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Communication from the Commission to the European Parliament pursuant to the second subparagraph of Article 251 (2) of the EC Treaty concerning the common position of the Council on the adoption of a Regulation of the European Parliament and of the Council on genetically modified food and feed

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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT pursuant to the second subparagraph of Article 251 (2) of the EC Treaty concerning the common position of the Council on the adoption of a Regulation of the European Parliament and of the Council on genetically modified food and feed

1- BACKGROUND

Date of transmission of the proposal to the EP and the Council (document COM(2001) 425 final - 2001/0173 COD): // 30 July 2001.

Date of the opinion of the Committee of the Regions: // 16 May 2002.

Date of the opinion of the European Economic and Social Committee: // 30 May 2002.

Date of the opinion of the European Parliament, first reading: // 3 July 2002.

Date of transmission of the amended proposal: // 9 October 2002.

Date of political agreement by the Council (qualified majority): // 28 November 2002.

Date of adoption by the Council of the common position: // 17 March 2003.

2- OBJECTIVE OF THE COMMISSION PROPOSAL

The objective of the proposal is to provide the basis for ensuring a high level of protection of human life and health, animal health, environment and consumer interest in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market.

The proposal lays down centralised Community procedures for the assessment, authorisation and supervision of genetically modified food and feed, as well as labelling requirements for these products.

3- COMMENTS ON THE COMMON POSITION

3.1. General remarks

The Commission accepted (as such, in principle, in part or subject to re-wording) 54 out of the 111 amendments adopted by the European Parliament at its first reading and revised its proposal consequently. All amendments of the European Parliament included in the Commission proposal have been taken into account, at least in part or subject to re-wording, in the common position.

The common position takes into account, in part and/or subject to re-wording, 17 other amendments of the European Parliament (amendments 25, 35, 37-was accepted only in part by the Commission, 39, 47, 52, 74, 81-was accepted only in part by the Commission, 84, 87, 92, 93, 98, 122, 162, 163 and 164), aiming to reach a compromise between the European

Parliament's opinion and the Commission's proposal mainly on the following issues: adventitious presence of GM material (as regards authorisation and labelling), public access to documents and involvement of the national competent authorities in the risk assessment process.

Additional changes have also been included in the common position as a result of discussions in the Council after the first reading of the European Parliament.

The common position takes the greatest possible account of the European Parliament's opinion and accommodates the specific concerns of most Member States, while maintaining all the essential elements of the Commission proposal. Key elements, such as the scope of the authorisation and labelling sections of the proposal as well as the centralisation of the risk assessment and authorisation procedure, are not affected.

3.2. Authorisation procedure and links with Directive 2001/18/EC

Further to the opinion of the European Parliament, the common position provides for more involvement of the Member States in the risk assessment and authorisation procedure.

European Parliament amendments taken into account in the Commission proposal and in the common position: 37, 81, 165.

Articles 5(2) and 17(2) of the common position provide that the Member States shall be informed without delay of the application and that this application shall be made available to them. Articles 6(4) and 18(4) (see also recital 33) of the common position provide that, in the case of GMOs or food/feed containing or consisting of GMOs, the national competent authorities designated under Directive 2001/18/EC shall have three months to give to the European Food Safety Authority (hereinafter "the Authority") their opinion on the environmental risk assessment. Paragraph 6 of the same Articles requires that these opinions be forwarded to all the Member States, the Commission and the applicant.

European Parliament amendments partly taken into account in the common position: 39, 84, 87.

Articles 6(3)(c) and 18(3)(c) (see also recital 34) of the common position require that the environmental risk assessment must be made by a national competent authority designated under Directive 2001/18/EC in the case of GMOs to be used as seeds or other plant propagating material. The Commission can accept this provision as a compromise with the European Parliament's opinion, considering that expertise at national level is more appropriate in respect of cultivation and that this will not affect the centralised nature of the procedure.

Additional changes incorporated in the common position:

- Articles 5(2) and 17(2) of the common position provide that the application shall be sent to the national competent authority of a Member State, which shall transmit it to the Authority.

- Articles 6(2) and 18(2) of the common position provide that national competent authorities may request the applicant, through the Authority, to provide supplementary information.

- Articles 6(5)(e) and 18(5)(e) of the common position lay down that the opinion of the Authority shall include, in the case of GMOs or food/feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas. This is in line with Article 19(3)(c) of Directive 2001/18/EC.

- Articles 7(8) and 19(8) provide that references made in Parts A and D of Directive 2001/18/EC to GMOs authorised under Part C of that Directive shall apply equally to GMOs authorised under the proposed Regulation. This is in accordance with Article 12 of Directive 2001/18/EC concerning sectoral legislation.

- Articles 7(1) and 19(1) of the common position no longer foresee derogations in the case of exceptionally complex cases from the obligation to submit a draft decision by the Commission within three months after receiving the opinion of the Authority.

- Articles 9(2), 10(3), 21(2) and 22(3) of the common position clarify that the risk assessment and authorisation procedure applies mutatis mutandis in case of modification, suspension and revocation of authorisations.

These changes can be accepted by the Commission as they do not affect the centralised Community procedure for the risk assessment (central role of the Authority) and for the authorisation (decision to be adopted by "comitology" procedure), nor do they modify the legal basis of the proposed Regulation.

3.3. Information requirements and public involvement in the authorisation procedure

The common position provides for strengthening of information requirements, taking into account the European Parliament's opinion.

European Parliament amendments taken into account in the Commission proposal and in the common position: 30, 38, 45, 55, 56, 57, 77, 82, 90, 101, 102, 103.

The common position includes a new specific Article on public access (Article 29), which provides for public accessibility of key documents such as the application for authorisation, supplementary information from the applicant and monitoring reports, excluding confidential information. This Article also refers to the application by the Authority and the Member States of the principles laid down in Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents.

Articles 5(3)(j), 6(5)(f), 17(3)(j) and 18(5)(f) of the common position require the availability and publication (at each stage of the procedure and in fine in the Register) of the place where the reference material of the authorised product can be accessed.

European Parliament amendments partly taken into account in the common position: 47, 52, 92, 98.

Articles 6(6) and 18(6) of the common position specify that the opinion of the Authority shall include the information on which it is based, in particular the opinions of the national competent authorities consulted. New Article 29 of the common position provides that the opinions of these competent authorities shall be made accessible to the public. The Commission agrees with this strengthening of transparency as regards the grounds for the opinion of the Authority.

Additional changes incorporated in the common position:

Article 30(5) of the common position provides that the use of the detection methods and the reproduction of the reference materials shall not be restricted by the exercise of intellectual property rights or otherwise. The Commission agrees that the use of the detection methods and reference materials of GM food and feed by competent authorities or operators is of paramount importance for control and monitoring purposes. The distribution of the control samples to the national reference laboratories, as provided for in the Annex to the common position, should also strengthen this possibility.

3.4. Role of the European Food Safety Authority ("the Authority")

European Parliament amendment taken into account in the common position: 93.

The common position no longer provides for the adoption by the Commission of a recommendation on the nature of the risk assessment to be performed by the Authority. The Commission can accept that this task is part of the Authority's competence, within the framework of the rules laid down in the proposed Regulation.

Additional changes incorporated in the common position: the common position brings small amendments to the distribution of tasks between the Authority, as risk assessor, and the Commission, as risk manager. Articles 8(1) and 20(1) provide for the notification of the existing products to the Commission instead of the Authority, Articles 9(1) and (3) and 21(1) and (3) make the Commission the interlocutor of the authorisation-holder in the context of supervision, Articles 11(1) and 23(1) require that the application for renewal of authorisation be sent to the Commission and Article 30(2) gives the Commission the competence to determine which information included in the application is confidential. The Commission agrees to consider these tasks as part of risk management rather than risk assessment and notes that the Authority and the Member States remain fully involved in the procedure concerned.

The common position also includes a new Article 36 providing for administrative review of the acts or failures to act of the Authority. The Commission agrees with this provision as it

constitutes a safeguard in case of acts/failures to act of the Authority producing legal effects.

3.5. Status of existing products

Additional changes incorporated in the common position: the common position (Articles 8 and 20) makes a distinction between the GM products already authorised under existing legislation (covered by the Commission proposal) and other GM products which have been lawfully placed on the Community market before the date of application of the Regulation. The second category of products will also be considered as existing products and be subject to the conditions laid down in the Articles concerned.

The Commission can accept to include this second category of products in the scope of the existing products regime and thus in the scope of the proposed Regulation, as it will enable better control and supervision of all GM food and feed existing on the Community market.

3.6. Community Reference Laboratory

European Parliament amendments taken into account in the Commission proposal and in the common position: 41, 44, 86, 89.

Articles 6(3)(d) and (5)(f), 18(3)(d) and (5)(f) of the common position make clear that the Community Reference Laboratory has to test and validate the method of detection in all cases before the Authority gives an opinion.

Additional changes incorporated in the common position: Article 32 of the common position provides that applicants for authorisation shall contribute to support the costs of the tasks of the Community Reference Laboratory and the European Network of GMO laboratories, subject to implementing rules to be adopted by "comitology" procedure (see also joint statement Council-Commission in annex to this Communication). The Commission agrees with this principle as the dedicated Community or national budget may not cover all costs of testing and validation of detection methods submitted by the applicant.

3.7. Adventitious presence of GM material in food and feed

The common position makes a compromise between the European Parliament's opinion and the Commission's proposal, in restricting the conditions for derogation to authorisation and to labelling laid down in the Commission's proposal in case of adventitious or technically unavoidable presence of GM material in food and feed.

3.7.1. Derogation to authorisation

European Parliament amendments partly taken into account in the common position: 25, 74, 122.

Additional changes incorporated in the common position:

New Article 47 of the common position includes the following restrictions to former Articles 5 and 18 of the Commission's proposal: transitional measure (application for three years) - maximum threshold of 0,5 % and lower thresholds in particular for GMOs sold directly to the final consumer - favourable Community scientific opinion on the GM material before the date of application of the Regulation - no rejection decision on the GM material - public availability of detection methods of the GM material. In addition, Article 47 provides for the adoption of implementing rules by "comitology" procedure and Article 48 of the common position makes explicit reference to review of the implementation of Article 47 no later than two years from the entry into force of the Regulation.

Amendment to Directive 2001/18/EC is adapted accordingly in Article 43 of the common position.

The Commission can accept these restrictions to the tolerance of the unauthorised GM material in food or feed the safety of which has been assessed in the Community and that has been recognised safe. The Commission prefers the original tolerance of 1% which would have had less interference with trade, but accepts the threshold of 0,5% retained in the common position in the context of an overall agreement and considering that the provision concerned will be reviewed (see also Commission statement in annex to this Communication).

3.7.2. Derogation to labelling

European Parliament amendments partly taken into account in the common position: 162, 163, 164.

Additional changes incorporated in the common position:

Articles 12(2)(3)(4) and 24(2)(3)(4) of the common position include the following restrictions or clarifications to the Commission's proposal: maximum threshold of 0,9% established in the Regulation - threshold to be calculated per component of the food or feed - possible lower thresholds in particular for food or feed containing or consisting of GMOs or in order to take into account advances in science and technology. In addition, Articles 14(1) and 26(1) of the common position provide for the possible adoption by "comitology" procedure of implementing rules on measures to be followed by the operators to comply with the labelling requirements.

The Commission can accept these changes as they make clearer already in the proposed Regulation what the basic rules are, but also allow implementing measures to help operators to comply with the rules. The threshold of 0,9% is very close to the threshold of 1% already applicable to the adventitious presence of GM material in food and should not have a major impact for commercial partners.

3.8. Labelling requirements

European Parliament amendments taken into account in the Commission proposal and in the common position: 70, 71, 110, 112, 123, 145, 146, 147.

Articles 13 and 25 of the common position bring precisions and clarifications to the labelling requirements for GM food and feed. Article 46(2) of the common position re-worded the provision on transitional measures for labelling: instead of laying down a general time limit for the application of these measures, it sets the criterion of start of the manufacturing process of the GM product before the date of application of the Regulation for the application of the new labelling requirements. This should make the labelling rules enforceable in practice.

Additional changes incorporated in the common position: Article 14(2) of the common position takes into account the specific situation of the labelling requirements applying to mass caterers providing food to the final consumer, through future adoption of implementing rules. This is supported by the Commission in order to ensure practicability of the labelling rules.

Article 27(2) of the Commission's proposal was deleted as amendments to the basic labelling rules for feed materials will be subject to a separate Commission proposal.

Article 27(3)(b) of the Commission's proposal was deleted as the transmission of the unique identifier relevant to GM feed falls within the scope of the proposal for a Regulation concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs.

3.9. Other

3.9.1. Precautionary principle

European Parliament's amendments 1 and 13 have been taken into account in Article 1 of the common position, referring more widely to the general principles laid down in Regulation (EC) No 178/2002, which include the application of the precautionary principle.

3.9.2. Concept of "risk"

European Parliament's amendment 23 has been taken into account in Articles 4(1)(a) and 16 (1)(a) of the common position, which replaces the "no risk" with a "no unacceptable risk" requirement, in line with the amended Commission proposal. A zero risk level can formally not be guaranteed, considering the definition of "risk" laid down in Regulation (EC) No 178/2002, which has been added in Article 2(1) of the common position. In accordance with the recent jurisprudence of the Court of First Instance of the E.C., it is incumbent on the risk manager to determine the level of acceptability of a risk on the basis of a risk assessment, taking also into account other factors legitimate to the matter under consideration and with regard to the objectives of the legislation concerned.

3.9.3. Emergency measures clause

European Parliament's amendments 117 and 118 aim at giving Member States the possibility to react quickly in case of emergency. Article 34 of the common position, in line with the Commission amended proposal, aligns this provision to the safeguard clause laid down in Articles 53 and 54 of Regulation (EC) No 178/2002, for consistency purpose in matter of food and feed safety. This gives the possibility to Member States to adopt interim protective measures under certain conditions.

3.9.4. Ethics groups

Article 33 of the common position concerning the consultation with the European Group on Ethics in Science and New Technologies adds the possibility to consult any other appropriate body the Commission might establish in order to obtain an opinion on ethical issues. This gives to the risk manager more possibilities and flexibility to receive opinions on particular ethical issues, before adopting a decision in the frame of the proposed Regulation.

3.9.5. Technical and editorial amendments, wording improvements and clarification

The common position brings a series of editorial changes, the majority of them resulting from European Parliament's amendments, on which the Commission agrees because they aim at improving the clarity and understanding of the text. These amendments in the common position include in particular:

- additions and precisions in the definitions, notably as regards the exclusion of contained use activities from the definition of "placing on the market" (Article 2), and precision of the scope of the definition of "feed" (recital 8);

- reference to the application of the general principles on imports (recital 43);

- reference to independent scientific studies and existing official sampling methods in the application for authorisation (Articles 5(3) and 17(3));

- clarification of the distinction between implementing rules and guidance concerning the application (Articles 5(7) and (8) and 17(7) and (8));

- precision of the scope of the supervision requirements (Articles 9(1) and 21(1));

- precision in the GM feed requirements (Article 16(1)(c));

- precisions in the transitional measures for requests and notifications (Article 46);

- formal adaptation of the wording of the provision on "comitology" procedure (Article 35);

- appropriate reference to Regulation (EC) No 178/2002 in various places of the text in relation with the tasks of the Authority;

- adaptation of the necessary amendments to other acts (Article 42) and updating of references to other acts (such as Directives 2002/53/EC and 2002/55/EC).

4- CONCLUSION

In the light of the above comments, the Commission supports the common position adopted by the Council by qualified majority.

5- COMMISSION STATEMENTS

The Commission statements and two joint statements made by the Council and the Commission are attached in annex to this Communication.

ANNEX

JOINT STATEMENTS COUNCIL-COMMISSION

AND COMMISSION STATEMENTS

Joint statement regarding Article 3:

"The Council and the Commission:

- agree that the status of food produced by fermentation using genetically modified micro-

organisms not present in the final product, needs to be clarified, at the latest in the context of the report to be presented by the Commission as foreseen in Article 46 [1] of the Regulation;

[1] Article 48 in the common position.

- note that the status of enzymes used as processing aids will be clarified in the context of the proposal which the Commission is currently elaborating to provide a regulatory framework for enzymes for food use."

Joint statement regarding Article 33 [2]:

[2] Article 32 in the common position.

"The Council and the Commission agree that due consideration shall be given to the specific case of biotechnology research originating in developing countries when drafting the implementing rules provided for in Article 33 ."

Commission statement:

"In its forthcoming proposal on control measures for food and feed, the Commission shall aim to ensure that these provisions, in particular for GMO food and feed, will be practical and enforceable. It shall also aim to ensure that the financial aspects of these control measures will not have a disproportionate effect on Member States and that they will be proportional to the intended objective."

Commission statement regarding Article 36 [3]:

[3] Article 35 in the common position.

"The Commission shall establish a new Section on "Genetically modified food and feed and environmental risk" of the Standing Committee on the Food Chain and Animal Health for the purpose of Article 36³ of the Regulation, and shall endeavour to facilitate the effective participation of appropriate expertise from the Member States in the work of the Section."

Commission statement regarding Article 45a [4]:

[4] Article 47 in the common position.

"In the context of the review foreseen in Article 46(1) [5], the Commission shall examine whether the application of Article 45a [6] has given reason for concern, or whether its expiration is likely to give reason for concern."

[5] Article 48(1) in the common position.

Haut