

Mrs. Karen Ellemann
Ministry of Environment and Energy
Højbro Plads 4
1200 Copenhagen
Denmark

13 April 2011

Re: EFSA guidance for the environmental risk assessment of genetically modified plants

Dear Mrs. Karen Ellemann,

We are writing to you to express our concerns on the guidance by the European Food Safety Authority (EFSA) for the environmental risk assessment of genetically modified (GM) plants¹. This was published in November 2010, is currently discussed at Standing Committee level and awaits adoption by EU countries.

Whilst it is positive that for the first time this environmental risk assessment guidance will be legally binding, the methodology put forward by EFSA is not sufficiently rigorous. Once again, there is a risk that the EU Directive on the Deliberate Release of GMOs (2001/18/EC) will not be properly implemented, and that the Environment Council's 2008 Conclusions on the need to improve the risk assessment will continue to be ignored.²

Choosing the right methodology for the risk assessment of genetically modified organisms (GMOs) is scientifically controversial. As a supposedly neutral EU agency, EFSA should have acknowledged this. However, in certain crucial parts of its new guidance, EFSA simply takes up the methodology favoured by scientists who work closely with the agro-biotech industry.³ If the draft guidance were adopted by Ministers as it stands, companies wishing to commercialise their GM plants in the EU could determine essential elements of risk assessment, allowing them quick and easy product approval.

The annex of this letter contains a detailed analysis for consideration by your experts. We have listed the most problematic parts in the new guidance, and the methodological improvements that we believe are necessary. European scientists⁴ and NGOs⁵ have already submitted their critiques on previous versions of the guidance to EFSA. While some of them have been included, crucial comments on essential parts of the guidance have not been taken into consideration.

We ask you 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 that you ensure that it is rigorously implemented: EFSA has to improve its assessments in practice, when formulating its opinions on the safety of GM crops.

Finally, as you know, 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

¹ European Food Safety Authority (EFSA), Scientific opinion. Guidance on the environmental risk assessment of genetically modified plants. EFSA Panel on Genetically Modified Plants, EFSA Panel on Genetically Modified Organisms (GMO), EFSA Journal 2010; 8(11):1879.

² Council Conclusions on Genetically Modified Organisms (GMOs) 2912th Environment Council meeting, Brussels, 4 December 2008.

³ 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). For more details, also see annex to this letter.

⁴ Submission of the European Network of Scientists for Social and Environmental Responsibility, April 2010.

⁵ E.g. Submission of Greenpeace, April 2010; see also: Testbiotech analysis of EFSA Guidance on the environmental risk assessment of genetically modified plants, December 2010.

uncertainty and apply the precautionary principle. Furthermore, an assessment of the socio-economic impacts of GM crops must be firmly included in the authorization process, alongside environmental risk assessment.

We urge you to bring these important matters to the attention of the European Commission and to ensure that EFSA's risk assessment for genetically modified plants is scientifically rigorous. No genetically modified plant should be authorised as long as its risk assessment does not comply with the strict requirements of EU law. This is in the interest of European consumers and the environment.

Yours sincerely,



Christoph Then,
Executive director,
Test Biotech




Magda Stoczkiewicz,
Director, Friends of
the Earth Europe




Pete Riley, Campaign
Director GM Freeze,
UK




Mahi Sideridou,
Greenpeace European
Unit Managing Director



Josef Settele, Chairman
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Miguel López
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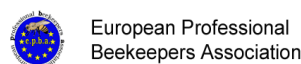
Rodrigo Gouveia, Secretary
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Pieter de Pous, EU Policy
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Walter Haefeker,
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Gabriella Zanzanini,
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