E U R O P E A N E C O N O M I C A R E A

S T A N D I N G C O M M I T T E E
O F T H E E F T A S T A T E S

1/00/W/162
7 November 2002
Brussels

SUBCOMMITTEE I ON THE FREE MOVEMENT OF GOODS

EEA EFTA COMMENTS ON THE PROPOSED REGULATION CONCERNING THE TRACEABILITY AND LABELLING OF GENETICALLY MODIFIED ORGANISMS[1] – COM (2001) 182 – 2001/0180(COD)

I EXECUTIVE SUMMARY

1. The EEA EFTA States welcome the proposed Regulation, which represents a major initiative designed to protect human and animal health, the environment and consumer interests. The proposed approach to introduce traceability and labelling requirements for genetically modified organisms (GMOs) and traceability of genetically modified (GM) food and feed in the entire food chain from farm to fork is supported. The introduction of a system for the development and assignment of unique codes to GMOs is particularly important for the operation of the traceability and labelling obligations. The EEA EFTA States are, however, concerned about the contamination thresholds, which trigger some of the exemptions and some possible lack of clarity between this proposal on the one hand, and the proposed Regulation on GM food and feed[2] and European Parliament and Council Directive 2001/18/EC on the deliberate release of GMOs into the environment, on the other hand.

II INTRODUCTION

2. On 10 April 2002, the EEA EFTA States submitted their Comments on the proposed Regulation on GM food and feed to the European Commission[3]. The Comments were at a later stage also submitted to the Council and to the rapporteur in the European Parliament. The Comments pointed out that there was some lack of clarity as regards the scope of the proposed Regulation and that a contamination threshold of 1% could, in certain instances, be too high, especially for living GMOs. These concerns are to some extent relevant also for the proposed Regulation on the traceability and labelling of GMOs.

---

[1] Proposal for a Regulation of the European Parliament and of the Council 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 (COM(2001) 182/ 2001/0180(COD)).
[2] COM(2001) 425 final/2001/0173 COD.
[3] SC I/L 17/02.

3. In the following analysis, the EEA EFTA States aim to present some views on more specific aspects of the proposal.

III COMMENTS ON SPECIFIC ASPECTS OF THE PROPOSED REGULATION

3.1 Scope

4. The proposed Regulation is closely connected to the proposed Regulation on GM food and feed. In the previous EEA EFTA Comments on the proposal for a Regulation on GM food and feed, the EEA EFTA States expressed the opinion that the scope of exclusion of products *"produced with a* GMO*"*, which may include GM enzymes and animal feed with GM feed or treated with GM medicinal products, should be clearly defined in the definition of the term *"produced from GMOs"* in the Regulation itself and not only in the explanatory memorandum. The same clarification should be made in Articles 2 and 3 of this proposal, possibly by means of a reference to the definition in the Regulation on GM food and feed.

5. Furthermore, it was pointed out that the proposed regulations were unclear, particularly regarding the application of the labelling requirements on GMOs for food and feed production, i.e., bulk quantities, which should be looked into more extensively. The EEA EFTA States consider it important to secure a comprehensive traceability and labelling regime, which covers products consisting of, containing or produced from GMOs, whether pre-packaged or not. However, the EEA EFTA States are of the opinion that the above mentioned concern would be safeguarded if the obligation for operators to ensure the transmission of information that a product consists of or contains GMOs, could be interpreted in such a way as to also cover products to be used for food and feed production.

3.2 Adventitious or technically unavoidable presence of genetically modified material

6. As pointed out in the the previous EEA EFTA Comments on GM food and feed, the EEA EFTA States are of the opinion that a threshold of 1% for the technically unavoidable presence of GM material could, in certain instances, be too high, especially for living GMOs. The EEA EFTA States also advocated the need for the inclusion in the Regulation of a possibility to reconsider the acceptance of the adventitious material if the relevant GM material is denied authorisation as a result of reasoned objections from Member States, which could be based upon other relevant aspects than risk.

7. In Article 6(3) and (4) of the proposed Regulation on the traceability and labelling of GMOs, the same thresholds and risk assessment bases are proposed for the triggering of the traceability and labelling requirements. The EEA EFTA States are concerned that the proposed threshold could be too high also in relation to these provisions. An extensive use of 1% risk assessed material while the authorisation process is pending and without traceability and labelling requirements could cause problems with regard to consumer confidence in foodstuffs in general. The EEA

EFTA States are of the opinion that a presence of 1% GM material could in most cases be technically avoidable, and that a threshold of 0.5 % or lower would, therefore, be more appropriate both in view of health and the environment and from a technical point of view. Furthermore, if the possibility to reconsider the acceptance of the adventitious material mentioned above is introduced, traceability requirements would be a prerequisite for the possibility to take the actions deemed necessary depending on the product concerned and the reasons for denial of authorisation.

8. Furthermore, the EEA EFTA States are of the opinion that a reduced threshold for the adventitious and technically unavoidable presence of GM material in the proposed regulations should also result in reduced thresholds in the proposed Commission Directive amending Council Directives 66/400-403/EEC, 69/208/EEC and 70/458/EEC and Commission Decision 95/232/EC concerning seeds[4].

3.3. Unique codes

9. The introduction of a system for the development and assignment of unique codes to GMOs is particularly important for operating traceability and labelling systems. The EEA EFTA States are pleased to note that the establishment of the system for the development and assignment of unique codes to GMOs will take into account the developments within the framework of the Biosafety Protocol and OECD. The EEA EFTA States particularly stress the importance to secure a system which is easy to apply, interconnectable with the Biosafety Clearing House and provides the necessary information on the transformation events.

10. In the previous EEA EFTA Comments on GM food and feed , the EEA EFTA States point to the need for clarification on the product coverage of the obligation to attribute and use unique codes. According to Articles 8(2) and 21(2) of the proposal, the draft decision on authorisation shall, where appropriate, include the unique code attributed to the GMO as referred to in the proposed Regulation on the traceability and labelling of GMOs. According to Articles 4 and 5 of the proposal on the traceability and labelling of GMOs, unique codes are only to be transmitted for products consisting of or containing GMOs, not for products produced from GMOs. However, given the coverage of authorisations according to Articles 4(4) and 17(4) of the proposal on GM food and feed, it would seem appropriate that all draft authorisations include unique codes. The exemption in Article 6(1) of the proposed Regulation on the traceability and labelling of GMOs does not change this conclusion, as it only covers the obligation to retain information on the unique codes of the products consisting of, or containing GMOs, not the obligation to transmit it. As the obligation to retain this information is only implicitly stated in Article 4(2) and (3), the exemption in Article 6(1) could induce misunderstanding. The EEA EFTA States would, therefore, propose to clearly state the obligation to retain the information also in Articles 4(2) and (3) and 5(1).

[4] SANCO/1542/02July2002

3.4 Traceability requirements

11. Articles 4(4) and 5(2), oblige operators to have in place systems and procedures to allow the identification, for a period of 5 years from each transaction, of the persons from whom and to whom products have been made available. The EEA EFTA States are of the opinion that this period should be extended to 10 years, in order to secure the possibility of withdrawing products, which, i.a., pursuant to the monitoring requirements of Directive 2001/18/EC, could be shown to have adverse effects on health or the environment.

12. Furthermore, the obligation to make this information available to competent authorities on demand, which is essential to ensure the possibility of targeted withdrawal and control and verification of labelling claims, is only mentioned in the Explanatory Memorandum to the proposal and not in the Regulation itself. The EEA EFTA States are of the opinion that it is crucial that the obligation to make information available when demanded by the competent authorities be clearly stated in the Regulation.

* * * * * *