DEVE-003

Brussels, 27 May 2002

OPINION

of the

Committee of the Regions

of 16 May 2002

on the

Proposal for a Regulation of the European Parliament and of the Council

on genetically modified food and feed

COM(2001) 425 final - 2001/0173 (COD)

and the

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

COM(2001) 182 final – 2001/0180 (COD)

and the

Proposal for a Regulation of the European Parliament and of the Council

on the transboundary movement of genetically modified organisms

COM(2002) 85 final – 2002/0046 (COD)

The Committee of the Regions

HAVING REGARD TO the 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 – COM(2001) 182 final – 2001/0180 (COD);

HAVING REGARD TO the Proposal for a Regulation of the European Parliament and of the Council on genetically modified food and feed – COM(2001) 425 final - 2001/0173 (COD);

HAVING REGARD TO the Proposal for a Regulation of the European Parliament and of the Council on the transboundary movement of genetically modified organisms (COM(2002) 85 final – 2002/0046 (COD);

HAVING REGARD TO the Proposal for a Directive on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC – COM(2000) 293 final;

HAVING REGARD TO the decisions taken by the Council on 15 September and 2 October 2001 and 1 March 2002 to consult it, under the first paragraph of Article 265 and Articles 152 and 175 of the Treaty establishing the European Community;

HAVING REGARD TO its Bureau's decision of 6 February 2002 to instruct the Commission for Sustainable Development to draw up the opinion;

HAVING REGARD TO its Opinion of 12 April 2001 on the Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the White Paper on Food Safety – COM(1999) 719;

HAVING REGARD TO its Opinion of 14 June 2001 on the establishment of a European Food Safety Authority;

HAVING REGARD TO the draft opinion adopted by the Commission for Sustainable Development on 25 March 2002 (CdR 33/2002 rev. 1 – rapporteur: **Mr Bertrand**, Mayor of Saint-Silvain-Bellegarde, F/EPP),

adopted the following opinion at its 44th plenary session, held on 15-16 May 2002 (meeting of 16 May 2002).

Position and recommendations of the Committee of the Regions

Preamble

1. In the light of the technical, scientific and legal aspects of the current situation – both within and outside the EU – there is a need to flesh out EU rules on genetically modified food and feed products. The forthcoming establishment of the European Food Safety Authority also increases the need to take action in this respect. The Committee of the Regions supports the European Commission's proposal aimed at ensuring coherent application of a body of EU rules enhancing food safety throughout the EU.

2. The Committee of the Regions is in favour of establishing a body of rules which would ensure transparency as regards the use of GMOs in the agri-food chain. There is a need for transparency, in respect of both the authorisation procedure and also the traceability of genetically modified products throughout the agri-food chain. With this aim in view, the Committee of the Regions points out that the concept of "from farm-gate to plate" seems to be too limiting as the agri-food chain extends from the suppliers of industrial products to farmers, right up to the final consumer. The Committee of the Regions therefore prefers to use the expression "from plough to plate".

3. The rules must also enable purchasers – be they intermediate users, such as stock-breeders, or final consumers – to exercise freedom of choice. Information must be comprehensive and clear and afford health and legal protection to the users of both food and feed products.

4. The Committee of the Regions stresses that "traceability" and "labelling" are different and complementary concepts. "Traceability" implies the establishment of a monitoring system which makes it possible to trace the history and origin of a product. "Labelling" provides transparency in commercial transactions. Labelling also involves a commitment and a legal liability on the part of the body which affixes the label to the product concerned.

5. The Committee of the Regions takes the view that the goal of affording a high level of protection for life, health and the environment can be achieved only through a coherent body of Community rules, defining the responsibility of all the players in the agri-food chain. This should also boost consumer confidence with regard to public health and food safety.

Development of Community rules and the current situation

6. The body of Community rules in force since the early 1990s has been supplemented and fine-tuned over the last ten years. Directive 90/219/EEC, which has itself been amended, deals with the contained use of genetically modified micro-organisms for research or for industrial purposes.

7. The first rules with regards to authorisation procedures were set out under Directive 90/222/EEC on the deliberate release into the environment of genetically modified organisms. This Directive covers the marketing of GMOs and products consisting of or containing GMOs, but it does not cover products derived from GMOs. This Directive provides for an environmental assessment and a step-by-step authorisation. The Directive requires a case-by-case assessment of the risks to human and animal health and the environment to be carried out before any genetically modified organisms are released into the environment in any of the EU Member States.

8. Directive 2001/18 as subsequently amended will come into force in October 2002; this Directive will carry forward and strengthen the current laws by:

- enhancing the effectiveness and the transparency of the decision-making process whilst, at the same time, ensuring a high level of protection of human health and the environment;
- clarifying a number of operational aspects, relating, inter alia, to the scope of the measures;
- promoting the harmonisation of the risk assessment;
- improving the transparency of the decision-making process through consultation, the establishment of reports on ethical issues and the participation of the public in the authorisation process;
- improving checks on the dissemination of GMOs into the environment by making it mandatory for the Member States to take measures to ensure traceability and the provision of labelling at all stages in the marketing of products and by strengthening the monitoring plans in respect of GMOs.

9. Regulation (EC) 258/97 on novel foods and novel food ingredients lays down rules governing the authorisation and labelling of food products derived from GMOs and other novel foods. The Regulation does not, however, specify how this information is to be presented and it does not define the concept of "equivalence". And Regulation 50/2000 fails

to stipulate a threshold in respect of adventitious presence. The situation is identical with regard to products derived from GMOs and intended for use in feed products since no specific provision has been introduced in respect of the labelling of products derived from GMOs. The proposals under review provide the requisite information on the concept of "equivalence" and the threshold in respect of adventitious presence.

10. On 24 May 2000 the European Community and all its Member States signed the Cartagena Protocol on Biosafety. This multilateral agreement was intended to include all the main GMO-producing countries. It was drawn up in order to improve the level of protection in the field of the transboundary movement, handling and use of living modified organisms. In the current proposal (COM(2002) 85 final), the Commission proposes ratification of the Protocol. The Protocol can enter into force only on the ninetieth day after the date of deposit of the fiftieth instrument of ratification by the parties to the Convention. The Committee of the Regions, together with the Member States and the European Parliament, are in favour of the rapid ratification of the Protocol.

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11. The Commission's proposal sets out the following provisions:

- an improved, harmonised, uniform and transparent procedure for the safety assessment of genetically modified food;
- a safety assessment and an authorisation procedure for genetically modified feed, based on the same improved and transparent authorisation procedure as for genetically modified food;
- that authorisation should not be granted for a single use either as food or feed in cases where such products are likely to be used both as food and feed;
- harmonised and comprehensive labelling requirements for genetically modified feed in order to provide users with accurate information about composition and properties.

12. The proposal under review covers products "produced from a GMO" but not products "produced with a GMO".

13. The Committee of the Regions welcomes the strengthening and clarification of the assessment procedure for genetically modified food and feed by the Commission which is aimed at establishing the necessary regulatory basis for ensuring a high level of protection of human life and health.

The opinion of the European Food Safety Authority should provide the scientific guarantee under the authorisation procedure. With this aim in view, the Committee of the Regions reiterates the view expressed in its earlier opinion that the European Food Safety Authority should be set up as soon as possible; this is a prerequisite for the implementation of the two draft Regulations under review.

14. The Committee of the Regions particularly welcomes the application of the "one door – one key" procedure which will make it possible to follow up applications for authorisation more effectively and accelerate authorisation. This should enhance consumer safety and bolster confidence. Experience has shown that products able to be used either as food or as animal-

feed need to meet both the criteria applicable to food and those for animal-feed.

15. In order to ensure safety and secure the confidence of consumers and all the players in the agri-food chain, food authorisation should hinge upon observance of the following criteria:

- absence of risk to human or animal health or to animal feed;
- the need to inform users and consumers.

16. The Committee of the Regions takes the view that the establishment of the threshold in respect of the procedure for authorising the placing of products on the market is a contributory factor to ensuring the necessary public-health and legal safety. In this context, the threshold level set should be applicable throughout the agri-food chain and be based on the "trace concept" used to define the purity of food products. Furthermore, the Committee of the Regions stresses that this threshold must be consistent with the establishment of other thresholds, for example the threshold for the mandatory labelling of genetically modified seeds (Directive 98/95/EC).

17. The authorisation procedure applies to food and feed containing a GMO or produced from a GMO. The Committee of the Regions highlights the need for Community law to be made more coherent in the case of food products requiring specific applications for marketing authorisation, namely food additives, baby-food, infant formulae and food supplements. In the case of these products authorisation is valid for a maximum period of ten years, which can be extended, depending on the results of a monitoring plan.

18. The Committee of the Regions supports the establishment of a Community Register of Genetically Modified Food and Feed which lists product information, studies demonstrating that the product is safe and methods of detection. The Committee of the Regions recommends that the Commission facilitate public access to this Community Register and specify the terms of access in order to ensure that people are fully informed as to these food products.

19. The Committee of the Regions feels that the transitional period during which existing authorisations for placing products on the market are maintained should end as soon as possible.

20. The Committee of the Regions supports the proposal made by the Commission in the draft Regulation that the products in question should be labelled since the current provisions are difficult to implement, difficult to enforce against third parties and do not ensure total transparency, either for the final consumer or the various operators, such as stock-breeders.

21. The Commission proposes to extend these labelling provisions to food and animal feed irrespective of the detectability of DNA or protein. The Committee of the Regions expresses reservations over this extension for the following reasons:

- the recent health scares have demonstrated that documentary traceability is not sufficient in itself to enable animal feed to be strictly monitored;
- the only way to ensure that commercial transactions are not fraudulent is by means of checks based on the detection of DNA or protein in a product placed on the market.

22. Purchasers (users or final consumers) must be able to select the quality of the food which they buy in a fully informed way and on the basis of the legal, public health and commercial

criteria which they set. The Committee of the Regions urges the Council and the European Parliament to draw a distinction, in the product description, between products containing GMOs and products containing no further trace of GMOs.

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23. The Committee of the Regions supports the draft regulation which specifies the implementing provisions in respect of the traceability and labelling of genetically modified food and feed.

24. The Commission proposes that these implementing provisions be applicable both to food produced in the EU and imported food. Responsibility for checking imported food rests with each of the Member States, which will also determine the penalties for fraudulent practices.

The Committee of the Regions supports the formulation of this principle and the clarification of responsibilities in the Community.

The Committee of the Regions wishes, however, to underline the fact that the implementing provisions set out in the draft regulation do not make for coherence between measures relating to the traceability of products imported into the EU and the additional measures we would like to see, over and above, for example, those set out in the Cartagena Protocol.

25. The Committee of the Regions calls for the Commission to be authorised to seek to harmonise assessment procedures for genetically modified food and feed and to seek to align the traceability measures applicable at international level with those which will apply in the EU.

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26. The Committee of the Regions supports the procedure set out in the Cartagena Protocol for the following reasons:

a. the need for the exchange of information between the exporter and the importer by means of complete notification before the first transboundary movement,

b. the establishment of a system for the exchange of information before products are placed on the market,

c. the establishment of a link between bilateral agreements and Community law, leaving the Member States scope, for example, to apply Community law rather than the provisions of the Protocol in relation to movements of GMOs within the European Union and the European

Economic Area,

d. recognition of the Community procedure for authorising the placing on the market of GMOs, with the opinion of the European Food Safety Authority.

27. The Committee of the Regions supports the proposed implementing strategy, i.e.:

e. imposing obligations on exporters which do not exist in European law,

f. applying current Community law to importers in the European Union.

28. The Committee reiterates its support for ratification of the Cartagena Protocol. The proposal concerns the specific requirements for exports of GMOs to non-Community countries, but the protocol deals exclusively with living modified organisms. This means that it is not always possible to lay down the detailed arrangements for the traceability and labelling of products containing a "non-living" GMO or derived from a GMO imported from a non-Community country.

29. The Committee of the Regions stresses the importance of the exchange of information between Member States in the case of unintentional transboundary movements. To the extent that food safety is concerned here, the Committee of the Regions proposes that the early warning system be integrated into the procedure. The Committee of the Regions calls on the Commission to ensure that suitable procedures are established by each of the Member States.

30. The Committee of the Regions notes that the proposal for a Regulation does not tackle the issue of legal liability in the event of withdrawal arising from an unintentional movement of GMOs, so as to provide the food chain players with legal certainty.

31. The Committee of the Regions endorses the conclusions of the Lisbon European Summit which aim to turn the EU into an area of knowledge and competitivity based in particular on biotechnologies. The CoR would like to see greater consideration given to food safety in world trade while maintaining the overall competitiveness of the EU's regions in the trading of agri-food products.

Conclusion

32. The Committee of the Regions feels that the introduction and implementation, at Community level, of the two draft Regulations will enhance both the quality and the safety of EU products and provide purchasers (users and consumers) with more information in order to enable
them to exercise freedom of choice. The Committee of the Regions calls for the extension of this requirement beyond the borders of the Community.

Brussels, 16 May 2002.

The President of the

The Secretary-General of the

Committee of the Regions

Albert Bore

Committee of the Regions

Vincenzo Falcone

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