

ESA Position Paper

on the

Proposal for a Regulation

on the

Transboundary movement of GMOs

[COM 2002/85 final]

Report Sjöstedt,

Committee on Environment and Public Health

ESA_02.0160.2

Brussels, 17th September 2002

General :

The following remarks and proposals for amendments are the result of the outcome of the vote of the EP Committee on Environment and Public Health on the report of MEP Sjöstedt on 10.09.2002.

Introduction:

The objective of this Regulation is to establish a common system of notification and information for exports to third countries of GMOs.

In view of the report as adopted by the Environment Committee of the EP, we would like to point out the following concerns and comments and to propose respective amendments:

I. Scope of the AIA procedure (Art. 4)

The scope of the Regulation should exclude the contained use of GMOs and transit of GMOs in the same way that these activities are excluded from the scope of the AIA procedure in the Biosafety Protocol. Contained use of GMOs will not have adverse effects on conservation and sustainable use of biological diversity.

(⇒Amendment A1)

II. GMOs for other purposes than placing on the market (Art. 4)

The export of research material to third countries will also be affected by this Regulation.

GMOs approved by third countries for release into their environment for purposes other than placing on the market should be exempted from the scope of this Regulation.

The full AIA notification procedure (270 + 60 = 330 days) is designed for the approval of commercial release and this is reflected in the requirements for specific information in the risk assessment and for the unique identifier issued on commercial approval. This Regulation should focus entirely on GMOs intended for placing on the market (commercial release), not such GMOs intended for other purposes.

(⇒Amendment A2)

III. Duplication of AIA procedure (Art. 4)

The AIA procedure should not apply to exports of GMOs to a third country when the respective GMO already has been notified to that country for a first transboundary movement in accordance with the AIA procedure.

The AIA procedure should also not apply to the export of a GMO to a third country when the respective GMO already has an approval for a deliberate release in that third country.

(⇒Amendment A3)

ESA proposals for Amendments

Amendment A 1

Chapter II, Section 1, Article 4

Third paragraph, NEW

***Section 1 shall not apply to GMOs
intended for contained use or for
transit***

Justification:

The purpose of this amendment is to provide a comprehensive list of exceptions to Section 1 (transit: Article 6(1) of the Protocol; contained use: Article 6(2) of the Protocol).

GMOs in contained use or in transit should not require the AIA procedure as they are either not intended to be released into the environment at all (contained use) or are still in transit to their final destination (transit).

Amendment A 2
Chapter II, section 1, article 4
Fourth paragraph, (new)

Section 1 shall not apply to GMOs intended for deliberate release for any other purpose than placing on the market, provided approval for that release has been given by the importing country.

Justification:

The proposed amendment exempts export to third countries of GMOs intended for purposes other than the commercial use and placing on the market, i.e. for purposes such as limited research and development. A specific requirement for this exemption is that the third country has provided an approval for respective specific deliberate release. The proposed amendment therefore uses the exact wording as laid down in Directive 2001/18/EC under Part B. The full AIA requirements of the Biosafety Protocol should be required only for GMOs imported for deliberate release for commercial purpose.

Amendment A 3
Chapter II, section 1, article 4
Fifth paragraph, (new)

Section 1 shall not apply to GMOs exported to a third country and for which a notification has already been submitted to that country, or for GMOs for which approval for deliberate release has been provided by that country.

Justification:

The AIA notification procedure is designed for the approval of a transboundary movement involving the commercial release of GMOs. The Protocol details specific review periods and extensive information requirements for this activity.

The purpose of this amendment is to prevent duplication of such notifications from different parties for the export of the same GMO into that country. There is also obviously no need for a notification of a specific GMO if an approval for a deliberate release for field trials and/or commercial purposes of that GMO is already available from the country of import.