EUROPEAN ECONOMIC AREA

STANDING COMMITTEE
OF THE EFTA STATES

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WORKING GROUP ON THE ENVIRONMENT

Comments by the EFTA EEA States on the proposal for a European Parliament and Council Directive amending Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms

I INTRODUCTION

1. The Commission adopted on 23 February 1998 a Proposal for a European Parliament and Council Directive amending Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms, COM (1998) 85 final. The purpose of the proposal is to take into account the recent developments in the area of biotechnology, the growing scientific knowledge as well as the concern of the general public with regard to the effects of genetically modified products.

2. In view of the information and consultation procedures provided for in the EEA Agreement, the EFTA EEA States are pleased to provide comments on the proposal, which cover an area directly linked to the Agreement. Directive 90/220/EEC is included as point 25 in Annex XX of the EEA Agreement with adaptations for the EFTA EEA States.

II GENERAL REMARKS

3. There has been a rapid development within the field of modern biotechnology since Directive 90/220/EEC was adopted in 1990, and a number of products are already on the market. The key issue to be addressed by policy makers today is how modern biotechnology could be used to contribute to sustainable development. A policy for sustainable use of modern biotechnology within Europe should actively stimulate the use of biotechnology which gives a positive contribution to a cleaner environment and a more efficient use of natural resources and on the other hand takes a clear stand against products that are not contributing to such a development.

4. The EFTA EEA States welcome the proposal for a revision of Directive 90/220/EEC as an important step towards improving the Directive. The proposal to a large extent recognises the need for a precautionary approach to a fast developing technology. The EFTA side appreciates especially the proposals concerning time limited market approval, mandatory post marketing monitoring, common principles for risk assessment, changes in the procedures for approval of products, ethical considerations and increased transparency. The EFTA EEA States would, nevertheless, like to comment on some specific provisions of the proposal.

III DEFINITIONS

5. In the view of the EFTA EEA States the definition of "deliberate release" in Article 1 of the proposal should, in order to avoid loopholes and grey areas in the regulation of GMOs, be expanded to include also "placing on the market", and thus be complementary to the definition of "contained use" in Directive 90/219/EEC. Directive 90/220/EEC would then cover all activities not covered by Directive 90/219/EEC.

IV TIME LIMITED AUTHORISATION / MONITORING

6. The EFTA EEA States support the proposal to give market authorisation for a fixed period of seven years and the introduction of mandatory post marketing monitoring (art. 11 and 13). This will strengthen the precautionary approach, and implies recognition of the uncertainties connected to the long-term effects of GMO-products. The proposed criteria in annex VII cover both direct, immediate and delayed effects. However, the proposed monitoring protocol for insect resistant maize does not seem to be in accordance with the intention of the proposal as such, and we believe there is a need to strengthen the focus on non-target insects and secondary effects on predatory animals in the protocol.

V FIELD TRIALS

7. According to the proposal for new articles 7 and 8, field trials in category I shall only be assessed by the country receiving the notification. The EFTA EEA States are of the opinion that in addition neighbouring countries should be given the opportunity to comment on field trials prior to a given consent. We do not believe that the SNIF database provides sufficient information about the results of the category I trials, and information about these results may also be of relevance to other EU/EEA States.

VI ADMINISTRATIVE PROCEDURES

8. In accordance with the intention of improved transparency, handling of notifications under the directive should involve a number of interested parties, such as different ministries, directorates, scientists, the industry, NGOs and the public. As the time limits in the current directive are marginal, the proposed reduction in time limits may compromise both transparency and safety.

VII RISK CATEGORIES AND SIMPLIFIED PROCEDURES

9. The EFTA EEA States welcome the discussion on simplified procedures and the proposal concerning GMO risk categories for field releases. Introduction of simplified procedures for certain categories of GMOs will extend the flexibility of the directive. However, the experience with deliberate releases of GMOs is still limited. Taking into account the wide variations in environmental and climatic conditions in the EEA the development of criteria for such categories is difficult. Classification of the organism will still require a full risk assessment. The experience with marketing notifications has clearly demonstrated that Member States conclude differently on risk assessments carried out according to the directive. There is a possibility that similar notifications will be handled under different procedures. The EFTA EEA States propose that GMO releases similar in terms of organism and trait to releases already approved without objections by any country could constitute a category for simplified procedures.

VIII PRODUCTS WITH ANTIBIOTIC RESISTANCE MARKER GENES

10. The EFTA EEA states appreciate the initiated work on antibiotic resistance. However, the directive still allows marketing of products with antibiotic marker genes, and some EFTA EEA States are of the opinion that such genes have no function in the commercial product, and techniques for removing them are available. They think that marker genes represent an unnecessary risk of contribution to the worldwide and increasing problem of antibiotic resistance in pathogenic bacteria. They would propose considering a general ban on antibiotic resistance marker genes in products intended for food and feed purposes, and a phase out of such genes in all GMO products.

IX RISK ASSESSMENT

11. The EFTA EEA States welcome the proposal (art.4/annex II) on common principles for risk assessment, and especially the suggestion to include indirect effects as for instance effects from use of pesticides on the GMO. However, the risk assessment must also take into account possible long-term effects, and be based on the precautionary principle. It is also important that secondary effects and additive consequences, which are not revealed in case-by-case assessments, are included as the number of GMO products on the market increases.

12. A common problem with the marketing notifications is the lack of crucial data on ecological effects and nutritional and toxicological questions. Experimental releases are limited both in time and space and will not produce data for the assessment of possible large scale or long term effects. This necessitates the development of specific documentation requirements in order to further increase harmonisation of risk assessment and improve the link between field trials and marketing of products. Priority should be given to the work of the Risk Assessment Group, and we would suggest that the group focuses on case studies in order to develop a common set of data requirements. We believe the title 'Principles for the environmental risk assessment' should be amended to include health aspects.

X SCIENTIFIC COMMITTEES

13. Concerning the proposal (Article 21) to consult scientific committees in various situations, the EFTA EEA States believe that a clarification of the envisaged powers of these committees is needed. This is especially important when their risk assessment is contradictory to the assessment made by a Member State. Furthermore, the existing composition of the committees does not reflect the different opinions in the scientific community with respect to risks relating to GMOs. We would also like to underline the pressing need to strengthen the ecological competence in the present committees, or even consider establishing a scientific committee with specific competence on ecology.

XI THE INTERPLAY BETWEEN DIRECTIVE 90/220/EEC AND SECTOR REGULATION

14. The EFTA EEA States are of the opinion that risk assessments under sectorial regulation should cover environmental aspects and include all requirements of directive 90/220. It is also of vital importance to ensure a procedure involving the competent authorities under Directive 90/220, and the 90/220-committee.

XII LABELLING

15. Labelling of genetically modified products is a very important issue. The EFTA EEA States therefore appreciate the steps taken in order to give both consumers and inspecting authorities sufficient information. However, some EFTA EEA States believe that the notion "may contain GMOs" may create an unclear situation.

16. Containment of GMOs can be proved by analytical methods or by accompanying documents. In this respect some EFTA EEA States would propose obligatory labelling of all products containing or consisting of more than a certain percentage of GMO. As stated by the Council, the threshold value should be established in the light of existing detection methods and adventitious contamination. Notwithstanding, segregation of bulk shipments with genetically modified and non-modified products is necessary in order to fulfil labelling and inspection requirements, and to offer the consumer a choice in real terms.

XIII ETHICS, SUSTAINABILITY AND SOCIAL BENEFIT

17. The EFTA EEA States welcome the proposal to include ethical aspects in the preamble. However, it is our view that the scope of the directive, in order to put the precautionary principle in more concrete terms, should be broadened and include ethical considerations, socio-economic impact, a risk-benefit evaluation and a general evaluation of contribution to sustainable development of each GMO product. The main obstacle for further development of the biotechnology industry in Europe at present is public acceptance and confidence. This lack of acceptance may have many reasons. Both uncertainties about possible harmful effects, and lack of obvious benefit to the consumer are weighty arguments. Introduction of a risk-benefit evaluation in the directive would meet these concerns, and on a long term be advantageous for industrial development.

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