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Subject: Consultation on EFSA Guidance documents on
Environmental Risk Assessment of GMOs

15 April 2011

Dear Ms André,

In response to your letter of 4 March 2011, the Public Research and Regulation Initiative (PRRI) hereby submits the following observations concerning the EFSA guidance on:

- the environmental risk assessment of genetically modified plants.
- the assessment of potential impacts of genetically modified plants on non-target organisms.

As PRRI expressed before in written submissions and through participation in EFSA meetings: we believe that the EFSA opinions on individual dossiers have been scientifically sound and robust and the original EFSA guidance documents provided helpful clarification of the process. We also stated that that guidance can be further fine tuned on the basis of experience gained.

However, we are deeply concerned that the new EFSA guidance documents are becoming increasingly confusing and seem to be steering way from sound science. In fact, we cannot escape the feeling that EFSA is trying to accommodate political pressure and that in the process sound science gradually gets sacrificed.

The DG Sanco meeting on 17 March 2011 and the EFSA meeting on 31 March 2011 showed clear signals of this worrying change of attitude. Where in the past the Commission and EFSA management – rightly – announced that the EFSA opinions were based on **the best and up to date science**, in more recent statements the Commission and EFSA seem to pride themselves about a system that is “**the strictest in the world**” (quote). This is troubling, because there is absolutely no sense or benefit in the notion of being “the strictest”. Biosafety systems are intended to be tools for informed decision making to allow the society at large to benefit maximally from biotechnology and to minimise risks.

The problem is that this apparent change has permeated throughout the guidance documents, which makes submitting specific, technical comments a futile exercise at this stage.

We therefore limit ourselves to some general observations:

1. The guidance is unclear and confusing.

The EFSA guidance is unclear and confusing on various levels:

- The current EFSA guidance is presented in several different documents of which it is unclear how they relate to each other.
- The guidance still too often presents in one and the same chapter concepts that are relevant to environmental risk assessment as well as concepts that are relevant to food/feed safety assessment. The EFSA meeting on 31 March revealed how people are still mixing those concepts.
- Given the key importance of the comparative approach of risk assessment, it would be very beneficial if that approach was explained more clearly in the guidance documents, whereby it is



also clarified that the choice of appropriate comparators will be different for the different stages in the risk assessment and is driven by the scientific issue that is addressed. Moreover, it should be clarified that in breeding organisms, changes are very common, and that not every change is significant and not every significant change is relevant in terms of risk.

- The two guidance documents subject to this consultation contain a collage of viewpoints collected during two years of consultations, but do not provide clear conclusions from EFSA for a common methodology for specific categories of cases.

2. The guidance is asking for more data and testing without justification.

Where the original guidance documents were based on a clear tiered approach, whereby additional information was only asked if that indicated to be necessary on the basis of earlier steps in the risk assessment, the current approach seems to ask for additional information and testing without such justification and in part even without clear explanation what to do and how to judge the additional data. As PRRI members expressed at the EFSA meeting on 31 March, this tendency seems to be based on the misconception that the technique of transformation itself causes all kinds of changes that would not occur in conventional breeding. As ample literature shows, there is no indication for that. On the contrary, there are many indications that it is the other way around. In short, this extensive and now increased searching for “unintended effects”, which is one of the main hurdles of the ERA, is introduced without scientific justification. In fact, the evidence accumulated in over 16 years of commercial growing of GM crops on over 1 billion hectares suggests that EFSA should go in the opposite direction, i.e. that for certain categories of GM crops, the requirements can be drastically reduced. Moreover, a large body of literature and meta analysis of those data also suggest that certain GM crops bring large environmental or health benefits over other choices (e.g. pesticide treatments). Not considering all these years of real life experience to relieve the regulatory burden where this is appropriate, is not sensible.

Finally, an observation about the proposed transformation of the guidance into regulations: the very nature of guidance is that it is flexible and allows for fine tuning on a case by case basis, and therefore cannot be transformed into regulations without losing that flexibility. PRRI strongly advised against cementing the EFSA guidance, even if revised to accommodate the above concerns, in regulations.

If you wish further information about any of the statements in this letter, please do not hesitate to contact us via: info@pubresreg.org.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Marc baron van Montagu', written over a light blue horizontal line.

Em. Prof. Marc baron van Montagu, Chairman of the Public Research and Regulation Initiative