GRACE
GMO Risk Assessment and Communication of Evidence

---

**GRACE Project Advisory Board (AB) Meeting**

5th June 2015, AgroBio Institute, Sofia University

---

Participants: Geoff Frampton (chair/rapporteur), Yaroslav Blume, Yann Devos, Huib de Vriend, Annette Poeting

Apologies: Didier Breyer, Kaja Kantorska

---

**Opening reflection**

Before discussing project matters the AB reflected, sadly, on the untimely passing of Piet Schenkelaars in 2014. Piet was a former member of the AB before he stood down due to ill health. We would like to express our condolences to Piet's family, friends and colleagues.

**MINUTES OF THE MEETING**

The AB first discussed the presentations given by the WP leaders and identified strengths, weaknesses, any lessons arising from the work that could be relevant to others, and any issues requiring action. Based on this information, the AB suggests recommendations for future activities and information requirements.

**WP1. Subchronic and one-year chronic toxicity studies with maize MON810**

The rat feeding studies have been successfully completed. This has involved a great deal of work on a large array of endpoints, for which the team should be congratulated.

The AB concurs with points raised after the WP presentation that the feeding study results should be reported and evaluated in the context of existing knowledge on the sensitivity and limitations of animal feeding trials with whole food.

The AB hopes that the data, once disseminated, will inform the debate about the role of animal feeding trials in GMO research.

Given the extensive data set that has been generated, the results could be used to explore the pros and cons of different possible statistical analysis approaches.

An overall summary of results/conclusions was not provided in the WP presentation. All presenters should be reminded of the importance of following good presentation etiquette to ensure efficient communication of information to the audience, e.g. providing a maximum of 5 bullet points per slide – which may require prioritisation of what are the key messages to be presented.

**WP2. Alternative *in vitro* testing approaches for commercialised GM food/feed**

An impressive array of analytical approaches including omics and cell cultures has been employed in this Work Package and the AB noted the dissemination work through publications is progressing well. The AB hopes that the information gained will contribute to an understanding of the relevance of the various methodological approaches to risk assessment, e.g. whether they have potential to replace animal feeding studies which is a topical debate.

As with WP1, the results should be evaluated in the context of existing knowledge on the sensitivity and limitations of animal feeding trials with whole food. The conclusions drawn should also be discussed taking into account the existing experience gained in relevant projects aimed at assessing the potential to replace or reduce animal studies in regulatory toxicology.

**WP3-5: evidence synthesis work packages**

These work packages were discussed together by the AB:

- WP3. Food feed and health impacts of GM plants
- WP4. Socio-economic impacts of GM plants
- WP5. Environmental impacts of GM plants

The AB recognises the hard work that teams have put in to developing the evidence synthesis projects in these work packages. Given that this is a new area of evidence synthesis, a lot has been achieved since the GRACE kick-off meeting in 2012. Some challenges have been encountered and some work is yet to be completed, but a number of valuable lessons have been learnt regarding how to conduct evidence syntheses related to GM plants.

In particular, results of these work packages highlight:

- The importance of comprehensive searching. For herbicide-tolerant GM crops WP5 found a considerable amount of unpublished (i.e. "grey") literature is available from reports held at USA universities but the reports have uninformative titles and abstracts and as such are challenging to locate (not identified in databases - contact with specific people/organisations may be necessary) and access.

- The importance of the USA as a potential source of evidence, as results from WP5 illustrate, given the extensive cultivation of GM crops there.

- The need to plan ahead with peer review of protocols. Since few journals in environmental science provide separate peer review of evidence synthesis protocols and the review question must be within the journal's scope, the choice of journal for publication of the evidence synthesis will need to be planned in advance. This may involve enquiring to several academic journals before a decision can be reached. If separate peer review of the protocol is not possible, then this should be stated as being a limitation in the critical reflection part of the discussion section of the evidence synthesis report.

- The need for careful project management of evidence syntheses. Especially, to:
  - avoid being over-ambitious with evidence syntheses - scoping and revisiting the problem may be appropriate to ensure that the work to be conducted can be accommodated within the agreed time and resource limits;

- plan to agreed deadlines, ideally with a contingency plan in case work does not proceed as expected;

- ensure adequate staff availability throughout the life of the evidence synthesis, keeping in mind that some steps require more than one reviewer and team members may have competing demands on their time;

- ensure reviewers have adequate staff training and experience or that this can be provided if necessary, since familiarity with processes improves efficiency;

- facilitate team communication - regular team meetings may be helpful to address problems arising, to discuss any disagreements, and to ensure reviewers know what is expected of them for the next steps of the work.

**WP6. Networking and database technology**

The AB recognises the important contribution that the CADIMA database will make towards transparent and efficient information dissemination for studies on GMO research. Although some concerns were raised about the functionality and flexibility of the database for accommodating completed and new evidence syntheses, the AB is pleased to hear that these concerns will be addressed when further developing CADIMA.

**WP7 & WP9. Communication and stakeholder involvement**

The AB considered the presentations on these two work packages together, and appreciates how well the stakeholder involvement has been coordinated and conducted in the face of various challenges. The approach for involving stakeholders has been experimental and it is crucial that lessons can be learnt from this, both for GRACE and also possibly to help identify, more generally, best practice for stakeholder involvement in evidence synthesis.

Regarding specifically the proposed Stakeholder Workshop in October 2015, the AB is concerned that the programme appears rather intensive, with relatively long presentations and short discussion times and quite a lot of material to cover in a relatively limited time. There is a risk that stakeholders may feel disappointed if not given enough time to contribute adequately. It will be important therefore to think beforehand how to structure each discussion, to ensure relevant issues are not missed and that minor issues do not dominate.

For the Stakeholder Workshop and also presentations in general the AB would like to remind all participants follow the principles of good presentation practice to ensure efficient communication of information to the audience, e.g. presenting clear conclusions preceded by slides substantiating each of these conclusions and providing a maximum of 5 bullet points per slide – which may require prioritisation of what are the key messages to be presented.

**WP8. Framework for good review practice**

The AB noted that during discussions in the current meeting the need for careful wording of any project documents became apparent, since some terms (such as “sensitivity” or “quality”) can have different meanings. Careful wording of any recommendations arising from GRACE is therefore important.

In particular, the scope of an assessment in terms of whether it is assessing “risk” or “impact” should be accurately reported.

The AB also stresses to project participants that any recommendations arising should be evidence-based and if there are limitations to any methods employed these should be acknowledged in the discussion section of reports and publications.

An IOBC paper has been produced regarding good practice in evidence synthesis, authored by the WP leaders. A further paper has been submitted by the WP8 leader to a Frontiers journal, discussing the potential role of systematic reviews in informing GMO risk assessment. Geoff Frampton is a co-author on both papers.

**Recommendations for future activities**

Based on information presented during the meeting, the AB agreed that:

(1) With the project nearing its end date, steps should be taken to maximise further research opportunities where possible to enable best use to be made of experiences gained during the project.

(2) In the context of GMO risk assessment, there is a need for guidance on the following:

- When should a systematic review be conducted?
- Who should be responsible for initiating a systematic review?
- Who should be responsible for conducting a systematic review?
- How to decide when an existing systematic review should be updated?

Additionally, in the interests of maintaining transparency and accountability, it was agreed as a procedural matter that the AB should be acknowledged and the AB minutes (past and present) should be made accessible to anyone who wishes to consult them via the GRACE website. The current AB members will provide declarations of interests (on a standard form when this is provided). It was reiterated that the role of Yann Devos is to specifically advise on the evidence synthesis work packages, not the animal feeding studies, and it is important that no confusion arises over this role.