SPEECH/11/13

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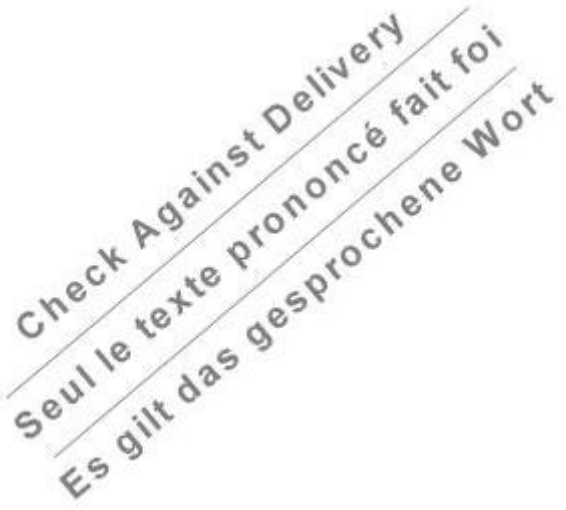
GMOs: guaranteeing safety is a priority



European Parliament, Alliance for Liberals and Democrats for Europe (ALDE) Seminar

Brussels, 12 January 2011

Honourable Members, Ladies and Gentlemen,

Let me first thank Mrs. LEPAGE and Mr. LYON for organising this conference and the invitation to participate in this debate.

As the title of this conference is "risk evaluation" I think everybody here can agree that this can only be based on solid science! Therefore my approach is to follow science-based decision-making, based on a thorough risk assessment in line with the legislation.

The fact that the EU-authorisation procedure, which is generally considered to be the world's strictest system of authorisation of GMOs -, and the science behind it is subject to lively and often controversial debate in the EU, shows how relevant the seminar today is.

Guaranteeing safety is one of my priorities, and I want to do this whilst listening to consumers' and societal concerns. Only in this way will the best available scientific knowledge respond to the needs of society.

To move forward in a fruitful manner, I would like to see everybody concerned coming around the table and discussing, not only today but also in the coming months, in different forums we will set up

Let me underline that such discussions must be done with an open mind and in a transparent manner, separating where possible identified risks from potential risks and facts from perceptions, so that these can be tackled.

Let me first use "the revision of the food and feed guidelines" as an example. This revision involved extensive public and stakeholder consultations, first by EFSA and then by the Commission.

After EFSA's scientific revision, the Commission in close cooperation with the Member States transformed the guidelines into a legal document – into a "proposal for a Regulation" -, which will be adopted in the coming months.

Our objective is that the redrafted guidelines will reinforce the current requirements by:

- Providing legally binding provisions, adopted with Member States endorsement
- Reinforcing scientific aspects by imposing internationally agreed protocols
- Specifying the objectives which have to be fulfilled at each stage of the risk assessment; and
- Establishing a protocol for the comparative analysis for GMOs.

There is a lot of misunderstanding on the strategy for risk assessment and the so-called concept of "Substantial equivalence".

In fact, the strategy is quite simple to understand:

A thorough comparison between a GMO and a conventional safe counterpart allows the identification of all the differences created by the genetic modification. This is in fact the starting point of the safety assessment. All these differences are then investigated in detail with respect to possible toxicological, allergenicity or nutritional aspects.

This is a sound scientific strategy that is followed by all authorities throughout the world as described in the guidelines established in 2004 by the Codex alimentarius which is the internationally recognised body for establishing food safety requirements.

In addition, there are a number of key aspects that we have identified during the process, listening to the views and concerns of Member States and stakeholders. I will mention two:

First, the 90-day studies with rats using the whole food, which are currently performed on a case-by-case basis.

Work is ongoing to reinforce these studies through a specific protocol. I have asked my services to reflect on the need to have such studies done in all cases. For the sake of transparency I want to underline that companies already carry them out in almost every case on their own initiative.

And secondly, the important issue of concern for many is the use of antibiotic resistance marker genes (ARMGs).

I passed a very clear message to Europabio over the last months, including at their recent innovation event on 9 December, insisting to step up efforts to phase out antibiotic resistance marker genes. . The food and feed guidelines will reflect this approach.

As a result, I believe that we have arrived to a document that is updated to technical progress and that also addresses main areas of concern.

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Allow me now to refer briefly to another topic you mention in the subtitle of your seminar - the need to reinforce the real and perceived independence of the risk assessment.

EFSA has in place a whole set of procedures aiming to prevent conflicts of interests. This will still be reinforced in the near future. The Commission is reflecting on the possibility to finance independent studies that would repeat tests provided by companies, for some GMOs.

In relation to the availability of company data I want to make clear that the rules regarding confidentiality of authorisation files limit to the absolute minimum the information that can be regarded as confidential.

This means that only names of people and the detailed genetic sequence may be kept confidential whilst all the rest such as the tests made on animals cannot be confidential. They are provided to anyone upon request. The risk assessors and risk managers of the 27 Member States have obviously access to the whole dossier (confidential and non confidential information) from the start of the risk assessment phase.

I have also asked Europabio to ensure that GM seeds are made easily available for researchers to repeat any tests that are part of the risk assessment. Companies need to continue improving transparency and access to their data proactively!

Let me move now to the environmental risk assessment guidelines, which will also go through this two-stage process, first the scientific revision led by EFSA and subsequently the transformation into a legal text to be endorsed by Member States.

EFSA published the much-awaited revision of the guidelines on the environmental risk assessment, as requested by the 2008 Environment Council Conclusions, on 12 November. The Commission launched discussions with Member States one month later, on 13 December 2010.

We had planned to hold a second meeting to discuss these environmental risk assessment guidelines at the beginning of February, but Member States have asked for extra time. We will consequently discuss these guidelines again with Member States' experts in March.

As with the food and feed guidelines, EFSA carried an extensive consultation in two rounds, involving NGOs, industry and other stakeholders, as well as Member States. The Commission will also demand stakeholders' input once a draft legal text is ready, including Members of the European Parliament.

Finally, I would like to stress the importance of monitoring. We have to undertake effective monitoring of GMO cultivation by companies and by Member States to ensure the accuracy of scientific assessments and to refine our techniques for future assessments.

Significant work has been done in this regard. EFSA is revising its guidelines for post-market monitoring, which will be ready in July 2011. This updated chapter on monitoring will be subsequently integrated into the environmental risk assessment guidelines.

We count on the active and constructive input from Member States and from all stakeholders with a view to achieving the swift adoption of these guidelines through comitology. When I meet NGOs and MPs who are vocal about GMOs, I keep asking them to make sure that their scientists and advisers get actively involved in this process. I would like to meet with Members of the European Parliament throughout this process.

To conclude, I would like to underline that underpinning resolute safety, efforts must be made to improve transparency and dialogue by all of us. I am personally committed to active and better dialogue and look forward to the follow up of today's discussion.

Thank you very much.