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***II
RECOMMENDATION FOR SECOND READING

on the Council common position for adopting a European Parliament and Council regulation on traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (15798/1/2002 – C5-0131/2003 – 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.

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PROCEDURAL PAGE

At the sitting of 3 July 2002 Parliament adopted its position at first reading on the proposal for a European Parliament and Council regulation on traceability and labelling of genetically modified organisms and the 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 27 March 2003 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 (15798/1/2002 – C5-0131/2003).

The committee had appointed Antonios Trakatellis rapporteur at its meeting of 13 September 2001.

The committee considered the common position and draft recommendation for second reading at its meetings of 29 April 2003 and 22 May 2003.

At the latter meeting it adopted the draft legislative resolution by 33 votes to 15, with 0 abstentions.

The following were present for the vote: Caroline F. Jackson, chairman; Guido Sacconi, vice-chairman;Antonios Trakatellis, rapporteur; and Bent Hindrup Andersen (for Jean-Louis Bernié), María del Pilar Ayuso González, Emmanouil Bakopoulos (for Mihail Papayannakis), Hans Blokland, Herbert Bösch (for María Sornosa Martínez, pursuant to Rule 153(2)), David Robert Bowe, Philip Bushill-Matthews (for John Bowis), Dorette Corbey, Chris Davies, Avril Doyle, Jillian Evans (for Hiltrud Breyer), Anne Ferreira, Pernille Frahm, Laura González Álvarez, Françoise Grossetête, Roger Helmer (for Karl-Heinz Florenz, pursuant to Rule 153(2)), Marie-Thérèse Hermange (for Martin Callanan), Bashir Khanbhai (for Christa Klaß, pursuant to Rule 153(2)), Eija-Riitta Anneli Korhola, Bernd Lange, Paul A.A.J.G. Lannoye (for Marie Anne Isler Béguin), Peter Liese, Giorgio Lisi, Torben Lund, Minerva Melpomeni Malliori, Patricia McKenna, Erik Meijer (for Jonas Sjöstedt), Winfried Menrad (for Jorge Moreira da Silva, pursuant to Rule 153(2)), Rosemarie Müller, Riitta Myller, Ria G.H.C. Oomen-Ruijten, Béatrice Patrie, Marit Paulsen, Frédérique Ries, Dagmar Roth-Behrendt, Yvonne Sandberg-Fries,Karin Scheele, Ursula Schleicher (for Emilia Franziska Müller), Inger Schörling, Renate Sommer (for Horst Schnellhardt), Bart Staes (for Alexander de Roo), Catherine Stihler, Nicole Thomas-Mauro, Kathleen Van Brempt and Phillip Whitehead.

The recommendation for second reading was tabled on 4 June 2003.

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the Council common position for adopting a European Parliament and Council regulation on traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (15798/1/2002 – C5-0131/2003 – 2001/0180(COD))

(Codecision procedure: second reading)

The European Parliament,

– having regard to the Council common position (15798/1/2002 – C5-0131/2003),

– having regard to its position at first reading[1] on the Commission proposal to Parliament and the Council (COM(2001) 182[2]),

– having regard to the Commission's amended proposal (COM(2002) 515[3]),

– 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 (A5-0204/2003),

1. Amends the common position as follows;

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

[1] TA (2002) 0353.
[2] OJ C 304 E, 30.10.2001, p. 327.
[3] OJ C 331 E, 31.12.2002, p. 308.

Council common position	Amendments by Parliament

Amendment 1
TITLE

Regulation (EC) No /2003 of the European Parliament and of the Council of ... concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms ***and amending Directive 2001/18/EC***	Regulation (EC) No /2003 of the European Parliament and of the Council of ... concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms

(Reflects Amendment 51 at first reading, adopted on 3 July 2003.)

Justification

Even if the Regulation will amend Directive 2001/18/EC, there is obviously no need to mention this in the - already lengthy - title of the Regulation.

Amendment 2
Recital 10

(10) Certain traces of GMOs in products may be adventitious or technically unavoidable. Such presence of GMOs should therefore not trigger labelling and traceability requirements. It is therefore necessary to fix thresholds for the adventitious or technically unavoidable presence of material ***consisting, containing or*** produced from GMOs both when the marketing of such GMOs is authorised in the Community and when their adventitious or technically unavoidable presence is tolerated by virtue of Article ***47*** of Regulation (EC) No .../2003. It is also appropriate to provide that, when the combined level of adventitious or technically unavoidable presence of the above material in a food or	(10) Certain traces of ***materials produced from*** GMOs in products may be adventitious or technically unavoidable. Such presence of ***materials produced from*** GMOs should therefore not trigger labelling and traceability requirements. It is therefore necessary to fix thresholds for the adventitious or technically unavoidable presence of material produced from GMOs when the marketing of such materials is authorised in the Community and when their adventitious or technically unavoidable presence is tolerated by virtue of Article ***12 or 24*** of Regulation (EC) No .../2003. It is also appropriate to provide that, when the combined level of adventitious or technically unavoidable presence of the

feed or in one of its components is higher than the aforesaid labelling thresholds, such presence should be indicated in accordance with the provisions of this Regulation and detailed provisions to be adopted for its implementation.	above material in a food or feed or in one of its components is higher than the aforesaid labelling thresholds, such presence should be indicated in accordance with the provisions of this Regulation and detailed provisions to be adopted for its implementation.

(Amends new text and reflects Amendments 26 and 55.)

Justification

If live GMOs are present in products they should be labelled irrespective of whether their presence is adventitious or technically unavoidable. The reference to Article 47 of the GM food/feed Regulation should be deleted as there should be no threshold for unauthorised GMOs.

Amendment 3
Recital 12 a (new)

(12a) The Commission must submit a report to the European Parliament and the Council on the implementation of this regulation and specifically on the effectiveness of the rules on traceability and labelling.

Justification

This amendment is not intended to change the content of the provisions of the regulation on traceability and labelling. On the basis of the innovative new elements introduced into the Council's common position in connection with the reinforcing of checks and the obligation on the Commission to draw up a report – see the insertion by new article 12 of the common position of a review clause for this regulation – the Commission must also be asked to examine the issue of the effectiveness of the rules on the labelling and traceability of GMOs and the traceability of food and feed produced from genetically modified organisms, detectability of genetically modified DNA or genetically modified protein in products produced from GMOs, using scientific methods. The aim is to promote further consumer protection and to put in place safety mechanisms in order to prevent deception, fraud, distortion of competition and obstruction of the market, in the event that it is impossible to use analytical methods to establish whether a product is derived from GMOs, since that product

is identical in every respect to the corresponding conventional product.

Amendment 4
Recital 10 b (new)

(10b) It is necessary to ensure that consumers are fully and reliably informed about GMOs and the products, foods and feed produced therefrom, so as to allow them to make an informed choice of product

Justification

Reinstates parts of amendments 6 and 35 from the European Parliament's first reading which strengthen the promotion of information and the provision of data to consumers on GMOs and their products. It should also be pointed out that the text of this amendment was recently adopted in two non-legislative European Parliament resolutions, concerning consumer policy strategy – see P5_TA-PROV (2003)0100, report by P Whitehead, A5-0023/2003 – and 'life sciences and biotechnology – a strategy for Europe' – see P5_TA-PROV (2002)0566, report by E M Damião, A5-0359/2002.

Amendment 5
Article 1

This Regulation provides a framework for the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objectives ***of facilitating accurate labelling, monitoring the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products.***	This Regulation provides a framework for the traceability of products consisting of or containing genetically modified organisms (GMOs), and food and feed produced from GMOs, with the objectives of***, in accordance with the precautionary principle:***
	- facilitating accurate labelling,

- 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,

- giving consumers the right of free and independent choice,

- allowing effective measures to be introduced to prevent the unintended presence of GMOs or products thereof in other food or feed, and

- enabling such products to be withdrawn immediately, rapidly and totally in the event that they should prove harmful or hazardous.

Justification

This amendment takes up Amendment 6 adopted at first reading.

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 6
Article 3, paragraph 10

(10) 'Placing on the market' means placing on the market as defined in the specific Community legislation under which the relevant product has been authorised; in other cases, it is defined as in Article 2(4) of Directive 2001/18/EC;	(10) "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 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms (1), including culture collections, shall not be regarded as placing on the market;*** ***(1) OJ L 117, 8.5.1990, p. 1 Directive as last amended by Decision 2001/204/EC (OJ L 73, 15.3.2001, p.32)***

(Reflects Amendment 12 at first reading, adopted on 3 July 2002.)

Justification

There should be one uniform definition of "placing on the market" for all GMOs and food and feed containing, consisting of or produced from GMOs.

Amendment 7
Article 4, paragraph 3

3. In the case of products consisting of or containing mixtures of GMOs to be used	***Deleted***

only and directly as food or feed or for processing, the information referred to in paragraph 1(b) may be replaced by a declaration of use by the operator, accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

(Reflects Amendment 16 at first reading, adopted on 3 July 2002.)

Justification

Given the Council's decision to reject the "may-contain" label for GMOs to be used only and directly as food or feed or for processing, originally proposed by the Commission, there is no reason to keep this paragraph, as these GMOs will now be treated just like any other product falling under Art. 4, paragraphs 1 and 2.

Amendment 8
Article 4, paragraph 4

4. Without prejudice to Article 6, operators shall have in place systems and procedures to allow the holding of information specified in paragraphs (1), (2) and (3) and the identification, for a period of ***five*** years from each transaction, of the operator by whom and the operator to whom the products referred to in paragraph 1 have been made available.	4. Without prejudice to Article 6, operators shall have in place systems and ***standardised*** procedures to allow the holding of information specified in paragraphs (1), (2) and (3) and the identification, for a period of ***ten*** years from each transaction, of the operator by whom and the operator to whom the products referred to in paragraph 1 have been made available.

(Reflects Amendments 17 and 50 at first reading adopted on 3 July 2003.)

Justification

Given the fact that marketing authorisations for GMOs (see Article 15(4) of Directive 2001/18/EC) and in the future also for GM food and feed (see Article 7(5) and 19(5) of 5204/3/2003) shall be valid for ten years, it seems appropriate to extend the time period during which the information has to be available to ten years.

Amendment 9
Article 4, paragraph 7

7. Paragraphs 1 to 6 shall not apply to traces of GMOs in products in a proportion no higher than the thresholds established in accordance with Article 21(2) or (3) of Directive 2001/18/EC and in other specific Community legislation, provided that these traces of GMOs are adventitious or technically unavoidable.	***Deleted***

(Proposes to delete new text.)

Justification

The provision would allow to set thresholds for the traceability of GMOs in comitology which is clearly not acceptable.

Amendment 10
Article 4, paragraph 8

8. Paragraphs 1 to 6 shall not apply to traces of GMOs in products intended for direct use as food, feed or for processing in a proportion no higher than the thresholds established for those ***GMOs*** in accordance with Articles 12, 24 ***or 47*** of Regulation (EC) No.../2003, provided that these traces of GMOs are adventitious or technically unavoidable.	8. Paragraphs 1 to 6 shall not apply to traces of ***materials produced from*** GMOs in products intended for direct use as food, feed or for processing in a proportion no higher than the thresholds established for those ***materials*** in accordance with Articles 12 ***or*** 24 of Regulation (EC) No.../2003, provided that these traces of GMOs are adventitious or technically unavoidable.

(Reflects Amendments 26 and 55 at first reading, adopted on 3 July 2003.)

Justification

Article 47 of the GM food/feed regulation would introduce a threshold for <u>unauthorised</u> GMOs. The reference should therefore be deleted. The traceability threshold should apply to materials produced from GMOs only.

Amendment 11
Article 5, paragraph 1 a (new)

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

(Reflects Amendment 21 at first reading adopted on 3 July 2003.)

Justification

Transmission of the unique code of the GMOs used is also relevant for products produced from GMOs.

Amendment 12
Article 5, paragraph 1 b (new)

1b. 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 product contains [ingredient] produced from GMOs" appear on a label and in connection with the display and the advertising of the product.

(Reflects Amendment 20 at first reading adopted on 3 July 2003.)

Justification

No difference in terms of traceability and labelling should be made between pre-packaged products containing or consisting of GMOs (see Art. 4(6) a) and pre-packaged products produced from GMOs.

Amendment 13
Article 5, paragraph 2

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

Justification

Reinstatement of amendments 17, 22 and 50 adopted at first reading. For reasons of safety and traceability, the information should be held for ten years. The introduction of standard procedures will also ensure effective and consistent storage of information and improve traceability.

Amendment 14
Article 5, paragraph 4

4. Paragraphs 1, 2 and 3 shall not apply to traces of GMOs in products for food and feed produced from GMOs in a proportion no higher than the thresholds established for those ***GMOs*** in accordance with Articles 12, 24 ***or 47*** of Regulation (EC) No.../2003, provided that these traces of GMOs are adventitious or technically unavoidable.	4. Paragraphs 1, 2 and 3 shall not apply to traces of ***materials produced from*** GMOs in products for food and feed produced from GMOs in a proportion no higher than the thresholds established for those ***materials*** in accordance with Articles 12 ***or*** 24 of Regulation (EC) No.../2003, provided that these traces of GMOs are adventitious or technically unavoidable.

(Reflects Amendments 26 and 55 at first reading adopted on 3 July 2003.)

Justification

Article 47 of the GM food/feed regulation would introduce a threshold for unauthorised GMOs. The reference should therefore be deleted. The traceability threshold should apply to

materials produced from GMOs only.

Amendment 15
Article 7

Directive 2001/18/EC is hereby amended as follows:	***Deleted***
1) Article 4(6) shall be deleted	
2) The following paragraph shall be added to Article 21:	
'3. For products intended for direct processing, paragraph 1 shall not apply to traces of authorised GMOs in a proportion no higher than 0,9% or lower thresholds established under the provisions of Article 30(2), provided that these traces are adventitious or technically unavoidable.'	

(Reflects Amendment 28 at first reading adopted on 3 July 2003 (point 1) and proposes deletion of new text.)

Justification

Directive 2001/18/EC requires traceability of GMOs regardless of the purpose for which they shall be used. The proposed regulation, however, requires traceability only of 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.

Point 2 should be deleted as it deals with processed non-food/feed GM products which do not fall under the scope of the traceability regulation.

Amendment 16
ARTICLE 7 A (new)
Article 26 a (new) (Directive 2001/18/EC)

	Directive 2001/18/EC is modified as follows:
	New Article 26a is added
	Co-existence
	1. Member States shall take all measures necessary to ensure that at all stages of the

placing on the market of the GMO that the notifier or any person selling the product, take appropriate measures to prevent the unintended presence of the GMO or part thereof in other products.

2. The Commission shall gather and coordinate information based on studies at Community and national level and observe the developments regarding co-existence in Member States, and based on this information develop guidelines on the co-existence of genetically modified, conventional and organic crops.

Justification

Given the Commission's decision of 5 March 2003, that "an approach based on subsidiarity could provide a fast and efficient solution" to the problem of co-existence, the proposed amendment adjusts amendments 43 and 88 adopted in first reading to this new situation. As decided by the Commission, Member States shall have the responsibility to ensure co-existence. The subsidiarity-based approach implies, however, that the amendment should be included in a Directive rather than in a Regulation.

Amendment 17
Article 9, paragraph 2

2. Prior to the application of Articles 1 to 7, the Commission, in accordance with the procedure referred to in Article 10(***3***), shall develop technical guidance on sampling and testing to facilitate a coordinated approach for the implementation of paragraph 1 of this Article. In developing the above technical guidance, the Commission shall take account of the work of national competent authorities, the committee referred to in Article 58(1) of Regulation (EC) No 178/2002 and the Community Reference Laboratory established under Regulation (EC) No…/2003.	2. Prior to the application of Articles 1 to 7, the Commission, in accordance with the procedure referred to in Article 10(***2***), shall develop ***and publish*** technical guidance on sampling and testing to facilitate a coordinated approach for the implementation of paragraph 1 of this Article. In developing the above technical guidance, the Commission shall take account of the work of national competent authorities, the committee referred to in Article 58(1) of Regulation (EC) No 178/2002 and the Community Reference Laboratory established under Regulation (EC) No…/2003.

Justification

Partially reinstates amendment 30 from the European Parliament's first reading. The adoption of technical guidance on sampling, testing and methods should be published, contributing to a coordinated approach and their successful implementation.

Amendment 18
Article 9, paragraph 2 a (new)

2a. 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

Reinstatement of amendment 31 adopted at first reading. The Council has addressed the problem in recital 8 of the common position. It should, however, be incorporated into an article since effective monitoring can be ensured only with access to specific information concerning sequencing and references etc., which also applies to GMOs not authorised in the EU.

Amendment 19
Article 10, paragraph 3

3. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to	***Deleted***

the provisions of Article 8 thereof.

(Proposes to delete new text.)

Justification

The comitology procedure to be used should be the regulatory procedure, mentioned in Art. 10(2).

Amendment 20
Article 12

No later than ....*, the Commission shall forward to the European Parliament and to the Council a report on the implementation of this Regulation, in particular with regard to Article 4(3) and, where appropriate, bring forward a proposal	***Member States shall send the Commission in 2005 and thereafter every three years, a report on their experience with inspections and other control measures referred to in Article 9. The Commission shall send to the European Parliament and the Council , in 2006 and thereafter every three years, a summary report on the experience of the Member States.***

(Proposes to amend next text.)

Justification

Member States should report regularly on their experience with inspections and other control measures and on the basis of these reports the Commission should report to Parliament and the Council.

Amendment 21
Article 13, paragraph 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	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 Union of the measure referred to in Article 8(a)**.**	Official Journal of the European Union of the measure referred to in Article 8(a) ***and must be consistent with Directive 2001/18/EC. Before the date of application of the measure referred to in Article 8(a), no GMOs, or food or feed products consisting of, containing or produced from GMOs, shall be approved.***

Justification

Reinstatement of amendments 32 and 33 adopted at first reading. No new products can be approved for marketing before the new rules are adopted and implemented.

EXPLANATORY STATEMENT

1. Background and comments on the procedure

On 3 September 2001, the Commission submitted to the European Parliament and the Council a proposal for a regulation on the **traceability** and **labelling** of genetically modified organisms and the **traceability** of food and feed products produced from genetically modified organisms, also amending Directive 2001/18/EC (COM(2001) 182 – C5-0380/2001 – 2001/0180 (COD))[1]. The Economic and Social Committee and the Committee of the Regions adopted opinions on the Commission's proposal on 21 March and 16 May 2002[2].

At the plenary session on 3 July 2002, the European Parliament adopted a legislative resolution at first reading[3], adopting 30 amendments to the Commission's proposal. Following this and prior to the publication of the Council's common position, on 16 September 2002 the Commission submitted an amended proposal under Article 250(2) of the Treaty[4].

On 17 March 2003, having reached a political agreement at the meeting held on 9 December 2002, the Council adopted, under Article 251(2) a common position by qualified majority without the support of the delegations of Denmark, Luxembourg, the Netherlands or the United Kingdom. Three statements were attached to the proceedings of the Council as annexes: (1) a statement by the Commission and the Council on the link between this regulation and the regulation on genetically modified food and feed, (2) a statement by the Netherlands and (3) a statement by the United Kingdom delegation, regarding aspects relating to the application of the regulation and the effectiveness of the measures proposed[5].

The Commission, taking into account the European Parliament's amendments at first reading and the Council's common position, published a communication under Article 251(2), second subparagraph, to provide Parliament with full information on its position[6].

2. Assessment of the Council's common position

The Council's common position reinforces the Commission's proposal, particularly those provisions designed to ensure that the regulation is implemented successfully. Thus the Council attempts, mainly on the basis of **traceability**, to ensure that the market will function smoothly and endeavours to achieve a high level of consumer protection in cases where it is not possible to use analytical methods to distinguish between conventional products and products produced from GMOs, in the following ways:

- introduction of systems to recognise the identity of GMOs by assigning a 'unique identifier' and procedures which ensure that it is possible, at all stages of operations, to verify who placed the products on the market and where the products come from;

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[1] OJ C 304 E, 30.10.2001, p. 327.
[2] OJ C 125, 27.5.2002, p. 69 and OJ C 278, 14.11.2002, p. 31.
[3] P5_TA-PROV (2002) 0353, by 305 votes to 207, with 40 abstentions.
[4] OJ C 331 E, 31.12.2002, p. 308.
[5] Council document 6903/03 ADD 1.
[6] SEC (2003) 362 final, 25.3.2003.

- a requirement for undertakings to transmit information on the 'identity' of the product, i.e. to state whether a product 'is produced from GMOs' in the case of a product which is produced from GMOs;

- a requirement for undertakings to retain additional information for at least five years and to make it available to the competent authorities on request.

Acknowledging in part the concept of **detectability** in the regulation's sphere of application and the monitoring measures (see 'detection' in recitals 5 and 8 of the common position), the Council has strengthened the provisions on compliance with the regulation, by including, for example, the content of amendment 47 on the work of the Community Reference Laboratory, sample checks and testing (qualitative and quantitative) in inspection and control measures and measures concerning the holding of products (see Article 9 of the common position).

Another significant innovation in the common position is the introduction of a new article bringing in a review clause for the regulation on the basis of a report drafted by the Commission, within two years of the regulation's entry into force, on its implementation and with particular reference to the successful implementation of the provisions on the traceability of products which consist of GMOs or contain GMOs (see Article 12 of the common position).

Certain other elements complement the Commission's proposal, such as the exemptions to the traceability and labelling system, on the one hand for products intended for direct processing with a maximum level of 0.9% of traces of authorised GMOs in respect of the adventitious or technically unavoidable presence of traces of GMOs (see Article 7, amending Directive 2001/18/EC), and on the other hand a reference to the maximum levels (see Article 4(7), 4(8) and 5(4)) set in the regulation on genetically modified food and feed (0.9% for GMOs authorised in the EU and 0.5% for those which are not permitted but have a favourable risk assessment).

With regard to the **fate of Parliament's amendments** at first reading, it should be noted that of a total of 30 amendments, the Council has incorporated into its common position 15 amendments in whole, in part or in spirit. The five amendments which were adopted verbatim concern the definitions of 'GMOs' (amendment 9), the 'operator' (amendment 10), 'food' (amendment 11) and 'pre-packaged' (amendment 13), and the improvement of the provision on labelling in Article 4(6) of the regulation (amendment 14). The remaining 10 amendments incorporated in part or in spirit are concerned with the precautionary principle (amendment 2), the protection of public health and ecosystems (amendment 6), the provision of information to operators and consumers (amendment 35), the exemption of genetically modified micro-organisms (GMMs) from the regulation's scope (amendment 12), the receipt of pre-packaged products (amendment 24), sample checks and testing (quantitative and qualitative) (amendment 29), the use of comitology for guidance on sampling and testing, but without publication of such guidance (amendment 30), registers with information on GMOs (amendment 31) and the work of the Community Reference Laboratory (amendment 47). With regard to good segregation practice (amendment 27) it was agreed that a declaration should be inserted into the proposal for a regulation on genetically modified food and feed.

15 amendments tabled by Parliament were not incorporated into the Council's common position, for reasons of legal coherence and legislative technique; clarity in technical

terminology; practicality, feasibility or enforceability; as well as avoidance of imposing excessive administrative burdens on operators and national authorities. These amendments relate to the deletion of the title (amendment 51), the threshold levels for the adventitious or technically unavoidable presence of GMOs or of traces of materials produced from GMOs (amendments 26, 52 and 55), mixtures of GMOs (amendment 16) and the standardisation of procedures for the identification of transactions (amendment 50), the doubling of the time for which information must be kept (amendments 17 and 22), derived products (amendment 20), the transmission of information on products which are produced from GMOs but do not contain GMOs (amendment 21), the coexistence of national and Community systems for traceability (amendment 28), entry into force (amendments 32 and 33), deletion of the term 'produced from GMOs' (amendment 39) and the application of comitology under Regulation 178/2002/EC (amendment 48).

The Council's common position incorporates, in fact, many of the European Parliament's amendments but leaves certain questions open.

3. Comments and proposals by the rapporteur

Since at voting at first reading there was a difference of opinions as to whether to vote for or against certain amendments, which resulted in a weak majority, I am only proposing in the draft recommendation for second reading certain changes which do not deal with substance of the provisions of the common position, in order to facilitate the obtaining of a qualified majority for its amendment.

In principle, from an analysis of the voting on the text which was adopted at first reading and the Council's common position, it is clear that the view which was expressed in the debate on the need to reinforce the **detectability** aspect of GMOs was incorporated, albeit only in part, in the provisions concerning the implementation of the regulation and the inspection and control measures, see Article 9 on **'the work of the Community Reference Laboratory'** (amendment 47), the introduction of **'sample checks and testing (quantitative and qualitative)'** (amendment 29) and the recitals 5 and 8 with the addition of the word '**detection'**.

Given, moreover, that the Council acknowledges that '*detectability as such is a phenomenon that depends on scientific facts and the availability of technical solutions'* and that *'it is therefore up to the Commission … to scrutinise and assess detectability and to suggest appropriate solutions'* (see reply to Parliamentary question H-0676/02), certain amendments to the recitals of the common position are being tabled which are designed to further **promote detectability** in addition to the provisions based on traceability, where the aim of the '*paper trail'* is to improve the capacity to implement the regulation. The aim is to promote further consumer protection and to put in place safety mechanisms in order to prevent deception, fraud, distortion of competition and obstruction of the market, in the event that it is impossible to use analytical methods to establish whether a product is derived from GMOs, since that product is identical in every respect to the corresponding conventional product.

At the same time, I suggest that the regulation's recitals should emphasise that the mechanisms of the internal market operate effectively when consumer protection policy is based on Community rules, the implementation of which can also be monitored by scientific and analytical methods which do not allow fraud, the misleading of consumers or distortion of

competition. Additionally, such an orientation enhances the chances of implementing the regulation world-wide, without creating barriers to trade. The text of the amendments suggested above was adopted recently in two non-legislative European Parliament resolutions concerning consumer policy strategy – see P5_TA-PROV (2003)0100, report by P Whitehead, A5-0023/2003 – and 'life sciences and biotechnology – a strategy for Europe' – see P5_TA-PROV (2002)0566, report by E M Damião, A5-0359/2002; consequently the Parliament's position should be identical and consistent on issues relating to GMOs.

Finally, I consider it useful to add the point regarding publication of the technical guidance on sampling (Article 9), testing and methods, since this improves transparency and contributes to a coordinated approach as well as to the successful implementation of the regulation.

In addition, I take the view that the swift adoption of this regulation, and of the regulation on genetically modified food and feed, will lead to the removal of the *de facto* moratorium on the approval of new GMOs and to the development of a strategy on life sciences and biotechnology, as described in the Council conclusions and roadmap[1]. The development of such a strategy is important for Europe which, it should be stressed, is lagging noticeably behind in the promising technology of the 21st century as compared with its competitors, with adverse results at all levels – economic, social and also environmental. I am putting forward, therefore, amendments which do not change the substance of the legislative text of the proposal for a regulation and which improve the law and strengthen certain aspects to promote compliance with the regulation's provisions.

[1] OJ C 39, 18.2.2003, p. 9.