John Dalli
Member of the European Commission

Brussels,

Dear Hon. Members of Parliament,

Thank you for your letter of 9 February 2012 where you express your reservations about some of the concepts included in the Draft Regulation concerning applications for authorisation of genetically modified food and feed.

Let me first highlight that this revised version of the draft Regulation is the result of an extensive consultation with Member States, stakeholders and also with MEPs during the different events organised last year either by the Parliament or by the Commission.

As you can see I have taken into consideration some of the received comments and I consider that the document has greatly improved. The main improvements which have been carried out should address your concerns on the independence of the studies, the absence in some applications on a 90-day feeding trial and the statistical power of the feeding trials. Indeed we propose:

- To formally require quality assurance for studies (Good Laboratory Practice (GLP) or ISO);
- To impose of a 90-day feeding study for each single event;
- Specific protocols to perform 90-day feeding studies, field trials and comparative analysis.

In addition, the revised version contains recommendations to limit the use of/phase out antibiotic resistance marker genes and foresees an oversight of safety information during the authorisation procedure.

Concerning the use of the comparative approach for the risk assessment of genetically modified (GM) food and feed, I think there is still a misunderstanding. Let me first highlight that Article 5 of Regulation (EC) 1829/2003 on genetically modified food and feed imposes this approach as being a key step in the procedure for risk assessment. The first step of the procedure is the assessment of the new inserted gene with respect to molecular, toxicological, nutritional and allergenicity aspects. Then, a comparative approach is performed which means that a thorough comparison between the GMO and its conventional safe counterpart is performed (compositional, agronomic and phenotypic characteristics), which allows the identification of all the differences (intended and unintended) potentially created by the genetic modification. This is in fact a key step of the safety assessment and not a safety assessment in itself. All these differences are then investigated in detail with respect to possible toxicological, allergenicity or nutritional aspects.

Let me also clarify the meaning of recital 6 of Regulation (EC) 1829/2003. This recital states that it is the notification procedure for GM foods under Regulation (EC) 258/97 itself which should be abandoned since these products are now covered by Regulation (EC) 1829/2003 and not the substantial equivalence.

I would like to highlight that we have even gone further as regards the 90-day feeding studies than discussed with MEPs. This should alleviate your new concern on the statistical power of the feeding trials. Following a request from the Commission, the European Food Safety Authority (EFSA) adopted on 7 December 2011 guidance on conducting repeated-dose 90-day oral toxicity study in rodents on whole food/feed. External experts have been associated to the process. This guidance document establishes in particular recommendations on the experimental design and the statistical power of the experiment and recommends some specific parameters to ensure appropriate statistical power, in particular:

- the total number of animals to be used,

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- the same number of animals in each group (tested and control),
- the number of experimental units in blocks.

It has to be stressed that as explained in the EFSA guidance any statistical difference between the control and treated rats leads to further investigation. Depending on the outcome, additional studies might be requested. The same approach is defined in the Commission draft guidelines (Annex II, point 1.4.4).

We agree with your statement that in some cases long term and multigenerational feeding studies should be performed and would stress that this is indeed mentioned in the draft Regulation (Annex II, point 1.4.4.2).

On your other concerns, please find the following elements addressing them:

- Metabolic profiling is referred by EFSA in its guidance from 2011 on risk assessment of GM plants, as possibly being a promising technique to further map the possible effects of a genetic modification. However, the potential to apply this technology has still to be further investigated.
- Evaluation on stacks: the approach proposed for the evaluation of stacks obtained by conventional crossing of GM plants containing a single event consists of a rigorous evaluation including the risk assessment of each single event and three specific aspects (stability, expression of the events and potential synergistic or antagonist effects between the events).
- Combinatorial effects are addressed in the draft guidelines as regards stacks with the requirement to assess the potential synergistic or antagonist effects between the events.
- The link to the pesticide regulation has to be provided when cultivation application are concerned. These draft guidelines address only the food and feed risk assessment of GM plants. It has however to be mentioned that any imported genetically modified product must comply with maximum residue levels set under Regulation (EC) 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin.

To summarise, let me reassure you that discussions are still ongoing with the objective to adopt before the summer a Regulation on the risk assessment of genetically modified food and feed, ensuring a high level of safety and a transparent authorisation procedure. This will hopefully as you say move the European debate in the direction of comforting citizens that authorisations are stringent and the safety of consumers ensured.

I would like to inform you that some Member States, third countries and stakeholders and in particular in their last discussion the "Eurogroup for Animals" consider that the actual draft Regulation goes too far and that the requirement of a 90-day feeding study for each single event has a too negative impact on animal welfare and suffering and is not based on any sound scientific basis. I would like to reemphasize that I do not share this view.

Yours sincerely,

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