EUROPEAN PARLIAMENT

1999 *2004*

Session document

FINAL
A5-0229/2002

12 June 2002

***I
REPORT

on the proposal for a European Parliament and Council regulation concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC
(COM(2001) 182 – C5-0380/2001 – 2001/0180(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Antonios Trakatellis

Symbols for procedures

*	Consultation procedure *majority of the votes cast*
**I	Cooperation procedure (first reading) *majority of the votes cast*
**II	Cooperation procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***	Assent procedure *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	Codecision procedure (first reading) *majority of the votes cast*
***II	Codecision procedure (second reading) *majority of the votes cast, to approve the common position* *majority of Parliament's component Members, to reject or amend the common position*
***III	Codecision procedure (third reading) *majority of the votes cast, to approve the joint text*

(The type of procedure depends on the legal basis proposed by the Commission)

Amendments to a legislative text

In amendments by Parliament, amended text is highlighted in ***bold italics***. Highlighting in *normal italics* is an indication for the relevant departments showing parts of the legislative text for which a correction is proposed, to assist preparation of the final text (for instance, obvious errors or omissions in a given language version). These suggested corrections are subject to the agreement of the departments concerned.

CONTENTS

Page

PROCEDURAL PAGE

By letter of 20 August 2001 the Commission submitted to Parliament, pursuant to Article 251(2) and Article 95 of the EC Treaty, the proposal for a European Parliament and Council regulation concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (COM(2001) 182 - 2001/0180 (COD)).

At the sitting of 3 September 2001 the President of Parliament announced that she had referred this proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and the Committee on Industry, External Trade, Research and Energy and the Committee on Committee on Agriculture and Rural Development for their opinions (C5-0380/2001).

The Committee on the Environment, Public Health and Consumer Policy appointed Antonios Trakatellis rapporteur at its meeting of 13 September 2001.

The committee considered the Commission proposal and draft report at its meetings of 19 February, 16 April, 22 May and 4 June 2002.

At the last meeting it adopted the draft legislative resolution by 30 votes to 24, with abstentions.

The following were present for the vote: Caroline F. Jackson, chairman;Alexander de Roo and Anneli Hulthén, vice-chairmen; Antonios Trakatellis, rapporteur; Per-Arne Arvidsson, María del Pilar Ayuso González, David Robert Bowe, John Bowis, Philip Bushill-Matthews (for Raffaele Costa), Martin Callanan, Dorette Corbey, Chris Davies, Véronique De Keyser (for María Sornosa Martínez), Jillian Evans (for Hiltrud Breyer), Anne Ferreira, Marialiese Flemming, Karl-Heinz Florenz, Christos Folias (for Caroline F. Jackson, pursuant to Rule 153(2)), Cristina García-Orcoyen Tormo, Robert Goodwill, Cristina Gutiérrez Cortines, Jutta D. Haug (for Catherine Stihler), Karin Jöns (for Elena Valenciano Martínez-Orozco), Eija-Riitta Anneli Korhola, Hans Kronberger, Bernd Lange, Paul A.A.J.G. Lannoye (for Marie Anne Isler Béguin), Torben Lund, Jules Maaten, Minerva Melpomeni Malliori, Helmuth Markov (for Pernille Frahm, pursuant to Rule 153(2)), Jorge Moreira da Silva, Rosemarie Müller, Riitta Myller, Giuseppe Nisticò, Ria G.H.C. Oomen-Ruijten, Neil Parish (for Avril Doyle), Béatrice Patrie, Marit Paulsen, Encarnación Redondo Jiménez (for Françoise Grossetête), Frédérique Ries, Didier Rod (for Patricia McKenna), María Rodríguez Ramos (for Phillip Whitehead), Dagmar Roth-Behrendt, Guido Sacconi, Giacomo Santini (for Christa Klaß), Karin Scheele, Ursula Schleicher (for Peter Liese), Inger Schörling, Elisabeth Schroedter (for Mihail Papayannakis, pursuant to Rule 153(2)), Jonas Sjöstedt, Renate Sommer (for Emilia Franziska Müller), Marianne L.P. Thyssen (for Horst Schnellhardt) and Kathleen Van Brempt.

The opinions of the Committee on Industry, External Trade, Research and Energy and the Committee on Agriculture and Rural Development are attached.

The report was tabled on 12 June 2002.

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 proposal for a European Parliament and Council regulation concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (COM(2001) 182 – C5-0380/2001 – 2001/0180(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and the Council (COM(2001) 182[1]),

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the Commission submitted the proposal to Parliament (C5-0380/2001),

– having regard to Rule 67 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Consumer Policy (and the opinion of the Committee on Industry, External Trade, Research and Eneergy and the Committee on Agriculture and Rural Development) (A5-0229/2002),

1. Approves the Commission proposal as amended;

2. Asks to be consulted again should the Commission intend to amend the proposal substantially or replace it with another text;

3. Instructs its President to forward its position to the Council and Commission.

Text proposed by the Commission	Amendments by Parliament
Amendment 1 Recital 1	
Directive 2001/18/EC of the European Parliament and the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Directive 90/220/EEC of the Council[2], as amended by Regulation (EC) No …/2002 [on	Directive 2001/18/EC of the European Parliament and the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Directive 90/220/EEC of the Council[3], as amended by Regulation (EC) No …/2002 [on

[1] OJ C 340, 30.10.2001, p. 327
[2] OJ L 106, 17.4.2001, p. 1.
[3] OJ L 106, 17.4.2001, p. 1.

genetically modified food and feed], requires Member States to take measures to ensure traceability and labelling of authorised genetically modified organisms (GMOs) at all stages of their placing on the market.	genetically modified food and feed], requires Member States to take measures to ensure traceability and labelling of authorised genetically modified organisms (GMOs) at all stages of their placing on the market.

Justification

(Concerns the Greek translation).

Amendment 2
Recital 2a (new)

	2a. Account must be taken of the precautionary principle in implementing this Regulation. In exceptional cases, where there is a risk to health or the environment, but where scientific data is as yet uncertain, the precautionary principle may be used to decide which risk control measures or other steps will be taken to ensure the high level of health protection that the Community desires.

Justification

Both the Commission's communication 2000/001 of 2 February 2000 concerning the precautionary principle and Regulation 2002/178 laying down the general principles and requirements of food law (Article 6, paragraph 3, Article 7, recitals 20 and 21) stress this new aspect of European food policy. The precautionary principle is also expressly enshrined in Directive 2001/0018/EC (Articles 1 and 4, Annex II). The precautionary principle should therefore also be enshrined in this proposal for a regulation.

Amendment 3
Recital 3

(3) Traceability requirements for GMOs should facilitate ***both*** the withdrawal of products where unforeseen adverse effects to human health, animal health or the environment are	**(**3) Traceability requirements for GMOs should facilitate the withdrawal of products where unforeseen adverse effects to human health, animal health or the environment are

established, and the targeting of monitoring to examine potential effects on, in particular, the environment.	established, ***or their temporary withdrawal or other restriction where there are reasonable grounds to suspect such effects and time is needed for further investigation,*** and the targeting of monitoring to examine potential effects on, in particular, the environment ***and human health and measures to ensure the viability of conventional and organic farming and their sustainable co-existence with genetically modified crops.***

Justification

On the basis of the precautionary principle, adverse effects should not need to be "established" before a product is withdrawn. Clearly, however, any product withdrawn on the basis of suspected adverse effects may be reintroduced if and when its safety is established.The proposed traceability scheme should also facilitate measures to prevent the uncontrolled spread of GMOs. In fact, the consumers' and operators' freedom of choice requires measures which ensure that animals, plants, micro-organisms as well as food and feed products which have not been genetically modified continue to be available. Consequently, Action 17 of the Commission's Communication on 'Life sciences and biotechnology – A Strategy for Europe' COM(2002) 27 calls for "measures to ensure the viability of conventional and organic farming and their sustainable co-existence with genetically modified crops".

Amendment 4
Recital 4

(4)	Traceability requirements for food and feed produced from GMOs should be established to facilitate accurate labelling of such products, in accordance with the requirements of Regulation (EC) No .../2002 [on genetically modified food and feed], so as to enable operators and consumers to exercise their freedom of choice in an effective manner as well as control and verification of labelling claims. Requirements for food and feed produced from GMOs should be similar in order to avoid	(4)	Traceability requirements for food and feed produced from GMOs ***and for animal products derived from animals fed with genetically modified feed*** should be established to facilitate accurate labelling of such products, in accordance with the requirements of Regulation (EC) No .../2002 [on genetically modified food and feed], so as to enable operators and consumers to exercise their freedom of choice in an effective manner as well as control and verification of labelling claims.

discontinuity of information in cases of change in end use.	Requirements for food and feed produced from GMOs should be similar in order to avoid discontinuity of information in cases of change in end use.

Justification

The current practise of many operators clearly indicates that consumers and operators wish to know whether animal products offered for human consumption stem from animals fed on GMOs. The regulation should therefore enable operators and consumers to exercise their freedom of choice also with regard to such products.

Amendment 5
Recital 9

(9) Certain traces of GMOs in products may be adventitious or technically unavoidable. ***Such presence of GMOs should therefore not trigger labelling and traceability requirements***.	(9) Certain traces of ***authorised GMOs or of materials produced from*** GMOs in products may be adventitious or technically unavoidable. ***To cover cases of adventitious or technically unavoidable traces of authorised GMO material, or of material produced from GMOs a threshold shall be set below which such products do not have to be labelled.*** ***These threshold values shall also be revised and adjusted in line with the results of scientific, socio-economic, health and environmental analyses of the effects of GMOs in the short, medium and long term.***

Justification

The adventitious or technically unavoidable presence of traces must only be authorised in the case of authorised GMOs. Dispensation from the labelling and traceability requirement can only be permitted in the case of authorised GMOs and below a threshold laid down by Regulation (EC) .../.../2002 [on genetically modified foodstuffs and animal feed]. Live GMOs as or in products should be labelled irrespective of whether their presence is adventitious or technically unavoidable.

Amendment 6
Article 1

This Regulation provides a framework for the traceability of genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objective of ***facilitating accurate labelling, environmental monitoring and withdrawals of products.***	This Regulation provides a framework for the traceability of genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objective of***, in accordance with the precautionary principle.***
	- ***protecting human and animal health,***
	- ***protecting the environment and ecosystems,***
	- ***ensuring the smooth operation of the internal market and monitoring such products by means of tracing and labelling. Whilst seeking to ensure the smooth operation of the internal market, it recognises the priority which must be accorded to human health and the environment, and to the right of the consumer to be given the information necessary to make a free and independent choice.***
	- ***give consumers the right of free and independent choice and,***
	- ***allowing effective measures to prevent the undeliberate presence of GMOs or products thereof in other food or feed.***
	In the event that those products prove harmful or hazardous, to enable them to be withdrawn immediately, rapidly and totally.

Justification

It is imperative that the objectives of the proposal are set out precisely and in detail to ensure

fully that we have in place:

- *implementable rules which are not susceptible to deception and fraud,*
- *rules which promote consumer protection without causing consumers confusion and doubt,*
- *rules which allow fair competition to develop on the market,*
- *rules which are the same and have the same requirements both for producers within the EU and those outside the EU.*

Finally, the objectives of this proposal, together with the previous legal provisions on GMOs, should promote the protection of human health and the environment and lay the foundations for ongoing monitoring and registering of the GMOs and their products circulating on the market.

The call for effective measures to prevent the uncontrolled spread of GMOs reflects amendment 12 of the Environment Committee's Recommendation for Second Reading on the Council common position for adopting Directive 2001/18/EC on the deliberate release of GMOs (A5-0083/2000). Moreover, action 17 of the Commission's Communication on 'Life sciences and biotechnology – A Strategy for Europe' COM(2002) 27 calls for "measures to ensure the viability of conventional and organic farming and their sustainable co-existence with genetically modified crops". Without such measures consumers and operators will sooner or later loose their freedom to choose products which do not contain genetically modified material.

It is important to make it clear that human health and the environment must always take priority over the internal market or any other commercial consideration.

Amendment 7
Article 2 (1) (c) (a) (new)

c a)	***animals fed at some stage on products labelled in accordance with Regulation (EC) No ----/---- on genetically modified food and feed, provided the animals are destined for the placing on the market for human consumption or for the production of food products;***

Justification

In order to ensure the traceability of animal products derived from animals fed with GM feed the animals themselves have to be traceable, too.

Amendment 8
Article 2 (1) (c) (b) (new)

	c b) food products derived from animals fed with products labelled in accordance with Regulation (EC) No ----/---- on genetically modified food and feed.

Justification

The current practise of many operators clearly shows that consumers wish to know whether animal products offered for human consumption stem from animals fed on genetically modified feed. The regulation should therefore enable operators and consumers to exercise their freedom of choice also with regard to such products.

Amendment 9
Article 3(1)

(1) 'genetically modified organism' means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC;	(1) 'genetically modified organism' ***(GMO)*** means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC***, with the exception of organisms yielded by the techniques of genetic modification listed in Annex 1B of Directive 2001/18***;

Justification

For greater legal clarity, the definition of GMO must be identical and contain the same specifications as Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (see the exceptions set out in Annex 1B.

Amendment 10
Article 3, paragraph (5)

(5) 'operator' means a person who places a product on the market and also a	(5) 'operator' means a person who places a product on the market and also a

person who receives a product that has been placed on the market in the Community, at any stage of the production and distribution chain, but does not include the ultimate consumer;	person who receives a product that has been placed on the market in the Community***, either from a Member State of the EU or from a third country,*** at any stage of the production and distribution chain, but does not include the ultimate consumer;

Justification

In order to be effective, the rules on traceability and labelling must be applicable both to products produced within the Community and to those imported from third countries.

Amendment 11
Article 3 (6)

(6) food' means food as defined in [Article 2 of ***the Proposal for a Regulation of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Authority, and laying down procedures in matters of food];***	(6) 'food' means food as defined in Article 2 of ***Regulation (EC) No 178/2002;***

Justification

Technical adaptation.

Amendment 12
Article 3, paragraph 13

(13) ‘placing on the market’ means making available to third parties, whether in return for payment or free of charge;	(13) ‘placing on the market’ means making available to third parties, whether in return for payment or free of charge; ***Making available genetically modified micro-organisms for activities regulated under Council Directive 98/91/EEC amending Directive 20/219/EEC of 23 April 1990 on the contained use of***

	genetically modified micro-organisms including culture collections.

Justification

It is expedient to use the definition set out in Directive 2001/18.

Amendment 13
Article 3 (15)

(15) 'pre-packaged' means any single item for sale ***to the ultimate user***, consisting of a product and the packaging into which it was put before being offered for sale, whether such packaging encloses the product completely or only partially, but in such a way that the contents cannot be altered without opening or changing the packaging.	(15) 'pre-packaged' means any single item for sale, consisting of a product and the packaging into which it was put before being offered for sale, whether such packaging encloses the product completely or only partially, but in such a way that the contents cannot be altered without opening or changing the packaging.

Justification

The Commission's proposal means that pre-packaged products must be labelled. The amendment means that labelling would apply to all stages of production, which obviously increases safety if a GMO product is to be withdrawn from the market.

Amendment 14
Article 4 (1)

1. When placing pre-packaged products consisting of, or containing GMOs on the market, operators shall ensure that the words 'This product contains genetically modified organisms' appear on the label.	1. When placing pre-packaged products consisting of, or containing GMOs on the market, operators shall ensure that the words 'This product contains genetically modified organisms' ***or 'This product contains genetically modified (or GM) ... (name of crop or GMO)' appear on the label***

Justification

Operators should be allowed to use the abbreviation "GMO" or to provide more specific information if they so wish.

Amendment 15
Article 4 (2) (b)

(b)	the ***relevant*** unique code(s) assigned to those GMOs in accordance with Article 8.	(b)	the unique code(s) assigned to those GMOs in accordance with Article 8.

Justification

The Commission's proposal to exempt mixtures of live GMOs from the information requirements referred to in point b could undermine the whole traceability scheme. Operators could escape the stricter information requirements referred to in point b by simply mixing their GMOs with other types of GMOs. Moreover, when it comes to the withdrawal of products, it is crucial that only those products which actually contain the GMO concerned may be withdrawn instead of all products which "may contain" the GMO.

Amendment 16
Article 4(2), last paragraph

However, the information referred to in point (b) may be replaced by a declaration by the operator that the product shall only be used as food or feed, or for processing, together with the unique codes for the GMOs that the product may contain.	***Deleted***

Justification

To ensure transparency.

Amendment 17
Article 4 (4)

4.	Without prejudice to Article 6, operators shall have in place systems and procedures to allow the identification, for a period of ***five*** years from each transaction, of the	4.	Without prejudice to Article 6, operators shall have in place systems and procedures to allow the identification, for a period of ***ten*** years from each transaction, of the

person from whom and to whom the products referred to in paragraph 2 have been made available.	person from whom and to whom the products referred to in paragraph 2 have been made available.

Justification

*Health or other problems may take time to become evident. In the light of recent experience, ten years is the absolute minimum period necessary for the maintenance of records***.**

Amendment 18
Article 5, paragraph 1

When placing products ***produced*** from GMOs ***on the market,*** operators shall ensure that the following information is transmitted to operators receiving the product:	When placing ***on the market*** products ***obtained or derived*** from GMOs ***in which the presence of DNA or protein resulting from the genetic modification may be detected,*** operators shall ensure that the following information is transmitted to operators receiving the product:

Justification

At present, methods of analysis do not always detect traces of genetic modification in products obtained from GMOs, for which reason applying traceability and labelling rules in all cases would result in countless cases of fraud and would fail to achieve the ultimate objective, which is to provide consumers with information so that they are able to choose freely. The draftsman considers that consumers would not be better informed than they are at present. Furthermore, since such products are identical to conventional ones, there would be no point in differentiating between the two types of product in the regulation to which this opinion relates.

Amendment 19
Article 5(1)(b)

(b) an indication of each of the feed materials or additives which is produced from GMOs;	(b) an indication of each of the feed materials or additives which is produced from GMOs ***or food produced from animals which have, at any time, been fed or are being fed with GMOs;***

Justification

Obviously, the provisions should cover food produced from animals fed with GMOs.

Amendment 20
Article 5 (1)(a) (new)

1(a. When placing pre-packaged products produced from GMOs on the market operators shall ensure that the information referred to in paragraph 1 is transmitted to operators receiving the product and, in addition, that either the words "This product is produced from GMOs" or the words "This products contains .[ingredient produced from GMOs" appear on a label and in connection with the display and the advertising of the product.

Justification

Like pre-packaged food and feed products containing or consisting of GMOs, pre-packaged products 'produced from' GMOs should be labelled.

Amendment 21
Article 5(1 a) new

1(a) With reference to the GMO from which the product is made, transmission of information in accordance with the first sentence shall include the relevant unique code assigned to the GMO in question in accordance with Article 8.

Justification

In the case of foodstuffs made from GMOs Article 5 requires that the food ingredients, additives and flavourings made from GMOs should be named. The same applies to animal feed. Transmission and registration of the unique code assigned to every authorised GMO is not provided for here. Registration, transmission and storage of the GMO code should, however, also be guaranteed in the case of foodstuffs and feed produced from GMOs.

Amendment 22
Article 5 (2)

2. Without prejudice to Article 6, operators shall have in place systems and procedures to allow the identification, for a period of ***five*** years from each transaction, as to the person from whom and to whom the products referred to in paragraph 1 have been made available.	2. Without prejudice to Article 6, operators shall have in place systems and procedures to allow the identification, for a period of ***ten*** years from each transaction, as to the person from whom and to whom the products referred to in paragraph 1 have been made available.

Justification

Consumers may not object to the use of genetically modified organisms in the production of foods solely out of fears for their personal health or that of their families. There are a wide range of reasons why they may not wish to purchase products in the processing of which GMOs have been used. These include religious, ethical and environmental reasons: followers of certain religions may object to any use of pig products, strict vegetarians to any use of animal products, and so on. For some, therefore, the actual presence or otherwise of GMOs in the final product is not the issue. As it is in all of our interests to respect the diversity and multicultural nature of our European societies, it is imperative that all of these consumers should have the right to make an informed choice on the basis of their beliefs. Health or other problems may take time to become evident. In the light of recent experience, ten years is the absolute minimum period necessary for the maintenance of records.

Amendment 23
Article 5(a) (new)

	Traceability of animals and animal products
	(1) When placing animals on the market which are destined for human consumption or for the production of food products and have been fed at some stage on feed containing, consisting of or produced from genetically modified organisms, operators shall ensure that the operators receiving the animals are informed that the

animals have been fed on these products.

(2) When placing food products on the market which have been derived from animals referred to in paragraph 1, operators shall ensure that operators receiving such animal products are informed that the animals from which the products have been derived, have been fed with products containing, consisting of or produced from genetically modified organisms.

(3) When placing pre-packaged products, as referred to in paragraph 2, on the market, operators shall ensure , that either the words "This product is derived from an animal fed with GM feed" or the words "This products contains ....[ingredient] derived from an animal fed with GM feed " appear on a label, in connection with the display and the advertising of the product.

(4) Without prejudice to Article 6, operators shall have in place systems and procedures to allow the identification, for a period of ten years from each transaction, as to the person from whom and to whom the products referred to in paragraphs 1 and 2 have been made available.

(5) Paragraphs 1 - 3 are without prejudice to other specific requirements in Community legislation.

Justification

The proposed new article extends the traceability scheme as to cover products derived from animals which have been fed with GM feed. For this purpose animals which have been fed with GM feed have to be traceable, too. The traceability regime for animal products can only take into account those feeding materials which have to be labelled. The (consumer) labelling

of feed (and food) is addressed by the Commission's proposal for a regulation on genetically modified food and feed. Paragraphs 4 and 5 equal Art. 4 (3) - (5) and Art. 5 (2) and (3).

Amendment 24
Article 6(1)

(1) In cases where Community legislation provides for specific identification systems, such as lot or batch numbering for pre-packaged products, operators shall ***not*** be obliged to retain the information specified in Articles 4(2), 4(3) and 5(1), provided that this information and the lot or batch number is clearly marked on the package and that information about batch or lot numbers is retained for the period of time referred to in Articles 4(4) and 5(2).	(1) In cases where Community legislation provides for specific identification systems, such as lot or batch numbering for pre-packaged products, operators ***who receive the pre-packaged product*** shall be obliged to retain the information specified in Articles 4(2), 4(3) and 5(1), provided that this information and the lot or batch number is clearly marked on the package and that information about batch or lot numbers is retained for the period of time referred to in Articles 4(4) and 5(2).

Justification

The amendment is designed to improve traceability.

Amendment 25
Article 6 (3)

3. Products intended for direct use as food, feed or processing which ***consist of or*** contain GMOs ***in respect of which the conditions set out in Article 12a of Directive 2001/18/EC* are met*** shall be exempt from the requirements of Article 4.	3. Products intended for direct use as food, feed or processing, which contain ***traces of materials produced from*** GMOs shall be exempt from the requirements of Article 4, ***provided the materials produced from GMOs have been authorised in accordance with Regulation (EC) No ----/---- on genetically modified food and feed and the proportion is no higher than established in accordance with that Regulation.***

Justification

The Commission proposes to legalise the presence of unauthorised GMOs in food and feed

products (see Art. 42 of Commission proposal COM(2001) 425). By reference to this provision, the Commission proposes to exclude such unauthorised GMOs also from the traceability scheme. Both suggestions might not increase consumer confidence, to say the least; nor are they necessary, as the example of the United States of America shows. The threshold applicable under the conditions set out in the Regulation on genetically modified food and feed should also apply to GM food and feed falling under this Regulation..

Amendment 26
Article 6 (4)

4	***Food and feed produced from GMOs in respect of which the conditions set out in Articles 5 and 18 of Regulation (EC) No …/2002 [on genetically modified food and feed] are met shall be exempt from the requirements of Article 5.***	***Deleted***

Justification

This paragraph would exclude from the traceability scheme the presence of food and feed produced from ***unauthorised*** *GMOs. It should be noted that even in the United States, unauthorised GMOs and GM derivatives must not be present in any food, feed or seed.*

Amendment 27
Article 6 a (new)

	Guide to good segregation practice for foodstuffs and food ingredients
	The Member States shall encourage and contribute to drawing up guides to good segregation practice, which businesses in the food industry shall apply in order to avoid the risks of adventitious or technically unavoidable contamination of foodstuffs with genetically modified material.

Justification

With the aim of guaranteeing the continued supply of non-GM foodstuffs and thus safeguarding consumers' freedom of choice, many operators in the food industry have

already set up effective traceability and segregation systems aimed at preventing the risk of accidental contamination by GMOs. Guides to good segregation practice based on risk analysis throughout the food chain, from seed merchant to distributor, have been drawn up and put in place by trade associations. Along the lines of the good hygiene practice guides developed in the context of the 1993 food hygiene directives, guides to good practice aimed at operators who wish to remain below the accidental GMO contamination threshold must be encouraged.

Amendment 28
Article 7

Article 4(6) of Directive 2001/18/EC is deleted	***Deleted***

Justification

Directive 2001/18/EC requires traceability of GMOs regardless of the purpose for which they shall be used. The proposed regulation only covers GMOs and their food and feed derivatives. The deletion of Art. 4 (6) of Directive 2001/18/EC would therefore abolish the obligation to trace GMO derivatives destined for purposes other than human or animal consumption.

Amendment 29
Article 9(1)

(1) Member States shall ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with this Regulation.	(1) Member States shall ensure that inspections ***and risk assessment on the basis of sample checks and testing (quantitative and qualitative)*** and other control measures, as appropriate, are carried out to ensure compliance with this Regulation.

Justification

Strengthening controls ensures product purity.

Amendment 30
Article 9(2)

2. Prior to the application of Articles 1 to 7, the Commission shall develop technical guidance on sampling ***and*** testing to	2. Prior to the application of Articles 1 to 7, the Commission shall***, in accordance with the procedure laid down in Article 10,*** develop ***and publish*** technical guidance on

facilitate a coordinated approach for the implementation of paragraph 1.	sampling, testing ***and methods*** to ***ensure*** a coordinated approach for the implementation of paragraph 1.

Justification

The technical guidance on sampling, testing and methods must be published. Furthermore, adoption of the guidance must not merely aim to achieve a coordinated approach but to ensure its effective application.

Amendment 31
Article 9(2)(a)(new)

	In order to support the Member States in meeting the requirements set out in paragraphs 1 and 2, the Commission shall ensure that a central register is put in place at Community level, which shall contain all available sequencing information and reference material for GMOs authorised to be put into circulation in the Community. The competent authorities in the Member States shall have access to the register. The register shall also contain, where available, relevant information concerning GMOs not authorised in the European Union.

Justification

The intended rules will only be analytically checkable if transformation-event-specific sequencing information and reference material is accessible, even for GMOs not authorised in the EU.

Amendment 32
Article 12 (2)

2. Articles 1 to 7 and Article 9(1) shall apply with effect from the ninetieth day following the date of publication	2. Articles 1 to 7 and Article 9(1) shall apply with effect from the ninetieth day following the date of publication

in the Official Journal of the European Communities of the measure referred to in Article 8(a).This Regulation shall be binding in its entirety and directly applicable in all Member States	in the Official Journal of the European Communities of the measure referred to in Article 8(a). ***Before the date of application of the measure referred to in Article 8(a), no genetically modified organisms, food or feed products consisting of, containing or produced from genetically modified organisms and no products derived from animals fed on any of these products shall be approved.*** This Regulation shall be binding in its entirety and directly applicable in all Member States.

Justification

It is for obvious reasons pivotal to have an effective traceability scheme in place before new products are approved for the placing on the market.

Amendment 33
Article 12(2)

2. Articles 1 to ***7*** and Article 9(1) shall apply with effect from the ninetieth day following the date of publication in the *Official Journal of the European Communities* of the measure referred to in Article 8(a).	2. Articles 1 to ***6*** and Article 9(1) shall apply with effect from the ninetieth day following the date of publication in the *Official Journal of the European Communities* of the measure referred to in Article 8(a) ***and must be consistent with Directive 2001/18.***

Justification

Self-explanatory.

EXPLANATORY STATEMENT

Introduction

The legislative proposal concerns (a) traceability and labelling of genetically modified organisms (GMOs), (b) traceability of food and feed products produced from genetically modified organisms, and (c) amendment of Directive 2001/18/EC.

Community legislation on GMOs is totally fragmented (see annex), making it difficult to adopt cohesive provisions and apply unequivocal Community rules. Moreover, there are already a number of Community regulations and provisions governing the placing on the market, circulation, labelling, presentation and advertising of food and its ingredients. This problem, in conjunction with the inability to monitor the rapid developments in biotechnology and the production of GMOs and their products, led to reservations and a moratorium over the last three years on the marketing authorisation procedures at EU level, pending the adoption of an integrated traceability and labelling system.

Directive 2001/18/EC on the deliberate release of GMOs into the environment does not in fact extend labelling to operators placing GMOs on the market, while the traceability and labelling of products produced from GMOs also remain outside its scope.

The need for a cohesive and integrated system of labelling and tracing

In the past, the European Parliament has criticised the Commission's piecemeal and inconsistent approach to GMOs[1] and called on the Commission to submit proposals, including proposals on animal feed labelling in a way which is more coherent and provides consumers with certainty of choice, on the one hand, and gives industry a solid legal framework to work with, on the other hand.

The objective of the current proposal is to make it possible to register and monitor the placing on the market of GMOs, and food and feed produced from them, and so facilitate consumer choice whilst at the same time facilitating the process of withdrawing a product should it be deemed necessary. It does not, however, fulfil the desired objective of a more consistent approach and coherent regulation of GMOs, as it results in further fragmentation of Community legislation. Ignoring in practice the need to simplify and improve the regulatory framework, the Commission has submitted two proposals for regulations, the one under review and another, separate proposal on genetically modified food and feed (COM (2001) 425). This fact demonstrates an inherent inability to adopt a coherent legal framework for GMOs at EU level and undermines any attempt at codifying and reformulating Community legislation on GMOs.

International aspects of GMOs

The need for legal certainty within the Community also arises when obligations under multilateral trade arrangements and international agreements on GMOs must be transposed

[1] OJ C 296, 18.10.2000, p. 122. EP Resolution on the follow-up to Parliament's opinion on genetically modified food labelling - B5-0313/1999.

into Community law. The proposal under review is directly related to the Cartagena Protocol on Biosafety adopted at the Conference on the Convention on Biodiversity held in Montreal on 29 January 2000, which concern transboundary movements of GMOs, and with the OECD's provisions concerning a unique code for GM (transgenic) plants.

The objective of the Protocol is to contribute to ensuring an adequate level of protection and safety during the transfer, handling and use of GMOs; it lays down the procedures for granting authorisation, following notification, for living modified organisms (LMOs) as well as a system of notification for LMOs intended for direct use as foods or feed, or for further processing. However, it does not contain any provision or specific reference to the traceability of GMOs and their products. This fact does not ensure legal certainty and is a shortcoming, possibly even an obstacle to adopting rules within the Community, not only for domestic Community products, but, principally, for imported products.

Furthermore, it cannot be predicted to what extent the uniform rules on monitoring, traceability and labelling of GMOs and their products will apply at international level. Moreover, the entry into force of the Protocol is dependent on the will of the parties concerned (of the 107 states which have signed it to date - which include the European Community and its Member States - only 12 states have completed the ratification procedures). However, the Commission recently submitted a regulation on the transboundary movement of genetically modified organisms[1], aimed at transposing the Protocol into Community law.

Effective implementation of the provisions of the regulation – shortcomings of the proposal

If the provisions of the regulation on traceability and labelling are to be effectively implemented in the EU, the rules must be equally applicable to products produced within the Community and to those imported from third countries. At the present time, the agro-food sector is developing at a pace and the area under cultivation with GMOs worldwide is expanding rapidly, totalling 50 million hectares, whereas in Europe the figure is no more than 12 000 hectares[2]. Given, however, that there are no uniform international rules or a single framework for regulating traceability and labelling, there are risks involved in venturing to adopt traceability and labelling rules for GMO products which cannot be applied to monitor products from third countries.

In the event that the EU unilaterally applies traceability and labelling requirements to imported products and carries out checks without an adequate scientific basis, it may create a trade dispute with third countries which results in the matter being referred to the WTO. It is indicative that during negotiations at the fourth WTO Ministerial Conference held in Doha in Qatar in November 2001, the USA (a country with 30.3 million hectares of GMOs under cultivation) refused to entertain any discussion of labelling GMOs.

Traceability and labelling should also apply to GMOs and products containing traces of

[1] COM (2002) 85, 18.02.2002.

[2] OJ C 55, 2.3.2002, Commission communication to the Council, European Parliament, the Economic and Social Committee and the Committee of the Regions, Life Sciences and Biotechnology – a strategy for Europe, COM(2002)27.

genetically modified DNA (GM-DNA) or genetically modified protein (GM protein), otherwise it would be increasingly misleading to consumers to label products produced from GMOs in which there is no trace of GM-DNA or GM protein. Furthermore, such a provision would be contrary to the objectives of the regulation and financially onerous for companies and consumers alike.

Another issue which must be given serious consideration is that although current techniques, such as the polymerase chain reaction (PCR), enable even traces of GM-DNA to be traced, there are products – for example citric acid, vitamin C or highly refined maize oil produced from GM maize – which nevertheless test negative, i.e. they show no difference from the corresponding conventional products. A regulation which aims to trace and label those substances, as the present proposal does, therefore represents a serious risk because their producers or importers could claim that they are produced from natural products or that they are free of GMO materials. These products would therefore clearly be in a more advantageous position than the corresponding products produced within the EU, while consumers could be misled.

A similar problem arises with products which are absolutely identical to the conventional products, such as sugar from GM beet and sugar from non-GM beet. In this case, traceability and labelling do not help consumers at all because, despite their similarity to the conventional products, it is possible that they may be priced differently since, owing to the poor information and doubt that surrounds GMO food, consumers are prepared to pay more for the 'natural' product. It is therefore obvious that the provisions of this EU regulation, in the case of products which do not contain GM-DNA or GM protein, will lead to:

- fraud and deception
- misleading of consumers
- distortion of prices and competition
- less favourable treatment of EU producers and companies.

The rapporteur's proposal

Clearly, both traceability and the ensuing labelling of products should fulfil certain conditions in regard to implementation. There is no doubt that we should seek to set up a regulatory system by taking appropriate administrative, legislative and regulatory measures in respect of GMOs so that we are able to facilitate their registration and movement in a way which safeguards human health and protects the environment and, above all, builds consumer confidence. In order to command respect, however, the rules of this system must be simple, clear, ensure transparent monitoring of their application, and not allow fraud, deception or distortion of competition, particularly between domestic and imported products. Moreover, the system should provide for the possibility of unilateral implementation of the rules by the EU, so that their effectiveness is not undermined by imports from third countries.

An unequivocal rule which sets a sound framework is one which ensures that every product which tests positive for GMOs or GMO material product is subject to mandatory traceability and labelling. Furthermore, the GMO concerned must have been granted authorisation pursuant to current EU rules (Directive 2001/18/EC) and therefore the original authorisation procedure should have safeguarded human health, ensured protection of the environment and eco-systems and the smooth operation of the market with regard to the GMO and its products.

Your rapporteur differentiates between the following three categories of products in the amendments to the regulation:

First category: GMOs and GMO products which are checked using analytical methods. This category includes products such as maize, soya, maize meal, soya meal and primary products in general in which **GMO material is easily traced.**

Second category: this category includes the conventional products corresponding to the first category which have been contaminated adventitiously or unavoidably through mixing with genetically modified material. In this case, in order to exempt them from the traceability and labelling requirements, certain conditions should apply together with a maximum level of GMO material. The following three conditions are proposed:

(a) The presence of GMO materials from one or more GMOs does not exceed 1% or the maximum permissible levels established in accordance with the procedures laid down in Directive 2001/18/EC. Your rapporteur has no problem with low levels but if we are to be rational and prudent, we must consider in detail what, in maximum terms, an adventitious or unavoidable admixture might amount to.

(b) The presence of these GMO materials is adventitious and technically unavoidable. Companies should be able to prove to the authorities that they have taken the necessary measures to avoid the presence of GMOs or GMO material.

(c) The specific GMO or, in the case of more than one GMO, the specific types, must have been subject to a risk assessment by the relevant scientific authority (authorities) or by the European Food Safety Authority as a basis for authorisation and must not pose a risk to human health or the environment.

Third category: products produced from GMOs but not containing GMO material such as vitamin C, citric acid, maize oil etc. For this category there should be no traceability and labelling requirement.

Your rapporteur's proposals are based on the above logical considerations. They also allow the EU to implement them unilaterally without creating barriers to trade and distortion of competition, and at the same time provide consumers with reliable information. In this respect, I would draw attention to the fact that the screening techniques are now so sensitive and reliable that in the event that a product does not test positive for GMO material, we can be fully confident in the results and not subject that product to the labelling requirement. That would be inconsistent when present legislation (see Regulation 49/2000/EC which exempts from labelling products produced from GM soya beans and GM maize) and the proposed regulation exempt from the traceability and labelling requirements products which have been contaminated adventitiously or unavoidably through mixing with genetically modified material, while the regulation imposes the traceability and labelling requirements on products which do not contain genetically modified material.

ANNEX

- **Horizontal provisions**

- Directive 98/81/EC amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms[1],
- Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EC[2].

- **Vertical/sectoral provisions**

- Regulation 97/258/EC concerning novel foods and novel food ingredients[3]
- Regulation 1139/98/EC concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC[4] (concerning only GM soya beans and GM maize),
- Regulation 49/2000/EC amending Regulation 1139/98/EC concerning the compulsory indication of the labelling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC[5]. This regulation exempts from labelling products produced from GM soya beans and GM maize and lays down a ceiling of 1% for adventitious contamination of foodstuffs with DNA or protein resulting from genetic modification,
- Regulation 50/2000/EC on the labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms[6],
- Commission Recommendation 2002/66/EC concerning a coordinated programme for the official control of foodstuffs for 2002[7] concerning compliance with GMO labelling.

[1] OJ L 330, 5.12.1998, p. 13.
[2] OJ L 106, 17.04.2001, p. 1.
[3] OJ L 43, 14.02.1997, p. 1.
[4] OJ L 159, 03.06.1998, p. 4.
[5] OJ L 6, 11.10.2000, p. 13.
[6] OJ L 6, 11.01.2000, p. 15.
[7] OJ L 26, 30.01.2002, p. 8.

24 January 2002

OPINION OF THE COMMITTEE ON INDUSTRY, EXTERNAL TRADE, RESEARCH AND ENERGY

for the Committee on the Environment, Public Health and Consumer Policy

on the proposal for a Council regulation concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC

(COM(2001) 182 – C5-0380/01 – 2001/0180(COD))

Draftsman: Esko Olavi Seppänen

PROCEDURE

The Committee on Industry, External Trade, Research and Energy appointed Esko Olavi Seppänen draftsman at its meeting of 3 September 2001.

It considered the draft opinion at its meetings of 18 December 2001 and 24 January 2002.

At the latter meeting it adopted the following amendments by 43 votes to 4, with 1 abstention.

The following were present for the vote: Carlos Westendorp y Cabeza, chairman; Peter Michael Mombaur, vice-chairman; Yves Piétrasanta, vice-chairman; Jaime Valdivielso de Cué, vice-chairman; Esko Olavi Seppänen, draftsman; Konstantinos Alyssandrakis, Sir Robert Atkins, Freddy Blak (for Fausto Bertinotti), David Robert Bowe (for Massimo Carraro), Gérard Caudron, Giles Bryan Chichester, Nicholas Clegg, Marianne Eriksson, Concepció Ferrer, Colette Flesch, Christos Folias (for Guido Bodrato), Jacqueline Foster (for Marjo Matikainen-Kallström), Monica Frassoni (for Nuala Ahern pursuant to Rule 153(2)), Norbert Glante, Michel Hansenne, Roger Helmer (for W.G. van Velzen), Hans Karlsson, Bashir Khanbhai, Werner Langen, Rolf Linkohr, Caroline Lucas, Eryl Margaret McNally, Minerva Melpomeni Malliori (for Harlem Désir), Erika Mann, Angelika Niebler, Giuseppe Nisticò (for Umberto Scapagnini), Reino Paasilinna, Elly Plooij-van Gorsel, Samuli Pohjamo (for Willy C.E.H. De Clercq), John Purvis, Godelieve Quisthoudt-Rowohl, Bernhard Rapkay (for Elena Valenciano Martínez-Orozco), Mechtild Rothe, Christian Foldberg Rovsing, Paul Rübig, Jacques Santer (for Paolo Pastorelli), Konrad K. Schwaiger, Gary Titley, Claude Turmes, Alejo Vidal-Quadras Roca, Dominique Vlasto, Myrsini Zorba, and Olga Zrihen Zaari.

SHORT JUSTIFICATION

When DNA sequences taken from other species are transferred to natural organisms ('old species'), new organisms emerge which have not undergone by natural selection and which have not developed a balance with other species in their habitat. For this reason there is every need to exercise caution, even excessive caution, regarding the modification of genes and the approval of the use of GMOs.

The aim of the Commission proposal for a regulation is to ensure the traceability and labelling of GMOs and to extend traceability, with the appropriate labelling, to the whole production, processing and distribution chain to cover foodstuffs and animal feeds produced from GMOs or containing GMOs. The EU, in which the marketing of GMOs is subject to licensing, is becoming a pioneer in the labelling and traceability of GMOs to enable consumers to make a choice.

Directive 2001/18/EC lays down provisions governing the deliberate release of GMOs into the environment. During the conciliation process between the European Parliament and the Council, no compromise could be found on the traceability of GMOs. In July 2001, the Commission published this proposal. It foresees that the Commission establishes a system for development and assignment of so-called unique codes to GMOs. The code is a simple numeric or alphanumeric code to identify a GMO which provides means to retrieve specific information about that GMO.

The Cartagena Protocol on Biosafety requires the identity of GMOs to be specified. The industrialised countries have been negotiating in the OECD on unique codes. To minimise the commercial effects the Commission is called upon to work towards the compatibility of systems.

Under the proposal for a regulation: 1. Operators shall have in place systems and procedures to identify to whom and from whom products are made available; 2. Operators shall transmit specified information concerning the identity of a product in terms of the individual GMOs it contains or whether it is produced from GMOs; and 3. Operators shall retain specified information for a period of five years and make it available to competent authorities on demand.

The traceability throughout the EU of food and animal feed has not hitherto concerned the traceability of GMOs. Now it is proposed that the provisions should be extended to cover not only GMOs but also products produced from GMOs. These include products derived from GMOs which do not contain and are not composed of GMOs. These products, which do not contain any viable GMOs, are covered by special traceability and labelling requirements.

It must be possible to establish the unique identity of GMOs at the initial stage of the production and distribution chain and when the data is to accompany the product to subsequent stages. The GMO data must accompany the product even in the case of loose goods. Genetically modified seeds, plants and derivatives must be kept separate from 'clean' products. The monitoring of unintentional contamination could be a problem.

Only GMOs approved by the EU's own authorisation procedure may be placed on the market

in the EU. The importer must receive the GMO identification data from the exporter or must determine its identity himself by samples and tests.

No deadline has been set for bringing this system into force, nor have any uniform penalties been proposed for breach of the provisions.

Producers are critical of the new regulation. They complain about problems in putting the provisions into effect in practice, extra costs, the ease of abuses and the commercial consequences. Consumers' associations have been cautiously welcoming. They do not want to see any GMO-based products on the market in the EU that is not clearly labelled and can see that the regulation opens the way to their arrival on the EU market.

AMENDMENTS

The Committee on Industry, External Trade, Research and Energy calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament
Amendment 1 Article 3, paragraph 1	
1. 'genetically modified organism' means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC;	1. 'genetically modified organism' means genetically modified organism as defined in Article 2(2) of Directive 2001/18/EC ***excluding organisms obtained through the techniques of genetic modification listed in Annex I B of Directive 2001/18;***
Justification *Article 2(2) of Directive 2001/18 defines GMOs with the explicit exemptions from the scope defined in Article 3 (1) of organisms obtained through techniques of genetic modification listed under Annex I B of that Directive. For legal certainty and consistency, the definitions of both the Directive 2001/18 and the Regulation on traceability and labelling must be coherent.*	
Amendment 2 Article 4	

[1] OJ C .

Traceability and labelling requirements for GMOs

1. When placing pre-packaged products consisting of, or containing GMOs on the market, operators shall ensure that the words "This product contains genetically modified organisms" appear on a label.

2. At the first stage of the placing on the market of a product consisting of or containing GMOs, including bulk quantities, operators shall ensure that the following information is transmitted to the operator receiving the product:

(a) that it contains or consists of GMOs;

(b) the relevant unique code(s) assigned to those GMOs in accordance with Article 8.

However, the information referred to in point (b) may be replaced by a declaration by the operator that the product shall only be used as food or feed, or for processing, together with the unique codes for the GMOs that the product may contain.

3. At all subsequent stages of the placing on the market of products referred to in paragraph 2, operators shall ensure that the information received in accordance with paragraph 2 is transmitted to the operators receiving the products.

4. Without prejudice to Article 6, operators shall have in place systems and procedures to allow the identification, for a period of five years from each transaction, of the person from whom and to whom the products referred to in paragraph 2 have been made available.

5. Paragraphs 1 to 4 are without prejudice to other specific requirements in Community legislation.

Food products claiming to be GMO free shall be labelled 'GM free'. In the case of all products not so labelled it can be assumed that they may contain or do contain GMOs.

Justification

The Commission's proposal for a Council regulation on traceability and labelling requirements for GMOs is complex, costly and will cause trade disputes. 'GM free' labelling meets the requirements of clear and accurate information to the consumer without creating unjustifiable costs and disputes.

Amendment 3
Article 5

Traceability requirements for products produced from GMOs

1. When placing products produced from GMOs on the market, operators shall ensure that the following information is transmitted to operators receiving the product:

(a) an indication of each of the food ingredients, including additives and flavouring(s), which is produced from GMOs;

(b) an indication of each of the feed materials or additives which is produced from GMOs;

(c) in the case of products for which no list of ingredients exists, an indication that the product is produced from GMOs.

2. Without prejudice to Article 6, operators shall have in place systems and procedures to allow the identification, for a period of five years from each transaction, as to the person from whom and to whom the products referred to in paragraph 1 have been made available.

3. Paragraphs 1 and 2 are without prejudice to other specific requirements in Community legislation.

Justification

The Commission's proposal for a Council regulation on traceability and labelling requirements for GMOs is complex, costly and will cause trade disputes.

Amendment 4
Article 6, paragraph 3 a (new)

3a. Seeds containing adventitious or technically unavoidable traces of GMOs authorised following the objectives of Directive 2001/18/EC for deliberate release into the environment and placing on the market are exempt from the requirements of Article 4. Minimum thresholds for adventitious presence may be established by the competent Standing Committee.

Justification

The scope of the Regulation on traceability and labelling explicitly concerns the traceability of GMOs including seeds (v. Explanatory memorandum 'Framework' p. 3). Therefore, for seeds, a specific provision concerning the adventitious presence of GMOs should be included in the Regulation.

Amendment 5
Article 6, paragraph 4 a (new)

4a. Highly processed food and feed products in which the genetic modification is not reliably and consistently verifiable using the technical guidelines established under Article 9, shall be exempt from Article 5. The European Food Safety Authority shall establish a list of such products.

Justification

This is necessary to provide for legal certainty for operators (see Recital 7) and Member State inspection and control authorities (in accordance with Article 9).

Amendment 6
Article 9, paragraph 1

1. Member States shall ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with this Regulation.	1. Member States shall ensure that inspections and other control measures, as appropriate, are carried out to ensure compliance with this Regulation. ***For the purposes of control, the Commission shall prepare technical guidelines concerning sampling and testing before [31 December 2002].***

Justification

Because the proposal for a regulation does not contain any time limits, this needs to be laid down so that the implementation of the system can take place as rapidly as possible.

17 April 2002

OPINION OF THE COMMITTEE ON AGRICULTURE AND RURAL DEVELOPMENT

for the Committee on the Environment, Public Health and Consumer Policy

on the proposal for a regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (COM(2001) 182 – C5-0380/2001 – 2007/0180(CNS))

Draftsman: Encarnación Redondo Jiménez

PROCEDURE

The Committee on Agriculture and Rural Development appointed Encarnación Redondo Jiménez draftsman at its meeting of 12 September 2001.

It considered the draft opinion at its meetings of 23 January, 19 February, 20 March and 17 April 2002.

At the last meeting it adopted the following amendments by 23 votes to 10, with 3 abstentions.

The following were present for the vote: Joseph Daul (chairman); Friedrich-Wilhelm Graefe zu Baringdorf, Albert Jan Maat, María Rodríguez Ramos (vice-chairmen); Encarnación Redondo Jiménez (draftsman); Gordon J. Adam, Danielle Auroi, Alexandros Baltas (for Vincenzo Lavarra), Carlos Bautista Ojeda, Sergio Berlato, Niels Busk, Arlindo Cunha, Michl Ebner, Christel Fiebiger, Ilda Figueiredo (for Dimitrios Koulourianos), Francesco Fiori, Jean-Claude Fruteau, Georges Garot, Lutz Goepel, Willi Görlach, Liam Hyland, Elisabeth Jeggle, Salvador Jové Peres, Hedwig Keppelhoff-Wiechert, Heinz Kindermann, Wolfgang Kreissl-Dörfler (for António Campos), Astrid Lulling (for Christos Folias), Xaver Mayer, Jan Mulder (for Giovanni Procacci), Karl Erik Olsson, Neil Parish, Mikko Pesälä, Christa Prets (for María Izquierdo Rojo), Agnes Schierhuber, Dominique F.C. Souchet, Robert William Sturdy and Eurig Wyn (for Giorgio Celli).

SHORT JUSTIFICATION

The proposal for a regulation (COM(2001) 182) lays down requirements and obligations which should ensure that GMOs are labelled and that both they and the food and feed products derived from them are traceable at all stages of the marketing process. At the same time the Commission has issued a second proposal relating to the authorisation, evaluation and labelling of genetically modified food and feed (COM(2001) 425). This 'package' will be supplemented in the near future by other proposals relating to seeds (purity criteria in respect of the accidental presence of GMO residues in batches of conventional seed), assessment of the risks which genetically modified vegetable varieties pose to the environment, the prevention of environmental damage caused by GMOs and a judicial instrument for implementing the Cartagena Protocol on biosafety (part of the Convention on Biological Diversity).

The procedures for authorising the marketing of GMOs are currently suspended pending the adoption of a harmonised labelling and traceability scheme. Such a scheme should be able to do all of the following at one and the same time: determine the identity of GMOs and the characteristics thereof, so as to allow selective monitoring of the effects which they may have on the environment; enable a product to be located at any stage of the production and distribution chain, so that it can be withdrawn if any unforeseen risk arises to public health, animal health or the environment; and, lastly, facilitate the labelling of pre-packaged products and the performance of checks on the accuracy of what is stated on such labels.

The Commission proposal seeks to attain these objectives but it often fails to distinguish between ambition and what can realistically be achieved, and on occasions the potential for internal inconsistency may be glimpsed. Furthermore, adoption of the proposal could lead to international trade conflicts, since the measures put forward are construed by certain countries (including the USA) as barriers to trade.

However, European consumers are entitled to proper information regarding the contents of any foodstuff, for which reason the provision of reliable information should be one of the main objectives of Community rules in respect of GMO labelling and traceability. That is the aim which this draft opinion seeks to achieve, for which reason it rejects any aspects which would give rise to dubious practices, thereby sowing confusion amongst consumers. Specifically, it rejects the requirement to ensure traceability (and, therefore, to supply labelling) for GMO-derived products from which all trace of genetic modification has disappeared and which do not therefore differ from conventional products. The fact that no method of analysis exists which can detect the DNA or the protein resulting from genetic modification could undoubtedly lead to countless cases of fraud, for which reason the ultimate aim (i.e. to give consumers greater freedom of choice) would not be achieved. Furthermore, the fact that such products are no different from conventional ones renders the Commission proposal pointless.

Furthermore, it should be pointed out that the labelling of any given product provides no guarantee regarding the safety thereof. Both for GMOs and for any other foodstuff, the European Union should have reliable checking and authorisation schemes designed to prevent products which are a threat to human health, animal health or the environment from being placed on the market.

One of the aims of this opinion is to ensure incorporation of the provisions laid down in the Cartagena Protocol in order to minimise the risk of trade conflicts (bearing in mind, however, that the USA has not signed that protocol).

In the interests of greater clarity, Parliament is asking the Commission to consolidate all legislation relating to genetically modified organisms intended for human and animal consumption into a single law.

AMENDMENTS

The Committee on Agriculture and Rural Development calls on the Committee on the Environment, Public Health and Consumer Policy, as the committee responsible, to incorporate the following amendments into its report:

Text proposed by the Commission[1]	Amendments by Parliament
Amendment 1 Title of the Regulation	
Proposal for a regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products ***produced*** from genetically modified organisms and amending Directive 2001/18/EC.	Proposal for a regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability ***and labelling*** of food and feed products ***obtained or derived*** from genetically modified organisms and amending Directive 2001/18/EC.
Justification	
The title needs to be amended so that it reflects the draftsman's proposed amendments to the proposal for a regulation.	
Amendment 2 Article 2, paragraph 1, subparagraphs (b) and (c)	
(b) foods and food ingredients, ***including food additives and flavourings***, ***produced*** from GMOs, placed on the market in accordance with Community legislation;	(b) foods and food ingredients, ***obtained or derived*** from GMOs, placed on the market in accordance with Community legislation;

[1] OJ C 304, 30.10.2001, p. 327.

(c) ***feed materials,*** compound feedingstuffs ***and feed additives, produced*** from GMOs, placed on the market in accordance with Community legislation.	(c) compound feedingstuffs ***obtained or derived*** from GMOs, placed on the market in accordance with Community legislation.

Justification

The correct terminology must be used in each language. There is no need to mention the substances which will be defined in the European Parliament and Council regulation laying down the principles and the general requirements of food legislation, establishing the European Food-Safety Authority and stipulating procedures relating to food safety.

Amendment 3
Article 3, paragraph 2

(2) '***produced*** from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;	(2) ***'obtained or derived*** from GMOs' means ***obtained or*** derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;

Justification

The correct terminology must be used in each language.

Amendment 4
Article 3, paragraph 5

(5) 'operator' means a person who places a product on the market and also a person who receives a product that has been placed on the market in the Community, at any stage of the production and distribution chain, but does not include the ultimate consumer;	(5) 'operator' means a person who places a product on the market and also a person who receives a product ***originating within a Member State or outside the EU*** that has been placed on the market in the Community, at any stage of the production and distribution chain, but does not include the ultimate consumer;

Justification

The fact that products which have been placed on the market will be treated in the same way irrespective of their origin (either inside or outside the Community) must be reiterated.

Amendment 5
Article 3, paragraph 7

(7) 'food additive' means food additive as defined in Article 1(2) of Council Directive 89/107/EEC.	***Deleted***

Justification

This definition will be framed in the new regulation laying down the principles and the general requirements of food legislation, establishing the European Food-Safety Authority and stipulating procedures relating to food safety.

Amendment 6
Article 3, paragraph 8

(8) 'flavouring' means flavouring as defined in Article 1(2) of Council Directive 88/388/EEC;	***Deleted***

Justification

This definition will be framed in the new regulation laying down the principles and the general requirements of food legislation, establishing the European Food-Safety Authority and stipulating procedures relating to food safety.

Amendment 7
Article 3, paragraph 11

(11) 'feed materials' means feed materials as defined in Article 2(a) of Council Directive 96/25/EC;	***Deleted***

Justification

This definition will be framed in the new regulation laying down the principles and the general requirements of food legislation, establishing the European Food-Safety Authority and stipulating procedures relating to food safety.

Amendment 8
Article 3, paragraph 12

(12) 'feed additives' means additives as defined in Article 2(a) of Council Directive 70/524/EEC;	***Deleted***

Justification

This definition will be framed in the new regulation laying down the principles and the general requirements of food legislation, establishing the European Food-Safety Authority and stipulating procedures relating to food safety.

Amendment 9
Article 3, paragraph 15

(15) 'pre-packaged' means any single item for sale ***to the ultimate user***, consisting of a product and the packaging into which it was put before being offered for sale, whether such packaging encloses the product completely or only partially, but in such a way that the contents cannot be altered without opening or changing the packaging.	(15) 'pre-packaged' means any single item for sale, consisting of a product and the packaging into which it was put before being offered for sale, whether such packaging encloses the product completely or only partially, but in such a way that the contents cannot be altered without opening or changing the packaging.

Justification

The labelling obligations foreseen for pre-packaged products should apply to all pre-packaged products whether they are for sale to the ultimate user or for sale to food/ feed business operators.

Amendment 10
Article 4, paragraph 2, second subparagraph

However, the information referred to in point (b) may be replaced by a declaration by the operator that the product shall only be used as food or feed, or for processing, together with the unique codes for the GMOs that the product may contain.	However, ***pending the entry into force of the exclusive-identification system laid down in the Cartagena Protocol on biosafety (part of the Convention on Biological Diversity),*** the information referred to in point (b) may be replaced by a declaration by the operator that the product shall only be used as food or feed, or for processing, together with the unique codes for the GMOs that the product may contain***, pursuant to Article 8.***

Justification

Until such time as the Cartagena Protocol's exclusive-identification system comes into force, the above safeguard needs to be incorporated in order to prevent trade conflicts.

Amendment 11
Article 5, title

Traceability requirements for products ***produced*** from GMOs	Traceability requirements for products ***obtained or derived*** from GMOs

Justification

The most accurate terminology must be used in each language.

Amendment 12
Article 5, paragraph 1

When placing products ***produced*** from GMOs ***on the market,*** operators shall ensure that the following information is transmitted to operators receiving the product:	When placing ***on the market*** products ***obtained or derived*** from GMOs ***in which the presence of DNA or protein resulting from the genetic modification may be detected,*** operators shall ensure that the following information is transmitted to operators receiving the product:

Justification

At present, methods of analysis do not always detect traces of genetic modification in products obtained from GMOs, for which reason applying traceability and labelling rules in all cases would result in countless cases of fraud and would fail to achieve the ultimate objective, which is to provide consumers with information so that they are able to choose freely. The draftsman considers that consumers would not be better informed than they are at present. Furthermore, since such products are identical to conventional ones, there would be no point in differentiating between the two types of product in the regulation to which this opinion relates.

Amendment 13
Article 5a (new)

	Requirements concerning the labelling of products obtained or derived from GMOs. ***1. Labelling shall not apply to products obtained or derived from GMOs in which the DNA or the protein resulting from the genetic modification cannot be detected.*** ***2. The labelling of products obtained or derived from GMOs in which the DNA or the protein resulting from the genetic modification is detectable shall be regulated by means of the European Parliament and Council Regulation on genetically modified food and feed products.***

Justification

At present, methods of analysis do not always detect traces of genetic modification in

products obtained from GMOs, for which reason applying traceability and labelling rules in all cases would result in countless cases of fraud and would fail to achieve the ultimate objective, which is to provide consumers with information so that they are able to choose freely. The draftsman considers that consumers would not be better informed than they are at present. Furthermore, since such products are identical to conventional ones, there would be no point in differentiating between the two types of product in the regulation to which this opinion relates.

Amendment 14
Article 7, first paragraph a (new)

With effect from the date upon which this Regulation comes into force, Directive 2001/18/EC shall be amended as follows:
'The following Article 12a is inserted:
Article 12a – Accidental presence of GMOs in products.
Articles 13 to 21 shall not apply to the placing on the market of GMO residues or GMO compounds in products intended for direct or indirect use as food or feed products or for further processing, provided that the proportion of such residues is no greater than 1% or does not exceed the lower thresholds established in accordance with the procedure laid down in Article 30(2), and provided that such GMO residues are accidental or technically unavoidable and that the GMO has been subjected by the relevant scientific committee(s) or by the European Food Authority to a scientific risk assessment which reveals that the substance does not pose a threat to human health or to the environment. In order to establish that such GMO residues are accidental or technically unavoidable, company operators must be able to demonstrate to the relevant authorities that they have taken appropriate action to exclude them.'

Justification

The acceptable level for the accidental presence of GMOs which is laid down in Directive 2001/18/EC must be adjusted by means of this regulation rather than via the draft document on genetically modified food and feed products which has been submitted by the Commission. The purpose of the change proposed by the draftsman is to achieve greater legislative consistency, since the regulation to which this opinion relates is intended precisely to amend Directive 2001/18/EC.

Amendment 15
Article 8, first paragraph, subparagraph (b)

(b) adapt the system provided for in point (a), as appropriate, taking into account further developments in international fora.	(b) adapt***, as easily and as simply as possible, so as not to hinder trade,*** the system provided for in point (a), as appropriate, taking into account further developments in international fora***, particularly in the light of the implementation of the Cartagena Protocol on biosafety (part of the Convention on Biological Diversity) as regards exclusive identification.***

Justification

It must be ensured that the section of the Cartagena Protocol which relates to exclusive identification is swiftly incorporated into Community law, so as not to distort trade and so as to prevent trade conflicts.

Amendment 16
Article 9, paragraph 2

Prior to the application of Articles 1 to 7, the Commission shall develop technical guidance on sampling and testing to facilitate a coordinated approach for the implementation of paragraph 1	Prior to the application of Articles 1 to 7, the Commission shall develop technical guidance on sampling and testing ***which ensures that such sampling and testing is not only effective but also simple and of minimal cost to operators.***

Justification

Methods of sampling and testing need to be simple and affordable to operators, so as to prevent any discrimination between external and internal operators.