

Brussels, 17 July 2002

**OPINION**  
of the Economic and Social Committee  
on the  
**Proposal for a Regulation of the European Parliament and of the Council on the  
transboundary movement of genetically modified organisms**  
(COM(2002) 85 final - 2002/0046 (COD))

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On 1 March 2002 the Council decided to consult the Economic and Social Committee, under Article 175 of the Treaty establishing the European Community, on the

*Proposal for a Regulation of the European Parliament and of the Council on the transboundary movements of genetically modified organisms*  
(COM(2002) 85 final - 2002/0046 (COD)).

The Section for Agriculture, Rural Development and the Environment, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 21 June 2002. The rapporteur was **Mr Espuny Moyano**.

At its 392<sup>nd</sup> plenary session (meeting of 17 July 2002), the Economic and Social Committee adopted the following opinion by 123 votes to two with two abstentions.

## 1. **Commission proposal**

1.1 In the framework of the Cartagena Protocol on Biosafety, the Commission proposes setting up a common system of notification and information on exports of GMOs to third countries, with the aim of helping to ensure an adequate level of protection in the field of safe transfer, handling and use of GMOs.

1.1.1 The Commission proposal is divided into four chapters: "Objectives, scope and definitions," "Exports of GMOs to third countries", "Unintentional transboundary movement" and "Common provisions".

## 1.2 **Scope**

1.2.1 The proposed Regulation applies to the export and unintentional transboundary movement of all GMOs that may have adverse effects on the conservation and sustainable use of biological diversity, also taking into account risks to human health.

1.2.2 The Regulation excludes pharmaceuticals for human use and GMOs intended for deliberate release into the environment that are identified in a decision of the parties to the Protocol as being unlikely to have adverse effects.

## 1.3 **Exports of GMOs to third countries (Chapter II)**

1.3.1 Before the first transboundary movement of any GMO intended for deliberate release into the environment, the exporter must provide notification to the competent national authority of the Member State of import.

1.3.2 If no reply is received within the proposed number of days after reception, the exporter must send a reminder. The exporter keeps a record of the notification and the

acknowledgement of receipt and sends a copy of these documents to the competent national authority of the Member State of export and to the Commission.

1.3.3 The Commission notifies to the Biosafety Clearing House (BCH), 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 direct use as food or feed or for processing.

1.3.4 Exporters ensure that the operator receiving the product is informed that it contains or consists of GMOs and is given the relevant unique code(s) assigned to those GMOs or a declaration from the operator that the product will only be used as food or feed, or for processing, together with the unique codes for the GMOs that the product may contain.

1.3.5 All the relevant information must be forwarded to the BCH so that it can be properly coordinated and harmonised.

#### 1.4 **Unintentional transboundary movement**

1.4.1 When an incident occurs resulting in unintentional transboundary movement of GMOs, the Member State takes the necessary steps to inform the public and notify without delay the Commission, other Member States, affected or potentially affected states, the BCH, and, where appropriate, relevant international organisations and to consult the affected or potentially affected State. This information must include the information specified in Annex III of the proposal.

#### 1.5 **Common provisions**

1.5.1 The proposal sets out the information that Member States must notify to the Commission and that the Commission must notify to the BCH.

1.5.2 The Commission must designate one focal point and each member state designates its own and the competent national authority.

1.5.3 Each Member State establishes an appropriate system of penalties.

#### 2. **General comments**

2.1 The Committee recognises the importance of implementing the Cartagena Protocol on Biosafety in order to effectively ensure conservation and sustainable use of biological diversity, as well as to avoid risks to human health.

2.2 The EESC welcomes the Commission proposal because it represents a further step towards clarifying the legislation governing GMOs and gives considerable weight to the precautionary principle.

2.3 The EESC believes that the coordinating role given to the BCH will definitely have positive effects.

2.4 The Commission's proposal will not have an economic impact on imports, which will still be subject to Community rules. It will have a slight effect on exports, but will improve legal security.

### 3. Specific comments

3.1 Article 23.2 of the Cartagena Protocol stipulates that the parties to the agreement shall endeavour to inform their public about the means of public access to the Biosafety Clearing-House (BCH). The EESC notes that the Commission's draft proposal makes no mention of this.

3.2 Article 13 of the proposed Regulation ("Penalties") stipulates that the Member States shall lay down the rules on penalties applicable to infringements and shall take all measures necessary to ensure that they are implemented. The EESC understands that Member States have sole responsibility for the system of penalties, but nevertheless suggests that the necessary steps be taken to harmonise both the definition of infringements and the level of penalties in the different countries.

3.3 The EESC is concerned about the problem that might arise if there is no response to notifications sent by the exporter, which could effectively freeze exports and so have negative economic effects. However, it considers that the long deadlines allowed (60 days for acknowledging receipt of the first notification, 270 days for responding to the notification, plus 60 days for responding to a second notification sent if there has not been a reply within the above-mentioned deadline of 270 days) could have a negative effect on trade. Could the deadlines be shortened?

3.4 The EESC welcomes the Commission's strict application of the precautionary principle – in accordance with Article 1 of the Cartagena Protocol – which was already referred to in Principle 15 of the Rio Declaration on Environment and Development, in such a controversial sphere as the deliberate or unintentional release of GMOs.

Brussels, 17 July 2002.

The President  
of the  
Economic and Social Committee

The Secretary-General  
of the  
Economic and Social Committee

**Göke Frerichs**

**Patrick Venturini**