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Committee on the Environment, Public Health and Food Safety

10.11.2010

NOTICE TO MEMBERS

(0016/2010)

Question for Question Time (Commission) 0016/2010
submitted in accordance with Rule 197 of the Rules of Procedure
by Corinne Lepage

Subject: New guidelines for the assessment of the health risks of GMOs

One of the major issues in the debate on genetically modified organisms (GMOs) is the assessment of their risks to health and to the environment. As regards the health assessment, Directive 2001/18 stipulates, in particular, that the chronic effects, the long-term effects, both direct and indirect, as well as the cumulative effects, must be assessed. Given that these regulatory requirements were not complied with in the context of the assessments carried out by EFSA (European Food Safety Authority), in December 2008 the Council (of Ministers for the Environment) unanimously called for a more stringent assessment of the risks of GMOs, a demand which was reiterated at the last Council meeting on 14 October 2010. In 2010 the Commission adopted a proposal with the intention of specifying exactly which data have to be provided by undertakings to the EFSA for the purposes of the health assessment (*Draft Commission Regulation 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)*. This proposal is supposed to be adopted by the comitology procedure before the end of the year.

Part of the scientific community and several Member States take the view that these new guidelines do not constitute a more stringent assessment, but that, on the contrary, they are a weakening of existing requirements, which are already regarded as inadequate.

For example, the revised guidelines propose that alimentarity studies on rats should not automatically be required. However, existing studies to date, which are often regarded as confidential and carried out following legal proceedings, indicate statistically significant biological effects on rats which have eaten GMOs, even though these studies were carried on a group of rats which was too small in relation to the control groups used, and are regarded as too short (90 days) to obtain results which would allow the chronic effects of GMOs to be assessed. GMOs are plants which produce insecticidal toxins or contain residues of herbicides. Pesticides are the subject of a two-year assessment, whereas GMOs are the subject of only a 90-day assessment.

Since millions of animals will be consuming GMOs, does the Commission intend to increase the number of rats studied and extend the length of the studies to 24 months, as in the case of pesticides? Does it also intend to order reproductive-toxicology tests and transgenerational tests on GMOs?

These guidelines are also lacking in statistical reliability as regards toxicity analyses. They do not tackle the question of verifying the power of the statistical tests unless the toxicology analysis method used shows the existence of positive false results, and for those results, and do not require such verification for those which might be suspected of producing negative false results; nor is the treatment of the aberrant data specified.

Moreover, one can detect a general slackening in the wording, making the text less restrictive towards the applicant, and total latitude allowed to the company in defining the protection objectives to be achieved, the definition of damages or the acceptability of the risk, while these elements are covered by decision of the legislature.

These deficiencies and relaxations, which are recognised by these revised guidelines, are contrary to the Conclusions of the 2008 Council which seek a more stringent expert opinion, and contrary to the requirements of Directive 2001/18. They do not make it possible to obtain results whose reliability is beyond question. It is not acceptable that this text should be adopted in its present form, without its having been the subject of a wide-ranging and transparent discussion.

Can the Commission explain in what way it considers that these new guidelines meet the Council's requirements, and how they constitute a tightening up of the health risk assessment of GMOs, as opposed to a relaxation of the requirements for companies placing GMOs on the market?

In order to play correctly its risk management role, the Commission must ensure that the risk assessment is carried out correctly. In particular, it must ensure that the scientific uncertainties are recognised and referred to in EFSA opinions, as stipulated in Directive 2001/18. **Why has the Commission not ensured that the requirements of Directive 2001/18 concerning the assessment of the long-term effects of GMOs are enforced? Why has the Commission never questioned EFSA about the fact that it has never identified any scientific uncertainty (except in one case), despite the fact that there are many uncertainties in this field? What is the Commission's conception of its risk management role and of the application of the precautionary principle in the area of GMOs? Finally, what solution does the Commission propose in order to guarantee an expert report procedure which is**

reliable, impartial and transparent and which does not involve any conflicts of interest regarding GMOs?