



**(DIS-)GRACE:**

**Risk assessment on the leash of the biotech industry**

Andreas Bauer-Panskus & Christoph Then for Testbiotech

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## *Summary*

GRACE (**G**MO **R**isk **A**ssessment and **C**ommunication of **E**vidence) is a publicly funded EU research project. The costs of the project add up to more than 7.7 million Euros, of which almost six million come from the EU.

About half the experts participating in GRACE have close connections with organisations funded entirely or partly by the biotech industry. However, none of these organisations (ISBR, ILSI and PRRI) are mentioned as participants in the project. Analysis shows that a relatively small circle of people close to the biotech industry have for many years been benefiting from public funding dedicated to risk assessment, and have also substantially influenced the standards used for assessing the risks associated with genetically engineered plants.

One further criticism must be that many people who worked for, or are still working for the European Food Safety Association (EFSA) are participating in the GRACE project. From the very start, GRACE appears to have been neither open nor unbiased, and subsequently there is an expectation that it will tend to justify the severely controversial standards of EFSA rather than challenge them.

Overall, GRACE does not ensure the necessary level of independence and is not sufficiently transparent. The EU Commission has assigned millions of Euros from research funds without reassessing the possible conflicts of interest of the participating experts. Consequently, genetically engineered plants may be incorrectly assessed, and potential hazards for humans and the environment not recognised.

The project should be frozen and assessed by a suitable commission before it is allocated any further funds. At the same time, some measures should be put in place regardless of the outcome of the audit. These should include reassignment of the leading project manager and a significant reduction in the number of experts tied to industry and EFSA.

Further, the EU Commission itself must tighten up and impose its own rules on reassessing conflicts of interest. Money from public funding should essentially be used to set up risk assessment that is independent of industry.

## ***What is GRACE?***

GRACE (GMO Risk Assessment and Communication of Evidence) is a publically funded EU research programme within the Seventh Framework Programme<sup>1</sup>. Project duration is between 2012 and 2015. The costs add up to more than 7.7 million Euros, of which almost six million are from the EU.

GRACE is coordinated by Prof. Joachim Schiemann, head of the Institute for Biosafety in Plant Biotechnology at the *Julius Kühn-Institut* (JKI), an agency of the Federal Ministry of Food, Agriculture and Consumer Protection (BMELV).

According to information on the project website GRACE will focus on two issues<sup>2</sup>:

- Assessment of the impact of GMO on health, the environment and socio-economic effects. Additionally, it will develop criteria to evaluate scientific papers on their scientific validity.
- Development of different kinds of feeding trials and other methods for assessing impacts on health. Additionally, it will assess whether long-term feeding trials add value to risk assessment. No long-term studies are planned.

**Table 1: Overview: Work packages and key subjects of GRACE**

Evaluation of animal feeding trials and alternative <i>in vitro</i> studies for the assessment of GMO impacts on human health	
Work package (WP) 1	Subchronic toxicity studies
WP 2	Alternative <i>in-vitro</i> testing approaches
Reviewing of data and research activities on beneficial and adverse impacts of genetically engineered crops	
WP 3	Review of food, feed & health impacts caused by GM crops
WP 4	Review of socio-economic topics
WP 5	Review of environmental impacts of GM plants
WP 6	Networking and database technology
WP 7	Stakeholder and user involvement
WP 8	Good practice for reviews in GMO risk assessment
Communication and dissemination WP 9	
Project management (WP 10)	

1 [http://cordis.europa.eu/search/index.cfm?fuseaction=proj.document&PJ\\_RCN=13017259](http://cordis.europa.eu/search/index.cfm?fuseaction=proj.document&PJ_RCN=13017259)

2 <http://www.grace-fp7.eu/content/grace-brief>

### *The importance of GRACE and its conceptual weaknesses*

Results from the GRACE project can have a significant impact on which future methods and criteria will be used in the EU to assess the risks of genetically engineered plants and animals designated for approval for cultivation or use in feed and food.

(1) The results from the project will be used to make decisions on whether feeding trials with genetically engineered plants must be conducted before they are granted approval in the EU. In 2013, the EU for the first time implemented a regulation requiring three-month feeding trials for some future new registrations – this regulation will be reconsidered, amongst others, on the basis of results from the GRACE project.

GRACE plans to carry out several 90-day feeding trials, but there are no planned long-term studies. Hence, the project, which, among other things, is supposed to assess the added-value of long-term studies, has obvious conceptual deficiencies. There will be feeding trials with the GM maize MON810 and potatoes, but there will be no studies with herbicide resistant plants. Neither will they consider so-called stacked events, which are plants consisting of several DNA constructs. This means that GM plants, which will be the largest part of EU approvals and EU imports, will not be included.

(2) The European Food Safety Authority EFSA will in future be able to use the model developed by GRACE to evaluate publications and test results, and to reject them on grounds of formal criteria. This might lead them to consider only the proven risks and reject as irrelevant studies not showing clear evidence of risks and dangers. EFSA assessments already show a similar approach. The precautionary principle, which is legally required for the assessment of risks in the EU, and requires the consideration of uncertainties and lack of knowledge, might be severely weakened by GRACE.

(3) Within GRACE, possible economic advantages are accorded considerable importance. There is a danger that in future, possible economic advantages will outweigh impacts on the environment and cause the protection of humans and the environment to fall further behind.

### ***GRACE experts - close ties to the GMO industry***

Due to its possible impact, the independence of experts in the GRACE project must be regarded as crucial. However, there are a remarkable number of ties between the GMO industry and the scientists involved in GRACE. The EU commission obviously failed to adequately check the applicants for possible conflicts of interest.

GRACE is a joint project of 17 participants from 13 countries. Amongst them are universities, federal research institutes and ministries. The US Department of Agriculture (USDA) is listed as an external cooperation partner. Formally, this is an assemblage of a broad range of scientific knowledge. However, it is obvious that some project partners are also developers of genetically engineered plants (such as the *Council for Scientific and Industrial Research*, CSIR), or explicitly serve as consultants for the GMO industry (like Perseus or Genius).

(1) Julius Kühn-Institut<sup>3</sup>, Germany  
(Coordinator)



(2) Agrobiointitute<sup>4</sup>, Bulgaria

(3) Aarhus Universitet<sup>5</sup>, Denmark

(4) Centre for European Policy Studies<sup>6</sup>,  
Belgium

(5) Centre de Recerca Agrigenòmica  
Consorti CSIC-IRTA-UAB<sup>7</sup>, Spain

(6) Eidgenössisches  
Volkswirtschaftsdepartement<sup>8</sup>, Switzerland

(7) Freie Universität Berlin<sup>9</sup>, Germany

(8) Genius GmbH<sup>10</sup>, Germany

(9) International Centre for Genetic  
Engineering and Biotechnology<sup>11</sup>, Italy

(10) Interdisziplinäres Forschungszentrum  
für Technik, Arbeit und Kultur<sup>12</sup>, Austria

(11) Institut National de la Recherche  
Agronomique<sup>13</sup>, France

(12) Perseus BVBA<sup>14</sup>, Belgium

(13) Stichting Dienst Landbouwkundig  
Onderzoek<sup>15</sup>, The Netherlands

(14) Sweet Environmental Consultant,  
United Kingdom

(15) Slovenska Zdravotnicka Univerzita v  
Bratislave<sup>16</sup>, Slovakia

(16) Technische Universität München<sup>17</sup>,  
Germany

(17) Council for Scientific and Industrial  
Research<sup>18</sup>, South Africa

Third Party participant:  
University of Girona<sup>19</sup>, Spain

Cooperation partner (external):  
United States Department of Agriculture, Agricultural Research Service<sup>20</sup>, USA

A closer look reveals that the project is indeed more heavily influenced by industry interests than is visible at first sight.

(1) Eight of the experts identified as project participants<sup>3</sup> are members of the *International Society for Biosafety Research* (ISBR). According to its self-declaration, ISBR is „an independent, non-profit scientific organisation”<sup>4</sup> However, there can be no doubt that ISBR has close ties with the GMO industry. ISBR conferences are regularly sponsored by companies such as Monsanto, Bayer, Dow AgroSciences, DuPont, Syngenta and by industry groups such as CropLife International.<sup>5</sup>

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3 The project website gives little clarity about the experts actually involved in GRACE. An overview that is at least partly verified can only be achieved by own investigations.

4 <http://www.isbr.info/?q=node/490>

5 <http://www.isbgmo.com/conference-sponsors.html>

Industry employees such as Tom Nickson<sup>6</sup> (Monsanto) and Alan Raybould<sup>7</sup> (Syngenta) hold or held leading positions within ISBR.

ISBR was founded in 1992 by scientists such as

- Klaus Ammann, a vehement and well-known advocate of genetically engineered plants with ties to Monsanto;
- Alan McHughen, the inventor of the genetically engineered flaxseed line „Triffid“; Triffid became well-known in 2009 when it was discovered that large parts of the Canadian flaxseed harvest were contaminated with this trait;
- Mark Tepfer, long-time employee at the *International Centre for Genetic Engineering and Biotechnology* (ICGEB), which is now a GRACE partner.

The following members of ISBR are also participants in GRACE:

- Joachim Schiemann (*Julius Kühn-Institut*, JKI), filed a patent for a genetically engineered plants (WO9816824). Prof. Schiemann has a long history of involvement in different organisations lobbying for GMOs.<sup>8</sup> Between 2004 and 2008, he acted as president of ISBR. He is project coordinator of GRACE.
- Patrick Rüdelsheim (Perseus) was a successor of Joachim Schiemann as president of ISBR. Amongst others, he is member of the industry organisation *European Federation of Biotechnology* (EFB) and a former employee of GMO companies such as Bayer or Aventis.<sup>9</sup> In GRACE, Perseus is responsible for organisation and communication.
- Kristina Sinemus and Klaus Minol are heads of the public relations agency Genius, which has industry clients such as BASF, Bayer Crop Science and Syngenta. Genius is responsible for the project communication and website.
- Jeremy Seet is a long-time expert of the EFSA GMO Panel. In GRACE, he is responsible for the assessment of scientific studies on environmental risks.
- Ralf Wilhelm (JKI) has worked with industry on the monitoring of genetically engineered plants.<sup>10</sup> Together with Joachim Schiemann, he is a project coordinator of GRACE.
- Jörg Romeis (Research Station Agroscope Reckenholz-Tänikon) is another example of a scientist who constantly appears in contexts where science converges with industry. His role

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6 <http://www.isbr.info/node/145>

7 <http://www.isbr.info/?q=node/665>

8 e.g. Lorch A. & Then C., (2008) Kontrolle oder Kollaboration, <http://www.testbiotech.de/node/88>

9 [http://www.perseus.be/perseus\\_englisch/people\\_eng.htm](http://www.perseus.be/perseus_englisch/people_eng.htm)

10 Lorch A. & Then C., (2008) Kontrolle oder Kollaboration, <http://www.testbiotech.de/node/88>

in GRACE is unclear.

- Wendy Craig of the *International Centre for Genetic Engineering and Biotechnology* (ICGEB) is a successor of ISBR-cofounder Marc Tepfer. In GRACE, she is responsible for the open access database of studies regarding the assessment of GMOs.

ISBR appears to be the main body running the GRACE project although there is no official mention of the organisation.

(2) Another organisation, which is not mentioned officially, but has close ties to several GRACE experts, is the *International Life Sciences Institute* (ILSI). ILSI is funded by Coca-Cola, Monsanto and others. Since 2012, scientists with an active role in ILSI are no longer allowed to serve as EFSA Panel members.<sup>11</sup> At least six GRACE participants have ties to ILSI:

- Joachim Schiemann (see above), co-author of ILSI publications,<sup>12</sup>;
- Patrick Rüdelsheim (see above), co-author of ILSI publication,<sup>13</sup>;
- Jörg Romeis (see above), co-author of ILSI publications, organiser of ILSI workshops,<sup>14</sup>;
- Esther Kok (RIKILT, EFSA), member of an ILSI task force, co-author of ILSI publication<sup>15</sup>; planning and execution of GRACE studies regarding risk assessment;
- Gijs Kleter (RIKILT, EFSA), member of an ILSI task force, co-author of ILSI publications;<sup>16</sup> planning and execution of GRACE studies regarding risk assessment;
- Jean-Michel Wal, (*Institut National de la Recherche Agronomique*, INRA), member of ILSI expert group, co-author of ILSI publications, ILSI conference speaker;<sup>17</sup> planning and execution of GRACE studies regarding risk assessment.

(3) A third organisation, which has to be mentioned is the *Public Research and Regulation Initiative* (PRRI). This organisation lobbies for GMOs in international bodies such as the Convention of Biological Diversity (CBD). Scientists involved in PRRI have advocated lower regulatory standards

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11 However, ILSI collaborators are allowed to serve in EFSA Panels if they are no longer active in ILSI.

12 [http://cera-gmc.org/docs/cera\\_publications/pub\\_01\\_2009.pdf](http://cera-gmc.org/docs/cera_publications/pub_01_2009.pdf)

13 <http://www.ilsi.org/Europe/Documents/ILSI-11-002%20FOOD%20CROPS03.pdf>

14 [http://cera-gmc.org/uploads/pub\\_01\\_2013.pdf](http://cera-gmc.org/uploads/pub_01_2013.pdf)

[http://cera-gmc.org/docs/cera\\_publications/pub\\_03\\_2010.pdf](http://cera-gmc.org/docs/cera_publications/pub_03_2010.pdf)

15 [http://www.ilsi.org/FoodBioTech/Publications/02\\_Nutritional%20Safety%20Assessment%20of%20GM%20Foods\\_2004.pdf](http://www.ilsi.org/FoodBioTech/Publications/02_Nutritional%20Safety%20Assessment%20of%20GM%20Foods_2004.pdf)

16 <http://www.ilsi.org/FoodBioTech/Pages/NutritionalandSafetyAssessments.aspx>

17 <http://www.sciencedirect.com/science/article/pii/S0278691507003456>

<http://www.hesiglobal.org/i4a/pages/index.cfm?pageid=3595>



for genetically engineered plants. PRRI was sponsored by Syngenta Foundation, CropLife International, US Grain Council, Monsanto and Arborgen.<sup>18</sup> Members of PRRI who also participate in GRACE are<sup>19</sup>:

- Joachim Schiemann (see above);
- Jörg Romeis (see above);
- Atanas Atanassov (AgroBioinstitute, Bulgaria; *European Federation of Biotechnology*, EFB); his function in GRACE is unclear;
- Justus Wesseler (TU Munich); in GRACE he's responsible for the review of the socioeconomic effects of GMOs.

Altogether, at least three organisations with strong industry involvement, are not mentioned as project partners, but are represented by half of the senior GRACE scientists.

The network of some leading scientists who operate at the fringes between science and industry goes even further. There is a noticeable convergence of GRACE participants with the working group "GMO's in integrated plant production" at the IOBC/WPRS.<sup>20</sup> The working group is led by the Swiss scientists Jörg Romeis and Franz Bigler, another expert is Alan Raybould (Syngenta, ISBR). Jeremy Sweet (ISBR), Joachim Schiemann (JKI, ISBR..) and Ralf Wilhelm (JKI, ISBR) are playing leading roles in the preparation of the June 2013 conference of the working group.<sup>21</sup> A representative of the seed company KWS is also a member of the Steering Committee for the conference. The public relations company, Genius, led by Kristina Sinemus is responsible for the conference website. As previously mentioned, Kristina Sinemus also leads public relations for GRACE and ISBR. One of the main activities of the group led by Romeis is the development of a different approach to the environmental risk assessment of genetically engineered plants. This new approach is being developed jointly with members of several federal research facilities (such as Joachim Schiemann) and companies such as Syngenta, Monsanto, Bayer, BASF, Pioneer, Dow, as well as the *International Life Sciences Institute* (ILSI).<sup>22</sup> The working group published its main

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18 [http://web.archive.org/web/20090709062104/http://pubresreg.org/index.php?option=com\\_content&task=view&id=12&Itemid=29](http://web.archive.org/web/20090709062104/http://pubresreg.org/index.php?option=com_content&task=view&id=12&Itemid=29)

19 <http://www.ppri.net/prri-members/>

20 International Organization for Biological and Integrated Control of Noxious Animals and Plants, West Palearctic Regional Section (IOBC/WPRS), [http://www.iobc-wprs.org/expert\\_groups/18\\_wg\\_gmo.html](http://www.iobc-wprs.org/expert_groups/18_wg_gmo.html)

21 <http://www.eigmo.info/content/home>

22 s. auch: Testbiotech (2010) European Food Safety Authority: A playing field for the biotech industry <http://www.testbiotech.de/en/node/431>

results in 2008<sup>23</sup> and 2011<sup>24</sup>.

Further, in the past, a closely associated group of people has already participated in other EU projects regarding genetically engineered plants. For example, the coexistence project „Co-Extra“ was almost identical to the same core group in GRACE. Members of „Co-Extra“ were:<sup>25</sup>

- Atanas Atanassov,
- Joachim Schiemann,
- Kristina Sinemus,
- Klaus Minol, and
- Jeremy Sweet.

Not even the GRACE participant representing the US Department of Agriculture (USDA) can be seen as neutral. Together with EFSA expert Howard Davies, William Belknap is the inventor of a patent on genetically engineered potatoes (United States Patent 7,375,259).

More critically, many of the people involved in GRACE are also current or former GMO experts for the European Food Safety Agency (EFSA). Overall, it appears that any GRACE findings will be predetermined and one can expect that the GRACE project is more likely to legitimate highly contentious EFSA standards rather than question them.

Analysis of the structure behind GRACE shows that a relatively small circle of people with close ties to the GMO industry have for a long time benefited from public funds allocated to risk assessment, and also exercise considerable influence on the standards of risk assessment of genetically engineered plants.

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23 Romeis, J., Bartsch, D., Bigler, F., Candolfi, M. P., Gielkens, M. M., Hartley, S. E., Hellmich, R.L., Huesing, J.E., Jepson, P.C., Layton, R., Quemada, H., Raybould, A., Rose, R.I., Schiemann, J., Sears, M.K., Shelton, A.M., Sweet, J., Vaituzis, Z., Wolt, J. D. (2008). Assessment of risk of insect-resistant transgenic crops to nontarget arthropods. *Nature biotechnology*, 26(2): 203-208. <http://web.entomology.cornell.edu/shelton/publications/pdf/Romeis%20et%20al%202008%20Assessment%20of%20risk%20of%20insect-resistant%20transgenic%20crops%20to%20non-target%20organisms.pdf>

24 Romeis, J., Hellmich, R.L., Candolfi, M.P., Carstens, K., De Schrijver, A., Gatehouse, A.M., Herman, R.A., Huesing, J.E., McLean, M.A., Raybould, A., Shelton, A.M., Waggoner, A. (2011) Recommendations for the design of laboratory studies on non-target arthropods for risk assessment of genetically engineered plants. *Transgenic research*, 20(1): 1-22. [http://www.iobc-wprs.org/expert\\_groups/Romeis\\_et\\_al\\_2011\\_Transgenic\\_Research\\_study\\_design.pdf](http://www.iobc-wprs.org/expert_groups/Romeis_et_al_2011_Transgenic_Research_study_design.pdf)

25 <http://www.coextra.eu/about.html>, [http://www.coextra.eu/project\\_description/coextra269.html](http://www.coextra.eu/project_description/coextra269.html)

GRACE suffers from a lack of independence and has hardly any independent leading scientists. To this list, one can add a considerable lack of transparency. According to the official press release of the project leader (JKI), transparency is one of the main concerns of GRACE<sup>26</sup>, but the GRACE website does not even clarify which experts are involved in GRACE or state their function. A reasonable overview can only be achieved by detailed investigations.

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26 [http://www.icgeb.org/tl\\_files/News\\_2012/News\\_2012pdf/Press\\_release\\_GRACE.pdf](http://www.icgeb.org/tl_files/News_2012/News_2012pdf/Press_release_GRACE.pdf)

**Table 2: Preliminary overview of GRACE participants and their affiliations to industry-oriented organisations**

GRACE expert	GRACE partner organisation	ISBR	ILSI	PRRI	IOBC/WPRS	EFSA	Other affiliations
Atanassov, Atanas	AgroBioinstitute			X			European Federation of Biotechnology (EFB), International Centre for Genetic Engineering and Biotechnology (ICGEB)
Barros, Eugenia	CSIR						Several publications with ILSI experts
Belknap, William	USDA						Genetically engineered potato patent
Craig, Wendy	ICGEB	X					
Damgaard, Christian	Aarhus University						
Einspanier, Ralf	FU Berlin					X	
Hendriksen, Niels Bohse	Aarhus University					X	
Kleter, Gijs	RIKILT		X			X	
Kok, Esther	RIKILT		X			X	
Krogh, Paul Henning	Aarhus University					X	
Minol, Klaus	Genius	X					
Pla, Maria	CRAG						
Romeis, Jörg	Agroscope	X	X	X	X		
Rüdelsheim, Patrick	Perseus	X	X				Bayer CropScience, European Federation of Biotechnology (EFB)
Schiemann, Joachim	Julius Kühn-Institut	X	X	X	X	X	
Sinemus, Kristina	Genius	X			X		Deutsche Industrievereinigung Biotechnologie (DIB)
Smets, Greet	Perseus						Advanta Seeds B.V., CropDesign
Spök, Armin	ITAS						
Sweet, Jeremy	Sweet Environmental Consultants	X			X	X	
Wal, Jean-Michel	INRA		X			X	
Wesseler, Justus	TU Munich			X			
Wilhelm, Ralf	Julius Kühn-Institute	X			X		
Zeljenkova, Dagmar	Slovak Medical University						

## *Conclusions and recommendations*

Many of the scientists participating in GRACE are too closely linked to the biotech industry. There is a danger that results from the project will be influenced by biased interests. At the same time, there is a certain probability that funds, which would be crucial for promoting independent risk assessment, will be spent with no substantial gain in knowledge.

### Recommendations:

- The project should be frozen and assessed by an independent commission before spending further funds.
- The aims and the planned studies should undergo a suitability assessment.
- Some measures should be put in place regardless of the outcome of the audit. The leading project manager should be reassigned. There should be a significant reduction in the number of experts with ties to industry and the EFSA. This includes the number of experts affiliated with EFSA committees.
- Comparable active and completed EU projects should be assessed in detail for possible influence from industry.
- The EU commission must tighten up and impose its own rules on reassessing conflicts of interest. Public funding should be directed at setting up independent risk assessment.
- Public funds should be specifically used to set up risk assessment that is independent of industry. Environment and consumer protection organisations should be included in design and funding decisions.

## *Abbreviations*

CRAG	Centre de Recerca Agrigenòmica Consorci
CSIR	Council for Scientific and Industrial Research
EFB	European Federation of Biotechnology
EFSA	European Food Safety Agency
GRACE	GMO Risk Assessment and Communication of Evidence
ICGEB	International Centre for Genetic Engineering and Biotechnology
IFZ	Interuniversitäres Forschungszentrum für Technik, Arbeit und Kultur
IOBC/WPRS	International Organization for Biological and Integrated Control of Noxious Animals and Plants, West Palearctic Regional Section
ISBR	International Society for Biosafety Research (ISBR)
JKI	Julius Kühn-Institut
PRRI	Public Research and Regulation Initiative
RIKILT	Rijks Kwaliteitsinstituut voor Land- en Tuinbouwproducten
USDA	US Department of Agriculture