



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 3 June 2008

10254/08

**ENV 346
AGRI 169**

NOTE

from : General Secretariat of the Council
to : COUNCIL

Subject : GMOs: the way forward
- exchange of views

Delegations will find in the Annex a written contribution from Hungary.

I. Systematic and independent regional level research on the potential risks involved in the deliberate release of GMOs

Hungary believes that the risks posed by particular GMOs on particular ecosystems should be thoroughly assessed before the authorization. The risk assessment must be based on concrete scientific studies carried out in *all* of the different biogeographical regions of the EU – such as the Pannonian biogeographical region – where release is envisaged.

In Hungary's view, such a regional approach is flows from the relevant legislative Community act: Directive 2001/18/EC¹.

The Directive is based on the precautionary principle and the principle that preventive action should be taken. In line with these principles the Directive makes it clear that a case-by-case environmental risk assessment prior to release is necessary and that such assessment must include a “satisfactory field testing at the research and development stage in ecosystems which could be affected”.² The “case-by-case” approach implies that risks have to be studied and assessed according to the nature of the receiving environment and that, as a result, “the required information may vary [...] depending on the potential receiving environment”.³

It is needless to point out that the ecological conditions of the various receiving environments may differ greatly in Europe. Consequently, scientific findings obtained in one region may not apply to another location of the Community. Therefore, as a minimum, adequate field testing should be carried out in all the main ecological zones of the Community – defined in the form of biogeographical regions – where a particular GM crop is intended to be released.

Hungary argues therefore for the strict interpretation of the Directive and underlines that satisfactory field tests for environmental and ecological safety have to be carried out in every biogeographical region during the research and development stage where release is intended.

Furthermore, Member States themselves should be enabled to carry out scientific studies regarding the environmental or health risks of particular GMOs which have entered into the authorization process in the framework of their national scientific institutions. In our opinion, exclusively in this way can it be proved and assured that risks of GMOs be studied and assessed in an appropriate manner during the research period.

¹ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC

² Recitals (19) and (25) of the Preamble to the Directive

³ Article 4 (3), Annex II, Point B

At present, Member States has the opportunity to study the documentation submitted by the notifiers during the authorization process. In this way, Member States do not have the possibility to verify whether all scientific data are accurate in the framework of control studies carried out by their national research institutions if notifiers disagree with these experiments and therefore not intend to cooperate in this regard.

In Hungary's view, a proper solution has to be found to the above mentioned problem at EC level and in accordance with the Directive which states that "Member States and the Commission should ensure that systematic and independent research on the potential risks involved in the deliberate release or the placing on the market of GMOs is conducted. The necessary resources should be secured for such research by Member States and the Community in accordance with their budgetary procedures and independent researchers should be given access to all relevant material, while respecting intellectual property rights".¹

Consequently, when commissioned by Member States' competent authorities to carry out control assessment research institutions as well independent researchers should be provided with all relevant material for carrying out studies on health or environmental risks of GMOs.

II. Proposal for special risk assessment criteria of insecticide producing GM plants

At present GM crops are considered as if they were simply new varieties, new hybrid lines. However, those plants that produce substances of pesticidal properties may give rise to environmental and health impacts identical or similar to those of ordinary pesticides. In this respect an insecticide producing GM plant can be considered as a biological formulation of the given pesticide. Therefore, chemical safety regulations (with particular regard to dosage) that apply to the pesticide should also apply to the GM plant itself. We believe that, if the Community's chemical safety regime is not applicable at present to the case concerned, work should commence as early as possible to eliminate such a lacuna of Community legislation.

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¹ Recital (21) of the Preamble to the Directive.