Parma, 11 February 2009

# EFSA ACTIONS ON COUNCIL OF THE EUROPEAN UNION CONCLUSIONS ON GENETICALLY MODIFIED ORGANISMS

At the 2912th ENVIRONMENT Council meeting 4 December 2008 the Council adopted conclusions addressing several aspects of the safety of genetically modified organisms (GMOs) for the environment.[1]

The Council recognises that the European Community has adopted a comprehensive legal framework for the authorisation of GMOs aiming to ensure a high level of protection of the environment, human and animal health. The Council also concludes that the cultivation of GMOs gives rise to discussions and questions concerning the possible impact on health, environment and ecosystems. The Council considers it necessary to look for improvements of the implementation of this legal framework.

In this respect the Council considers certain areas of particular importance. Only two of these areas, "*Strengthening of environmental assessment and monitoring arrangements***"** and "*Better use of expertise*" fall within the remit of the EFSA and are addressed in this document. Below the respective sections of the Council conclusions are summarized briefly as an introduction to the EFSA reflections and actions.

## Strengthening of environmental assessment and monitoring arrangements

Summary of Council conclusions n. 2, 3 and 4

*The Council [2] welcomes the European Commission (EC) mandate to the EFSA to undertake a revision of its guidelines on environmental risk assessment (ERA) of genetically modified (GM) plants between March 2008 and March 2010. The Council also invites Member States to ensure full participation of their competent scientific bodies in the consultation the EFSA will undertake. The Council also [3] notes with satisfaction that the EC mandate includes detailed assessment of long term environmental effects of GM plants and that [4] to this end the mandate also will address GM plants that are tolerant to treatment of certain herbicides.*

EFSA Action 1

Action 1-1. The EFSA has discussed in a meeting with Member State Competent Authorities[2] this mandate and all the additional elements of the ERA of GM plants that will be updated by the GMO panel.

[1] Conclusions of 2912th ENVIRONMENT Council of 4 December 2008 are attached as Annex 1.

Action 1-2. The EFSA has committed to give a state-of-play document to Competent Authorities of Member States in March 2009 with ongoing work and to perform a public consultation on the final outcome before delivering it to the European Commission in March 2010.

Action 1-3. Competent Authorities of Member States have been invited to submit comments they might have at any stage of the process to be considered by the EFSA and its GMO Panel in the course of the work with the ERA guidelines for GM plants. The EFSA will continue to participate and contribute to meetings with Member State Competent Authorities and has committed to address this mandate in close contact with the above Member State Competent Authorities.

Summary of Council conclusion n. 5

*The Council [5] welcomes the EC intention to give normative status to the revised guidelines to be adopted through comitology – thereby involving Member States and recalls that these guidelines must respect Directive 2001/18/EC and where needed, regularly be updated to take account of continuous developments in scientific knowledge and analysis procedures.*

EFSA Action 2

Action 2-1. The EFSA continuously reviews its guidance to applicants in the light of developments in scientific knowledge and analysis procedures. The guidance for GMO food and feed was updated in close collaboration with the European Commission and a draft updated guidance document was adopted during the 21 May 2008 plenary of the EFSA GMO panel. A public consultation was held from 21 July – 21 September 2008 after which the GMO panel has analysed the comments received.

Action 2-2. The EFSA (staff as well as panel members) have given technical advice to the European Commission and the Member States during the discussions in the WG of the Standing Committee for the Food Chain and Animal Health as well as during EFSA GMO panel plenary meetings and working group meeting to which the European Commission were invited observers. These discussions have focussed on the draft updated guidance document of EFSA and in a later stage on a European Commission draft document to be an annex to a Commission Regulation on guidance to applicants.

Action 2-3. During the spring of 2009 the EFSA and its GMO panel expects to have the opportunity to communicate on the final version of the Commission Regulation through a formal consultation procedure.

Action 2-4.The EFSA will continue to develop and update guidance to applicants in order to take account of the continuous developments in scientific knowledge and analysis procedures. EFSA

[2] Regulatory Committee for Competent Authorities under Directive 2001/18/EC, 17 November 2008

will continue to do public consultations on draft guidance in order to collect views from stakeholders and Member States.

**Better use of expertise**

Summary of Council conclusions n. 8 and part of n. 9

*The Council [8] welcomes the efforts and actions taken by the EFSA to improve transparency in taking account of Member States' comments in its opinions. The Council [9] emphasises that Member States should have the opportunity to provide their views on the additional information gathered during the risk assessment period and that their concerns should be duly taken into account, without prolonging the procedure.*

EFSA Action 3

Action 3-1. Currently the legal framework for cultivation dossiers foresees consultation with Member State Competent Authorities. In order to maximise scientific input from Member States, EFSA opened the consultation as normal work practice not only National Competent Authorities under directive 2001/18 but also other GMO Member State Competent Authorities and Member State organisations and invites them to submit scientific comments on all applications (not only on GMOs for cultivation, as legally required).

Action 3-2. Member States can submit scientific comments also on the additional information that will be communicated to the panel, while it still has to be noted that the EFSA must respect legal deadlines.

Summary of Council conclusion part of n. 9

*The Council also [9] welcomes the proposal by the EFSA to directly involve, in addition to the Member State to which the environmental risk assessment is delegated, additional Member States for conducting the ERA and underlines that the proposal will allow an improvement of the involvement of the Member States and a better consideration of specific national or regional characteristics.*

EFSA Action 4

Action 4-1. The GMO panel is required to ensure that a comprehensive European wide ERA is conducted and will continue to support this undertaking. EFSA sends a call of interest to all Member States when applications with scope cultivation are to be assessed. EFSA subsequently initiates a cooperation with a Member State based on experience, expertise and availability. This first ERA is entirely delegated to this responsible Member State. This allows the delegated Member State to raise questions to the applicant in order to carry out a comprehensive European wide ERA taking into account all relevant receiving environments in the EU. The EFSA believes that if a delegated Member State would like to perform this ERA with another Member State, that

approach would enable more Member States to cooperate with EFSA on this essential task and thus make better use of European wide expertise.

Summary of Council conclusion n. 10 (see annex 1 for full text)

*The Council [10] invited 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 GMO in food and feed in accordance with Article 36 of Regulation No 178/2002, and thus ensure effective coordination and cooperation between scientists. The Council also 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.*

EFSA action 5

Action 5-1. To harmonize and simplify access to information received by EFSA the Authority has implemented the GMO EFSAnet, an IT tool which allows the sharing of all documentation related to applications with Member State authorities and organizations. This EFSA-Member State network has 210 members representing 108 organizations and authorities in all Member States and in addition the European Commission, Norway and Liechtenstein. To ensure effective communication the EFSA sends weekly newsletters to all members of the EFSA-Member State network with updates on all application dossiers. More than a quarter of the Member State organizations that are members of the EFSAnet are also listed under the Article 36 of Regulation No 178/2002.

Action 5-2. In line with the EFSA Strategy for networking and Scientific Cooperation prepared by the Advisory Forum and adopted by the Management Board 2006, EFSA has launched two article 36 calls in the area of GMO (review of the Cry-proteins as well as the potential effects of GM HT crops on non-target organisms). EFSA is also seeking scientific input from European organisations in connection to the development of guidance on environmental risk assessment of GM animals. During 2008 EFSA has published one call for procurement on the definition of criteria for assessment of environmental risk of GM fish, and two more calls will be published in spring 2009 (insects, mammals and poultry).

Action 5-3. To strengthen harmonisation of risk assessment of GMOs EFSA has organized joint meeting sessions with the Meeting of European Advisory Committees on Biosafety (MEACB; yearly since 2007), as well as special EFSA Advisory Forum Meetings on GMOs (2006, 2007 and planned 2010). EFSA will further develop areas of contacts with stakeholders and Member State scientists by organizing a GMO conference focussing on present risk assessment practices and future development during September 2009.

Action 5-4. In the spirit of the Article 30 procedure, the EFSA has organized meetings with Member State scientists in order to identify at an early stage any potential divergence between scientific opinions (two meetings during 2008 and one meeting 2009). Such bilateral meetings

have also been held in the context of safeguard clauses invoked by Member States (four meetings during 2008 and three planned for 2009).

Action 5-5. In accordance with the EFSA Commitment to openness and transparency, EFSA has published meeting reports of all bilateral meetings between the GMO panel and Member State Scientists and will, as a matter of normal working procedure, continue to do so.

COUNCIL OF
THE EUROPEAN UNION

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# Council Conclusions on Genetically Modified Organisms (GMOs)

***2912th ENVIRONMENT Council meeting***
***Brussels, 4 December 2008***

The Council adopted the following conclusions:

"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 on 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 restrictions 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."