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Dear Commissioner

EFSA consultation on Guidance on the environmental risk assessment of genetically modified animals

I write regarding a number of serious concerns in relation to EFSA's draft guidance on the environmental risk assessment (ERA) of GM animals, including issues regarding conflicts-of-interest and the competence of the Authority to undertake this task.

It is hard to understand why the Commission has requested much of this draft Guidance which falls so far outside EFSA's food safety role. It is clear that the biotech industry has exerted pressure to adopt guidelines which would allow the introduction of GM fish and insects to the EU market. However, EFSA's focus on risks to the food chain means that it does not have the competence to address many of the issues that should be covered in the Guidance. Whilst EFSA's original remit was to build on work done in the context of Codex Alimentarius (i.e. covering food safety standards) the later revisions to the mandate for the report extend way beyond this e.g. to population suppression techniques involving the release of millions of GM insects a week and intended to engineer whole ecosystems, or alter disease transmission or pollination. The release of GM mosquitoes in an attempt to alter disease transmission, for example, has nothing to do with the free movement of food and feed within the EU. Although some aspects do fall within EFSA remit, these aspects have been deliberately ignored and explicitly excluded from any form of consultation: in particular, the risks of ingestion of GM insect eggs, larvae or adults in vegetables and fruits.

It is clear that GM insects and fish will be harmful to some environments even if they may perhaps be authorised for use in others, yet here is no discussion in the EFSA draft Guidance of how GM insect eggs and fish eggs could possibly be restricted to particular receiving environments within the single market.

EFSA's Working Group on GM Insects is heavily influenced by the company Oxitec, making EFSA open to allegations of conflicts-of-interest. Oxitec has been funded by Syngenta to develop GM agricultural pests and most of the company's management and Board are ex-Syngenta staff. GeneWatch UK has documented how the companies have influenced the guidance in our consultation response on:

www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/EFSA_GWresponse.pdf

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f. It is particularly unclear why Dr Bonsall was required to leave the room when Oxitec's GM diamond back moths were discussed by the UK Advisory Committee on Releases to the Environment (ACRE), due to a declared conflict-of-interest, whilst he is allowed to play a central role in drafting EFSA's guidance for the same GM insects.

In lines 4092-4094 of the draft Guidance a sentence has been inserted which completely changes EFSA's remit and the purpose of Environmental Risk Assessment (presumably this sentence was added at Oxitec/Syngenta's request). This is not consistent with the requirements of the relevant Directive (2001/18/EC) which the Guidance is supposed to implement.

In addition, EFSA has not adequately addressed animal health and welfare issues, despite an explicit request from the Commission to do so (25th March 2010): in particular, concerns about spontaneous abortions, miscarriages, stillbirths and deformed births during the production of GM mammals, including pets, have not been considered.

These are important matters which require urgent action to be taken. In view of the public importance of these issues, GeneWatch UK will be publishing this letter.

I respectfully request that you:

- Revise EFSA's mandate for this work to clarify that it should be drafting guidance only for areas which fall within its competence and expertise;
- Prevent the attempt within the draft Guidance to change EFSA's remit and the purpose of an ERA;
- Remove any persons with conflicts-of-interest from a role in developing the Guidance;
- Commission further work to: (1) consider the important issue of traceability of GM fish and insects (eggs, larvae and adults) in the environment and food chain; (2) fully document the harmful impacts on mammals of the GM animal production process.

I look forward to hearing from you.

Yours sincerely,

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Cc: Catherine Geslain-Lanéelle, Executive Director, European Food Safety Authority
Cc: Janez Potočnik, European Commissioner for the Environment
Cc: Dacian Cioloș, European Commissioner for Agriculture
Cc: Martin Schulz, President of the European Parliament