EUROPEAN PARLIAMENT

Thursday, 9th January 2012

**To :**
John Dalli, Commissioner for Health and Consumer Protection
Ida Auken, Minister for the Environment, EU Presidency
Mette Gjerskov, Minister for Food, Agriculture and Fisheries, EU Presidency

**Cc :**
Permanent Representatives of the Member States and national expert members of the Standing Committee on the Food Chain and Animal Health

**Letter from MEPs to the Commission and Member States on the draft GM food and feed guidelines**

**Concerns :** *Draft COMMISSION REGULATION of XXX on implementing rules concerning applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Regulations No (EC) 641/2004 and (EC) No 1981/2006*

Dear Commissioner, Dear Ministers,

Improving the quality of the risk assessment of GMOs is a fundamental step in order to move forward in the European debate on this contentious issue. We therefore welcome the fact that, for the first time, legally binding requirements for the data that companies will have to submit with their application will be adopted by the Commission and Member States. However, we have strong reservations about some of the concepts included in these guidelines. We consider that the changes proposed, as they stand, will not allow the assessment to meet the legal requirements of Directive 2011/18/EC nor the demands of the Council from December 2008. If adopted as such, this draft regulation would defeat the purpose of improving the risk assessment of GMOs in the EU.

Our two strongest concerns lie with:

a) the use of a "comparative risk assessment", which might allow a GM food or feed to bypass the normal safety and nutritional assessment on the basis of flawed data;

b) the statistical power of the feeding trials, which is insufficient to reach a conclusion on the safety of the organism concerned.

The comparative risk assessment is based on the controversial concept of substantial equivalence. This concept is based on the assumption that there is no difference between a GMO and its conventional counterpart, except for the introduced trait. It therefore renders impossible the identification of unintended changes in the plant. Moreover it allows an applicant to introduce unspecified historical data in the process of comparison between the GMO and its conventional counterpart, so as to take into account unspecified "natural variations", which will result in minimizing or hiding significant differences between the two organisms. That is why Recital 6 of Regulation 1829/2003/EC stipulates that substantial equivalence "*is not a safety assessment in itself*" and "*should be abandoned in respect of genetically modified foods*[1]". We believe that this concept should not be re-introduced through the back door under the name of comparative risk assessment in these legally binding standards, and that all applications should go through the complete testing procedure.

The introduction of mandatory feeding trials is a significant improvement. But these trials are only useful if the toxicological analysis is robust enough, which is not the case. The required numbers of tested animals, of animal species and of feeding periods are too few, and result in tests whose statistical power is too low to allow a valid conclusion on innocuity. Conversely, the number of rats in the control groups is too high, and such an imbalance between control and treated rats is likely to conceal some visible effects. Subchronic feeding trials should at least include mandatory *in vitro* examinations, more targeted investigations on specific health risks and, in some cases, long term and multigenerational feeding studies. Any statistical difference between control and treated rats should lead to further investigations.

We also believe that these draft guidelines should be improved in a number of other ways, with the inclusion of metabolic profiling, data on combinatorial effects, a more rigorous evaluation of stacked events and a link to the pesticide regulation, as requested by the Council in 2008.

This draft regulation is a unique opportunity to appease the debate on GMOs in Europe, as it could set requirements that are coherent and comprehensive, and would allow a proper assessment of the health and environmental risks of GMOs. Companies that stand to benefit from the dissemination of GMOs in the environment and in the

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[1] Recital 6 : "*Regulation (EC) No 258/97 also provides for a notification procedure for novel foods which are substantially equivalent to existing foods. Whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself. In order to ensure clarity, transparency and a harmonised framework for authorisation of genetically modified food, this notification procedure should be abandoned in respect of genetically modified foods.*" - http://ec.europa.eu/food/food/animalnutrition/labelling/Reg_1829_2003_en.pdf

food chain should provide all the information necessary to conduct a comprehensive and valid assessment of the risks of GMOs. We therefore urge you to further improve the requirements on the data that applicants have to submit, so that this opportunity is not missed and that Europe does not lose another 10 years in this debate.

Signatures

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