This is an unofficial translation of a letter of the Netherlands Commission on Genetic Modification (COGEM) to the Secretary of State for Infrastructure and Environment with reference "170111-03 signalerende brief stakeholderparticipatie onderzoek controversiele onderwerpen"[a]

To the Secretary of State of
Infrastructure and Environment
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PO Box 20901
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DATE January 11, 2017
FEATURE CGM / 170111-03
TOPIC Points of attention and pitfalls related to stakeholder involvement in research on controversial topics

Dear Ms Dijksma,

With this letter the COGEM wishes to inform you concerning the value of stakeholder participation when conducting investigations on controversial subjects such as the safety of genetically modified organisms (GMOs), and possible pitfalls with this participation format.

The discussion concerning the safety of genetically modified (GM-) crops is, as a result of publications - that concluded that GMOs would form a danger for humans, animals or environment - still current in Europe, and also elsewhere. It is not expected that this will change, as became clear again from a recent publication concerning GM maize.[1,2] The discussion concerning these studies (indicated as alarming studies) has a recognizable and recurring character where those involved cannot agree on the meaning and consequences of the research results.
In 2013 COGEM pointed out that when alarming studies appear, it may be desirable to repeat the studies, because this is sometimes the only way to reject or to confirm the results.[3] At the same time these kind of safety studies are very complex and social acceptance of the final results depends on several factors, including the support among the stakeholders. To increase support for and acceptance of the results, increasing attention is giving to stakeholder participation during investigations.

The European GMO Risk Assessment and Communication of Evidence (GRACE) project was performed between 2012 and 2015.[b] In this project about value, usefulness and necessity of feeding trials of GM maize in rats, amongst others, stakeholders were involved from the beginning. The project has been a unique test case for carrying out scientific research on the safety of GMOs supported by active and widespread stakeholder involvement. The stakeholder participation has made a valuable contribution to the performance of the research, but despite considerable effort from the project team and the stakeholders, there was ultimately no agreement regarding the final results.

[a] http://www.cogem.net/index.cfm/nl/publicaties/publicatie/aandachtspunten-en-valkuilen-stakeholdersbetrokkenheid-bij-onderzoek-naar-controversiele-onderwerpen?
[b] www.grace-fp7.eu

The COGEM actively monitored the project in recent years.[c] Based on the evolution and the results COGEM identifies some issues and pitfalls of stakeholder participation in research on controversial topics. This letter does not deal with the scientific results of GRACE.

GRACE project: stakeholder engagement is key

The GRACE project aimed at improving the methodology of research on safety of GM crops, particularly in the area of feeding trials with animals. Stakeholder involvement, transparency and accessibility of information were explicitly part of the project. The purpose of this was to inform on and improve the research process and to increase support in respect of the results from a societal perspective.

The research was carried out by 19 partners from 13 EU countries and consisted of two parts: 1) a systematic review of literature on safety and socioeconomic aspects of GM crops and 2) a repetition and improvement of the 90-day feeding trials with rats that are part of the risk assessment for market authorization of GM crops.[d] With this letter COGEM mainly focuses on the second part because it has a direct link with the previously presented topic report on alarming studies regarding the safety of GMOs.[3]

The results of the feeding experiments were not intended as a re-evaluation of the safety of the GM crops concerned, but to enable making conclusions and recommendations on the adequacy of the design of the feeding trials in the current safety assessment. Stakeholders were involved in the research in two phases: during the planning and design of the tests and at the interpretation of the results. In this way, the opportunity was given to influence the research that was done, how it was done, how the results were interpreted, what conclusions were drawn and what recommendations were made in response to the results. A total of three workshops and four written consultation rounds were held.

Stakeholders from various sectors (including competent authorities of Member States, scientists, industry, non-governmental organizations (NGOs) and Civil Society Groups (CSGs)) were actively approached to participate in the process. In addition, anyone could volunteer for participation. Only journalists were excluded to facilitate an open discussion in which participants could speak freely. All concept papers and project data were made publicly available and a forum was held to discuss these. The comments that stakeholders brought in and the answers by the GRACE investigators are documented in order to trace back whether and how the comments have been incorporated into the project. The valuation of stakeholder engagement itself was also evaluated via electronic questionnaires and interviews.

Results of the stakeholder consultation on experiments with rats

The results of the GRACE project have in the meantime been published.[4] For the workshops and written consultations, depending on the subject, 500 to 1300 stakeholders were invited. The actual participation in workshops ranged from 25 to 54 participants. In total, more than 1,100 written comments were submitted by approximately 30 different stakeholders. All comments were addressed in the consultation reports, which are accessible to everyone through the GRACE project website. As an illustration: during the planning phase 17 different stakeholders submitted 146 written comments on the study design for the 90-day feeding trials. About half of them were finally incorporated or explained

[c] by means of inter alia, participation in the workshops and presentation by one of the GRACE team members in the Subcommittee on Ethics and Social Aspects of COGEM (November 2015).
[d] Commission Implementing Regulation (EU) No. 503/2013

in the study plan. Reasons not to include suggestions included, amongst others, scientific and contractual constraints, and available resources.
In the whole process a total of 143 individual stakeholders were involved coming from 19 EU Member States, EU-related bodies, Switzerland, Norway, the United States and international organizations. The majority of stakeholders was involved in one of the two phases (planning or outcomes), and a small core group of representatives from competent authorities of EU Member States, NGOs, CSG and industry was involved in all steps of the process. In numbers competent authorities were most represented, followed by industry. The participation from the scientific and social field fluctuated per meeting.[5]

The GRACE team observes that there was overall a good participation and responsiveness during the research process. The way of engagement from beginning to end has contributed to the design and execution of the study. Constructive discussions were held that contributed to the implementation of the project, with a focus on technical and scientific issues (such as experimental design and statistics).[6.7]

At the same time, there appeared to be several challenges to this type of investigation. For instance, the non-selective and open participation of stakeholders may lead to discussions during the process about independence of the results, for example through the participation of companies.[8] Stakeholder participation and incorporation into the project plan also calls for a flexible approach, but can simultaneously interfere with contractual arrangements and the timetable. With long-term projects like this it also proved virtually impossible to guarantee the continuity of stakeholder involvement, as stakeholders do not always have the time, resources and expertise for active and sustained participation.
Stakeholder participation also presented challenges in content for the researchers. Providing insight into the (partial) results of the study beforehand may conflict with the usual scientific procedure for publishing in journals. Scientific journals generally do not accept articles whose results are already made public. Moreover, publishing interim (partial) results made the project vulnerable to misinterpretation and criticism. In addition to the appreciation for and positive contribution by stakeholder participation to the process, criticism on the (partial) results remained.[9,10,11] The content of this criticism was not entirely unexpected and stems from, among others, differing risk perceptions, politicization of science and prolonged controversy over protocols, implementation and data interpretation of feeding trials. Therefore, one cannot speak about (full) agreement regarding the results of the research.
At the moment, two similar European projects are running where stakeholder participation likewise plays an important role (GMO90+ and G-TwYST).[12,13,14]

COGEM reflection: governance of alarming studies
The GRACE project has been a unique test case for carrying out scientific research into the safety of GMOs using active and widespread stakeholder involvement. The involvement of stakeholders has been meticulous, transparent and intense and has contributed to the social robustness of the results by clarifying points of discussion and arguments underlying them. Simultaneously COGEM also identifies a number of problems, which were raised in its 2013 report.
In controversial and highly polarized issues - such as GM crops but also discussions on shale gas or nuclear power - it will be difficult to arrive at a broadly supported conclusion with all stakeholders. Already these discussions are lasting so long, that various stakeholders have dug in and are so fixated on their own arguments and vision, that reflection and interaction becomes difficult. Before, during and after the project, a few stakeholders criticized the GRACE process because of lack of confidence,

alleged dependence of the involved researchers and a premeditated outcome of the results.[15,16] Intensive communication between the project team and these stakeholders could change little about this.[9.11] It shows that science including active involvement of stakeholders cannot (fully) settle the debate about controversial topics.
COGEM notes that some of the comments from stakeholders could not be processed in the GRACE project because they exceeded the objective of the safety study and were related to broader issues. These are structural issues that deserve attention in the current policy, including addressing context-related arguments about the relationship between GMOs and socio-economic aspects or sustainability, the industrialization of agriculture, the power of large companies and independency of researchers. The impetus for the consideration of a number of context-related arguments has been made with the entry into force of the new Directive 2015/412 on cultivation of GM crops in Europe.

Concerning scientific research and innovation there is an increasing focus on social robustness through stakeholder participation. This is reflected in the emergence of themes such *responsible research and innovation (RRI)* and *participatory* or *cooperative governance* of scientific developments, but also in the introduction of the national science agenda. Stakeholder consultations are also used as a tool by the Dutch government for projects related to biotechnology, such as the Biotechnology Trend Analysis and the assessment framework for national growing authorisations.[17,18] Although less controversial than safety research, the same questions regarding support for the results are relevant here.
Studies such as the GRACE project provide valuable new insights and additional considerations, but also require significant additional effort and resources. Moreover, the project shows that this approach to controversial issues such as GM crops, will nevertheless lead to criticism. Therefore, the debate on this issue - and alarming studies - continues to exist. COGEM points out that the specifics of stakeholder involvement should be evaluated for each case and that they require a realistic assessment of time, resources (for both researchers and stakeholders) and expected results. The following points may be helpful:

- Before and during the process the purpose and limitations of stakeholder input have to be made explicit, as well as the method of decision-making on the input, since this is important to prevent or reduce unrealistic expectations of those concerned;
- Publically-accessible processing of stakeholder input is essential for the transparency of the debate and may limit allegations of exclusion afterwards;
- Representation from all relevant stakeholders is essential. The preservation of continuity of such representation and keeping the dialogue open contributes to the learning process. Mapping of the different opinions and underlying values and interests, and accordingly adjustment of the agenda and methodologies may increase commitment and continuity of participation;
- The fixation of those involved on their own arguments in long-term discussions is a pitfall. Highlighting differences in vision or disqualifying partners based on non-substantive and personal reasons reinforces this effect. Also media involvement may increase the polarization and hamper the willingness to reflect. Facilitating an open discussion forum in which there is room for divergent views and where shared values are sought for, may contribute to a fruitful dialogue;
- Stakeholder participation should not be used to settle the debate, but may, subject to these concerns, be an instrument for mutual learning and dialogue in scientific research on controversial topics.

Yours sincerely,

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Chair COGEM

c.c. MA. H.P. de Wijs, Head GMO Office
Mr. JKBH Kwisthout, Ministry of Infrastructure and the Environment

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