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The impact of industry on publicly-funded risk research projects on genetically engineered plants

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Content

Summary

Several large-scale research projects on genetically engineered plants are currently underway in the European Union as part of the 7th Research Framework Programme (FP7). Some of these are nearing completion or have already been completed. In total, we identified six research projects to which around twenty million euros of public money were allocated. We, further, found evidence that five out of the six coordinators of the research projects had strong ties to institutions affiliated to the biotech industry. The research projects were:

- **GRACE** (GMO Risk Assessment and Communication of Evidence)
- **G-TwYST** (GMP Two Year Safety Testing)
- **MARLON** (Monitoring of Animals for Feed-related Risks in the Long Term)
- **PRICE** (PRactical Implementation of Coexistence in Europe)
- **PRESTO** (Preparatory steps towards a GMO research ERA-Net)

The coordinators of the above listed projects have particularly strong ties to the International Life Sciences Institute (ILSI), which has in the past been heavily criticised as a lobbyist institution for the biotech industry. Two other institutions that repeatedly show up in this context are the International Society for Biosafety Research (ISBR) and the Public Research and Regulation Initiative (PRRI), both of which receive financial support from the biotech industry.

The networks documented in this report that exist between the coordinators of the projects and some institutions with strong affiliations to the biotech industry cannot simply be regarded as coincidental. On the contrary, we have to assume that there were mechanisms active in the selection of the projects that led to a relatively small number of biased experts taking up a dominant position in the FP7 risk research programme on genetically engineered plants.

As this report shows, the interests of the biotech industry seem to have had a substantial impact on the outcome of the projects. Some results were not well presented or interpreted from a biased point of view and, in several cases, the most relevant questions and problems were not taken into account. Overall, the outcomes of the research projects are tailored to assumptions that largely fulfil the expectations of industry. These are that:

- the standards of risk assessment can be lowered, in particular mandatory feeding trials are seen as unnecessary;
- the targeted monitoring of the health impacts of genetically engineered plants in feed is not practical and not needed;
- current regimes of coexistence are sufficient to protect farmers and food producers who want to avoid genetically engineered plants.

At the meetings with GRACE, G-TwYST, MARLON and PRICE research projects, it became apparent that some of the experts and coordinators had from the outset held very clear views on

what the final results of projects would be. For example, several GRACE experts repeatedly stated that feeding trials as a mandatory part of risk assessment would not be necessary. Their view was that feeding trials might only be necessary in a few exceptional cases.

In 2016, the EU Commission will be making further decisions on the standards of risk assessment for genetically engineered plants. When it makes its decision, the Commission will be specifically referring to the outcome of these projects to assist in the decision-making process. In this context, there is a substantial risk that the EU Commission will intentionally or unintentionally come to false conclusions and, therefore, fail to set standards that take full account of the precautionary approach required by EU regulations. For example, some observers expect the EU Commission to abandon feeding trials that only recently became mandatory.

The consequences of such a decision can be exemplified by taking a closer look at EFSA risk assessment. Currently, around 60 genetically engineered plants or events have been assessed and authorised for import into the EU. An overview of EFSA risk assessment from 2012-2015 shows that there is either no, or only inadequate data available from 90-day feeding trials. In fact, in only two of the twenty cases can the data be said to come anywhere near to fulfilling the necessary quality standards for such trials. Furthermore, as yet no information has been provided on any feeding trials with genetically engineered plants lasting longer than 90 days. In addition, the combinatorial effects of genetically engineered plants mixed into food and feed have not been assessed.

The discussion about the possible carcinogenic effects of red meat may help in understanding the complexity of the questions at stake: The IARC Working Group of the World Health Organisation (WHO), in October 2015, published a statement saying that the consumption of red meat in certain amounts is probably carcinogenic to humans. The causes of these effects were described as small and not well understood. Contrary to the risk assessment of chemically defined substances with potential toxicity, such effects can only be detected after data has been gathered from an extremely large number of people over a longer period of time. These questions show some strong similarities to those that are seen as decisive and being asked in the context of the risk assessment of genetically engineered plants. There is no answer to these questions at the present time.

In the light of the many open questions and uncertainties in risk assessment, Testbiotech recommends stopping any further authorisations for genetically engineered plants. If market authorisations continue to be issued at the current rate, then risk assessment needs to be thoroughly re-organised and much higher standards implemented to comply with the precautionary principle which underpins EU regulation.

Furthermore, Testbiotech is calling for full transparency of the selection processes for research projects such as GRACE, and an independent and critical analysis of the experts chosen to work on projects and the outcome of the projects. Testbiotech is, in addition, calling for a systematic

approach to promoting risk research that is completely independent of the interests of the biotech-industry. For example, NGOs such ass environmental or consumer organisations should be involved right from the start in the selection process of projects for risk research and not just when the projects have already started.

1. Introduction

Several large-scale research projects on genetically engineered plants are currently underway in the European Union as part of the 7th Research Framework Programme (FP7). Some of these are nearing completion or have already been completed:

- **GRACE** (GMO Risk Assessment and Communication of Evidence)
- **G-TwYST** (GMP Two Year Safety Testing)
- **MARLON** (Monitoring of Animals for Feed-related Risks in the Long Term)
- **PRICE** (PRactical Implementation of Coexistence in Europe)
- **PRESTO** (Preparatory steps towards a GMO research ERA-Net)
- **AMIGA** (Assessing and Monitoring the Impacts of Genetically modified plants on Agro-ecosystems)

Table 1: Overview of EU funding and duration of the projects

Project	EU funding (€)	Duration
GRACE	5.981.013	2012 – 2015
G-Twyst	2.999.890	2014 - 2018
MARLON	999.593	2012 - 2015
PRICE	2.999.751	2011 – 2015
AMIGA	5.997.963	2011 – 2015
PRESTO	996.739	2013 - 2015
Total sum	19.974.949	

At least some of these projects may be crucial to the future risk assessment of transgenic plants in the EU. This is especially true for the GRACE research project: The results of this project will provide a basis for the evaluation of the current legal basis for the risk assessment of genetically engineered plants. The Commission Implementing Regulation 503/2013 2013 states that:[1]

> *„The Commission shall monitor the application of this Regulation, the developments in scientific knowledge on replacement, reduction and refinement of animal use in scientific*

1 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:157:0001:0048:EN:PDF

procedures and the publication of new guidance from EFSA. The Commission shall in particular monitor the outcome of the research project called GRACE (GMO Risk Assessment and Communication of Evidence) under the 2012 work programme of the seventh Framework Programme for Research (FP7).“

In 2013, using the example of the GRACE research project, Testbiotech showed that the majority of the project participants and the GRACE coordinator had close contacts to industry, industry-funded think-tanks or other lobby groups (Bauer Panskus & Then, 2013).

Current Testbiotech investigations concern the coordinators of six EU research projects. Although EU projects always include a number of project partners, the coordinators of the projects play a particularly crucial role.

"The task starts with the coordination of the notification and submission and outlasts the duration of the project and the follow-up of the project. The coordinators are the sole contact for the European Commission for all the project issues. They also coordinate the preparation of all project reports to be provided to the Commission."[2]

Through their central role, project coordinators may influence EU projects to a greater extent than other project participants. At the same time, many of the coordinators also serve as experts in other EU projects and can thus magnify influence on the projects. Although (as shown in GRACE), connections to industry-related organisations are not restricted to the coordinators, the connections of other project participants are not the subject of this report.

2 http://www.forschungsrahmenprogramm.de/projektpartner.htm

2. Overview of research projects and their coordinators

The following sections provide an overview of the EU FP7 research projects on genetically engineered plants and the connections of the project coordinators to industry-related organisations. An overview of research projects and their coordinators is shown in Figure 1.

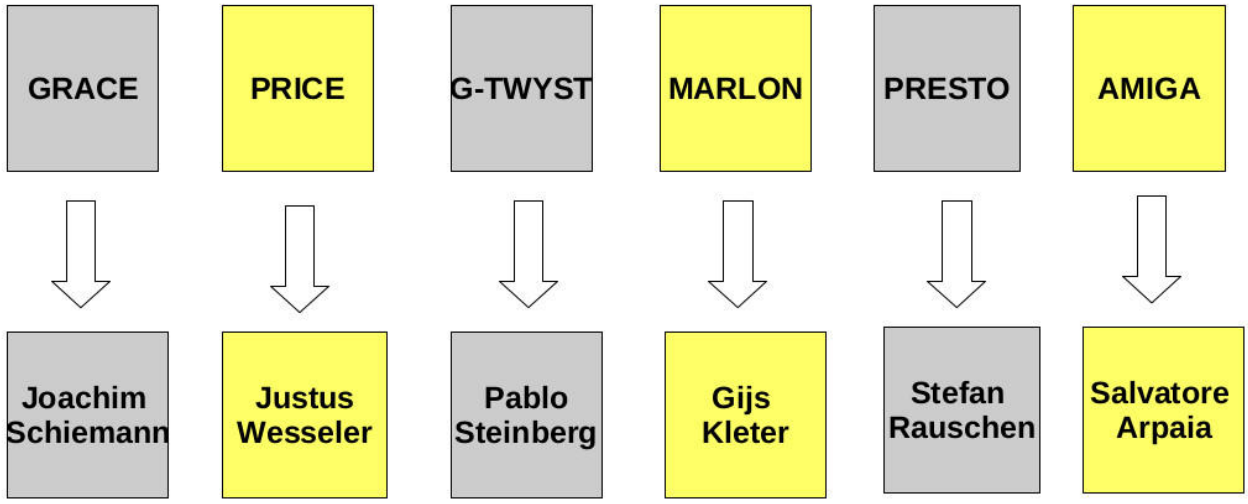

Figure 1: Current EU research projects and their coordinators

More information about ILSI, ISBR and PRRI can be found in Table 2.

Table 2: Overview of ILSI, ISBR and PRRI

Institution	Activities
ILSI (International Life Sciences Institute)	The International Life Sciences Institute (ILSI) is mainly funded by food, pharmaceutical and agrochemical companies. For example, the European branch of the organisation (ILSI Europe) lists among others, BASF, Bayer CropScience, DuPont and Monsanto as members.[3] A Monsanto representative was until recently president of the international governing body of ILSI, the Board of Trustees.[4] ILSI's work has been criticised for many years. For example, the organisation was officially rebuked by the WHO because of its collaboration with the tobacco industry.[5] The European Food Safety Authority voiced its criticism of the work of the organisation in a letter to the European Parliament that was written in 2012. According to the letter, ILSI experts "cannot be considered for the role of chair or vice-chair of any of EFSA's scientific groups, nor can [s/he] become a member of a single mandate Working Group in a scientific area for

3 http://www.ilsi.org/Documents/ILSI_2013_Member_List.pdf

4 Bauer-Panskus & Then, 2015; https://web.archive.org/web/20141107190641/http://www.ilsi.org/Pages/Leadership.aspx

5 http://www.who.int/tobacco/media/en/ILSI.pdf

Institution	Activities
	which [s/he] ha[s] current experience at ILSI".[6] This statement applies to all relevant areas of expertise such as biotechnology, pesticides or food additives. In 2012, ILSI was also excluded from EFSA's Stakeholder Platform.[7]
IOBC/WPRS (International Organization for Biological Control West Palearctic Regional Section)	Working Group „GMOs in integrated plant production“.[8] A central focal point of this working group is the development of a new approach to environmental risk assessment. This has so far resulted in joint publications with researchers from biotechnology corporations such as Syngenta, Monsanto, Bayer, BASF, Pioneer, Dow International Life Sciences Institute (ILSI) in 2008[9] and 2011[10]. Until recently, the board of the working group includedd Alan Raybould from Syngenta.[11]
ISBR (International Society for Biosafety Research)	The International Society for Biosafety Research (ISBR) is closely linked to the biotechnology and agrochemical industry as well as other organisations such as ILSI. Only a few details regarding the funding of ISBR are available. However, the society's conferences are regularly sponsored by biotech corporations such as Monsanto, Bayer, Dow AgroSciences, DuPont and Syngenta as well as the international federation of the genetic engineering industry, CropLife International.[12] The ISBR Board consists almost exclusively of experts from industry or with ILSI affiliations.[13]
Public Research and Regulation Initiative	The organisation is committed to international negotiations regarding genetically engineered plants and warns of an increasing burden of authorisation standards. Numerous researchers from German authorities and universities are members of the organisation.[14] PRRI received funds from Syngenta Foundation, CropLife

6 http://www.efsa.europa.eu/en/press/news/120516.htm

7 http://elc-eu.org/uploads/press_room/ELC_June_2012_press_clippings.pdf, http://www.efsa.europa.eu/en/events/event/120614a.htm

8 http://www.iobc-wprs.org/expert_groups/18_wg_gmo.html

9 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.

10 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.

11 Bauer-Panskus & Then, 2015; https://web.archive.org/web/20130705145159/http://www.iobc-wprs.org/expert_groups/18_wg_gmo.html

12 Bauer-Panskus & Then, 2015.

13 http://isbr.info/Board_of_Directors

14 http://www.prri.net/prri-members/

Institution	Activities
(PRRI)	International, US Grain Council, Monsanto and Arborgen.[15]

2.1 GRACE (GMO Risk Assessment and Communication of Evidence)

GRACE is an EU research project testing various types of feeding trials and looking at alternative methods of studying the health effects of genetically engineered plants.[16] Among other things, the aim of the project is to investigate whether long-term feeding trials provide useful information for risk assessment. In this context, feeding trials with maize MON810 were conducted on rats for three months (90 days) and for one year. The results of the 90-day feeding trials have already been published in a scientific paper.[17] The other feeding trials have been completed, but as yet no publications are available. GRACE also conducted systematic reviews of existing publications in the area of risks research on genetically engineered plants.

Coordinator

Joachim Schiemann is the coordinator of the GRACE project. He is head of the Institute for Biosafety in Plant Biotechnology at the Julius Kühn Institute (JKI), the Federal Research Centre for Cultivated Plants. There are numerous indications of his close ties to the biotech industry. He is:

- Co-author of scientific publications funded by the International Life Sciences Institute (ILSI) (see Bauer Panskus & Then, 2015),
- a member of the Public Research and Regulation Initiative (PRRI)[18],
- and from 2004 to 2008, he was president of the International Society for Biosafety Research (ISBR), which is closely linked to the biotechnology and agrochemical industries, in addition to other industry-related institutions such as ILSI (see Bauer Panskus & Then, 2015).

Schiemann has a clear position regarding standards of risk assessment: He is co-author of a report commissioned by the European Academy Scientific Advisory Panels (EASAC, 2013) and as such has demanded the lowering of the standards of risk assessment for genetically engineered crops in the EU (see Then, 2013).

He is also involved in the EU research projects MARLON, PRESTO, G-TwYST and PRICE. At the same time, the coordinators Gijs Kleter, Pablo Steinberg and Justus Wesseler also participated in the GRACE research project. GRACE and G-TwYST are also closely interlinked in the feeding trials: The trials are conducted at the same laboratories, Steinberg is in leading position in all of these feeding studies.

15 https://web.archive.org/web/20090709062104/http://pubresreg.org/index.php?option=com_content&task=view&id=12&Itemid=29

16 http://www.grace-fp7.eu/
http://cordis.europa.eu/project/rcn/104334_en.html

17 http://link.springer.com/article/10.1007/s00204-014-1374-8

18 http://www.prri.net/prri-members/

2.2 G-TwYST (GMP Two Year Safety Testing)

The objective of the "GMP Two Year Safety Testing" research project (G-TwYST) is to test the health effects of transgenic maize NK603 in a 90-day feeding trial, and in a combined one- and two-year feeding trial.[19] The starting point for this project is a study conducted by the French scientist Gilles-Éric Séralini that was published in 2012. Séralini found an increase in the incidence of tumours when rats were fed maize NK603 in long-term feeding trials (two years). Several authorities, including the European Food Safety Authority, declared that the study was flawed, and it was consequently withdrawn from the scientific journal, Food and Chemical Toxicology. In 2014, the Séralini study was re-published in the open-access journal Environmental Sciences Europe.[20]

Coordinator

Prof. Pablo Steinberg is the coordinator of the G-TwYST research project. He is a toxicologist at the University of Veterinary Medicine Hannover. In the 1980s and 1990s, Pablo Steinberg was at the Institute of Toxicology, University of Mainz. Many experts in this institute were associated with the tobacco industry.[21] Since 2008, he has held the position of Director of the Institute of Food Toxicology and Chemical Analysis at the University of Veterinary Medicine Hannover.[22]

Prof. Steinberg has close links with the International Life Sciences Institute (ILSI). Among other things, he was a member of the expert group "Determination of the Effectiveness of Dietary Exposure Reduction Measures on Human Health" of the ILSI Task Force "Process-Related Compounds and Natural Toxins", along with scientists from Nestlé or PepsiCo.[23] Task force participants are mainly employees of large food companies such as Nestlé, Kellogg, Mars or Südzucker. Steinberg was also involved in ILSI-led projects funded by the EU[24] and has published several joint studies with ILSI staff and scientists with long-standing ties to the industry think-tank.[25] Pablo Steinberg is also a member of the Scientific Advisory Council of the Institute Danone of food company, Danone.[26]

Steinberg also participates in the EU research projects GRACE and MARLON. G-TwYST and GRACE are interlinked (see above).

The results of this project (the feeding trials) are not yet available.

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19 http://cordis.europa.eu/project/rcn/191522_en.html

20 http://www.enveurope.com/content/26/1/14

21 http://www.testbiotech.org/node/1130

22 http://www.tiho-hannover.de/?id=1051

23 https://web.archive.org/web/20140731110025/http://www.ilsi.org/Europe/Pages/Process-related-Compounds-and-Natural-Toxins-Expert-Groups.aspx

24 http://www.ilsi.org/Europe/Documents/FOSIENews.pdf

25 Barlow, S. M., Greig, J. B., Bridges, J. W., Carere, A., Carpy, A. J. M., Galli, C. L., ... & Steinberg, P. (2002). Hazard identification by methods of animal-based toxicology. Food and Chemical Toxicology, 40(2), 145-191. http://www.sciencedirect.com/science/article/pii/S027869150100117X

Dybing, E., Doe, J., Groten, J., Kleiner, J., O'Brien, J., Renwick, A. G., ... & Younes, M. (2002). Hazard characterisation of chemicals in food and diet: dose response, mechanisms and extrapolation issues. Food and Chemical Toxicology, 40(2), 237-282. http://www.sciencedirect.com/science/article/pii/S0278691501001156

26 http://www.institut-danone.de/institut/vorstand-und-wissenschaftlicher-beirat/

2.3 MARLON (Monitoring of Animals for Feed-Related Risks in the Long Term)

The aim of the MARLON project is to develop an epidemiological model for the case-specific monitoring of health effects of genetically engineered feed.[27]

Coordinator

Project coordinator is Gijs Kleter of Wageningen University. Kleter was vice chairman of the GMO Panel of the European Food Safety Authority until 2015, and has been criticised for his links to ILSI. For example, in 2010, Testbiotech pointed out that Kleter was a long-term member of an ILSI Task Force that developed guidelines for the risk assessment of genetically engineered plants.[28] As a task force member, he was also co-author of several ILSI publications.[29] Kleter is closely involved in the GRACE research project. Joachim Schiemann (coordinator GRACE) and Pablo Steinberg (Coordinator G TwYST) were also involved in the MARLON project.

2.4 PRICE (PRactical Implementation of Coexistence in Europe)

Among others, the objective of the PRICE research project is to look at the economic analysis of coexistence practices in Europe and the development of a decision support system for coexistence issues.[30]

Coordinator

Project coordinator is Prof. Justus Wesseler, who teaches at the Technical University of Munich-Weihenstephan and the University of Wageningen.[31] Amongst other roles, Wesseler is the editor of the magazine AgBioForum that is funded by the Illinois-Missouri Biotechnology Alliance (IMBA).[32] Their goal is to improve the situation of companies in the US food and agricultural sector.[33]

He is also a member of several industry-related organisations such as the International Consortium on Applied Bioeconomy Research (ICABR).[34] Organisers of the last ICABR conference were mainly scientists with known proximity to the biotech industry as well as employees of the industry lobby organisation, ISAAA (International Service for the Acquisition of Agri-Biotech Applications).[35] Wesseler is a member of the GM lobby organisation PRRI (Public Research and Regulation Initiative)[36] and has been repeatedly quoted in press releases and information materials

27 http://cordis.europa.eu/project/rcn/104250_en.html, http://web.spi.pt/marlon/index.html
28 http://www.ilsi.org/FoodBioTech/Pages/NutritionalandSafetyAssessments.aspx
29 http://www.ilsi.org/FoodBioTech/Publications/02_Nutritional%20_Safety%20Assessment%20of%20GM%20Foods_2004.pdf http://www.ilsi.org/FoodBioTech/Publications/10_ILSI2008_CaseStudies_CRFSFS.pdf
30 http://cordis.europa.eu/project/rcn/101403_en.html, http://price-coexistence.com/
31 http://www.wageningenur.nl/en/Persons/dr.-JHH-Wesseler.htm
32 http://www.agbioforum.org/welcome.htm
33 https://web.archive.org/web/20130722134842/http://www.imba.missouri.edu/index.php?region=2
34 https://web.archive.org/web/20130108075639/http://www.icabr.org/cms/people
35 http://www.economia.uniroma2.it/icabr-conference/sarea.php?p=19&sa=263
36 http://www.prri.net/prri-members/

of the lobby group EuropaBio.[37] In 2014, he published a scientific work whose core message was that the (irrational) opposition to the introduction of "Golden Rice", a genetically modified rice line that contains vitamin A produced in the grain, was responsible for the death of 1.4 million people in India alone.[38] This is factually incorrect. According to the International Rice Research Center IRRI, which deals with a possible cultivation of GM rice, data crucial to the decision on the introduction of Golden Rice is still missing.[39]
Justus Wesseler is also involved in the GRACE research project. Joachim Schiemann (coordinator GRACE) is also involved in PRICE.

2.5 PRESTO (Preparatory steps towards a GMO research ERA-Net)

The aim of the PRESTO research project is, inter alia, the coordination of research on the effects of genetically modified organisms (GMOs) on human and animal health and the environment.[40]

Coordinator
Stefan Rauschen is the coordinator of the PRESTO research project. Together with researchers from Monsanto, Syngenta, and other companies, he is one of the authors of an ILSI publication on the risk assessment of genetically engineered plants.[41] He is a member of various GMO-related organisations, including the lobby association Public Research and Regulation Initiative (PRRI). Rauschen once served as secretary of PRRI.[42] By his own account,[43] he is also a member of other industry-related organisations such as the International Society for Biosafety Research (ISBR), as well as being a member of the working group "GMO's in integrated plant production" of the organisation IOBC / WPRS. Rauschen is also a board member of the "Forum Bio- und Gentechnologie - Verein zur Förderung der gesellschaftlichen Diskussionskultur e.V.".[44] The association edits the internet portal TRANSGEN, which is, according to its own account, financed by Bayer CropScience, BASF, Dow AgroSciences, Monsanto Agriculture, Du Pont / Pioneer Hi-Bred International and Syngenta Agro.[45]
The results of the PRESTO research project are not yet available.

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37 http://www.europabio.org/agricultural/press/global-farmers-ask-why-are-european-farmers-not-allowed-take-advantage

38 Wesseler, J., & Zilberman, D. (2014) The economic power of the Golden Rice opposition. *Environment and Development Economics,* 1-19. http://journals.cambridge.org/action/displayAbstract?fromPage=online&aid=9136416&fileId=S1355770X1300065X

39 http://irri.org/golden-rice/faqs/when-will-golden-rice-be-available-to-farmers-and-consumers

40 http://www.presto-gmo-era-net.eu/, http://cordis.europa.eu/project/rcn/110106_en.html

41 Carstens, K., Anderson, J., Bachman, P., De Schrijver, A., Dively, G., Federici, B., Hamer, M., Gielkens, M., Jensen, P., Lamp, W., Rauschen, S., Ridley, G., Romeis, J., Waggoner, A. (2012) Genetically modified crops and aquatic ecosystems: considerations for environmental risk assessment and non-target organism testing. Transgenic research, 21(4): 813-842. http://link.springer.com/article/10.1007/s11248-011-9569-8

42 http://web.archive.org/web/20111007031541/http://pubresreg.org/index.php?option=com_content&task=view&id=15&Itemid=53

43 http://www.researchgate.net/profile/Stefan_Rauschen/info

44 http://www.forum-biotechnologie.de/de/impressum.html

45 http://www.transgen.de/leitlinien.html

2.6 AMIGA (Assessing and Monitoring the Impacts of Genetically modified plants on Agro-ecosystems)

The aim of the Amiga research project is to obtain data on possible environmental effects and the economic impacts of cultivation of GM crops in the EU.[46]

Coordinator

Coordinator of the Amiga research project is Salvatore Arpaia, who was also member of the EFSA GMO Panel from 2006 to 2015.[47] The composition of the AMIGA project appears to be more balanced than the other EU research projects. There are also far fewer personnel overlaps with the GRACE, G-TwYST, Marlon, and PRESTO PRICE (see Figure 2) research projects. Therefore we did not asses this project in detail.

Figure 2 gives an overview of the networks within the five other projects.

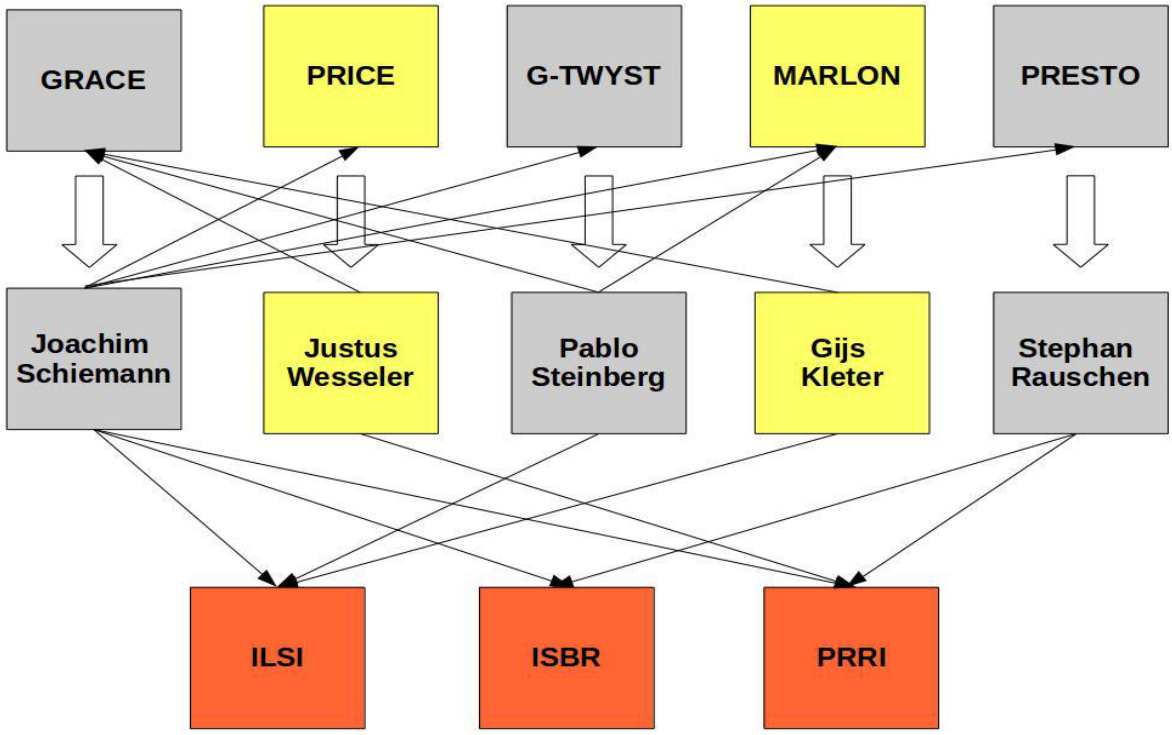

Figure 2: The EU research projects GRACE, G-TwYST, MARLON, PRESTO and PRICE, their coordinators and relevant links to industry-related institutions, as well as participation of the coordinators in other projects.

46 http://cordis.europa.eu/project/rcn/101406_en.html
http://www.amigaproject.eu/

47 http://www.efsa.europa.eu/en/gmomembers/gmopreviousmembers.htm

3. Impact on the results of the research projects

While G-TwYST and PRESTO are not yet finished, results from the GRACE, MARLON and PRICE research projects have already been published. The following paragraphs explain why we believe that there are strong signs that these results have been impacted by the interests of the biotech industry.

3.1 GRACE

3.1.1 Feeding studies and alternatives

It became clear at the stakeholder workshop in Vienna in October 2015, to which Testbiotech was invited, that there is a tendency amongst GRACE experts to no longer recommend or request 90-day animal feeding trials. The EU only made these feeding trials mandatory from the beginning of 2014 onwards.[48] No longer requesting the feeding trials would substantially lower the standards of risk assessment and the requirements for data to be provided by companies. Some of the arguments against feeding trials raised concerns about animal welfare. Others stated that feeding trials were in general not suitable for investigating the health risks of genetically engineered plants. In this context, concerns were raised that it would be problematic if significant findings emerged with no clear biological relevance. GRACE, it was contended could now provide more precise alternative methods.

However, it became very clear from presentations made by several GRACE experts and from the discussions in Vienna that the alternative methods referred to have not yet been developed to the extent that they could, in fact, replace animal feeding studies. This is also true for the so-called Omics methods, which can be used to measure gene activity and metabolism in the plants. Moreover, in-vitro methods using cell cultures for the assessment of genetically engineered plants are not yet fit for purpose. Experts at the workshop in Vienna commented that a period of ten years would be needed to develop sufficiently advanced methods and protocols. The methods currently available can be quite helpful if they are used additionally, but they cannot replace animal feeding trials at the present time.

Despite these issues, several GRACE experts were keen to give the impression that the new alternatives could, in most cases, be used to replace feeding trials. Their statements are not based on the outcome of the project, but on specific expectations and predetermined assumptions. In particular, there could, for example, be a certain amount of interest in harmonising US and EU authorisation processes to overcome trade barriers and enhance free trade (see also Van Eenennaam & Young, 2014). Feeding trials are not required in the US.

48 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:157:0001:0048:EN:PDF

3.1.2 Systematic Reviews

So-called systematic reviews were conducted as part of the GRACE research project - these assessed scientific publications according to specific criteria. For example, a systematic review outcome was presented on the impacts of the cultivation of herbicide resistant plants. The review was led by Jeremy Sweet, a member of the GMO panel at EFSA, who is active in a consulting company as well as in ISBR[49]. In this review, the most relevant problems such as the emergence of herbicide resistant weeds and increasing herbicide applications were not taken into account. Consequently, it might have given the impression that there are no major negative impacts from the large-scale cultivation of herbicide-resistant genetically engineered plants.

As the above example shows, systematic reviews as requested by GRACE have to be viewed with a certain amount of caution, since the outcome of these reviews or meta-analyses can be manipulated, for example, through data selection (also see below).

3.2 MARLON

During this research project a great many obstacles were thrown into the process that made it more or less impossible to gather appropriate data for sound monitoring. It was, for example, argued that it would be practically impossible to gather sufficient data on the exposure of farm animals to feed derived from genetically engineered plants (see for example the presentation made by Louise Vince „Animal Health Surveillance in the context of Genetically Modified feed“[50]).

This is incorrect. The amount of imports into the EU are, for example, monitored by Eurostat. In this context, soybeans as a source of protein are the most important animal feed. There is also no problem in obtaining data on the overall percentage of genetically engineered plants in the imports. One can, for example, request these data directly from industry. Furthermore, in the EU there are many animal production sites that have been certified as free from feeding with genetically engineered plants, so it would be relatively easy to find appropriate groups for comparison. This kind of monitoring, using data from similar animal production sites would be much more informative and provide more relevant data than just a collection of data on animal health without appropriate control. From a scientific point of view, there can be no justification for this not being discussed in the MARLON research project.

Instead, in the context of the MARLON research project, data and methods were presented that are apparently unsuitable for drawing conclusions on the impact of genetically engineered plants on animal health. For example, during the final conference, a former Monsanto member of staff, van Eenennaam, presented via a video conference data on somatic cell counts, milk production, carcass weight, days to slaughter in dairy cows since the introduction of genetically engineered plants in the

49 www.testbiotech.org/node/1272

50 http://marlon-project.eu/downloads/final-conference/final-conference/03_Louise-Vince.pdf

US[51] (see also Van Eenennaam & Young, 2014). For many years there have been breeding programs designed to influence these criteria and to enhance production. Further, there are other relevant impact factors here such as housing of the animals and standards of hygiene. Thus it can be expected that potential effects from feed will be masked by other much more influential impact factors, especially if no groups for comparison are incorporated.

3.3 PRICE

A media release from March 2015 summarised the outcome of the PRICE research project.[52] Experts involved in the project stated that the outcome of the project showed that current EU regulations were sufficiently robust to avoid major problems with contamination from genetically engineered plants. They made special reference to field trials with genetically engineered maize in Spain.

They did not, however, mention findings from investigations in Portugal, where bakery products were found to be contaminated with genetically engineered maize, in some cases to quite a high level. PRICE experts took samples from bread baked with maize and sold in Portugal. Altogether, they analysed sixteen bread samples from seven regions. All the samples were contaminated with genetically engineered maize MON810 and NK603. Some of them showed a content of genetically engineered maize of up to ten percent. A lack of control in the supply chain was presumed to be the cause.[53] None of this was mentioned in the recent PRICE media release. Instead, the PRICE media release, went on to claim that current measures implemented to ensure coexistence in the EU “are practically feasible, both at the farm level and along the supply chain”.

51 http://marlon-project.eu/downloads/final-conference/final-conference/06_Alison_Van_Eenennaam.pdf
52 http://price-coexistence.com/home.html
53 http://price-coexistence.com/page/downloads/Newsletter_03-04-08_-_The_Portuguese_maize_bread_supply.pdf

4. Further impacts

In the following chapter we present a more detailed review of the outcome of the projects and explain possible implications.

4.1. The GRACE feeding trials

Standard toxicological studies routinely use 90-day feeding trials for which OECD standards apply. However, in comparison, it might be much more difficult to detect possible unintended effects caused by genetically engineered plants. The composition of these plants is not as clearly defined as specific chemical compounds, and the mechanisms that can cause negative health effects can be various, such as altered plant composition, effects of intended additional proteins or any unintended gene products. In general, most potential health effects due to genetically engineered plants are much more difficult to investigate compared to plants composed of defined chemical substances.

However, 90-day feeding trials are so far the only method frequently used to not only assess single isolated compounds, but also the whole food and feed derived from these plants. Further, feeding trials with whole feed are carried out with poultry, which normally last for a period of 42 days. However, these trials are only meant to provide information about the nutritional quality of the feed, and cannot provide reliable information on health effects. Only experts with specific interests might try to use such data to assess potential health effects (see for example Van Eenennaam & Young, 2014).

90-day feeding trials are certainly not sufficient in regard to the complexity of the risks they are used to assess, but at least they can deliver some basic data that can inform further risk assessment. This is the reason why in 2013, the EU Commission made such feeding trials mandatory for market applications being filed after beginning of 2014 (but stacked events derived from crossing of genetically engineered plants are excluded).[54] However, as yet this implementation regulation has not been applied because since then EFSA has not assessed any relevant application.

In 2016, the EU Commission will be making further decisions on the standards of risk assessment for genetically engineered plants. Apparently several of the experts and coordinators had very clear ideas what the final results of projects would be right from the outset of the projects. For example, several GRACE experts such as Joachim Schiemann, Gijs Kleter and Esther Kok repeatedly said at the meetings with stakeholders that it would not be necessary to have feeding trials studies as mandatory element of risk assessment. Their view was that feeding trials might only be required in a few exceptional cases.

In this context, the GRACE research project suffers from a general problem: Feeding trials, 90 days and 1 year, were performed with one specific maize event (MON810). However, the outcome of

54 http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:157:0001:0048:EN:PDF

these trials should not be regarded as conclusive for other events or feeding trials that are differently designed. If the feeding trials were performed correctly, the outcome of these trials can reduce uncertainties in regard to the health risks of MON810 (the project came to the conclusion that no evidence on negative health effects could be concluded). But no further general conclusions can be drawn as, for example, to whether longer feeding trials can provide better results than shorter trials or what the outcome would have been if other genetically plants had been part of the diet. But drawing such general conclusions is precisely the objective of the GRACE research project:

> *„GRACE will test various types of animal feeding trials and alternative in vitro methods in order to determine how suitable they are and what useful scientific information they provide for health risk assessments of GM food and feed. The European Commission is considering whether 90-day feeding trials should be a mandatory test method for the risk assessment of GM foods and feeds.“*[55]

Currently, around 60 genetically engineered events have been assessed and authorised for import into the EU. Many of those were never tested in a 90-day feeding trial. One example is the genetically engineered maize known as SmartStax, which produces six insecticides and is engineered to be resistant to two herbicides. The EU Commission issued market authorisation for this stacked event without requesting any feeding trials with whole food and feed to assess potential health effects.[56] It should further be noted that the combinatorial effects of genetically engineered plants mixed into food and feed have likewise never been assessed.

There are further levels of complexity that will add to these problems in the near future: Market applications for so-called stacked events such as SmartStax are increasing. In addition, several applications have been filed for plants that are changed in their nutritional quality. The risk assessment of these plants might prove to be much more complicated than for plants that were only made resistant to one herbicide. [57]

Table 3 (Annex) shows that there is a huge disparity between the approach of the GRACE research project and the real situation: Either no, or no adequate, data from 90-day feeding trials is available for the vast majority of genetically engineered plants positively assessed by EFSA in recent years. Only in two of twenty cases does the data made available come close to fulfilling the necessary quality standards for such trials. Furthermore, we do not yet have any information on the feeding trials with these plants that lasted longer than 90 days. From this point of view, either with or without GRACE, it is not possible to conclude on the biosafety of these genetically engineered plants, or even which feeding trials would be adequate to assess them.

The discussion about the possible carcinogenic effects of red meat may help in understanding the complexity of the questions at stake: The IARC Working Group of the World Health Organisation

55 http://www.grace-fp7.eu/en/content/grace-brief
56 See: www.testbiotech.org/sites/default/files/Briefing%20_Testbiotech_Complaint_SmartStax_0.pdf
57 See: www.testbiotech.org/sites/default/files/Technical%20Dossier%20altered_oil_soybeans_complaint.pdf

(WHO), in October 2015, published a statement saying that the consumption of red meat in certain amounts is probably carcinogenic to humans.[58] The causes of these effects are described as small and not well understood. Such effects can only be detected after data has been gathered from an extremely large number of people over a longer period of time:

> *„The IARC Working Group considered more than 800 different studies on cancer in humans (some studies provided data on both types of meat; in total more than 700 epidemiological studies provided data on red meat and more than 400 epidemiological studies provided data on processed meat).“*[59]

The complexity of the underlying scientific problems shows strong similarities to the questions that are decisive and being asked in in the context of the risk assessment of genetically engineered plants. These questions cannot be answered at the present time.

Basically, there are two scenarios for decision-making on future developments:

1. One possible solution is to reduce uncertainties by stopping or at least substantially reducing the number of market authorisations. Testbiotech strongly recommends this approach.
2. Developing better methods for assessing health impacts to generate more reliable results. This would mean making feeding trials over the lifetime of the animals and following generations compulsory. At the same time, much more effort must be put into developing more reliable methods that can be used to complement or to replace feeding studies.

4.2 Systematic Reviews within GRACE

The application of systematic evidence synthesis has to be viewed with caution when it comes to the area of genetically engineered organisms and their impact on the environment. The data are often heterogeneous and less standardised as, for example, in the area of pharmaceuticals and chemicals. There is a risk of streamlining data to such an extent that most relevant information is lost. Another risk is that data that are too heterogeneous are compared without making the factual limitations explicit. As a result, the risk of producing what could be called 'pseudo-evidence' is very high.

As the example of frequently quoted studies by Klümper & Qaim (2014) or Van Eenennaam & Young (2014) show, meta-analysis based on heterogeneous and partially biased data can lead to misleading conclusions. In the cases mentioned above, the conclusions were immediately communicated by various proponents to the wider public to give the impression that decisive evidence had been found for the economic advantages and safety of genetically engineered plants. These examples show that many politicians and journalists are often unable to critically appraise or analyse the methods used in meta-analyses, even if the methods and sources of data are made available. Further, the GRACE research project did not, for example, scrutinise the controversially

58 http://www.iarc.fr/en/media-centre/pr/2015/pdfs/pr240_E.pdf

59 http://www.iarc.fr/en/media-centre/iarcnews/pdf/Monographs-Q&A_Vol114.pdf

discussed and flawed study by Klümper & Qaim[60] but rather used it as a template for developing its own model for systematic reviews. Consequently, it has to be taken into account that systematic reviews as proposed by GRACE are susceptible to the construction of either intentionally or unintentionally biased evidence. Even if the source of data is known and transparent there cannot be an expectation that resources and skills from independent sources are available to the extent needed to critically assess these reviews.

4.3 MARLON

EU Directive 2001/18 (see Kraemer, 2012) requires the monitoring of the potential impacts of genetically engineered food and feed but, at the same time, there are no sufficiently robust and efficient models to collect adequate data. Consequently, there is no reliable data available to assess, for example, possible impacts on the emergence of chronic diseases. So far, there has never been a request to monitor the health effects in a specific case.

As the EU Commission stated in 2005[61]:

> *"As regards food safety, even if some GM products have been found to be safe and approved on a large scale..., the lack of general surveillance and consequently of any exposure data and assessment, means that there is no data whatsoever available on the consumption of these products – who has eaten what and when. Consequently, one can accept with a high degree of confidence that there is no acute toxicological risk posed by the relevant products, as this would probably not have gone undetected – even if one cannot rule out completely acute anaphylactic exceptional episodes. However, in the absence of exposure data in respect of chronic conditions that are common, such as allergy and cancer, there simply is no way of ascertaining whether the introduction of GM products has had any other effect on human health."*

This situation has not changed substantially in recent years, even though some experts have tried to give an impression to the contrary (see Van Eenennaam & Young, 2014).

Because imports of genetically engineered plants into the EU are mostly used in animal feed, robust epidemiological data on the health of these animals could help to assess the long-term health effects. Thus, there should be some recognition and acknowledgment of the fact that the official purpose of the MARLON research project is to establish suitable models for case specific monitoring.

However, it certainly appears that the experts involved in this project did not really have an intention of establishing models to improve the situation. Consequently, the likelihood is that there will be no specific monitoring in future cases.

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60 See www.gen-ethisches-netzwerk.de/GID/228/frieling/positive-effekte-agro-gentechnik

61 European Communities - Measures affecting the approval and marketing of biotech products (DS291, DS292, DS293). Comments by the European Communities on the scientific and technical advice to the panel. 28 January 2005

5. Conclusions

The research projects GRACE, G-TwYST, MARLON, PRESTO and PRICE are strongly interlinked through their coordinators, their cooperating institutions and cooperation partners. Such a strong interlinking can deliver positive effects. However, in this case, it means that all the projects suffer from a similar problem i.e. the biased interests of experts and coordinators. This is not only evident from the interconnections between the experts and institutions such as ISBR and ILSI, but is also mirrored in the results presented so far.

The networks documented in this report existing between the coordinators of the projects and some institutions with strong affiliations to the biotech industry cannot be regarded as having simply arisen. The reasons they have arisen must be assumed to lie in the very early stages of the research projects. We have to assume that there were mechanisms inherent in the selection of these projects and experts, which in the end, enabled a relatively small number of biased experts to gain a predominant position in the overall FP7 risk research programs on genetically engineered plants. According to EU decisions, the EU-Commission is obliged to make sure that the highest scientific standards are applied to the EU research projects at all stages, reaching from the selection of the projects to the final publication of the results.[62] Furthermore, according to EU Directive 2001/18, the Commission is obliged to establish independent risk research. Clearly, the EU Commission has failed to fulfil these obligations.

The way in which industry is systematically influencing publically-funded research projects can be compared to the strategy of tobacco industry, that had a detrimental impact on international research on the health impacts of tobacco for several decades (see, for example Grüning et al., 2012). There are also parallels to more recent cases in the US, where scientists claiming in public discussions on genetically engineered plants to be independent, were actually being paid by the agrochemical companies.[63]

As we exemplify in our report, the interests of industry appear to have substantially impacted the outcome of the research projects. Some results were not well presented or were interpreted with a particular bias. In several cases the most relevant questions and problems were not even taken into account. Overall, the outcome of the research projects are tailored to assumptions that largely fulfil the expectations of industry. These are that:

- the standards of risk assessment can be lowered, especially mandatory feeding studies are not necessary, in particular mandatory feeding trials are seen as unnecessary;
- the targeted monitoring of the health impacts from feeding genetically engineered plants is not practical;
- current regimes of coexistence are sufficient to protect farmers and food producers who want to avoid genetically engineered plants.

62 Decision 2011/161/EU of 28/2/2011 http://ec.europa.eu/research/participants/data/ref/fp7/100406/fp7-evrules_en.pdf

63 www.nytimes.com/2015/09/06/us/food-industry-enlisted-academics-in-gmo-lobbying-war-emails-show.html, www.buzzfeed.com/brookeborel/when-scientists-email-monsanto

In 2016, the EU Commission will be making further decisions on standards of risk assessment for genetically engineered plants. The outcomes of the above-described research projects will play an important role in the decision-making process. There is in this respect a substantial risk that the EU Commission will come to false conclusions and, therefore, fail to set standards that take full account of the precautionary approach as required in EU regulations.

In the light of the many open questions and uncertainties in risk assessment, Testbiotech recommends stopping the issue of any further authorisations for genetically engineered plants, or at least a substantial reduction in further authorisations. If political circumstances prevent this measure from being implemented, then the risk assessment standards need to be raised substantially.

Testbiotech is, further, calling for full transparency in the selection processes for research projects such as GRACE, an independent and critical analysis of the chosen experts and, finally, transparency in the outcome of the projects. In addition, Testbiotech wants to see a systematic approach to promote independent risk research free of the interests of the biotech-industry. For example, NGOs should be involved right from the start in the selection processes of projects for risk research and not just when the projects have already started.

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Annex

Table 3: Genetically engineered plants for import assessed by EFSA since 2012 (Source: EFSA / Testbiotech)

Event	Year	Company	Species	Traits	Feeding trials for 90 days	Comment
MON87705 x MON89788	2015	Monsanto	Soybean	Resistance to glyphosate / changed oil composition	(Yes)	The soybeans were defatted – the changed oil composition was not part of the trials
FG72	2015	Bayer	Soybean	Resistance to glyphosate and isoxaflutole	No	Data from trials not accepted by EFSA because of lack of scientific standards.
NK603 x T25	2015	Monsanto	Maize	Resistance to glyphosate and glufosinate	No	
MON87708 x MON89788	2015	Monsanto	Soybean	Resistance to glyphosate and dicamba	No	
MON 87769	2014	Monsanto	Soybean	Changed oil composition	(Yes)	The soybeans were defatted, the changed oil was tested separately.
MON15985	2014	Monsanto	Cotton	Several Bt toxins	(Yes)	Content of genetically engineered plants in the diet very low (2% and 5%)
MON88302	2014	Monsanto	Oilseed rape	Resistance to glyphosate	No	
GHB614 x LLCotton25	2014	Bayer	Cotton	Resistance to glyphosate and glufosinate	No	
BPS-CV127-9	2014	BASF	Soybean	Resistance to imidazoline	No	Data from trials not accepted by EFSA because of lack of scientific standards.
DP305423	2014	DuPont/ Pioneer	Soybean	Resistance to ALS-inhibitors / changed oil composition	(Yes)	Plants were not treated with herbicides.
T25	2013	Bayer	Maize	Resistance to	No	Data from trials not accepted by

Event	Year	Company	Species	Traits	Feeding trials for 90 days	Comment
				glufosinate		EFSA because of lack of scientific standards.
MON87798	2013	Monsanto	Soybean	Dicamba	Yes	
MON87460	2013	Monsanto	Maize	Drought tolerance	(Yes)	Controls were contaminated with genetically engineered plants.
T304-40	2013	Bayer	Cotton	Resistance to glufosinate / Bt toxine	No	Data from trials not accepted by EFSA because of lack of scientific standards.
DP59122	2013	DuPont/ Pioneer	Maize	Bt toxine	(Yes)	Controls were contaminated with genetically engineered plants.
GT73	2013	Monsanto	Oilseed rape	Resistance to glyphosate	No	
Ms8, Rf3 und Ms8 x Rf3	2012	Bayer	Oilseed rape	Resistance to glufosinate / pollen sterility	No	
MON87705	2012	Monsanto	Soybean	Changed oil composition	(Yes)	The soybeans were defatted – the changed oil composition was not part of the trials
MIR162	2012	Syngenta	Maize	Bt toxine	Yes	
MON87701 x MON89788	2012	Monsanto	Soybean	Resistance to glyphosate / Bt toxin	No	