GREENPEACE Briefing

Flaws in the EU authorisation process for GMOs

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There exists a fundamental problem in the process by which GMOs are assessed for safety and authorisation in Europe.

Scientific opinions provided by a single organisation, the European Food Safety Authority (EFSA), are translated into decisions with no broader consideration of societal or economic arguments for and against the introduction of GMO crops and products into Europe.

This situation contravenes EU legal requirements for a broad consideration of a GM product's risks and impacts.

Risk assessment versus risk management

EFSA's founding regulation articulates the distinction between risk management and risk assessment:

Risk assessment is EFSA's task. It coordinates scientific committees, which provide advice to decision-makers.[1]

Risk management, in contrast, is the job of the European Commission. To make a decision, it should consult experts, including EFSA, but also national authorities, the European Group on Ethics in Science and New Technologies, and other stakeholders.

> 'Risk management' "means the process, distinct from risk assessment, of weighing policy alternatives in consultation with interested parties, considering risk assessment and other legitimate factors, and, if need be, selecting appropriate prevention and control options"[2].

At present, EFSA's decisions form the sole basis for EU authorisations of GMOs (all positive decisions to date).

Socio-economic factors must be considered

The European Commission is obliged, under EU law, to consider other available scientific evidence, socio-economic implications and scientific uncertainty. Armed with this broader set of data, it must take a decision.

> Over 20 member states criticised EFSA for failing to conduct long-term evaluations of GMOs and for ignoring member states' comments and concerns (Environment Council, 9 March 2006).

As EC Regulation 178/2002 states: "It is recognised that scientific risk assessment alone cannot, in some cases provide all the information on which a risk management decision should be based, and that other factors relevant to the matter under consideration should legitimately be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls".[3]

There is no evidence to suggest that the European Commission currently takes these 'other factors' into account.

Duty to follow predominant position

The European Commission pledged (in 1999) 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".[4]

> The Commission asked EFSA (April 2006, IP/06/498) "to provide more detailed justification, in its opinions on individual applications, for not accepting scientific objections raised by the national competent authorities" and "to address more explicitly potential long-term effects and bio-diversity issues in their risk assessments for the placing on the market of GMOs".

In fact, the Council has consistently questioned the safety and usefulness of the GM products submitted for authorisation and has voted against the Commission's positive proposals. Never have member states given majority backing to a GMO for marketing or cultivation in Europe.

By approving every GMO application to date, the Commission has consistently disregarded its pledge to respect a 'predominant position' within the Council.

European Food Safety Authority (EFSA) risk assessments

EFSA must also bear its share of the blame, as it, too, has violated obligations.

- By not requesting that GMO producers submit any data on the long-term effects of GM products for which they seek EU authorisation, EFSA has failed to identify and evaluate cumulative long-term effects of GMOs as required under Directive 2001/18 and Regulation 178/2002;[5]

Figure 1: Authorisation process according to EU law

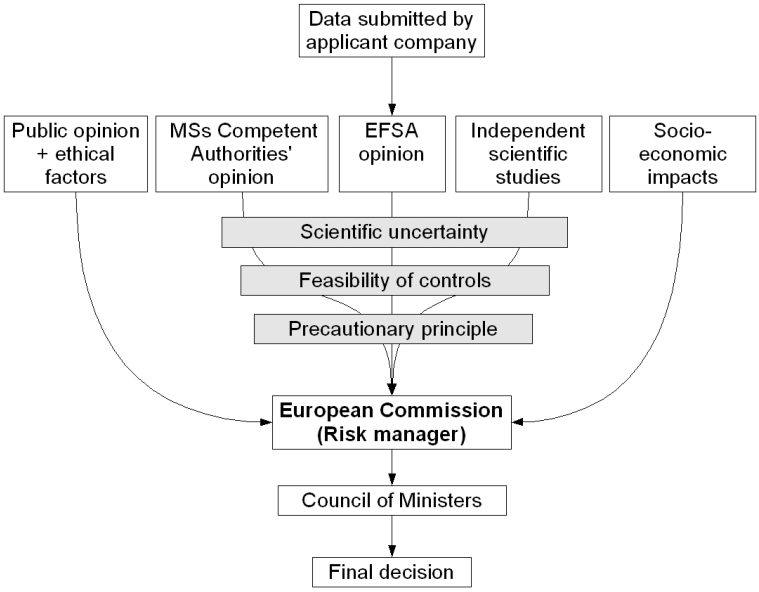
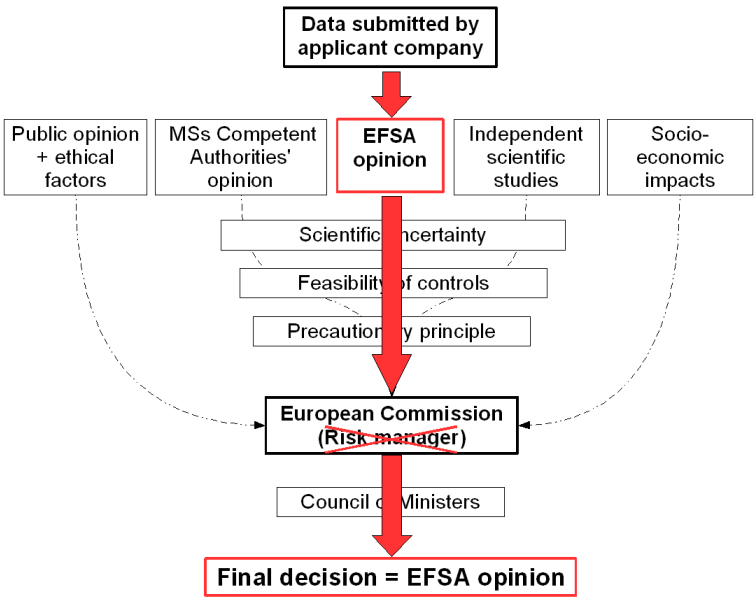


Figure 2: Current process



- Despite a legal requirement to consider diverging scientific opinions [Reg. 178/2002],[6] there is no evidence that the EFSA has given due consideration to differences between the scientific opinions of member states' competent authorities and those of its own GMO panel.
- EFSA is supposed to identify areas of scientific uncertainty [Comm Decision 2002/623; Reg. 178/2002][7] but, in practice, EFSA does not do so. Failing to acknowledge that uncertainty exists compromises the ability of risk managers (Commission and member states) to make informed decisions in the public interest.

Proper assessment of GMOs would include a study of direct, indirect, cumulative and long-term effects of GMOs on the environment and on health, taking into account various stress conditions and different regional environments.

Conclusion

EFSA was not set up to rubber-stamp GMO applications from agro-chemical firms. EFSA must respect EU law and strictly follow the prescribed procedures.

The Commission must perform its role as risk manager and consider other available scientific evidence, socio-economic implications and scientific uncertainty.

References

1 EFSA Executive Director Catherine Geslain-Lanéelle says the role of EFSA is to "advise European Union risk managers on the safety of GMOs. EFSA's experts make an independent scientific assessment of GMO applications. It is then up to Member States and the European Commission to decide whether or not to authorise a specific GMO". http://www.efsa.europa.eu/EFSA/News_PR/pr_gmo_en,0.pdf

2 Regulation 178/2002 establishing the European Food Safety Authority, Article 3(1) n.12

3 Regulation 178/2002, Recital 19

4 European Commission Declarations on Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (1999/C 203/01).

5 See Directive 2001/18/EC on the deliberate release of GMOs, Annex II as well as Regulation 178/2002 establishing the European Food Safety Authority, Article 14(4).

6 Regulation 178/2002, Article 30(4) "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"

7 Regulation 178/2002, Article 7(1) "In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment".