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GMO Campaign Blog

EU rules on GMOs - No GMOs by the backdoor

EU member states are currently discussing (1) a set of rules that concern how applications for the authorisation of genetically modified organisms (GMOs) are assessed. The rules themselves are quite technical but the implications could be far-reaching for future GMO assessments in Europe.

The European Commission expects the rules to be finalised and agreed by the summer. While the European Parliament does not have a direct decision making role, a cross-party group of MEPs has written to the Commission and the EU member states, outlining their concerns.

Improving the quality of the risk assessment of GMOs is a vital step to move forward in the European debate on this contentious issue. It is therefore welcome that the proposals would introduce legally binding requirements on the data that companies will have to submit for their application. However, there are serious concerns about some of the concepts included in the guidelines.

The 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; and with 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. This makes it impossible to identify unintended changes in the plant. It also 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 could minimise or hide significant differences between the two organisms.

The concept of substantial equivalence was explicitly excluded under existing EU rules (Regulation 1829/2003) and should not be re-introduced through the back door under the name of comparative risk assessment in these legally binding standards. 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 small, resulting in statistical tests with too low a

sample to yield a valid conclusion on innocuousness. 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.

Legally binding rules could help resolve the debate on GMOs in Europe, if they set requirements that are coherent and comprehensive, allowing for a proper assessment of the health and environmental risks of GMOs. It is therefore important to get them right for all stakeholders. EU member states should address the concerns raised in the letter before signing off on the new rules.

(1) The latest meeting of the Standing Committee is on 10 February.

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