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FINAL  
**A5-0083/2000**

23 March 2000

**\*\*\*II**

## **RECOMMENDATION FOR SECOND READING**

on the Council common position for adopting a European Parliament and Council directive on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (11216/1/1999 – C5-0012/2000 – 1998/0072(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: David Bowe

<i><b>Symbols for procedures</b></i>	<i><b>Abbreviations for committees</b></i>
<p>* Consultation procedure <i>majority of the votes cast</i></p> <p>**I Cooperation procedure (first reading) <i>majority of the votes cast</i></p> <p>**II Cooperation procedure (second reading) <i>majority of the votes cast, to approve the common position</i> <i>majority of Parliament's component Members, to reject or amend the common position</i></p> <p>*** Assent procedure <i>majority of Parliament's component Members except in cases covered by Articles 105, 107, 161 and 300 of the EC Treaty and Article 7 of the EU Treaty</i></p> <p>***I Codecision procedure (first reading) <i>majority of the votes cast</i></p> <p>***II Codecision procedure (second reading) <i>majority of the votes cast, to approve the common position</i> <i>majority of Parliament's component Members, to reject or amend the common position</i></p> <p>***III Codecision procedure (third reading) <i>majority of the votes cast, to approve the joint text</i></p> <p>(The type of procedure depends on the legal basis proposed by the Commission)</p>	<p>I. AFET Committee on Foreign Affairs, Human Rights, Common Security and Defence Policy</p> <p>II. BUDG Committee on Budgets</p> <p>III. CONT Committee on Budgetary Control</p> <p>IV. LIBE Committee on Citizens' Freedoms and Rights, Justice and Home Affairs</p> <p>V. ECON Committee on Economic and Monetary Affairs</p> <p>VI. JURI Committee on Legal Affairs and the Internal Market</p> <p>VII. INDU Committee on Industry, External Trade, Research and Energy</p> <p>VIII. EMPL Committee on Employment and Social Affairs</p> <p>IX. ENVI Committee on the Environment, Public Health and Consumer Policy</p> <p>X. AGRI Committee on Agriculture and Rural Development</p> <p>XI. PECH Committee on Fisheries</p> <p>XII. REGI Committee on Regional Policy, Transport and Tourism</p> <p>XIII. CULT Committee on Culture, Youth, Education, the Media and Sport</p> <p>XIV. DEVE Committee on Development and Cooperation</p> <p>XV. AFCO Committee on Constitutional Affairs</p> <p>XVI. FEMM Committee on Women's Rights and Equal Opportunities</p> <p>XVII. PETI Committee on Petitions</p>

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## PROCEDURAL PAGE

At the sitting of 11 February 1999 Parliament adopted its position at first reading on the proposal for a European Parliament and Council directive on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (COM(1999) 85 - 1998/0072(COD)).

At the sitting of 20 January 2000 the President of Parliament announced that the common position had been received and referred to the Committee on the Environment, Public Health and Consumer Policy (11216/1/1999 - C5-0012/2000).

The committee had appointed David Rowe rapporteur at its meeting of 6 January 1998.

It considered the common position and the draft recommendation for second reading at its meetings of 22 February and 21 March 2000.

At the latter meeting it adopted the draft legislative resolution by 27 votes to 9, with 4 abstentions.

The following were present for the vote: Caroline Jackson, chairman; Carlos Lage, Alexander de Roo and Ria G.H.C. Oomen-Ruijten, vice-chairmen; David Robert Rowe, rapporteur; Per-Arne Arvidsson, Maria del Pilar Ayuso González, Jean-Louis Bernié, Hans Blokland, Hiltrud Breyer, Philip Rodway Bushill-Matthews, Niels Busk, Chris Davies, Avril Doyle, Carlo Fatuzzo, Christel Fiebig, Marialiese Flemming, Karl-Heinz Florenz, Robert Goodwill, Françoise D. Grossetête, Catherine Guy-Quint, Heidi Anneli Hautala, Roger Helmer, Mary Hilda Rosamund Honeyball (for Marie-Noëlle Lienemann), Marie Anne Isler Béguin, Christa Kläß, Hans Kronberger, Bernd Lange, Rolf Linkohr, Torben Lund, Jules Maaten, Patricia McKenna, Jorge Moreira Da Silva, Riitta Myller, Giuseppe Nisticò, Karl Erik Olsson, Marit Paulsen, Encarnación Redondo Jiménez, Guido Sacconi, Renate Sommer, Catherine Taylor, Nicole Thomas-Mauro, Antonios Trakatellis, Phillip Whitehead.

The recommendation for second reading was tabled on 23 March 2000.

The deadline for tabling amendments will be indicated in the draft agenda for the relevant part-session.

## DRAFT LEGISLATIVE RESOLUTION

**European Parliament legislative resolution on the Council common position for adopting a European Parliament and Council directive on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (11216/1/1999 – C5-0012/2000 – 1998/0072(COD))**

**(Codecision procedure: second reading)**

*The European Parliament,*

- having regard to the Council common position (11216/1/1999 – C5-0012/2000),
  - having regard to its position at first reading<sup>1</sup> on the Commission proposal to Parliament and the Council (COM(1998) 85<sup>2</sup>),
  - having regard to the Commission's amended proposal (COM(1999) 139<sup>3</sup>),
  - having regard to Article 251(2) of the EC Treaty,
  - having regard to Rule 80 of its Rules of Procedure,
  - having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Consumer Policy (A5-0083/2000),
1. Amends the common position as follows;
  2. Instructs its President to forward its position to the Council and Commission.

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<sup>1</sup> OJ C 150, 28.5.1999, p. 380.

<sup>2</sup> OJ C 139, 4.5.1998, p. 1.

<sup>3</sup> OJ C 139, 19.5.1999, p. 7.

(Amendment 1)  
Recital 13

(13) The content of this Directive duly takes into account international experience in this field and international trade commitments;

(13) The content of this Directive duly takes into account international experience in this field and international trade commitments and should respect the requirements of the Cartagena Biosafety Protocol concluded in Montreal in January 2000; where necessary the Commission should, in the context of the ratification of the Protocol, submit proposals for the amendment and clarification of this Directive;

*Justification:*

*This is a significant new development since the first reading. The Directive should comply with the Cartagena Protocol.*

(Amendment 2)  
Recital 16

(16) The provisions of this Directive should be without prejudice to national legislation in the field of liability;

(16) There may be a wide range of causes of damage to the environment, not only GMOs; whereas EU-wide environment liability rules should therefore be introduced to provide wide-ranging regulation of possible cases of damage; the Commission is to submit an appropriate proposal for a directive following the discussion on the white paper on environmental liability;

*Justification:*

*Amendment adopted in first reading but not accepted by Council. In the meantime, the Commission has presented its white paper on responsibility; EP has on numerous occasions called for legislation in this area.*

(Amendment 3)  
Recital 19a (new)

19a. Risk assessments should be made of the accumulated long-term effects associated with granting consent and releasing any new genetically modified organism. The accumulated long-term effects should also form a compulsory part of the monitoring process.

*Justification*

*There is a need to include a reference to the accumulated long-term effects of releasing genetically modified organisms as it is precisely from this point of view that an assessment of the risks is relevant. There is a need not just to carry out risk assessment of the individual notification and product but to consider the aggregate effects of all consents in relation to each individual new consent.*

(Amendment 4)  
Recital 20a (new)

20a. It is necessary to carry out independent, systematic research into the risks involved. The necessary resources should be secured for such research and the independent researchers should be given access to all relevant material.

*Justification*

*Independent systematic research into the risks is crucial for future confidence in the safety of GM crops and GM products.*

(Amendment 5)  
Recital 26

26. Concerning the environmental risk assessment for Part C, risk management, labelling, monitoring, information to the public and safeguard clause, this Directive should be a point of reference for GMOs as or in products authorised by other Community legislation which should therefore provide for a specific environmental risk assessment, to be carried out in accordance with the principles set out in Annex II and on the basis of information specified in Annex III without prejudice to additional requirements laid down by the Community legislation mentioned above,

26. Concerning the environmental risk assessment for Part C, risk management, labelling, monitoring, information to the public and safeguard clause, this Directive should be a point of reference for GMOs as or in products authorised by other Community legislation which should therefore provide for a specific environmental risk assessment, to be carried out in accordance with the principles set out in Annex II and on the basis of information specified in Annex III without prejudice to additional requirements laid down by the Community legislation mentioned above,

and for requirements as regards risk management, labelling, monitoring as appropriate, information to the public and safeguard clause at least equivalent to that laid down in this Directive;

and for requirements as regards risk management, labelling, monitoring as appropriate, information to the public and safeguard clause at least equivalent to that laid down in this Directive.

Regulations to ensure that risk assessment, risk management, labelling, appropriate monitoring, information to the public and safeguard clause are equivalent to those laid down in this directive should be implemented in cooperation with the relevant authorities responsible for implementation of this directive in the Commission and the Member States;

*Justification*

*It is important that implementation in product legislation of Articles 12-23 should take place in cooperation with the authorities responsible for implementation of this directive.*

(Amendment 6)  
Recital 27a (new)

27a. The long-term aim should be to create a centralised procedure at Community level for the release of GMOs, for instance along the lines of that used for the licensing of medicinal products; the Commission should conduct a study of the possibility of centralised monitoring of the release of genetically modified organisms, for instance by the European Environment Agency in Copenhagen or the proposed European Food Authority;

*Justification:*

*The amendment was adopted at first reading. In the meantime, in its White Paper on Food Safety the Commission has proposed a European Food Authority which could take over this task.*

(Amendment 7)  
Recital 59

(59) In order to increase the effective

(59) In order to increase the effective

implementation of the provisions adopted under this Directive it is appropriate to provide for penalties to be applied by Member States;

implementation of the provisions adopted under this Directive it is appropriate to provide for penalties to be applied by Member States; it is also appropriate to provide for penalties against the unintentional release of GMOs;

*Justification:*

*Amendment adopted in first reading but not accepted by Council.*

(Amendment 8)  
Recital 59a (new)

(59a) A study should be made annually of the likely socio-economic costs and benefits of the proposed deliberate release/market authorisation, which will also take due account of the interests of farmers and consumers.

*Justification:*

*Amendment adopted in first reading but not accepted by Council. When carrying out a preliminary investigation of the possible consequences of giving consent, the interests of farmers and end consumers must be taken into consideration as well as the interests of biotechnology patent-holders*

(Amendment 9)  
Article 2 (6a)(new)

(6a) "use" means the deliberate release of a product which has been placed on the market. The persons carrying out this use will be referred to as 'users';

*Justification:*

*Amendment adopted in first reading but not accepted by Council.*

(Amendment 10)  
Article 3(1a)(new)

1a. Nor shall it apply to pharmaceutical products for human use consisting of or containing a GMO or a combination of GMOs, provided that the Community

legislation governing them provides for an environmental risk assessment equivalent to that set out in Annexes II and III of this Directive.

*Justification:*

*Amendment adopted in first reading but not accepted by Council.*

(Amendment 11)  
Article 4(2)

2. Any person, before submitting a notification under Part B or Part C, shall carry out an environmental risk assessment. The information which may be necessary to carry out the environmental risk assessment is laid down in Annex III. Member States and the Commission shall ensure that GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment are taken into particular consideration when carrying out an environmental risk assessment, with a view to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment.

2. Any person, before submitting a notification under Part B or Part C, shall carry out an environmental risk assessment. The information which may be necessary to carry out the environmental risk assessment is laid down in Annex III. Member States and the Commission shall ensure that GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment are not released into the environment.

*Justification:*

*Amendment adopted in first reading but not accepted by Council.*

(Amendment 12)  
Article 4(2), last paragraph (new)

When consenting to a deliberate release, Member States and the Commission shall ensure that measures are taken to prevent gene-transfer from GMOs to other organisms in the environment.

*Justification:*

*Amendment adopted in first reading but not accepted by Council.*

(Amendment 13)  
Article 4(4a)(new)

(4a) Member States and the Commission shall ensure that no GMO and/or products thereof leave the territory of the European Union without the prior informed consent of the importing party/country.

*Justification:*

*Amendment adopted in first reading but not accepted by Council.*

(Amendment 14)  
Article 4(4b)(new)

(4b) Member States and the Commission shall ensure that, when GMOs or products made from GMOs are exported to non-Member States, the importing states are informed of the authorisation procedure in the European Union - if appropriate through exchange of data held by the Commission, having regard to Article 24 - to enable them to make an independent decision.

*Justification:*

*Amendment adopted in first reading but not accepted by Council.*

(Amendment 15)  
Article 4(5)

5. Member States shall take measures to ensure, in line with the requirements laid down in Annex IV, traceability, at all stages of the placing on the market of GMOs authorised under Part C.

5. Member States shall take measures to ensure, in line with the requirements laid down in Annexes III and IV, traceability, at all stages of the deliberate release or placing on the market of GMOs authorised under Parts B and C.

*Justification:*

*This Common Position text was not included in the original proposal considered at first reading- the traceability requirement should apply to all releases.*

(Amendment 16)  
Article 5(6)

6. For the purpose of calculating the 90-day period referred to in paragraph 5, no account shall be taken of any periods of time during which the competent authority:

(a) is awaiting further information which it may have requested from the notifier, or

(b) is carrying out a public inquiry or consultation in accordance with Article 8; this public inquiry or consultation shall not prolong the 90-day period referred to in paragraph 5 by more than 30 days.

6. For the purpose of calculating the 90-day period referred to in paragraph 5, no account shall be taken of any periods of time during which the competent authority is awaiting further information which it may have requested from the notifier.

A public inquiry or consultation in accordance with Article 8 shall not prolong the 90-day period referred to in paragraph 5.

*Justification:*

*To ensure the efficiency of the decision-making process.*

(Amendment 17)  
Article 5(6)(b)a (new)

ba) If the competent authority requests new information it must give its reasons for so doing.

*Justification:*

*This requirement is to prevent arbitrary action on the part of authorities.*

(Amendment 18)  
Article 6(5)second subparagraph

The decision taken under paragraphs 3 and 4 may provide that releases of a GMO or of a combination of GMOs on the same site or on different sites for the same purpose and within a defined period may be notified in a single notification.

The decision taken under paragraphs 3 and 4 may provide that releases of a GMO or of a combination of GMOs on the same site or on different sites for the same purpose and within a defined period may be notified in a single notification. This provision shall not be used to permit authorisation for releases in more than one Member State.

*Justification:*

*Parliament in its first reading deleted the multi-state approval procedure but without this*

*proviso it could be re-introduced on the initiative of the Commission under this Article.*

(Amendment 19)

Article 7(2)

2. If information becomes available to the competent authority referred to in paragraph 1 which could have significant consequences with regard to risks for human health and the environment or under the circumstances described in paragraph 1, the competent authority shall evaluate such information and may require the notifier to modify the conditions of, suspend or terminate the deliberate release.

2. If information becomes available to the competent authority referred to in paragraph 1 which could have significant consequences with regard to risks for human health and the environment or under the circumstances described in paragraph 1, the competent authority shall evaluate such information, inform the general public and may require the notifier to modify the conditions of, suspend or terminate the deliberate release.

*Justification:*

*The general public has a right to be informed about problems, analogous to the situation with medicinal products.*

(Amendment 20)

Article 11(2)

2. As far as Council Regulation (EEC) No 2309/93 is concerned, Articles 12 to 23 of this Directive shall not apply to any GMO as or in products as far as they are authorised by that Regulation provided that a specific environmental risk assessment is carried out in accordance with the principles set out in Annex II to this Directive and on the basis of information specified in Annex III to this Directive without prejudice to additional requirements provided for in Regulation (EEC) No 2309/93.

2. As far as Council Regulation (EEC) No 2309/93 is concerned, Articles 12 to 23 of this Directive shall not apply to any GMO as or in products as far as they are authorised by that Regulation provided that a specific environmental risk assessment is carried out in accordance with the principles set out in Annex II to this Directive and on the basis of information specified in Annex III to this Directive and subject to requirements as regards risk management, labelling, monitoring as appropriate, information to the public and safeguard clause at least equivalent to that laid down in this Directive.

*Justification:*

*This Article is new. The Amendment matches the wording of Recital 26 and Article 11.1 on sectoral legislation and is consistent with Articles 6 and 28 of Regulation 2309/93 which already refer to Directive 90/220 procedures.*

(Amendment 21)  
Article 11(3)

3. Procedures ensuring that the risk assessment, requirements regarding risk management, labelling, monitoring as appropriate, information to the public and safeguard clause are equivalent to those laid down in this Directive shall be introduced, in a Regulation of the European Parliament and of the Council. Until that Regulation enters into force any GMO as or in products as far as they are authorised by other Community legislation shall only be placed on the market after having been accepted for placing on the market in accordance with this Directive.

3. Procedures ensuring that the risk assessment, requirements regarding risk management, labelling, monitoring as appropriate, information to the public and safeguard clause are equivalent to those laid down in this Directive shall be introduced, in a Regulation of the European Parliament and of the Council pursuant to Article 95. As regards the other articles of the directive, the Regulation shall refer to this Directive. Until that Regulation enters into force any GMO as or in products as far as they are authorised by other Community legislation shall only be placed on the market after having been accepted for placing on the market in accordance with this Directive.

*Justification*

*It is important that there is full parallelism between this directive and vertical legislation – this also applies to rules on labelling, the possibility of consulting one or more scientific committees, the possibility of consulting one or more committees on ethical matters, committee procedures, exchange of information and reporting, including the socio-economic consequences of releasing and marketing GMOs, sanctions, etc. (Art. 24 and following paragraphs).*

(Amendment 22)  
Article 12(2)(d)

(d) a proposed period for the consent which should not exceed 10 years;

(d) a proposed period for the consent which should not exceed 10 years commencing after the first registration of the final product;

*Justification:*

*The Parliament in first reading recognised that in practice '12 years after the start of marketing' could mean as many as 18 years after the 'placing on the market', due to the way in which the plant breeding industry functions. The concept is now one of a maximum period (previously a fixed period) and other criteria relating to monitoring, new information, more stringent risk assessment, etc. have all been met.*

(Amendment 23)

Article 14(4)

4. The consent shall be given for a maximum period of 10 years.

4. The consent shall be given for a maximum period of 10 years, commencing after the first registration of the final product.

*Justification:*

*The Parliament in first reading recognised that in practice "12 years after the start of marketing" could mean as many as 18 years after "the placing on the market", due to the way in which the plant breeding industry functions. The concept is now one of maximum (previously a fixed period) and other criteria relating to monitoring, new information, more stringent risk assessment, etc. have all been met.*

(Amendment 24)

Article 15(3)

3. Before the procedure laid down in Article 29(2) on a decision for criteria and information requirements referred to in paragraph 1 is initiated, the Commission shall make the proposal available to the public. The public may make comments to the Commission within 60 days.

3. Before the procedure laid down in Article 29(2) on a decision for criteria and information requirements referred to in paragraph 1 is initiated, the Commission shall make the proposal available to the public. The public may make comments to the Commission within 60 days. Any such comments shall be forwarded to the Article 29 Committee together with a reasoned response.

*Justification:*

*The procedure foreseen in the Common Position differs from the original proposal. Public comments need a public response.*

(Amendment 25)

Article 15(3a)(new)

3a. If sufficient experience has been obtained from marketing certain GMO's in certain ecosystems and the GMO's concerned meet the criteria set out in Annex V, a competent authority may submit to the Commission a reasoned proposal for the application of differentiated procedures to

such types of GMO's. A decision shall be taken in accordance with the procedures laid down in Articles 6.2 to 6.4.

*Justification:*

*In the case of GMOs for which the risk is very small, according to scientists, a simplified procedure should be possible.*

(Amendment 26)  
Article 16(6)

6. In the case of paragraph 3(a) and in the absence of any reasoned objection from a Member State or the Commission within 60 days from the date of circulation of the assessment report, the competent authority which prepared the report shall transmit to the notifier the final decision in writing and shall inform the other Member States and the Commission thereof within 30 days. The validity of the consent may be limited as appropriate.

6. In the case of paragraph 3(a) and in the absence of any reasoned objection from a Member State or the Commission within 60 days from the date of circulation of the assessment report, the competent authority which prepared the report shall transmit to the notifier the final decision in writing and shall inform the other Member States and the Commission thereof within 30 days. The validity of the consent may not exceed 10 years and may be limited as appropriate for other reasons.

*Justification*

*All consents should be reviewed every ten years even if they are renewals.*

(Amendment 27)  
Article 17(1) last sentence

The period of time that the Council takes to act in accordance with the procedure laid down in Article 29(2) shall not be taken into account.

Deleted

*Justification:*

*A notifier should not be forced to wait endlessly for his authorisation because of political problems in the Council.*

(Amendment 28)  
Article 18a (new)

## Article 18a

### Export

1. In connection with the export of GMOs and/or products containing GMOs to non-Member States, the exporter or importer must obtain

- consent to the import from the country of destination and

- export authorisation from the authority of the competent Member State.

2. The country of destination must give its consent to the import before the authority of the competent Member State can issue its authorisation.

3. The Commission shall bring forward a legislative proposal for implementing in detail the Cartagena Protocol on Biosafety within six months of signature.

### *Justification:*

*Further implementing measures will be required when the Cartagena Protocol enters into force.*

## (Amendment 29)

### Article 19(3)

3. If information becomes available to the competent authority which could have consequences for the risks of the GMO(s) to the human health or the environment, or under the circumstances described in paragraph 2, it shall immediately forward the information to the Commission and the competent authorities of the other Member States and may avail itself of the provisions provided for in Articles 14(1) and 16(7) where appropriate, when the information has become available before the written consent. When the information has become available after the consent has been given, the competent authority shall, within 60 days after receipt of the new information, forward its assessment report indicating whether and

3. If information becomes available to the competent authority which could have consequences for the risks of the GMO(s) to the human health or the environment, or under the circumstances described in paragraph 2, it shall immediately forward the information to the Commission and the competent authorities of the other Member States and may avail itself of the provisions provided for in Articles 14(1) and 16(7) where appropriate, when the information has become available before the written consent. When the information has become available after the consent has been given, the competent authority shall, within 60 days after receipt of the new information, forward its assessment report indicating whether and

how the conditions of the consent should be amended or the consent should be terminated to the Commission which shall, within 30 days of its receipt, forward it to the competent authorities of the other Member States.

Comments or reasoned objections to further placing on the market of the GMO or on the proposal for amending the conditions of the consent shall be forwarded, within 60 days following the circulation of the assessment report, to the Commission which shall immediately forward them to all competent authorities.

The competent authorities and the Commission may discuss any outstanding issues with the aim of arriving at an agreement within 75 days from the date of circulation of the assessment report.

In the absence of any reasoned objection from a Member State or the Commission within 60 days following the date of circulation of the new information or if outstanding issues are resolved within 75 days, the competent authority which prepared the report shall amend the consent as proposed, shall transmit the amended consent to the notifier and shall inform the other Member States and the Commission thereof within 30 days.

how the conditions of the consent should be amended or the consent should be terminated to the Commission which shall, within 30 days of its receipt, forward it to the competent authorities of the other Member States.

Comments or reasoned objections to further placing on the market of the GMO or on the proposal for amending the conditions of the consent shall be forwarded, within 90 days following the circulation of the assessment report, to the Commission which shall immediately forward them to all competent authorities.

The competent authorities and the Commission may discuss any outstanding issues with the aim of arriving at an agreement within 105 days from the date of circulation of the assessment report.

In the absence of any reasoned objection from a Member State or the Commission within 90 days following the date of circulation of the new information or if outstanding issues are resolved within 105 days, the competent authority which prepared the report shall amend the consent as proposed, shall transmit the amended consent to the notifier and shall inform the other Member States and the Commission thereof within 30 days.

*Justification:*

*Lengthening the time allowed for the presentation of comments and reasoned objections gives due weight to the possible difficulty and gravity of the decisions involved and the need for a reasonable period for investigation, consultation and reflection.*

(Amendment 30)  
Article 19(3a)(new)

3a. To facilitate monitoring, the location of GMOs placed on the market shall be recorded in public registers.

*Justification:*

*The Common Position text and the associated Annex VII have changed from that considered*

*at first reading. For monitoring to be effective, the commercial release sites have to be recorded.*

(Amendment 31)  
Article 22(2) last sentence

Likewise, the period of time the Council takes to act in accordance with the procedure laid down in Article 29(2) shall not be taken into account.

Delete

*Justification:*

*A notifier should not be forced to wait endlessly for his authorisation because of political problems in the Council.*

(Amendment 32)  
Article 28(1)

1. Without prejudice to the competence of Member States as regards ethical issues, the Commission, on its own initiative or at the request of the European Parliament or the Council, shall consult any committee it has created with a view to obtaining its advice on the ethical implications of biotechnology, such as the European Group on Ethics in Science and New Technologies, on ethical issues of a general nature.

This consultation may also take place at the request of a Member State.

1. Without prejudice to the competence of Member States as regards ethical issues, the Commission, on its own initiative or at the request of the European Parliament or the Council, shall consult any committee it has created with a view to obtaining its advice on the ethical implications of biotechnology, such as the European Group on Ethics in Science and New Technologies, on ethical issues of a general nature.

This consultation may also take place at the request of a Member State.

The Commission shall take the necessary measures to ensure that these consultation processes are conducted under clear rules of openness and transparency with full public accessibility.

*Justification:*

*Amendment adopted in first reading but not accepted by Council.*

(Amendment 33)

Article 31a (new)

Article 31a

Liability

Those legally responsible for deliberate releases of genetically modified organisms shall have strict civil liability for any damage to human health and the environment caused by the releases in question. Before the activities begin, they shall take out sufficient liability insurance to cover such losses as might be occasioned thereby.

*Justification:*

*Amendment adopted in first reading but not accepted by Council.*

(Amendment 34)

Annex II, introduction (new indent)

- A general principle for environmental risk assessment shall also be an assessment/analysis of the “accumulated long-term effects”. “Accumulated long-term effects” refers to the accumulated effects of all consents on natural flora, other crops, soil fertility, soil degradation of organic material, the food chain, biological diversity, human health, and resistance problems in relation to antibiotics.

*Justification*

*It is absolutely crucial to have an assessment of the long-term accumulated effects as a principle of environmental risk assessment. Risk assessment should not merely be based on an assessment of the individual consent and the individual product, but on the aggregate effects of all consents in relation to each individual new consent.*

(Amendment 35)

Annex IV, A(8)

8. proposed labelling on a label or in an accompanying document. This must

8. proposed labelling on a label or in an accompanying document. This must

include, at least in summarised form, a commercial name of the product, the name of the GMO and the information referred to in point 2, the labelling should indicate how to access the information in the publicly accessible part of the register.

include, at least in summarised form, a commercial name of the product, a statement that “this product contains or consists of GMOs”, the name of the GMO and the information referred to in point 2, the labelling should indicate how to access the information in the publicly accessible part of the register.

*Justification:*

*Amendment adopted in first reading but not accepted by the Council.*