to be used for contained use operations (see Article 11), the common position does not address food and feed products produced from or with the aid of GMOs.*

Amendment 14

CHAPTER II

Article 12, paragraph 2, second sub-paragraph

***Paragraph 1(b) shall not apply to products consisting of or containing mixtures of GMOs to be used only and directly as food or feed, or for processing. These products shall be subject to the traceability requirements of Directive 2001/18/EC and, when applicable, future Community legislation covering traceability, labelling and identification of such GMOs.***

***In the case of products consisting of or containing mixtures of GMOs to be used only and directly as food or feed or for processing, the information referred to in paragraph 1(b) may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.***

*Justification*

*The amendment proposes to amend a part of the text of the common position which was not included in the proposal submitted in first reading. The proposed new text is identical with Article 4 (3) of the common position adopted by the Council with a view to the adoption of the Regulation on traceability of GMOs and feed and food produced from GMOs (15798/02). To avoid any confusion, it would certainly be wise to quote the relevant provision here rather than to refer to the according regulation.*

Amendment 15

CHAPTER IV

Article 16 (1)

1. The Commission and the Member States shall not divulge to third parties any confidential information received or exchanged under this Regulation.

1. The Commission and the Member States shall not divulge to third parties any confidential information received or exchanged under this Regulation. ***However, they shall make available information***

*received in accordance with  
Article 6 of this Regulation  
provided this information is not  
confidential.*

*Justification*

*The amendment clarifies the fact that the Commission and the Member States are the addressees of Amendment 24, adopted in the first reading and should also be the addressees of the new Art. 16, proposed by the Commission*

Amendment 16  
CHAPTER IV  
Article 16 (3)

3. *The Party or, where appropriate, the non-Party of Import shall, after consultation with the exporter, decide which information will be kept confidential and shall inform the exporter of its decisions.* Deleted

*Justification*

*The Community cannot regulate parties of import. Art. 16 addresses the Commission and the Member States*

Amendment 17  
CHAPTER IV  
Article 16 (4) (a)

- a) name and address of the exporter, a) name and address of the exporter *and importer,*

*Justification*

*Whilst confidentiality is of great importance for the protection of intellectual property rights, this aspect must be balanced against the public's right to be informed. This restores an amendment from first reading which in the Rapporteur's view relates to information which the confidentiality of which is unnecessary to the defence of intellectual property rights and should therefore be in the public domain.*

Amendment 18  
CHAPTER IV  
Article 16 (4) (c)

- |  |  |
|--|--|
| (c) a summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and | c) a summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, <b><i>giving in addition the purpose for which the release is intended and the location of the intended release, and</i></b> taking also into account risks to human health, and |
|--|--|

*Justification*

*See justification Am. 16.*



## EXPLANATORY STATEMENT

The Council's Common Position accepted almost 70% of the amendments adopted by the Parliament at first reading and thus provides the basis for the speedy accord which must, given our anxiety to see the Biosafety Protocol operational as soon as possible, be the priority for both institutions. To date, 45 countries have ratified the Protocol, which will come into force when that figure reaches 50.

The Council accepted many of the most important of Parliament's amendments. It agreed that no first GMO export should take place without the express consent of the country of import; that Member States should take appropriate measures to prevent unintentional transboundary movements; and that the exporter of GMOs should be the party to which the Regulation gives clear responsibilities and obligations.

There remain, however, a number of points of difference and unresolved issues which I have attempted to address through represented or reworded amendments..

The Council accepted in principle that non-decision by a Party or non-Party of Import should not be taken as "silent consent", though here I believe there are omissions in the Council text which could be construed as allowing exceptions to this important principle and which I have attempted to set right.

Secondly, the Commission proposal excluded "pharmaceuticals for human use". In line with the Protocol and Parliament's amendment (AM 10), the common position excludes "pharmaceuticals for humans that are addressed by other relevant international agreements or organisations". However, the Council text does not include the Parliament amendment's additional condition, that only international agreements to which the Community or its Member States are party or organisations of which one or the other is a member would be recognised. This is clearly necessary to avoid abuse and to bring the Regulation into line with Art. 5 of the Biosafety Protocol and I have therefore proposed its reinstatement as part of Art2.2.

Thirdly, Council also rejected Parliament's attempt to clarify what is meant by "deliberate release". It is not always the case that GMOs intended for eventual release are released immediately they reach the territory of the country of import. Instead, the GMOs might first be stored, crossed with other organisms or propagated under contained use conditions and only then released into the environment. EP AM 60 therefore proposed that all GMOs should fall under the export notification procedure if they are intended "directly or indirectly" for deliberate release. I have represented this amendment to Article 4, which was carried by a very large majority at First Reading.

Fourthly, in line with Parliament's AM 60, the Council accepted that no first GMO exports should take place without the express consent of the country of import. However, Art. 5 (3) still states that where a Party or non-Party of Import does not reply to a notification, the exporter may proceed with the movement in accordance with procedure required by the Party or non-party of import. I have therefore attempted to eliminate this confusion through the presentation of a reworded amendment. In addition, I have proposed a further amendment to

Art. 4 in an attempt to resolve the confusion over the obligations and rights of Parties and non-Parties of Import in relation to releases of GMOs subsequent to the first release. Finally, I have proposed an amendment which reinstates part of AM 29 and ensures that Article 5's procedures also apply in cases covered by the provisions of Art. 10.2.

The final amendments proposed would reinstate Parliament's attempt to find a balance between the right to confidentiality and the defence of intellectual property and other rights, and the right of the public to be informed of matters touching the general interest.