COMMON POSITION (EC) No 21/2003

adopted by the Council on 17 March 2003

with a view to adopting 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

(2003/C 113 E/02)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95(1) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

Having regard to the opinion of the Committee of the Regions [3],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [4],

Whereas:

(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 [5] 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.

(2) Differences between national laws, regulations and administrative provisions concerning traceability and labelling of GMOs as products or in products as well as traceability of food and feed produced from GMOs may hinder their free movement, creating conditions of unequal and unfair competition. A harmonised Community framework for traceability and labelling of GMOs should contribute to the effective functioning of the internal market. Directive 2001/18/EC should therefore be amended accordingly.

(3) Traceability requirements for GMOs should facilitate both the withdrawal of products where unforeseen adverse effects on human health, animal health or the environment, including ecosystems, are established, and the targeting of monitoring to examine potential effects on, in particular, the environment. Traceability should also facilitate the implementation of risk management measures in accordance with the precautionary principle.

(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 .../2003 of the European Parliament and of the Council of ... on genetically modified food and feed [6], so as to ensure that accurate information is available to operators and consumers to enable them to exercise their freedom of choice in an effective manner as well as to enable control and verification of labelling claims. 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.

(5) The transmission and holding of information that products contain or consist of GMOs, and the unique codes for those GMOs, at each stage of their placing on the market provide the basis for appropriate traceability and labelling for GMOs. The codes may be used to access specific information on GMOs from a register, and to facilitate their identification, detection and monitoring in accordance with Directive 2001/18/EC.

(6) The transmission and holding of information that food and feed have been produced from GMOs also provide the basis for the appropriate traceability of products produced from GMOs.

(7) The Community legislation concerning GMOs as or in feed should also apply to feed intended for animals which are not destined for food production.

(8) Guidance on sampling and detection should be developed in order to facilitate a coordinated approach for control and inspection and provide legal certainty for operators. Account should be taken of registers containing information on genetic modifications in GMOs established by the Commission in accordance with Article 31(2) of Directive 2001/18/EC and Article 29 of Regulation (EC) No .../2003.

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[1] OJ C 304 E, 30.10.2001, p. 327 and OJ C 331 E, 31.12.2002, p. 308.

[2] OJ C 125, 27.5.2002, p. 69.

[3] OJ C 278, 14.11.2002, p. 31.

[4] Opinion of the European Parliament of 3 July 2002 (not yet published in the Official Journal), Council Common Position of 17 March 2003 and Decision of the European Parliament of ... (not yet published in the Official Journal).

[5] OJ L 106, 17.4.2001, p. 1.

[6] OJ L ...

(9) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation.

(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 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.

(11) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1].

(12) Systems for the development and assignment of unique identifiers for GMOs should be established before the measures relating to traceability and labelling can be applied.

(13) This Regulation respects the fundamental rights and observes the principles recognised in particular by the Charter of Fundamental Rights of the European Union,

HAVE ADOPTED THIS REGULATION:

Article 1

Objectives

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.

[1] OJ L 184, 17.7.1999, p. 23.

Article 2

Scope

1. This Regulation shall apply, at all stages of the placing on the market, to:

(a) products consisting of, or containing, GMOs, placed on the market in accordance with Community legislation;

(b) food produced from GMOs, placed on the market in accordance with Community legislation;

(c) feed produced from GMOs, placed on the market in accordance with Community legislation.

2. This Regulation shall not apply to medicinal products for human and veterinary use authorised under Regulation (EEC) No 2309/93 [2].

Article 3

Definitions

For the purpose of this Regulation:

1. 'Genetically modified organism' or 'GMO' 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 IB to Directive 2001/18/EC;

2. 'Produced from GMOs' means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;

3. 'Traceability' means the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains;

4. 'Unique identifier' means a simple numeric or alpha-numeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO;

5. 'Operator' means a natural or legal person who places a product on the market or who receives a product that has been placed on the market in the Community, either from a Member State or from a third country, at any stage of the production and distribution chain, but does not include the final consumer;

[2] Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal products (OJ L 214, 24.8.1993, p. 1). Regulation as amended by Commission Regulation (EC) No 649/98 (OJ L 88, 24.3.1998, p. 7).

6. 'Final consumer' means the ultimate consumer who will not use the product as part of any business operation or activity;

7. 'Food' means food as defined in Article 2 of Regulation (EC) No 178/2002 [1];

8. 'Ingredient' means ingredient as referred to in Article 6(4) of Directive 2000/13/EC [2];

9. 'Feed' means feed as defined in Article 3(4) of Regulation (EC) No 178/2002;

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;

11. 'The first stage of the placing on the market of a product' means the initial transaction in the production and distribution chains, where a product is made available to a third party;

12. 'Pre-packaged product' means any single item offered 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, provided that the contents cannot be altered without opening or changing the packaging.

Article 4

Traceability and labelling requirements for products consisting of or containing GMOs

A. **Traceability**

1. 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 in writing to the operator receiving the product:

(a) that it contains or consists of GMOs;

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

2. At all subsequent stages of the placing on the market of products referred to in paragraph 1, operators shall ensure that the information received in accordance with paragraph 1 is transmitted in writing to the operators receiving the products.

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

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.

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

B. **Labelling**

6. For products consisting of or containing GMOs, operators shall ensure that:

(a) for pre-packaged products consisting of, or containing GMOs, the words 'This product contains genetically modified organisms' or 'This product contains genetically modified (name of organism(s))' appear on a label;

(b) for non-pre-packaged products offered to the final consumer the words 'This product contains genetically modified organisms' or 'This product contains genetically modified (name of organism(s))' shall appear on, or in connection with, the display of the product.

This paragraph shall be without prejudice to other specific requirements in Community legislation.

C. **Exemptions**

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.

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[1] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

[2] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p. 29). Directive as amended by Commission Directive 2001/101/EC (OJ L 310, 28.11.2001, p. 19).

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.

Article 5

Traceability requirements for products for food and feed produced from GMOs

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

(a) an indication of each of the food ingredients 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 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.

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

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.

Article 6

Exemptions

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

2. Paragraph 1 shall not apply to the first stage of placing on the market of a product or to primary manufacture or re-packaging of a product.

Article 7

Amendment of Directive 2001/18/EC

Directive 2001/18/EC is hereby amended as follows:

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.'

Article 8

Unique identifiers

In accordance with the procedure referred to in Article 10(2), the Commission shall:

(a) prior to the application of Articles 1 to 7 establish a system for development and assignment of unique identifiers to GMOs;

(b) adapt the system provided for in point (a), as appropriate.

In so doing, account shall be taken of developments in international fora.

Article 9

Inspection and control measures

1. Member States shall ensure that inspections and other control measures including sample checks and testing (qualitative and quantitative), as appropriate, are carried out to ensure compliance with this Regulation. Inspection and control measures may also include inspection and control regarding the holding of a product.

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.

Article 10

Committee

1. The Commission shall be assisted by the committee set up by Article 30 of Directive 2001/18/EC.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. The Committee shall adopt its rules of procedure.

Article 11

Penalties

Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission, not later than . . . (*) and shall notify it without delay of any subsequent amendment affecting them.

Article 12

Review clause

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.

Article 13

Entry into force

1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

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 Union* of the measure referred to in Article 8(a).

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, . . .

For the European Parliament

The President

For the Council

The President

(*) 180 days following the date of publication of this Regulation.

(**) Two years from the date of publication of this Regulation.

STATEMENT OF THE COUNCIL'S REASONS

I. INTRODUCTION

1. The Commission submitted to the Council on 21 August 2001 a **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.

2. The Economic and Social Committee adopted its **opinion** on 21 March 2002.

3. The Committee of the Regions adopted its **opinion** on 16 May 2002.

4. The European Parliament adopted its **opinion** on 3 July 2002.

5. The Commission submitted to the Council on 16 September 2002 an **amended proposal** on the above subject.

6. On 17 March 2003, the Council adopted its common position in accordance with Article 251(2) of the Treaty.

II. OBJECTIVE

The Regulation aims at the establishment of a traceability and labelling system for genetically modified organisms (GMOs) as or in products and of a traceability system for food and feed derived from GMOs. Such a system shall apply at all stages of the placing on the market, and it will facilitate:

— targeted monitoring of potential effects,

— control and verification of labelling claims,

— withdrawal of products, should an unforeseen risk to human health or the environment be established.

The traceability system involves the following elements:

— the establishment by the Commission (through a comitology procedure) of a system to specify the identity of GMOs by the assignment of a 'unique identifier', allowing the retrieval of information concerning its traits, characteristics and authorised transformation events,

— systems and procedures to identify the operators to whom and from whom products are made available,

— the transmission by operators of information concerning the identity of a product, i.e.

  (i) whether it contains GMOs as well as the 'unique identifiers' for the individual GMOs that the product contains, or

  (ii) that the product is 'produced from GMOs' in case of GMO-derived food and feed products,

— retention by operators of specified information for a period of five years, to be made available to competent authorities upon request,

— Commission guidance on sampling and testing methodology to facilitate a coordinated approach to inspections and controls.

Labelling requirements are foreseen for products consisting of or containing GMOs, complementary to the existing ones in Directive 2001/18/EC (on the deliberate release of GMOs) and to those foreseen by the Commission in its proposed Regulation on genetically modified food and feed.

III. ANALYSIS OF THE COMMON POSITION

1. General

The main issues of the Regulation are requirements for traceability and labelling of products that consist of or contain GMOs (Article 4), and provisions for traceability of products that are produced from GMOs but do not contain GMOs themselves (Article 5). In this respect, as well as with regard to the scope of the Regulation, the Council fully accepts the Commission proposal.

Exemptions from the traceability and labelling scheme shall be allowed for the adventitious or technically unavoidable presence of traces of GMOs (Articles 4(7), 4(8) and 5(4)). The thresholds for these exemptions are introduced in this Regulation by way of reference to the respective Articles of the Regulation on genetically modified food and feed (as discussed in parallel with this Regulation), where the threshold level has been set at 0,9 % and can be lowered via a regulatory committee procedure, as well as by way of reference to Directive 2001/18/EC. While the exemptions generally cover only GMOs that have been authorised in the EU, the adventitious or technically unavoidable presence of such GMOs that have not been authorised but have benefited from a favourable risk evaluation will be permitted below a threshold level of 0,5 %, or lower as set by a regulatory committee procedure, for a transitional period of three years.

The Council has tightened the Commission proposal with regard to the information that has to accompany bulk shipments of products containing mixtures of GMOs (Article 4(3)) by allowing only for '. . . a list of the unique identifiers for all those GMOs that **have been used to constitute the mixture**', instead of '. . . unique codes for the GMOs that the product **may contain**' as originally proposed by the Commission.

Complementary to this provision, the Council has introduced a review clause (Article 12) in order to call on the Commission

— to present a report after the first experiences with the provision of Article 4(3) have been gained in practice, and

— where appropriate, to make proposals for changes to the Regulation.

While the Regulation generally covers all stages of placing on the market of the products, the Council has filled a gap by introducing that inspection and control measures can also target the holding of a product.

The Commission has accepted the common position agreed by the Council.

2. European Parliament amendments

In its plenary vote on 3 July 2002, the EP adopted 30 amendments to the proposal. While 15 of these amendments could not be accepted by the Council, another 15 have been incorporated either verbatim, in part or in spirit into the common position.

(a) *The 15 amendments that have been incorporated can be grouped as follows:*

Five amendments accepted verbatim:

Amendment 9 has been incorporated in the definition of 'Genetically modified organism' in Article 3.

Amendment 10 has been incorporated in the definition of 'Operator' in Article 3.

Amendment 11 has been taken on board in the definition of 'Food' in Article 3.

Amendment 13: 'to the ultimate user' has been deleted from the definition of 'Pre-packaged' in Article 3.

Amendment 14: an improved provision for labelling as proposed in this amendment has been incorporated in Article 4(6).

10 amendments accepted in part or in spirit:

Amendment 2: the reference to the precautionary principle has been incorporated in Recital 3, and Article 1 now refers to appropriate risk management measures.

Amendment 6: several aspects of this long amendment have been taken up in Article 1 (reference to health) and Recital 3 (references to the precautionary principle, to the protection of human and animal health, and to the protection of ecosystems).

Other issues mentioned in the amendment are not regarded as appropriate for consideration in the Regulation.

Amendment 12 has been, in principle, incorporated in the definition of 'Placing on the market' in Article 3 by way of referring to Article 2(4) of Directive 2001/18/EC. However, for reasons of consistency, the Council gives priority to definitions, in the event that they exist, in the specific Community legislation under which the relevant product has been authorised.

Amendment 24: the spirit of this amendment has been taken on board by clarifying the exemption in Article 6 through the addition of the sentence *'This Article does not apply to the first stage of placing on the market of a product or to primary manufacture or re-packing of a product.'*, as contained in the amended Commission proposal.

Amendment 27: with regard to 'good segregation practice', the Council has agreed upon a declaration in connection with the Regulation on genetically modified food and feed. The declaration was added to the minutes of the Agriculture/Fisheries Council of 28/29 November 2002 and reads as follows:

'The Council invites the Member States to encourage and contribute to the drawing up of ***guides in particular on good segregation practice*** *to be applied by food and feed operators in order to minimise the adventitious or technically unavoidable presence of genetically modified material in food and feed.'*

Amendment 29: the reference to 'sample checks and testing (quantitative and qualitative)' has been incorporated in Article 9(1). Mentioning 'risk assessment' is not deemed appropriate in this respect, as inspection and control rather constitute risk management measures.

Amendment 30 has been taken into account in part in Article 9(2). The regulatory committee procedure, however, has been replaced by an advisory committee procedure and the Council prefers not to include an explicit provision for publishing the technical guidance to be developed by the Commission.

Amendment 31: a reference to existing and future registers containing information on GMOs has been included in Recital 8.

Amendment 35: the spirit of this amendment has been integrated into Recital 4: *'. . . so as to ensure that accurate information is available to operators and consumers . . .'*.

Amendment 47 has been completely incorporated in Article 9(2) with the only exception that reference is made to the work rather than to the rules of the Community Reference Laboratory.

(b) *The 15 amendments that have not been incorporated can be grouped as follows:*

Information accompanying mixtures of GMOs **('may contain', Amendment 16**): instead of deleting this provision, which would have costly and non-practicable consequences, the Council has considerably tightened the conditions by allowing a list of identifiers only for those GMOs that **have been used to constitute the mixture** (Article 4(3)).

Holding of all information relevant for traceability of GMOs and derived products for a period of ten years instead of five **(Amendments 17 and 22)**: the Council is of the opinion that the proposed doubling of the time period is of no added practical value, but also puts additional burden on operators and inspection authorities.

Amendment 20 has not been taken on board because additional labelling of products produced from GMOs (derived products) is not necessary to meet the objectives of the proposal.

Amendment 21: the transmission of information on the unique code of GMOs from which a product is made is not deemed necessary by the Council, as the products in question do not contain any GMOs. For the purpose of labelling products produced from GMOs (under the Regulation on genetically modified food and feed), it is sufficient to transmit the information that they are produced from GMOs, but it is not necessary to establish a detailed history and documentation of the origin of each product.

Thresholds for the adventitious or technically unavoidable presence of GMOs or of traces of materials produced from GMOs **(Amendments 26, 52 and 55)**: the provisions of these amendments are not appropriate in the framework of the traceability and labelling scheme that was proposed by the Commission and that has been in general accepted by the Council. Also, they cannot be accepted in order to keep consistency with Directive 2001/18/EC and the Regulation on genetically modified food and feed. Furthermore, the Council agrees with the arguments as outlined by the Commission in its amended proposal of 13 September 2002.

Deletion of Article 4(6) of Directive 2001/18/EC **(Amendments 28 and 51)**: Article 4(6) of Directive 2001/18/EC has to be deleted in order to avoid a dual system of national and Community systems for traceability. It is the firm intention of the Council to provide for a harmonised framework for all measures related to traceability of GMOs, as expressed also in Recital 2.

Entry into force **(Amendments 32 and 33)**: as the Council does not intend to delete Article 7, this Article may not be excluded from the provisions for entry into force.

Furthermore, the Council does not agree to link the authorisation procedure for GMOs with the establishment of the system of unique identifiers by the Commission, as contained in Article 8 of the Regulation.

Definition of 'Produced from GMOs' **(Amendment 39)**: the Council cannot accept this amendment for reasons of consistency with other legislation (Novel Foods Regulation (EC) No 258/97 and the proposed Regulation on genetically modified food and feed).

Reference to comitology **(Amendment 48)**: with regard to the scope of this Regulation, the Council deems most appropriate the committee established under horizontal Directive 2001/18/EC.

Standardisation of the procedures for the identification of transactions **(Amendment 50)**: the Council does not share the opinion of the EP that the procedures referred to in Article 4(4) need to be standardised at Community level. The choice of the procedure should be left to the Member States in order to allow them to apply existing systems.

3. **Important innovations introduced by the Council**

Apart from the innovations already described under III.1:

— thresholds for exemptions from traceability and labelling,

— information accompanying mixtures of GMOs,

— review clause,

— control and inspection also for the holding of products

and described under III.2 (EP amendments), the Council has introduced the following main innovations in the text of the Regulation:

— new recital 7, addressing feed for animals not destined for food production (pets),

— further detailing of recital 10, addressing the need for thresholds for the exemption of the adventitious or technically unavoidable presence of GMOs from the traceability and labelling rules,

— revision of the definitions (Article 3): elimination of the definitions of food/feed additives, (compound) feedingstuff, flavourings and feed materials and the inclusion of the definitions of 'Final consumer' and 'Ingredient',

— re-structuring of the Articles 4 to 6 that describe the traceability and labelling rules and the exemptions thereof,

— amendment of Directive 2001/18/EC by way of inclusion of a new Article 21(3), which provides for an exemption from labelling for GMOs intended for direct processing.

IV. **CONCLUSION**

Despite the fact that the Council is not able to accept all amendments adopted by the European Parliament, it considers that the common position coincides to a large extent with the concerns of the Parliament and it is in almost complete agreement with the Commission's amended proposal.

The common position represents a balanced approach between practicability and the concerns for the protection of health and environment, without compromising biosafety.

After the entry into force of Directive 2001/18/EC, this Regulation is another milestone in the legislation for the safe management of products originating from modern biotechnology.

With regard to the political relevance of this Regulation and also in the light of the de-facto moratorium on the authorisation of new GMOs being linked to its entry into force, the Council expresses its firm hopes that it will be possible to achieve an agreement soon.