



COMMISSION OF THE EUROPEAN COMMUNITIES

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2002/0046 (COD)

Amended proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
ON THE TRANSBOUNDARY MOVEMENT OF GENETICALLY MODIFIED
ORGANISMS

(presented by the Commission pursuant to Article 250 (2) of the EC Treaty)

Amended proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
ON THE TRANSBOUNDARY MOVEMENT OF GENETICALLY MODIFIED
ORGANISMS

1. BACKGROUND

Transmission of the Proposal to the Council and the European Parliament (COM(2002)85 final – 2002/0046(COD)) in accordance with Article 175(1) of the Treaty

-	18 February 2002
-	17 July 2002
-	16 May 2002
-	24 September 2002

2. OBJECTIVE OF THE COMMISSION PROPOSAL

In accordance with the precautionary principle, the objective of this Proposal is to establish a common system of notification and information for exports to third countries of genetically modified organisms (GMOs) 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 the sustainable use of biological diversity, taking also into account risks to human health.

3. COMMISSION OPINION ON THE AMENDMENTS ADOPTED BY THE PARLIAMENT

At the Plenary Session of 24 September 2002, the European Parliament adopted 48 amendments, out of the 60 amendments that were tabled.

The Commission can accept 15 amendments fully, 12 in principle and 2 partly. The Commission cannot accept 19 amendments.

More specifically, the Commission fully agrees to **amendments 2, 6, 8, 11, 28, 35, 37, 39, 40, 41, 43, 46, 50, 51 and 56**. The Commission agrees in principle to amendments **10, 12, 13, 14, 15, 18, 23, 24, 25, 26, 34 and 36**. Amendments **21 and 60** can be accepted partly. The Commission cannot accept amendments **1, 3, 4, 5, 7, 9, 16, 17, 27, 29, 30, 31, 32, 38, 44, 45, 47, 53 and 59**.

3.1. Amendments accepted by the Commission

Amendment **2** recognises the fundamental right of citizens to a free choice in regard to GMOs, which is in line with the Commission's general approach to biotechnology. The

Commission can accept this amendment and therefore proposes to add its text to recital 4 of the Proposal.

Amendments **6, 8, 39, 40, 41** and **43** improve the editorial quality of the Proposal and are in line with the Cartagena Protocol. Therefore, the Commission can accept all these amendments and proposes to modify the following parts of the Proposal in line with these six amendments respectively: Recitals 8, 13 and Articles 10(1), 10(1)(b), 11 and 11(2)(j).

Amendments **11** and **56** move the exemption of notification for GMOs intended for deliberate release into the environment, which have been identified as being not likely to have adverse effects, from the article related to the scope to the article dealing with notification to Parties and non-Parties of Import. The Commission can accept both amendments, since they only improve the structure of the text, and do not have any impact on its substance. The Commission proposes to amend Article 2(3) of the Proposal according to Amendment 11 and to create a new Article 4, paragraph 2a in the Proposal, in line with amendment 56.

Amendment **28** clarifies the objective of the information procedure for GMOs intended for direct use as food, feed, or for processing. The Commission can accept this amendment, and therefore proposes to amend Article 8(1) of the Proposal accordingly.

Amendment **35** improves the provisions of the Proposal on the identification of GMOs, in line with article 18 of the Biosafety Protocol and in coherence with the Commission's Proposal for a Regulation on the Labelling and Traceability of GMOs. The Commission can accept this amendment, and therefore proposes to create a new Article 9(1) subparagraph 1 point (ba) in the Proposal.

Amendment **37** ensures a better transposition of article 11(4) of the Biosafety Protocol. The Commission can accept this amendment, and therefore proposes to create a new Article 9(a) in the Proposal.

Amendment **46** adjusts the deadlines for monitoring and reporting obligations of the Proposal so that they conform to Art. 31 (4) of Directive 2001/18/EC on the deliberate release into the environment of GMOs¹. The Commission can accept this amendment, and therefore proposes to modify Article 14(1) of the Proposal accordingly.

Amendment **50** clearly rules out re-notification of subsequent movements of a specific GMO that has already been approved in a given country, in line with the Biosafety Protocol and Community practices. The Commission can accept this amendment, and therefore proposes to add the text of this amendment to Article 4(2) of the Proposal

Amendment **51** is acceptable for the Commission, in line with Article 7 of the original Proposal. The Commission therefore proposes to create a new Article 4(2)(a) in the Proposal.

3.2. Amendments accepted in part or principle by the Commission

Amendment **10** improves the consistency of the Proposal with the Protocol for GMOs that are pharmaceuticals for human use. The Commission can accept it in principle, but would prefer a simpler wording for Article 2(2) of the Proposal: ***“Pharmaceuticals for humans that are addressed by other relevant international agreements or organisations are excluded from the scope of this Regulation”***.

¹ OJ L 106, 17.4.2001, p. 1-39

Amendments 12 and 13 update the Proposal, in line with the adoption of Regulation (EC) 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety². The Commission can accept these amendments in principle, but sees no need to quote the full title of the legislation in the text. This should be done in footnotes to Articles 3(7) and 3(8) of the Proposal.

Amendment 14 deletes the definition of “notifier” in Article 3(11) of the Proposal. In the original Proposal, the Commission wished to reflect the practical situation where the “notifier” and the “exporter” are different legal entities. However, this question can also be dealt with under general civil law and the Proposal can refer solely to the “exporter”, in line with the Biosafety Protocol. The Commission can therefore accept, in principle, the deletion of Article 3(11) of the Proposal, but only if the reference to “notifier” is suppressed in all linguistic versions, not just Swedish, as it might be understood from the wording of Amendment 4³.

Amendment 15 aims at simplifying the definition of “exporter”. The definition within the actual Proposal is taken out of the Community’s Customs Code. The Commission shares the objective of the Parliament to simplify the wording of the Proposal, but the proposed definition is not necessarily in line with customs procedures. The Commission can accept amendment 15 in principle, provided that a reference to the relevant Article of the Customs Code is inserted in Article 3(14) of the Proposal, instead of the original text, as for technical definitions under Directive 2001/18/EC. This could read as follows: ***“Exporter” means exporter as defined in Article 788 of Commission Regulation (EEC) n°2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) n°2913/92 establishing the Community’s Customs Code”***.

Amendment 18 aims at providing a definition of “transboundary movements“. The Commission can accept this amendment in principle. However, it needs to be reworded in order to ensure that: (i) *intentional* transboundary movements do not cover imports of GMOs into the European Union and movements of GMOs between Member States of the European Union; (ii) *unintentional* transboundary movements do cover the above-mentioned situations. This has to be done in order to reflect the provisions of Article 14 of the Biosafety Protocol. The new Article 3(16)(a) of the Proposal could read as follows: ***‘Transboundary movement’ means the intentional or unintentional movement of a genetically modified organism between one Party or non-Party and another Party or non-Party, excluding intentional movements into and between Parties, or non-Parties, within the Community.’***

Amendment 23 is intended to develop the information obligation of exporters towards Member States and the European Commission regarding transboundary movements of GMOs. It also intends to make this information available to the public through the European Commission. The Commission can accept this amendment in principle, but proposes to split it into two sentences and introduce the following modifications. The deletion of the reference to “notifier” in the first sentence of Article 6 of the Proposal can be accepted, in line with amendments 14 (Art 3(11)) and 60 (Art 4(1)). However, this must concern all linguistic versions, not just Swedish, as might be understood from the wording of Amendment 4. The second sentence of amendment 23 cannot be accepted since the notification is addressed to a Third country, not to the Commission, and it should be for this country to decide how to deal

² OJ L 31, 1.2.2002, p. 1–24

³ Which the Commission cannot accept, partly for this reason. See also amendments 23 and 60.

with this document. It is therefore not for the Commission to make the notification available to the public.

Amendments **24** and **25** reflect the provisions of Article 21 of the Biosafety Protocol that deals with confidential information. The original Proposal did not deal with this issue, leaving it to existing Community legislation, namely Article 25 of Directive 2001/18/EC. The Commission can accept both amendments in principle, since they clarify the original Proposal. However, the Commission would like to introduce a reference to Directive 2001/18/CE to ensure coherence with this piece of legislation. The Commission proposes to draft the new Article 6(1)(a) of the Proposal as follows: *“In accordance with Directive 2001/18/EC, the Commission and the competent authorities shall not divulge to third parties any confidential information notified under this Regulation and shall protect intellectual property rights relating to the data received. The exporter may indicate the information, in the notification submitted under this Regulation⁴, [...]”*. For the same reason, the Commission proposes to introduce the following modification in the new Article 6a: *“In accordance with Directive 2001/18/EC, in no case may any of the following information be considered confidential [...]”* should be added at the beginning of the new Article 6(a).

Amendment **26** is an editorial change that the Commission can accept in principle. However, the Commission proposes to replace *“must ensure notification”* in the original Article 7 of the Proposal by *“shall notify”*, in line with the original wording of the Protocol⁵.

Amendment **34** is in line with the identification requirements of the Protocol, as well as with those of the Commission Proposal on Labelling and Traceability of GMOs. Therefore, the Commission can accept it in principle. However, information under Annex 1 (e) – (i) is already available via the unique code(s). Therefore, the Commission proposes to add the text of the amendment to Article 9(1) subparagraph 1 point (b) of the Proposal, with the exception of points (e) – (i), for which a reference is not needed.

The Commission can accept Amendment **36** in principle, since it is in line with Article 18 of the Biosafety Protocol. However, as worded now, this is too general and disproportionate for the operator given the broad scope of the Protocol. If such a provision were to be introduced, it should only impose a declaration on the conformity of the movements with the requirements of this Proposal applicable to the exporters. The Commission proposes to reword Article 9(1) subparagraph 1 point (bb) of the Proposal as follow: *“(d) a statement that the movement is in conformity with the relevant provisions of this Regulation.”*

Amendment **21** clarifies the procedure to be followed in cases of non-decision by a Party of Import on a notification of a GMO. The Commission can accept this amendment in part. The new heading of Article 5 of the Proposal, as well as its first sentence, can be accepted, since they are in line with the original Proposal and the Biosafety Protocol. The second and third sentences can also be accepted since they improve the consistency of the Proposal with the Protocol. The fourth sentence cannot be accepted since it goes beyond the provisions of the Protocol and prejudices future international discussions and practices. The Protocol only says that the absence of reply/decision does not imply consent. It does not “per se” forbid exports in such a situation⁶.

⁴ Editorial change.

⁵ And not by *“must notify”* as suggested.

⁶ For the same reason, the Commission cannot accept the first sentence of Amendment 60.

Amendment **60** aims at clarifying the notification procedure for GMOs intended for deliberate release into the environment. The Commission can accept this amendment in part and proposes to reword Article 4(1) the following way: the first sentence cannot be accepted since it goes beyond the provisions of the Protocol and prejudge future international discussions and practices⁷. The second sentence could be accepted but without using the terms "directly or indirectly", since it will in any case be impossible to monitor from the EU subsequent use of a GMO in the Party of Import. The third sentence was not amended. The fourth sentence can be accepted, in line with amendments 14 and 23.

3.3. Amendments not accepted by the Commission

The Commission cannot accept Amendment **1**, which deletes in Recital 3 of the Proposal the reference to an eventual amendment of Directive 2001/18/EC by the upcoming Regulation on the Labelling and Traceability of GMOs. The Commission's amended proposal on Labelling and Traceability still mentions an amendment of Directive 2001/18/EC. Therefore, the Commission cannot accept this amendment.

Amendments **3** and **4** raise problems of redaction and of substance:

- On a linguistic point of view, in both amendments, the modification, in the Swedish text of Recital 6 and 7 of the Proposal, from 'should' to 'shall' (in Swedish) could be seen as inconsistent with the inter-institutional rules on the wording of recitals (*Le considérant est formulé dans un langage non-impératif, ne devant pas pouvoir être confondu avec celui du dispositif*).
- On the substance, Amendment **3** adds in Recital 6 a reference to the precautionary principle, which should not be a problem as such, but shall be reflected in all languages, and not just Swedish. The same applies to Amendment 4 where an important question of substance (suppression of the reference to "notifier" and replacement by a single reference to exporter) is introduced in Recital 7 and would need to be reflected in all languages, not just Swedish.

For these reasons, the Commission cannot accept amendments 3 and 4 as they stand now.

Amendments **5** and **47** raise the important issue of capacity building in developing countries, but do not provide for operational mechanisms. The Commission believes that this issue would be better addressed in a more appropriate framework, like for example the European Development Fund. Therefore, these amendments cannot be accepted.

Amendments **7** and **45** raise the issue of environmental liability. The Commission believes that this Proposal is not the right instrument to tackle this issue. This should be addressed in the horizontal instrument on environmental liability currently discussed at Community level and, in parallel, in international negotiations in this field. Therefore, the Commission cannot accept these amendments.

Amendment **9** recognises the need for exporters to respect the importing country's regulatory framework for GMOs. The Commission believes that such an obligation is implicit and that this addition is not necessary. It may also give an "a priori" legitimacy to legislation of third countries, which are not in line with the Biosafety Protocol (i.e. authorisation procedures that

⁷ See also Amendment 21.

do not rely on scientific risks assessment). For these reasons, the Commission cannot accept this amendment.

Amendments **16** and **17** raise drafting problems. “Conclusion” is the appropriate general terminology, even if “ratification” is more used in common language. “Conclusion” allows encompassing different terminology amongst Member States and at international level. Therefore, the Commission cannot accept these amendments.

Amendment **27** imposes on the Commission an obligation to notify to the Biosafety Clearing House, on behalf of the Community, any final decision regarding Community use, including placing on the market, of a GMO that may be subject to transboundary movements for release into the environment. This is not in line with the procedures foreseen in Articles 8, 9, 10 and 12 of the Biosafety Protocol for GMOs for deliberate release and in Article 11 of the same agreement for GMOs to be used as food or feed, or for processing. This risks creating legal uncertainty. Therefore, the Commission cannot accept this amendment.

Amendment **29** raises a fundamental problem. It, first of all, sets up procedures for GMOs intended for direct use as food or feed, or for processing, that does not fully reflect Article 11 of the Biosafety Protocol. More importantly, by limiting Community exports to GMOs that have been approved into the EU for direct use as food or feed, or for processing, it contradicts Article 12 of Regulation 178/2002/EC laying down the general principles and requirements of food law. Therefore, the Commission cannot accept this amendment.

Amendment **30** is not in line with the scope of both the Biosafety Protocol and the Labelling and Traceability Proposal, mainly by enlarging the scope of the Proposal to food and feed produced with the aid of GMOs. The Commission insists on maintaining coherence between different pieces of legislation on biotechnology, and therefore cannot accept this amendment.

Amendment **31** on transit of GMOs is not entirely in line with Article 6 (1) of the Biosafety Protocol, notably by confusing transport and transit and not mentioning the role of the Biosafety Clearing House. Article 7 of Commission’s Proposal is clearer and more in line with Protocol. For these reasons, the Commission cannot accept amendment 31.

Amendment **32** aims at detailing the obligation to transmit accompanying documentation throughout all the different steps of the transboundary movement of a GMO (notably transit and storage). However, the wording of the amendment is rather cumbersome, and the added value limited since the original provisions already encompass the practical situations the Parliament wishes to cover. Therefore, the Commission cannot accept this amendment and wishes to retain the original wording, which is more clear and general, avoiding potential practical problems and gaps.

Amendments **38** and **59** put an obligation on Member States to take appropriate measures to prevent unintentional transboundary movements of living modified organisms. The Commission believes that the concept of unintentional transboundary movements mainly covers cases of accident. This aspect is already adequately covered by Community legislation, namely Directive 2001/18/EC. Therefore, the Commission cannot accept these amendments.

Amendment **44** puts an obligation on Member States to lay down, after joint consultation, rules on uniform penalties applicable to infringements of the provisions of this Proposal for a Regulation. This aspect is of Member State competence. If there is certainly a need for co-ordination and harmonisation of sanctions is to be encouraged, this goes legally beyond what

can be inserted into a Community Regulation. For these reasons, the Commission cannot accept this amendment.

Amendment **53** introduces transit in the scope of the Proposal. The Commission believes that transit is already covered by the notification and information procedures foreseen under its Proposal. For this reason, the Commission cannot accept this amendment.

4. AMENDED PROPOSAL

Having regard to Article 250, paragraph 2 of the EC Treaty, the Commission modifies its Proposal as indicated above.