# Problems regarding risk-assessment of GMOs for food and feed. Which improvements of EFSA procedures could be imagined?

Dear minister
At the 9 March Environment Council you will continue the policy discussion on GMOs that you started on 2 December 2005. We would like to draw your attention on crucial shortcomings in the implementation of the EU legislation on GMOs, and on the need to urgently address the failures of the European Food Safety Authority (EFSA) on GMO risk assessment. The EU legislation on GMOs also needs to be implemented in a transparent and democratic way.

The EFSA has ignored its legal requirements to conduct a long-term evaluation of GM products, to identify areas of scientific uncertainties, to answer Member States diverging opinions and to take their scientific concerns into account. The EFSA bases its opinions solely on data provided by the applicant company, most of which is kept confidential in breach of EU law, preventing independent scientists to assess the risks of a product. Even when the company's own data shows a detrimental impact on health, like in the case of Monsanto's GM maize MON863 rat study, the EFSA has dismissed the need to conduct further investigations, without providing a clear reasoning for doing so. Moreover, the independence of the experts sitting on the EFSA GMO panel from interests of the biotech industry is not even guaranteed.

The failures of the EFSA are not acceptable: flawed scientific opinions, which do not even identify areas of uncertainties, do not enable risk managers (the Commission and governments) to take informed decisions. This is even more worrying since the latest scientific research confirms that the genetic engineering process can lead to unexpected and detrimental effects to health and the environment, such as unpredictable changes in protein structures (like in the case of the Australian GM peas, which provoked allergies and lung inflammation in mice) and decrease in biodiversity, which are not taken into account by the current risk evaluation process.

We urge you to demand that :

- the risk assessment requirements of the EU legislation are strictly implemented by the EFSA and national scientific bodies,
- more detailed requirements for GMO evaluation be made mandatory on EFSA,
- full transparency and public access to data are ensured,
- Member States concerns are taken into account and answered by the EFSA and the Commission,

The negligences of today are the food scandals of tomorrow. Until these problems are solved, we ask you to demand that the EFSA immediately stop issuing new opinions on GMOs. It is your responsibility to ensure that European consumers and the environment are protected from the irreversible impacts of GMOs, to make sure that EU institutions do not undermine their own legislation and act in a transparent and democratic way.

You will find in the attached Annex our detailed concerns and proposals. Be assured of our vigilance.

Yours sincerely,

Eric Gall
Greenpeace
European Unit

Dan Belusa
Greenpeace
Copenhagen office

**ANNEX:**

**1) The impact of the WTO dispute on GMOs and national bans**

According to the leaked preliminary conclusions of the WTO ruling, the panel has dismissed all the claims of the US, Argentina and Canada, except for the accusation that the EU has acted with "*undue delays*" and that national bans should be based on a risk assessment in the sense of the WTO Sanitary and Phytosanitary (SPS) Agreement. As these accusations relate to the 1998-2003 period, the WTO panel makes no further recommendations. The EU legislation itself was never at stake in the case. **However, pressures from the US and the WTO should not result in the EU system being implemented in a way that sacrifices a strict and transparent risk assessment, so as to serve the interests of GMO exporting countries or the GMO industry.** The WTO is not the right forum to address biosafety issues and it has no legitimacy to decide the level of health and environment protection in the EU. In no case should the WTO interfere with EU decisions regarding the cultivation of GMOs.

Therefore the Commission should stop using the WTO case as an excuse to automatically give approval to GMO authorisations, to disregard Member States scientific and economic concerns, and to delay any attempt to bring the risk assessment and public access to data in line with the legal requirements of the EU legislation. Risk management measures should not be undermined either, and **we urge you to ask the Commission to refrain from any new attempt to lift the national safeguard measures, which a qualified majority of Member States considered as justified on 24 June 2005**.

**2) Legal and scientific problems with the EFSA risk assessment of GMOs**

The European Food Safety Authority (EFSA) GMO panel has simply ignored many of the legal requirements on GMO evaluation :

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 which 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.

The GMO panel of the EFSA was set up to contribute to an improved risk assessment of GM crops in the EU. However, analysis of the assessments made so far by the EFSA shows that it has not contributed to a higher level of consumer and environmental protection from GM crops and foodstuffs. The criticisms made of the old regulatory framework are still valid. The data are often of poor quality and where differences and irregularities have been found, these have not been followed up sufficiently. There is no rigorous scientific consideration of high quality data where any departures from substantial equivalence are investigated thoroughly. The European Commission and Member States have the duty to take action in order to make sure that the requirements and standards for risk assessment in the European legislation are met by the EFSA and by national competent authorities. For now, the key role given to EFSA in Regulation 1829/2003 (centralised procedure for GMO authorisations, through which most applications will now be processed) is a serious cause for concern.

**No furher opinion on GMOs should be issued by the EFSA until these problems are solved. We urge you to demand clear decisions to force the EFSA to 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.

**3) <u>The GMO authorisation process should be made transparent and democratic</u>**

**a) 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.

**b) 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.

**c) 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.**

**Greenpeace urges you to demand that no GMO authorisation be given until the legislation is properly implemented, in a transparent and democratic way.**