GRACE
GMO Risk Assessment and Communication of Evidence

Minutes of the GRACE Project Advisory Board (AB) meeting

CRAG, Barcelona, 22 November 2013

Participants:

Geoff Frampton (Evidence synthesis) (chair)
Huib de Vriend (Communication)
Didier Breyer (Competent Authority)
Kaja Kantorska (DG SANCO)

Observer: Jens Hoegel (EC DG Research / E2 <<Biotechnologies>>)

Apologies: received from Yaroslav Blume, Yann Devos, Annette Pöting

The AB meeting was structured as follows:

1) Reflection on progress with the GRACE project following the initial AB meeting in June 2012

2) Issues raised by GRACE participants for AB comment/advice

3) Issues raised by members of the AB for the GRACE project participants to consider

1) Reflection on progress since the June 2012 AB meeting

For minutes of the June 2012 AB meeting please refer to the members' area of the GRACE website.

The AB agreed that its key recommendations made at the inaugural meeting in June 2012 have been addressed satisfactorily. In particular, the AB noted that:

- GRACE project participants have attended evidence synthesis training and have considerably improved their understanding of evidence synthesis approaches;
- GRACE participants have a clearer awareness of the resource requirements associated with the conduct of different types of evidence synthesis;
- GRACE has implemented processes to address how its evidence syntheses will be peer-reviewed and disseminated;
- the role of GRACE project databases has been refined and clarified;
- Stakeholders have been sought and actively involved in the prioritisation of questions for evidence synthesis;
- Awareness of the GRACE project has increased.

On balance, the AB felt that progress has been good, given the complexity of the evidence synthesis approaches and their relative novelty of application in the risk assessment of GMOs. The same feeling was expressed with regards to WP1 and WP2, the AB being very satisfied with the results already obtained at this early stage of the project.

The AB also recognized that the communication strategy of the GRACE project was innovative and adaptive, and that an important aspect of the project was the development of tools (such as CADIMA) usable beyond the lifetime of GRACE.

2) Issues raised by GRACE participants for AB comment/advice

Although numerous issues were discussed among GRACE participants during the PEC and GA meetings, no specific issues arising were directed to the AB for consideration.

3) Issues raised by members of the AB for the GRACE project participants to consider

Three issues were discussed by the AB, leading to some recommendations for the GRACE project participants to consider:

3a) Communication strategies for informing and involving stakeholders

The AB is aware that some stakeholders incorrectly believe the GRACE project to be intimately involved in the regulatory process for GMOs. This misunderstanding was evident at the April 2013 GRACE Stakeholder Workshop in Berlin and from subsequent stakeholder feedback. Some stakeholders appear to presume that methods employed by the GRACE project are being adopted as regulatory practice (this has, for example, raised concerns about differences between GRACE methods and EFSA guidance for conducting sub-chronic toxicity studies). The misunderstanding may reflect (or be reinforced by) the way the Commission Implementing Regulation (EU) No 503/2013 refers to GRACE or to approaches used in GRACE, and also requires that systematic reviews are required in the current GMO regulatory risk assessment process. [The AB felt that the wording of the Regulation (Annex6, point 1), i.e. requiring systematic reviews to be conducted, does not reflect the intended regulatory practice – since systematic reviews may not be feasible and are not required for example in regulatory submissions for active substances.]

The AB discussed possible communication strategies that might facilitate clarification to stakeholders that GRACE is specifically a research project and is not involved in the GMO regulation process. The AB requests that GRACE participants, especially WP7 (stakeholder involvement) and WP 9 (communication), consider the following:

Communication is most likely to be effective if clearly targeted. GRACE could identify which stakeholder groups should be the focus of communication and then engage directly with them (although potentially labour intensive). Since stakeholders may vary in their information needs, it may be appropriate to employ different communication strategies for different stakeholder groups.

It will be necessary to demonstrate/clarify that GRACE research and GMO regulation are different processes. Possibly, meetings in which GRACE as well as DG SANCO or Competent Authorities present information could be considered (to ensure that information is presented in a way that is regarded as authoritative and balanced by stakeholders). Potential communication opportunities could include:

- SANCO Advisory Forum meetings (e.g. could involve industry and NGOs as participants, in an open discussion format with officials from the EC).

- The next Stakeholders' meeting in Brussels: (a) Could there be a role for DG RTD and DG SANCO here? (b) should the meeting be structured in such a way as to clearly differentiate between the research project and the regulatory context?
- European Biosafety Committee meetings (EU-wide representation of biosafety advisory committees every 2 years).
- Other meetings/opportunities to communicate GRACE to EU Member States.

Are there stakeholder groups that GRACE has not considered but should reach? The AB agreed that young people are relevant stakeholders given the long-term potential implications of GRACE. Young scientists in particular might be considered as a target audience. At national and EU research policy levels there is interest in engaging young scientists, so could GRACE be represented at young scientist meetings at EU level?

3b) Training of stakeholders

The AB noted that stakeholders are being asked to comment on the evidence synthesis process and in particular on draft evidence synthesis protocols, yet most stakeholders have not received any training in evidence synthesis methods. GRACE participants could consider possible options for stakeholder training (e.g. in collaboration with the CEE) if sufficient resources can be identified. Some discussions had already taken place along these lines, e.g. mentioned by Armin Spök during the PEC/GA meeting. Biosafety Committees in Europe could provide potential opportunities. Advantages of stakeholder training could be (1) improved understanding of the role of and need for evidence synthesis by stakeholders; (2) training is a useful project output in its own right; (3) training may help to reduce misunderstandings about the research/regulatory boundary of ERA.

3c) Resources and deadlines

Based on experiences in other areas (e.g. health research) there is a risk that poor management of evidence syntheses can lead to "mission creep", in which work expands beyond the a priori agreed deadlines and/or resources. This can have implications for review quality and sets a bad example in terms of resource management. Since GRACE evidence syntheses may be viewed by stakeholders as examples of good practice, the AB feels that it is important to ensure that WP tasks should be kept to their planned timetables and staff resources. Any "slippage" of work should therefore be identified by WP leaders as early as possible so that corrective steps can be taken where needed.