



Friends of
the Earth
Europe

Press Briefing

EU Environment Council policy debate on GMOs
March 9th 2006

EEB, Friends of the Earth Europe and Greenpeace welcome the tabling of a policy debate on GMOs at the Environment Council. In this short briefing we outline some of our main concerns on the two questions that have been put to the Council by the Austrian Presidency.

Flaws in the GMO authorisation process: a need for more transparency and democracy

- a) **Lack of democracy** : The current system is inappropriate and only helps to discredit EU institutions. Moreover, the Commission has abused its power by breaking several times its own statement to "act in such a way as to avoid going against any predominant position which might emerge within the Council against the appropriateness of an implementing measure" (Declarations 1999/C 203/01 on Council Decision 1999/468/EC). **Member States should demand that the Commission respect its commitment to follow predominant positions expressed in the Council.** Moreover, stakeholder involvement in preparing Committee meetings as well as opening the meetings to observers would improve the transparency.
- b) **Lack of transparency** : GMOs are only evaluated by unaccountable scientific committees on the basis of the applicant company's own data. Most of this data is classified as "business confidential information", thus preventing the public and independent scientists from scrutinising the risk evaluation process. **All data related to risk assessment should be systematically and without delay accessible to the public.** Article 25 (4) of Directive 2001/18/EC indicates that "in no case" should the information related to "environmental risk assessment" be kept confidential, while Article 21 (1) states that "verifiable justification" must be given for the documents for which the applicant seeks confidentiality. Given that most feeding studies on animals provided by the applicants remain "confidential" as of today, these legal requirements have clearly been breached by both Member States and by the Commission.
- c) **Socio-economic considerations** : When making a decision on the approval of a GMO for cultivation the Commission has, the possibility to take into account other considerations than environmental and human health aspects, i.e. socio-economic as well as ethical considerations (c.f. Annex II C.2 of Directive 2001/18/EC, complemented by Commission decision 2002/623/EC ; Articles 7, 19 and 33, and considerations 32 of Regulation (EC) No 1829/2003). **We strongly believe that a transparent procedure regarding these considerations and the opportunity for Member States as well as for other stakeholders to contribute to such considerations should be established by the Commissioner and Member States.**
- d) **The new centralised procedure** : Regulation 1829/2003, through which most GMO applications are now going to be processed, will give an even bigger role to the EFSA and further marginalise Member States involvement and their concerns. This centralised procedure does not even guarantee that the more detailed requirements of Directive 2001/18/EC regarding risk evaluation, risk management, information to the public and post-market monitoring, be respected. We are concerned by the fact that the Commission decided to transfer most applications under Directive 2001/18 to the centralised procedure of Regulation 1829/2003. **The Council should demand immediate measures to guarantee that the requirements of Directive 2001/18/EC be strictly respected by all GMO sectoral legislation, including Regulation 1829/2003.**

Legal and scientific problems with the EFSA risk assessment of GMOs

- a) The EU has a comprehensive legislative framework to protect consumers and the environment. **A key aspect is the legal requirement to consider the long-term effects of a particular food and probable combination effects.** This is particularly relevant for new technologies such as genetic modification. The legal obligation for this can be found in article 14.4 of the EU's 178/2002 regulation, which is often omitted particularly when it comes to EFSA's opinions on GM products. In addition other legislation such as Directive 2001/18 also call for the assessment of long term environmental effects of GMOs.
- b) The EFSA has a legal requirement **to address differences in scientific opinions.** Sometimes substantial differences can be found between Member States and EFSA opinions. Article 30.4 of 178/2002 states that: "*Where a substantive divergence over scientific issues has been identified and the body in question is a Member State body, the Authority and the national body shall be obliged to cooperate with a view to either resolving the divergence or preparing a joint document clarifying the contentious scientific issues and identifying the relevant uncertainties in the data. This document shall be made public.*" Despite the substantial differences that can be found between Member States and EFSA scientific opinions, there is no evidence that the EFSA has fulfilled its obligations under this article.
- c) Commission Decision 2002/623 explicitly states that areas of **scientific uncertainties** should be clearly identified in the evaluation. EFSA opinions often do not state where the scientific uncertainties arise even though this is a long-established scientific practice and is legally binding to do so. EFSA has only given scant regard to uncertainties in any of their opinions for GMO products under 2001/18. An assessment of the scientific uncertainties in an EFSA opinion is crucial to enable risk managers (e.g. the Commission and Member States) to make judgements in the public interest. It also avoids abuse of EFSA opinions by risk managers who can claim that a product is safe just because EFSA said so.
- d) In those cases where a declaration of interest or activities of members of the GMO panel are indicating a **conflict of interest**, these experts should be excluded from GMO panel. Experts which are involved in risk assessment of GMOs at the national level should not be members of the EFSA's GMO panel. These experts should be seen as a necessary separate element of quality check of EFSA's opinions.

We urge you to demand clear decisions to ensure that EFSA must respect its legal requirements, and that the role of national scientific authorities be recognised. Moreover :

- **A new comprehensive, coherent and mandatory regime is necessary for the risk assessment of GMOs.** This regime should address the quality and amount of data to be presented by the applicant company, as well as the way how these data are assessed. The material produced by the company has to undergo a much more comprehensive quality check before used in EFSA assessments.
- A rigorous, comprehensive and **mandatory testing regime** should also be set up for immunological testings as well as toxicity and antinutrition tests (for example testing regimes for the toxicity of pesticides are precisely defined in law). In addition there is a need for a broad ethical debate on the use of laboratory animals in this context.
- The opinions presented by the GMO panel of EFSA have to reflect **all open questions and uncertainties** without prejudice.
- The Precautionary Principle has to be applied in a way that uncertainties regarding safety are seen as an **obligation for further investigations**, and no positive opinion can be filed by EFSA.
- **Monitoring and general surveillance** has to take into account all levels of complexity, interactions and possible effects regarding human health and environment.
- **Full and free access to data** has to be provided.