



Working for organic food and farming in Europe

International Federation of
Organic Agriculture Movements –
EU Regional Group

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Stakeholder consultation on the EFSA Guidance on ERA of GMO from November 2010

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Dear Ms André,
Dear Ms Nienstedt,
Dear Ms Torppa,

The IFOAM EU Group welcomes the possibility to comment on the ongoing debate on risk assessment. IFOAM EU Group is actively participating in the GMO debate, as both the possible environmental, health and socio-economic impacts of GMO cultivation and admixtures are of great concern for the organic agriculture movement. With this letter, the IFOAM EU Group answers to the European Commission's invitation to comment on the EFSA [Guidance on the environmental risk assessment of genetically modified plants of November 2010](#), published on 12th November 2010.

Legal background

The IFOAM EU Group underlines that the legal basis for a cautious approach in the risk assessment of GMOs exists. Article 191 of the Treaty of the Functioning of the European Union lays down the precautionary principle as a basis of the Communities Environmental policy. EU-regulation 1829/2003 on genetically modified food and feed aims to "a high level of protection of human life and health"(recital 2). Also recitals 3, 9, 14 and 43 refer to human health and environment protection. Article 1 lays down as objective of the regulation to "provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market."

Underlying principles and concepts of ERA

We welcome that Commissioner Dalli stressed in his speech on "GMOs: towards a better, more informed decision-making process" on March 17, 2011, that "all

differences" "between a GMO and a conventional safe counterpart" are "investigated in detail with respect to possible toxicological, environmental, allergenic or nutritional aspects". But this was in contradiction to the EFSA proposal to introduce a "comparative safety assessment" (content equivalent to the previous "substantial equivalence" concept) in conjunction with the "concept of familiarity". Both concepts not appropriate to guide the GMP ERA. The notion that the concept of substantial equivalence is a safety assessment in itself has been explicitly rejected by the EU legislator and by the Codex Alimentarius. The "concept of familiarity" can be used by risk assessors to paint the differences between a GMP and its parents as "irrelevant" before any ERA on these differences is conducted. Finally, it should be noted that both concepts have not been recognized by the Cartagena Protocol on Biosafety¹, which the EU has signed in 2000 nor are they covered by EU Directive 2001/18.

Approach lacks complex thinking

In certain crucial parts of its new guidance, EFSA takes up the methodology favoured by scientists who work closely with the agro-biotech industry². If the draft guidance was adopted by Ministers as it stands, companies wishing to commercialise their GMP in the EU could determine essential elements of risk assessment, allowing them quick and easy product approval. The guidance for ERA was not rigorously constructed and the sections on principles and concepts do not provide sound guidance about operability of concepts in regards to their normative and scientific challenges. The ERA as constructed in the EFSA guidelines would ignore synergistic or other effects (such as signs of stress, genetic instability or gene scrambling) because it appears to have decided in advance that it won't find them.

Substantial improvements necessary

Therefore we ask the European Commission to substantially improve the guidance. Otherwise, it will be "business as usual" with EFSA continuing to rubber-stamp industry data without ensuring thorough testing, and it will be impossible for Member States to justify GMO environmental risk assessments to their citizens. Once the text of the guidance is strengthened, it is of utmost importance to that it is rigorously implemented: EFSA has to improve its assessments in practice, when formulating its opinions on the safety of GM crops.

IFOAM EU demands the following changes to the guidance:

- Deletion of Chapter 2.1 and abandonment of the concept of "comparative safety assessment and of the "concept of familiarity"
- Adherence to Directive 2001/18
- Establishment of scientific criteria to interpret statistically significant differences in unintended effects.
- Rewriting of Chapter 2.2 giving a comprehensive overview about approaches to problem formulation.

- Adding a chapter on methodological and institutional approaches for normative elements of ERA as problem formulation, selection of protection goals, or ecological relevance.

The IFOAM EU Group moreover endorses the comments of the European Network of Scientists for Social and Environmental Responsibility (ENSSER) on the EFSA Guidance on the Environmental Risk Assessment of Genetically Modified Plants³.

Beyond the assessment of environmental risks in a strict sense, the IFOAM EU Group would like to add the following comments regarding risk assessment and management in the EU:

Role of the EU Commission

The approval of GMOs does not only require strict environmental risk assessment, but also risk management, as well as the correct implementation of all aspects of EU law. As risk managers, the European Commission and EU governments must act on scientific uncertainty and apply the precautionary principle.

Assessment of socio-economic impacts of GMOs

The IFOAM EU Group underlines that also socio-economic impacts need to be considered in the risk assessment of GMOs. Cases of GMO commingling in GMO-free products have already cost millions, paid by farmers, food industry and taxpayers (see list of publications in Annex). Socio-economic risks for the whole society must be balanced against the economic benefits for those who want to place a GMO on the market in a socio-economic risk assessment. Costs for the prevention of GMO contamination occur throughout the food chain, for testing and segregation measures on the fields, in transport, storage, processing, as well as compensation for loss of premium prices for GMO free/organic products and withdrawal of products from the market.

Composition of the EFSA GMO Panel

It has been repeatedly observed that the EFSA GMO panel neglected scientific evidence that pointed to potential dangers of GMO in the form of statistically significant differences between the GMO and its conventional counterpart; moreover it disregarded many comments from national authorities while producing scientific opinions on GMO applications. The IFOAM EU Group therefore asks for a re-evaluation of the profile of EFSA GMO panel members. Conflict of interest and dependencies with industries that benefit from GMO must be excluded. More emphasis needs to be put on a diversity of attitudes to the protection of human welfare and the environment of the panel members must be guaranteed by a diversity of professional backgrounds.

Recommendation to the European Commission and the Member States:

- Reforming the EFSA as the risk assessment authority. Independence of EFSA scientists, transparency of risk assessment procedures as well as the acknowledgment of uncertainties and differing scientific opinions within these procedures must be guaranteed.
- Ensuring participatory and transparent processes including all relevant stakeholders to establish the normative elements of the ERA process prior to new applications for GMP market approvals.
- Including evaluation of socio-economic implications in the GMP ERA.

We thank you for your consideration of this letter and we hope that you will take up our proposals in the ongoing debate on the risk assessment and risk management in GMO policies.

Sincerely yours,



Marco Schlüter, Director of the IFOAM EU Group

¹ EU Council adopted on 15 May 2000 by written procedure a decision on the signing of the Cartagena Protocol on Biosafety on behalf of the European Community. Press release: <http://europa.eu/rapid/pressReleasesAction.do?reference=PRES/00/173&format=HTML&aged=1&language=EN&guiLanguage=en>

² See the parts of the EFSA guidance introducing problem formulation (EFSA Guidance, section 2.2.1.) and comparative assessment (EFSA Guidance, Figure 1, p.11 and Chapter 2.1, p.12-13).

³ ENSSER Comments on the EFSA Guidance on the Environmental Risk Assessment of Genetically Modified Plants (2010) http://www.ensser.org/fileadmin/files/ENSSER_comments_ERA_guidance.pdf

Annex

Some extracts of publications about economic costs of GMO contamination and prevention in the food sector:

- Six case studies of small and medium sized food and feed processors for the prevention of GMO contaminations reveal costs between 48 000 and 876 800 Euro per year: Economic impacts of labelling thresholds for the adventitious presence of genetically engineered organisms in conventional and organic seed, study published by IFOAM EU Group 2009:

http://www.ifoam.org/about_ifoam/around_world/eu_groupnew/positions/publications/pdf/IFOAM_EU_GMO-freeSeedStudy.pdf

-A baby food producer (90% organic, 10% conventional) spends per year 5000 Euro for testing/sampling plus analysis; 40 000 Euro for reporting (traceability), 35 000 Euro for staff training, 50 000 Euro for audit of commodity suppliers and has moreover to cover 770 000 Euro of additional costs for raw materials, that result from higher costs of the raw material suppliers. Source: Schadensbericht Gentechnik, Bund Ökologische Lebensmittelwirtschaft (Hrsg.) 2009:

http://www.boelw.de/uploads/media/BOELW_Schadensbericht_Gentechnik090318.pdf

-The overall costs the contamination with L601 rice has caused in 2007 throughout the food chain are estimated between 741 Million und 1.285 Billion US \$. Source: NEAL BLUE, E. (2007): Risky Business. Economic and regulatory impacts from the unintended release of genetically engineered rice varieties into the rice merchandising system of the US. Greenpeace International (Amsterdam).

<http://www.greenpeace.org/raw/content/international/press/reports/risky-business.pdf>

-In 2007, the disqualification of his harvest for sale on the organic market forced organic farmer Felipe Agustín Esteve to sell in the conventional market at 10 cents/kg less, and he lost the organic farming subsidy (CAP) of €300 per hectare. Source: Testimonies of Contamination, published by Greenpeace 2009:

<http://www.greenpeace.org/raw/content/international/press/reports/testimonies-of-contamination.pdf>

-Already between 1998 and 2006, 9 organic maize contamination cases have been report by 3 different EU organic certification bodies in Navarra, Aragón and Cataluña. Source: Bello A; Porcuna JL; González V; Fabeiro C. 2007. Organic Farming integrity in maize cultivation in Spain. In: Stein AJ &Rodríguez-Cerezo E (2007). Third International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains. Seville 20-21st of November 2007 (Book of abstracts) 373-374pp. Edited by IPTS-JRC European Commission;

http://www.agroecologia.net/recursos/posicionamientos/transgenicos/034-Bello-Organic_as1.pdf