COMMISSION OF THE EUROPEAN COMMUNITIES

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2001/0180 (COD)

Amended 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

(presented by the Commission pursuant to Article 250 (2) of the EC Treaty)

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1. BACKGROUND

Transmission of the Proposal to the Council and the European Parliament (COM(2001)182 final – 2001/0180(COD) in accordance with Article 95(1) of the Treaty - 20 August 2001

Opinion of the Economic and Social Committee	-	21 March 2002
Opinion of the Committee of the Regions	-	16 May 2002
Opinion of the European Parliament – first reading	-	3 July 2002

2. OBJECTIVE OF THE COMMISSION PROPOSAL

The Proposal lays down a Community framework for traceability and labelling of GMOs, as well as traceability of food and feed products produced from GMOs, at all stages of their placing on the market.

3. COMMISSION OPINION ON THE AMENDMENTS ADOPTED BY THE PARLIAMENT

3.1. Amendments accepted by the Commission

Amendments 11 and 13 concern the definitions for 'food' and 'pre-packaged' and provide helpful clarification.

3.2. Amendments accepted in part or principle by the Commission

Amendment 9 refers to Article 3(1) of the Proposal and exempts certain organisms from the definition of 'GMO' as per the exemption under Article 3(1) Directive 2001/18/EC. This is achieved via inclusion of '*with the exemption of certain organisms yielded by the techniques of genetic modification listed in Annex 1B of Directive 2001/18/EC'*. This is a helpful clarification and acceptable in principle provided the precise wording of the Directive is used ***'excluding organisms obtained through the techniques of genetic modification listed in Annex IB of Directive 2001/18/EC'***.

Amendment 10 refers to the definition of 'operator' under Article 3(5) of the Proposal and clarifies that a person handling products placed on the market in the Community could be '*either from a Member State of the EU or from a third country'*. The Commission considers that this additional wording is implicit in the original text but can accept the amendment in principle. Whilst the wording ***'either from a Member State of the EU or from a third***

country' can be included in the definition, it should be noted that Community requirements cannot be extended beyond the borders of the EU.

Amendment 12 refers to the definition of 'placing on the market' under Article 3(13) of the Proposal and in part, ensures further consistency with Directive 2001/18/EC. The amendment can be accepted provided that the full wording, rather than only a part, of the definition under the Directive is included. On this basis, the definition should read ***'placing on the market' means placing on the market as defined under Article 2(4) of Directive 2001/18/EC***. This removes the need for the full text of the definition.

Amendment 14, in terms of labelling under Article 4(1) of the Proposal, retains the wording provision of Directive 2001/18/EC for products containing GMOs but provides for an alternative in that the name of the crop or GMO can be included on the label. This does not detract in substance from the requirement of Directive 2001/18/EC but consistency should be ensured with other Community legislation, including the Proposal on GM food and feed. The Commission can accept this amendment in principle on the basis that it is without prejudice to other specific requirements in Community legislation. To increase clarity in the context of accepting this amendment, the wording of Article 4(5) is re-worded as follows. Paragraphs 1 to 4 are without prejudice to other specific ***labelling and traceability*** requirements in Community legislation.

Amendment 24 provides that operators who receive pre-packaged products have to retain the information specified in Articles 4 (2) and (3) and 5 (1). However, the obligation to retain this information is already provided for in Article 4 (2) and (3) and 5 (1) and is therefore already accepted by the Commission. The Commission can accept to clarify the exemption proposed in Article 6 (1), which aims to ease the administrative burdens of operators by adding the following wording. ***'This paragraph does not apply to the first stage of the placing on the market of a product or to primary manufacture or repackaging of a product'***. This takes into account the first part of amendment 24.

Amendment 29 adds additional wording to the standard wording for inspection and control measures under Article 9(1) of the Proposal. This is acceptable, in part, provided that the wording of the amendment '*and risk assessment on the basis of sample checks and testing (quantitative and qualitative)'* is replaced by ***'including sample checks and testing'***. Inspection and control constitute risk management measure, which should not be confused with risk assessment.

Amendment 30 refers to Article 9(2) of the Proposal and the involvement of Member States in the development of guidance. This is acceptable in part provided that the wording of the amendment '*in accordance with the procedure laid down in Article 10*' is replaced by ***'in close co-operation with Member States'***.

Amendment 31 introduces a new paragraph in Article 9 concerning further measures (registers) to be developed for the purpose of inspection and control. The establishment of registers to contain sequence information and reference material for GMOs is already provided for under Article 31.2 of Directive 2001/18/EC and Article 30 of the GM food and feed Proposal. It is not, therefore, necessary to include an Article to establish such a register(s) in this Proposal. This amendment can, however, be accepted in principle provided that its contents are transferred to recital 7 and are subject to the following re-wording. ***'Account should be taken of the register(s) containing information on genetic modifications in GMOs to be established by the Commission in accordance with Article 31(2) of Directive 2001/18/EC'.***

Amendment 35 refers to the need to ensure that consumers receive reliable information and in this context, introduces a new recital 1a. The content of the amendment is acceptable, in principle, given that the availability of information to the public is in line with one of the objectives of this Proposal and can include part of the text in Recital 4 as follows; 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 ***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 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.

Amendment 47 introduces a new paragraph in Article 9(2)(a) of the Proposal and refers to consultation of relevant bodies during the development of technical guidance. This is acceptable in part on the proviso that the wording 'take account' is not construed as legally binding and that it is not precluded that the Commission takes account of work in other relevant groups. This would, as a matter of course, include Member States and discussions with their national competent authorities. The following wording is, therefore acceptable. ***'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 laid down pursuant to Regulation (EC) No .../2002 [on genetically modified food and feed].***'

3.3. Amendments not accepted by the Commission

Amendments 2 and 6 make reference to the precautionary principle in the context of this Proposal, which cannot be accepted. The precautionary principle relates to the risk analysis of products and is accounted for as part of the approval process under the authorising legislation (Directive 2001/18/EC and Regulation 178/2002/EC). Any safety measures to protect human health and the environment arise directly from this authorising legislation. Traceability is not a 'safety measure' *per se* but can be used to **'facilitate'** the application of other measures, such as product withdrawals and monitoring, as a means to ensure safety. The precautionary principle cannot, therefore, be taken into account when implementing traceability requirements.

Amendment 16 is not acceptable as it removes the derogation concerning traceability requirements for products intended for direct use as food, feed or processing. The derogation allows operators to state that these products are intended for direct use as food, feed or processing and provide the unique codes of the GMOs that the product 'may contain'. The Commission believes that this derogation is essential for an operational traceability system for such products. Imposing further requirements for these products would be very difficult and burdensome for operators to implement. Whilst the identity (unique codes) of specific GMOs to be released into the environment for cultivation is essential given that they are capable of establishing and reproducing, this is not the case for GMOs intended for food, feed or processing, where any potential environmental risk is extremely limited. The Biosafety Protocol, similarly, does not include a requirement for full listing of GMOs intended for food, feed, or processing in bulk consignments for trans-boundary movement.

Amendments 17 and 22 extend the period for retention of information by operators from 5 to 10 years and cannot be accepted. Even if traceability were possible after 5 years, the benefits of this information would be minimal with no practical value. Extension of the time limit would also place an unnecessary burden both on operators and inspection authorities.

Amendment 20 includes additional labelling requirements for pre-packaged products produced from GMOs under a new Article 5(1)(a) and cannot be accepted. Article 5(1) already requires that this information is transmitted to the next operator in the chain and it is not necessary to impose labelling with the same information to meet the objectives of the Proposal.

Amendment 21 requires that the GMOs from which food and feed products are derived have to be precisely identified with provision of their unique codes and this cannot be accepted. The main objective of the Proposal as regards products produced from GMOs is to ensure accurate labelling (recital no. 4). It is not necessary to establish the detailed history and origin of individual GMOs, through a traceability system including the unique codes to provide for comprehensive labelling. For the purpose of providing appropriate information to the purchaser or consumer it is sufficient that the label documents that the product is produced from GMOs.

Amendment 27 refers to measures for co-existence and segregation, which cannot be accepted given that the objective of this Regulation is to trace products and not to avoid adventitious or technically unavoidable presence of GM material in food. The Commission has put forward an action concerning the issue of co-existence between different types of crops, including GM crops in the Communication on life sciences and biotechnology adopted in January 2002.

The Commission cannot accept amendment 28, which requires that the traceability provisions under Article 4(6) of Directive/2001/18/EC would remain in place rather than repealed when the Proposal enters into force. This would mean that national measures for traceability could proceed alongside the Community system for traceability under this Proposal, creating possible disruption of the internal market. Recital 2 specifically refers to the fact that a harmonised Community framework for traceability and labelling of GMOs should contribute to the effective functioning of the internal market and that Directive/2001/18/EC should be amended accordingly. The Commission cannot accept amendment 51 removing the wording 'and amending Directive 2001/18/EC' from the title in order to maintain the legal consistency of the Proposal.

Amendments 32 & 33 mean that no new products could be authorised prior to the entry into force of the system to assign unique codes under the Proposal and are not acceptable. The authorising legislation for new products provides for a comprehensive pre-market risk assessment. Products are only granted authorisation on the basis that they will not present a risk to human health or the environment. The requirement to assign unique codes to GMOs under this Proposal does not impinge on the approval procedure under the authorising legislation. The Commission is firmly against extending the conditions of authorisation to include formal adoption of the provisions of this Proposal.

Amendment 39, which removes part of the wording for the definition of 'produced from GMOs' is not acceptable. The Commission considers that the definition of 'produced from GMOs' needs to be the same in the GM food and feed proposal and in this proposal. Furthermore, the wording 'but not containing GMOs' is already enshrined in the Novel Foods Regulation (EC) 258/97, which has been in force for more than 5 years.

Amendment 48, which shifts assistance for the development of unique codes from the committee under Directive 2001/18/EC to that under Regulation (EC) No. 178/2002, cannot be accepted. The Proposal requires that unique codes shall be assigned to all GMOs, including seeds for cultivation, and not merely those intended for food, feed and processing. The Commission considers that the committee under the 'horizontal' Directive 2001/18/EC, which

contains the foundations for environmental risk assessment, is most appropriate for this purpose.

Amendment 50 introduces the word 'standardised' with regard to procedures for transmitting and retaining information to ensure traceability and is not acceptable. The Proposal specifically does not require standardised procedures to be used as a means to accommodate use of existing systems, where appropriate. Operators must be in a position to identify to whom and from whom products have been made available. The Commission considers that this does not hinge on use of standardised procedures.

Amendments 26, 52 and 55 either remove or restrict the possibility to establish thresholds to address the issue of adventitious presence and are not acceptable.

More than 50 million hectares of GM crops are grown in the world and adventitious or technically unavoidable presence of traces GMOs or GM materials in conventional products is inevitable and largely unavoidable. The Commission therefore agrees with the Parliament that a threshold should apply to traces of authorised GMOs and GM materials below which such products do not have to be labelled or traced. The possibility of establishing labelling thresholds for such traces of GMOs is already provided for in Directive 2001/18/EC and under the Novel Foods Regulation. It is, therefore, logical and consistent to provide for such traces of GMOs and GM material to be exempted from the labelling and traceability requirements of this Proposal.

However, the Commission also considers it necessary to provide thresholds for GMOs that have been scientifically assessed as without risk to human health or the environment but are pending approval under Community legislation. This is necessary because these GMOs have been approved in third countries and traces of such GMOs in imported commodities will be largely unavoidable. This issue will have to be addressed in order to avoid trade grinding to a halt. However, we need to acknowledge the fact that authorisation processes can take some time. On this basis, the Commission has suggested that a tolerance level should be introduced for such materials BUT only under certain stringent conditions that do not compromise safety. These thresholds would be limited to adventitious or technically unavoidable traces of GMOs or GM material that have been positively assessed by a Community scientific committee as without risk to human health or the environment and which is pending administrative approval under Community legislation.

The intention of the Commission proposal is to provide that products containing or consisting of traces of such GMOs and GM material below a threshold do not have to be traced. This possibility has been deleted by the above amendments. This will not only undermine the feasibility and practicability of the traceability and labelling requirements under the Proposal but also have major implications and restrictions for trade.

3.4. Amended Proposal

Having regard to Article 250, paragraph 2 of the EC Treaty, the Commission modifies its Proposal as indicated above.