**COUNCIL OF THE EUROPEAN UNION**

**Brussels, 5 December 2008**

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**NOTE**

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| from : | General Secretariat |
| on : | 5 December 2008 |
| Subject : | Genetically Modified Organisms (GMOs)<br>- Council conclusions |

At its meeting on 4 December 2008, the "Environment" Council adopted the conclusions which are set out in Annex.

# COUNCIL CONCLUSIONS ON GMOs

THE COUNCIL OF THE EUROPEAN UNION,

WHEREAS:

(1) The European Community has adopted a comprehensive legal framework for the authorisation of Genetically Modified Organisms (GMOs) aiming at ensuring a high level of protection of the environment, human and animal health with respect to potential risks of GMOs and taking into account the precautionary principle.

(2) GMOs, in particular cultivation of genetically modified plants (GMPs), give rise to discussion and questions, within the scientific community and society at large regarding their possible impact on health, environment and ecosystems.

(3) It is therefore necessary to look for improvement of the implementation of this legal framework in order to better meet the objectives of the EC legislation, taking into consideration the necessity of continuing processing applications without undue delays and respecting the relevant EC international obligations.

THE COUNCIL

CONSIDERS, in this context, of particular importance the following areas:

*(i) Strengthening of environmental assessment and of monitoring arrangements*

1. EMPHASISES THE NEED to improve harmonisation of the Member States' assessment practices while ensuring that each GMP should be analysed on a case-by-case basis taking account of the characteristics of ecosystems/environments and of the specific geographical areas in which GMPs may be cultivated in accordance with existing legislation;

2. WELCOMES the Commission's mandate to the EFSA to undertake a revision exercise started in March 2008 and to be completed no later than March 2010 regarding its guidelines on environmental risk assessment; CALLS for this work to be carried out if possible before March 2010, providing that this does not influence the quality of the consultation process; INVITES the Member States to ensure full participation of their competent scientific bodies in the consultation the EFSA will undertake during the revision process, by offering their contribution on the project within the required time frame;

3. NOTES WITH SATISFACTION that the Commission's mandate to the EFSA to further develop and update its guidelines as regards the environmental risk assessments of GMOs includes in particular detailed assessment of the long-term environmental effects of GMPs and covers the following areas: Environmental risk assessment of potential effects of genetically modified plants on non-target organisms, development of criteria for field trials to assess the potential ecological effects of the GMPs in receiving environments, identification of the EU geographic regions where the GMPs may be released, selection of appropriate techniques to assess potential long-term effects of GMPs including experimental and theoretical methodologies, and recommendations for establishing relevant baseline information;

4. NOTES WITH SATISFACTION that, to this end, the mandate includes examination of the criteria and requirements for assessing all GMPs, including GMPs that produce active substances covered by directive 91/414/EEC and herbicide-tolerant GMPs with a view to reviewing them if necessary; UNDERLINES in particular the need to study the potential consequences for the environment of changes in the use of herbicides caused by herbicide-tolerant GMPs and to ensure coherence between risk assessments of GMPs which produce active substances covered by directive 91/414/EEC and those of the corresponding plant protection products; RECALLS that the use of plant protection products implies authorisations at national level and EMPHASISES THE NEED for competent authorities involved with the implementation of Directive 2001/18/EC and of Council Directive 91/414/EEC concerning the placing of plant protection products on the market, within the Commission and at national level, to co-ordinate their action as far as possible;

5. WELCOMES the Commission's intention to give normative status to the revised version of the guidelines to be adopted in accordance with appropriate comitologie, in order to involve the Member States fully in their formulation and adoption without prejudging the final positions of the Member States on the text that will be proposed by the Commission; RECALLS that these guidelines must respect the criteria for risk assessment contained in the annexes of Directive 2001/18/EC and be, where needed, regularly updated to take account of continuous developments in scientific knowledge and analysis procedures;

6. EMPHASISES that regular and in-depth monitoring performed by authorisation holders, in accordance with the procedures appropriate to each GMO, is essential for the detection of any potentially adverse effects; WELCOMES the Commission's preparation of a standard monitoring report form in which all relevant information concerning monitoring by authorisation holders can be collected in a harmonised way; EMPHASISES the importance of monitoring activities at national level and INVITES the Member States to considering developing and conducting their own monitoring activities and forward their findings as soon as possible not withstanding the legal responsibilities of the authorisation holders; RECALLS that the results of such monitoring have to be made available to the general public; INVITES the Commission and the Member States to ensure an appropriate follow up of all the information provided by the monitoring activities. Such a follow up of monitoring activities in the intervening years since authorisation should consolidate, where appropriate, the main findings in order to address, interactive or cumulative effects that are difficult to assess fully in a single year**.** RECALLS that if new information becomes available with regard to the risk of the GMOs to human health or the environment, the competent authority shall prepare an assessment report indicating whether and how the conditions of the consent should be revised or the consent should be terminated, for consideration by the competent authorities of the other Member States.

*(ii) Appraisal of socio-economic benefits and risks*

7. POINTS OUT that under Regulation 1829/2003 it is possible, under certain conditions and as part of a case by case examination, for legitimate factors specific to the GMO assessed to be taken into account in the risk management process which follows the risk assessment. The risk assessment takes account of the environment and human and animal health. POINTS OUT that under Directive 2001/18/EC, the Commission is to submit a specific report on the implementation of the Directive, including an assessment, inter alia, of socio-economic implications of deliberate releases and placing on the market of GMO.

   INVITES the Member States to collect and exchange relevant information on socio-economic implications of the placing on the market of GMO's including socio-economic benefits and risks and agronomic sustainability, by January 2010. INVITES the Commission to submit to the European Parliament and to the Council the report based information provided by the Member States by June 2010 for due consideration and further discussions.

*(iii) Better use of expertise*

8. WELCOMES the EFSA's efforts and action taken since 2006 to improve transparency in taking account of Member States' comments in its opinions;

9. EMPHASISES the key role of the Member States in the assessment process, notably of GMOs for cultivation, and INVITES all Member States to play an active part in the assessment process; WELCOMES the proposal of EFSA to directly involve, in addition to the Member State to which the environmental risk assessment is delegated, additional Member States for conducting this risk assessment, UNDERLINES that the said proposal will allow an improvement of the involvement of the Member States and a better consideration of specific national or regional characteristics; CALLS UPON Member States to provide their views on information gathered during the risk assessment period; EMPHASISES that Member States should have the opportunity to provide their views on the additional information gathered during the risk assessment period, without prolonging the procedure, in order to keep EFSA informed of their opinion on the entire dossier; and that their concerns should be duly taken into account.

10. INVITES the EFSA and the Member States to pursue the formation of an extensive network of European scientific organisations representing all disciplines including those related to ecological issues with the assessment of risks associated with the cultivation or use of GMPs in food and feedingstuffs in accordance with Article 36 of Regulation No 178/2002, and thus ensure effective coordination and cooperation between scientists; UNDERLINES the importance of full application of Article 30 of Regulation (EC) No 178/2002, which calls for EFSA to exercise vigilance in order to identify at an early stage any potential divergence between scientific opinions, and cooperate with Member States and national bodies with a view to resolve or clarify the contentious scientific issues;

11. EMPHASISES 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; NOTES that the necessary resources should be secured for such research by the Community and Member States in accordance with their budgetary procedures, and that independent researchers should be given access to all relevant material, while respecting intellectual property rights, INVITES the Member States and the Commission to collect and exchange information on this research;

*(iv) European labelling thresholds for seeds*

12. WELCOMES with interest the forthcoming completion of Commission impact studies on the establishment of seed thresholds;

13. REAFFIRMS the need at European level for one or more labelling thresholds for the adventitious presence of authorised GMOs in conventional seeds on the basis of relevant criteria, such as species-specific criteria and scientific information; UNDERLINES that these thresholds must be set at the lowest practicable, proportionate and functional levels for all economic operators, must contribute to ensuring freedom of choice to producers and consumers of conventional, organic and GM products alike;

14. INVITES the Commission to adopt appropriate thresholds in accordance with the procedure laid down in Article 5 a of Decision 1999/468/EC as soon as possible, taking account of the most recent scientific observations and information on dispersal, adventitious presence and mixing in the process of breeding, multiplication, marketing and using seeds.

*(v) Sensitive and/or protected areas*

15. UNDERLINES the need to take full account of the specific regional and local characteristics of the Member States, particularly ecosystems/environments and specific geographical areas of particular value in terms of biodiversity or particular agricultural practices in line with the existing legislation;

16. UNDERLINES the possibility, under existing authorisation procedures of GMOs for cultivation, of taking case specific management or restriction measures, including prohibition measures, in order to ensure biodiversity protection in fragile ecosystems such as, NATURA 2000 sites designated under directives 79/409/EEC and 92/43/EEC on the basis of an environmental risk assessment based on scientific information; CALLS for particular attention to be given to these ecosystems on these grounds; INVITES Member States and applicants to provide appropriate information as early as possible in the evaluation procedure; POINTS OUT that in accordance with Community law, which includes the precautionary principle, regions with specific agronomical and environmental characteristics, including small isolated islands, may require particular case-specific management or restriction measures, including prohibition measures for GMO cultivation.

17. POINTS OUT that the Member States may take measures, to regulate the cultivation of GMPs, under national coexistence measures in conformity with Article 26 a of Directive 2001/18, taking into account Commission Recommendation 2003/556/EC, NOTES that the Commission will issue in 2009 a report on the implementation of national co-existence strategies, on the basis of contributions from the Member States;

18. NOTES that GMO-free zones can be created on the basis of voluntary agreement which, in line with relevant national law, could be tacit between the economic operators concerned in the area in question and that in order to ensure freedom of choice all concerned operators must be properly informed about an intention to create the GMO-free zone.