OPINION OF THE COMMISSION

pursuant to Article 251 (2) (c) of the EC Treaty,
on the European Parliament's amendments
to the Council's common position regarding the
proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT
AND OF THE COUNCIL

on the deliberate release into the environment of genetically modified organisms and

AMENDING THE PROPOSAL OF THE COMMISSION
pursuant to Article 250 (2) of the EC Treaty
EXPLANATORY MEMORANDUM

Article 251, paragraph 2, letter c) of the Treaty establishing the European Community establishes that the Commission gives an opinion on the amendments proposed by the European Parliament in the second reading.

The Commission hereafter gives its opinion on the twenty-nine amendments proposed by the European Parliament.

1. Background


Opinion of the Economic and Social Committee 9 September 1998

Opinion of the European Parliament – first reading 11 February 1999


Adoption of the Common Position 9 December 1999


The Common Position maintains in principle the basic structure of the Commission Proposal. The Commission supports the Common Position and is satisfied it will provide for an efficient, effective as well as transparent regulatory framework for genetically modified organisms.

2. Objective of the Commission Proposal


The Directive clarifies a number of operational aspects, in particular the scope, the definitions and the administrative procedures of the current Directive 90/220/EEC. It also promotes a harmonisation of the risk assessment and introduces clear labelling requirements for all GMOs which are placed on the market in accordance with this Directive. In addition it improves transparency of the decision-making and the involvement of the public in the authorisation process.

The key objectives therefore are to:

– clarify the scope and the definitions and to define common principles for the risk assessment conducted on a case by case basis

– improve the administrative procedures and the approval system by introducing stricter administrative delays
– introduce mandatory post-marketing monitoring and a mandatory time limitation of maximum ten years for first-time consent
– increase the transparency of the decision-making process and provide for consultation of the public
– broaden the labelling requirements

3. Commission opinion on the amendments adopted by the Parliament

Twenty-nine amendments have been adopted by the Parliament. The Commission can accept fully four amendments (9, 17, 19 and 47) and nine in principle (1, 3, 4, 8, 24, 35, 36, 38 and 48). The remaining amendments (5, 6, 10, 16, 20, 21, 22, 23, 25, 26, 27, 28, 31, 32, 34, and 39) are not acceptable.

The Commission position with regard to the amendments adopted by the European Parliament is as follows.

3.1. Amendments accepted by the Commission

Amendment 9 which reintroduces the definition of the term ‘use’ in the text as defined by the existing Directive is acceptable to the Commission. Although the legal text is self-explanatory regarding this term, the Commission accepts to introduce this definition into the Common Position, since it stresses the legal difference between ‘user’ and ‘notifier’ as referred to in the Directive.

Amendment 17 adds an obligation for the competent authorities of Member States to state the reasons when demanding further information from the notifier under Part B of the Directive. This requirement is already included in Article 13(4) for the assessment of Part C notifications and it is appropriate to include it also for Part B notifications. This amendment is therefore acceptable to the Commission.

The Commission also accepts Amendment 19 which clarifies that Member States are to inform the public when information becomes available which could have significant consequences as regards risks for human health and the environment. This amendment strengthens transparency and ensures that the public is informed about relevant additional information as regards risks to human health and the environment after consent has been granted to a Part B release.

Amendment 47 states in the recital regarding sanctions that these should include penalties for the negligent release of GMOs. This is a useful clarification and is therefore acceptable to the Commission.

3.2. Amendments accepted in principle by the Commission

Amendment 1 is acceptable to the extent that it refers to the need to submit the appropriate Proposals for the implementation of the recently agreed Protocol on Biosafety in the context of ratification. However, the Commission cannot accept to include provisions in the text of the Directive on export obligations in the present revision and therefore rejects the first part of the amendment. Prior to implementation of the Cartagena Protocol on Biosafety, the implications of the Protocol on the overall Community legislative framework have to be fully assessed in order to avoid inconsistent piecemeal legislation.
The Commission accepts Amendment 3 in substance. However, in order to make it consistent with the text of the Directive, in particular with Annexes II and VII, the Commission proposes to split and reword the text as follows. At the end of recital 19, the following new paragraph should be added: “it should also take due account of potential cumulative long-term effects associated with the interaction between different GMOs in the environment.”. Recital 20 should be supplemented by the following: “; potential cumulative long-term effects should be considered as a compulsory part of the monitoring plan.”.

Amendment 4 introduces a new recital which stresses the need for independent, systematic research on potential risks associated with the release of GMOs and that researchers should be given access to all relevant material. Research concerning potential risks associated with genetic engineering is a significant part of the Fifth Framework Programme of Research and Technological Development. The Commission therefore accepts this amendment provided that it is clarified that intellectual property rights are respected.

The Commission can agree to a recital concerning studies of the likely socio-economic implications associated with the release or placing on the market of GMOs which refers to the regular three-year report of the Commission as laid down in Article 30(5). Amendment 8 is therefore acceptable in principle and the following wording is suggested: “The three-year reports of the Commission should include a study of the likely socio-economic implications of the deliberate release or the placing on the market of GMOs, which will take due account of the interests of farmers and consumers.”.

Amendment 24 which requires that any comments received from the public on a proposal for establishing criteria and information requirements for specified GMOs under Part C of the Directive be forwarded to the Regulatory Committee is acceptable to the Commission. It should however be clarified that an analysis should be done only where it is deemed to be appropriate.

The Commission can accept Amendment 35. It adds a requirement in Annex IV concerning additional information for Part C notification dossiers to include a statement on the wording of the proposed labelling. However, the text has to be aligned with the corresponding Article 12(2)(f).

Amendment 36 introduces a new recital which refers to the need for Community wide environmental liability rules and that the Commission is to submit a proposal which includes the impact of biotechnology on all areas of the European Union before the end of 2001. The Commission can accept this amendment in principle, but indicates that it has to be reworded in order to align it to the objective of the Directive. The last part of the text of the recital must apply to “the impact of GMOs on the environment”. The amendment should also refer to the discussions in the institutions on the Commission White Paper on environmental liability.

Amendment 38 requires that Member States and the Commission ensure that the implications of gene transfer are accurately assessed on a case by case basis. This provision constitutes a balanced approach between a total prevention of gene transfer and a permissive approach and is therefore acceptable in principle. However, the wording has to be aligned with the legal text of the Directive. In addition, the reference to the Commission should be deleted, since the Commission does not regularly play a role when risk assessments are conducted under Member States competence. This is in particular the case when granting consents for Part B releases.
Amendment 48 introduces in Article 4(2) the year 2005 as the deadline for the phasing out of antibiotic resistance marker genes. The Commission is of the opinion that antibiotic resistance marker genes need to be phased out and be replaced with alternatives as soon as practically possible. A phasing out is foreseen in the Common Position and the Commission can agree to strengthen this political message. A fixed deadline for the phasing out of the use of these markers seems, however, not to be advisable. In that context the Commission would also prefer a differentiation between research activities and the placing on the market of GMOs. Within these limits Amendment 48 is therefore acceptable in principle.

3.3. Amendments not accepted by the Commission

Amendment 5 is not acceptable as a matter of principle. The text of the proposed recital is not consistent with the corresponding provision in the legal text and would therefore introduce legal uncertainty.

Amendment 6 concerning the creation of a centralised procedure at Community level for the release of GMOs is not acceptable. The second part of the recital is already appropriately covered by recital 60 and the corresponding Art 30(6)(b), which states that in 2003 the Commission shall report on the feasibility of various options to improve further the consistency and efficiency of this framework, including a centralised Community authorisation procedure. The first part of the proposed recital is a political statement which prejudges the outcome of that report.

For pharmaceuticals, the Common Position maintains the current state of play under the existing Directive regarding the verticalisation into product legislation. In certain circumstances these products may have environmental implications and it is therefore appropriate that at least the general obligations of the Directive apply to these products. Therefore, the Commission cannot accept Amendment 10 which seeks to exclude pharmaceuticals for human use from the scope of the Directive at all. Amendment 20 is also not acceptable. The Commission is of the opinion that the text of Article 11(2) of the Common Position represents the appropriate flexible requirements for the verticalisation of Part C of the Directive as far as pharmaceuticals are concerned.

The Commission cannot accept Amendment 16. It is necessary that public consultation under Part B of the Directive can be properly prepared and carried out. Therefore, the prolongation of the 90-day assessment period by a maximum of 30 days for the carrying out of a public inquiry or consultation is appropriate and may in certain cases even be too short.

Amendment 21 is not acceptable as a matter of principle. The legal basis of future legislation has to be chosen in accordance with the content of the measure. The Commission will propose the appropriate legal basis when submitting the Proposals for Regulations ensuring equivalence of product legislation and this Directive as referred to in Article 11(3).

The Commission cannot accept Amendments 22 and 23 as they stand. The provisions foreseen in these amendments would not be workable within the authorisation system established by the Directive, both for administrative and legal reasons. However, the Commission acknowledges that these amendments aim at addressing the possible problems that certain industries, in particular the plant breeding industry, might face with the strict time limited consents. The Commission will therefore consider how due account can be taken of these concerns, while ensuring political, legal and administrative consistency.
Amendment 25 seeks to introduce a provision, which allows for establishing differentiated procedures under Part C of the Directive for the placing on the market of GMOs. This builds on the original Commission Proposal as presented in the first reading in the European Parliament. However, this amendment goes beyond the original Commission Proposal and is therefore not acceptable to the Commission as it stands. The Commission is, however, willing to reconsider this amendment in the light of its original Proposal and in the framework of an overall compromise.

Amendment 26 requires that in the case of renewal the consent granted may not exceed 10 years and may be limited as appropriate for other reasons. This amendment is not acceptable to the Commission, since it would limit the flexibility of the optional time limitation of consents for the renewal as foreseen in the Common Position.

The deletion of the provisions that the periods of time that the Council takes to act shall not be taken into account in the deadline for adopting a decision by comitology procedure is not acceptable (Amendments 27 and 31). This puts into question the administrative feasibility of the procedure because it would mean that this period, which is set at three months by Article 29(2) of the Directive, is included in the 120-day period within which the Commission shall adopt and publish a decision in accordance with the comitology procedure.

Amendment 28 which seeks to introduce obligations for the exporter to apply for an export authorisation and for the Commission to submit a legislative Proposal for the implementation of the Cartagena Protocol on Biosafety within six months of signature is not acceptable. The Commission cannot agree to any piecemeal legislation for the implementation of the Cartagena Protocol on Biosafety. On 30 March, the Commission adopted a Draft Council Decision for the signature of the Protocol as soon as possible in order to give a political signal stressing the importance of the Protocol as a multilateral environmental agreement. Prior to ratification, it will be necessary to ascertain the implications on all relevant existing EU legislation.

The Commission agrees that access to the work of the European Group on Ethics and their opinions are an important part of the general evaluation. However, the remit of the European Group on Ethics is much wider than genetic engineering and it works already on the basis of specific rules of procedure, which ensure openness and transparency. These rules of procedure include the possibility for holding public hearings and round table discussions, to which representatives of the institutions are invited. These rules as well as the composition, opinions and reports of the Committee are publicly available on its website. It is inappropriate to establish rules concerning transparency of the European Group on Ethics within this specific Directive and Amendment 32 is therefore not acceptable.

The proposed provision of Amendment 34 is in substance already covered in a more general way by Annex II. In addition, it would be counterproductive to provide a specific list of aspects to be taken into account in case of the assessment of cumulative aspects which is different from the general requirements in the text of the Directive. An extensive list like the proposed one is not flexible enough and might turn out to be too limited in relation to certain cases. This amendment is therefore not acceptable.
Amendment 39 requires that in order to facilitate monitoring, the location of where GMOs are grown shall be recorded in public registers. This provision does not improve the quality and clarity of the text. Article 30(2), in connection with Annex IV(A)(7), already lays down in detail the requirements for the establishing of publicly accessible registers for the purpose of recording the information on genetic modifications in GMOs in order to facilitate post-marketing control and inspection. Further aspects should be considered in the framework of the discussions concerning the implementation of a traceability system.