

Transboundary movement of genetically modified organisms (GMOs). Cartagena Protocol on Biosafety

2002/0046(COD) - 16/10/2002 - Modified legislative proposal

The European Commission can accept 15 amendments fully, 12 in principle and 2 partly out of the 48 amendments adopted by the European Parliament. The Commission cannot accept 19 amendments. As regards the amendments accepted by the Commission, these refer to those which : - recognise 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; - improve the editorial quality of the Proposal and are in line with the Cartagena Protocol. It proposes to 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; - clarify the objective of the information procedure for GMOs intended for direct use as food, feed, or for processing; - improve 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; - ensures a better transposition of article 11(4) of the Biosafety Protocol; - 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 GMOs; - 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. With regard to the amendments accepted in part or in principle by the Commission, these refer to those which : - improve 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: "Pharmaceuticals for humans that are addressed by other relevant international agreements or organisations are excluded from the scope of this Regulation"; - update the Proposal, in line with the adoption of Regulation 178/2002/EC laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety; - delete the definition of "notifier" in Article 3(11) of the Proposal; - aim at simplifying the definition of "exporter"; - aim at providing a definition of "transboundary movements; - intend to develop the information obligation of exporters towards Member States and the European Commission regarding transboundary movements of GMOs; - reflect the provisions of Article 21 of the Biosafety Protocol that deals with confidential information; - aligning the proposal with the identification requirements of the Protocol, as well as with those of the Commission Proposal on Labelling and Traceability of GMOs; - clarify the procedure to be followed in cases of non-decision by a Party of Import on a notification of a GMO; - aim at clarifying the notification procedure for GMOs intended for deliberate release into the environment. As regards the amendments not accepted by the Commission, these concern : - deleting the reference to an amended proposal on Labelling and Traceability which is still mentioned an amendment of Directive 2001/18/EC; - raising the important issue of capacity building in developing countries, but do not provide for operational mechanisms; - raising the issue of environmental liability; - recognises the need for exporters to respect the importing country's regulatory framework for GMOs; - imposing 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; - setting 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; - enlarging the scope of the Proposal to food and feed produced with the aid of GMOs; - the transit of GMOs which 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; - detailing the

obligation to transmit accompanying documentation throughout all the different steps of the transboundary movement of a GMO (notably transit and storage); - putting an obligation on Member States to take appropriate measures to prevent unintentional transboundary movements of living modified organisms; - putting 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 coordination and harmonisation of sanctions is to be encouraged, this goes legally beyond what can be inserted into a Community Regulation.