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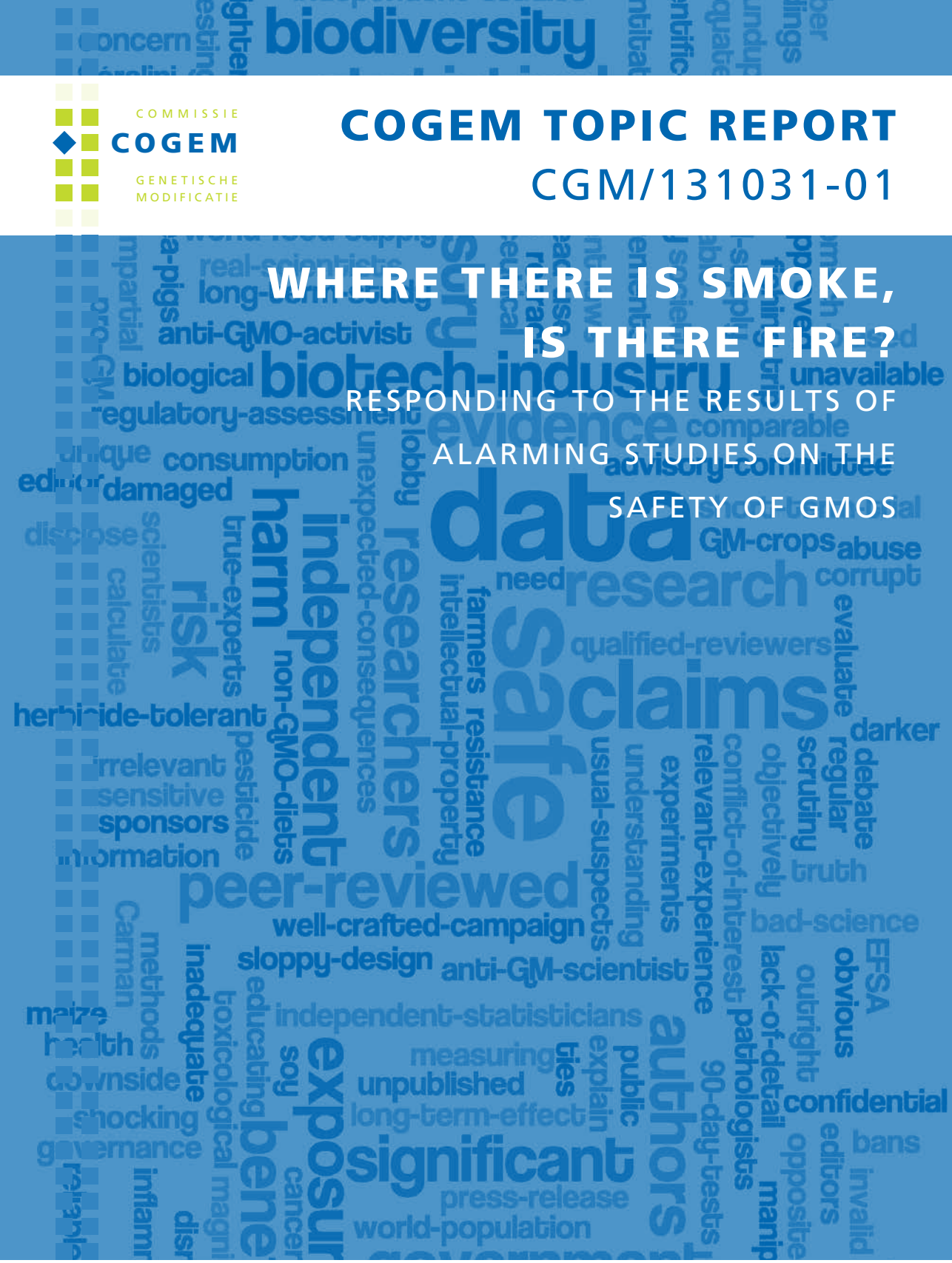
COGEM TOPIC REPORT
CGM/131031-01

WHERE THERE IS SMOKE, IS THERE FIRE?

RESPONDING TO THE RESULTS OF ALARMING STUDIES ON THE SAFETY OF GMOS



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WHERE THERE IS SMOKE, IS THERE FIRE?

RESPONDING TO THE RESULTS OF ALARMING STUDIES ON THE SAFETY OF GMOS

COMMISSION ON GENETIC MODIFICATION
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COGEM provides scientific advice to the government on the risks to human health and the environment of the production and use of GMO's and informs the government of ethical and societal issues linked to genetic modification. (Environmental Management Act §2.3).

To the State Secretary for
Infrastructure and the Environment
Mrs W.J. Mansveld
P.O. Box 20901
2500 EX The Hague

DATUM 31 October 2013
KENMERK CGM/131031-01
ONDERWERP Topic Report 'Where There Is Smoke, Is There Fire? Responding to the results of alarming studies on the safety of GMOs'

Dear Mrs Mansveld,

Please find enclosed out topic report 'Where There Is Smoke, Is There Fire? Responding to the results of alarming studies on the safety of GMOs' (CGM/131031-01).

SUMMARY

Results of studies that cast doubt on the safety of genetically modified (GM) crops and products are published occasionally in the media; these are called 'alarming studies'. The debates that arise as a result follow a familiar pattern and do not finally come to a resolution that commands broad support. Moreover, evaluations or reviews by scientific advisory bodies are often not sufficient to bring these debates about (the safety of) GM crops to a conclusion.

Alarming studies will always provide an excuse to reignite the national or international scientific and public debate, and therefore also the political debate. Because it is not possible to determine straight away whether the conclusions of an alarming study are correct or not, COGEM observes that it is always necessary to determine whether the new findings provide grounds for reviewing or revising the risk assessment that has already been carried out and/or follow-up research. However, debates about alarming studies bring to light several fundamental issues that cannot be dealt with in an ad hoc manner, but which need to be addressed as part of current policy. In this context, COGEM recommends the following:

- **Encourage monitoring of scientific research (e.g. by advisory bodies) and where necessary encouraging further examination and review of alarming studies.**
- **Take a decision to include or exclude context-related arguments (such as wider issues about the relation between GMOs and sustainability or naturalness, and also the debate about the**

industrialisation of agriculture and the power of major companies) in discussions and policy decision making by:

- **organising forums and 'thinking laboratories' or facilitating a broader and non-GMO-specific debate about food supplies,**
- **monitoring context-related arguments and identifying fundamental sticking points (e.g. arising from new technological developments),**
- **regularly re-examining and revising biotechnology policies based on monitoring scientific developments (possible policy tool: trend analyses).**

- **Carry out random repeat studies or supervised inspections of GMO safety studies by companies.**
- **Promote scientific research into the safety of GMOs by making it more attractive for researchers to carry out counter-studies and repeat studies (for example through the provision of funding and access to research materials).**
- **Ensure in-house knowledge and competences in specific areas of science and science communication within the ministries.**

When an alarming study appears, the government should respond quickly and appropriately. In this regard, COGEM raises the following points for consideration:

- **Make it clear to all concerned that the political decision will be based on the scientific assessment, but that the final decision and the responsibility for this decision will lie unreservedly with the government.**
- **Consider whether additional expertise should be obtained.**
- **Define and carefully observe the scope of consultations between national and European advisory bodies in order to ensure an independent judgement.**
- **Continue to actively communicate policy decisions about the authorisation of GMOs (such as the decision to guarantee individual consumers the right to choose by requiring GM food to be labelled as such).**

The full text of the report is attached.

Yours sincerely,

Professor Bastiaan C.J. Zoeteman
Chair of COGEM

SUMMARY

Results of studies that cast doubt on the safety of genetically modified (GM) crops and products are published occasionally in the media. In this report we call these 'alarming studies'. Sometimes these studies are almost impossible to verify, but in other cases the results are published in scientific journals. The debate about these studies often follows a familiar and recurring pattern, in which those involved ultimately cannot agree on the significance of the results and the consequences that should be attached to them. The dynamics and characteristics of these public debates on the safety of genetically modified organisms (GMOs) are not unique. Similar debates take place about other controversial technologies or developments which affect social values. Examples are shale gas, nuclear power, mega farms, culling wild animals in nature reserves and vaccination programmes.

This topic report draws on an argument analysis and several case studies (Pusztai 1998, Rosi-Marshall 2007, Huber 2010, Séralini 2012 and Carman 2013) to examine the dynamic of debates about the safety of GMOs. The questions investigated are: What are the different types of arguments used? What is the purpose of these arguments? and What effects do these arguments have on the course of the debate? The options for action open to government and advisory bodies in response to the appearance of an alarming study are also examined. These include things like monitoring, making an initial response and taking specific measures, selecting experts/advisory bodies, dealing with missing data or new lines of reasoning, national and international consultations, follow-up actions and communication during the process. The various options for action each have their own benefits, risks and pitfalls, from which some lessons and pointers can be drawn. These are looked at in detail and recommendations are made on how to respond to alarming studies.

Familiar pattern to debates on alarming studies about GMOs

The most important catalyst for preparing this report was a publication in the journal *Food and Chemical Toxicology* (September 2012). A French research team led by Gilles E. Séralini published the results of a two-year feeding test on rats fed with the GM maize NK603 and various concentrations of the herbicide Roundup. The researchers concluded that the rats fed with NK603 and Roundup developed more and more serious tumours than the control group, and also developed the tumours earlier in their lives. The EFSA (European Food Safety Authority) and various national authorities and scientific advisory bodies reviewed the study and concluded that it had such serious methodological shortcomings that the conclusions could not be justified.

The debates that usually break out following the appearance of alarming studies tend to develop according to the same pattern. The authors and opponents of GMOs point to the publication as proof that GM crops are dangerous and argue that measures should be taken immediately. The government responds in a procedural manner by referring the study to its scientific advisory bodies for their opinions. The advisory bodies assess the publication on its scientific merits and come to the conclusion – so far – that it does not pass the test of scientific credibility and that there is no reason to revoke or postpone authorisations for GM crops. For the government, that appears to be the end of the matter. However, those that think the results are reason enough to ban GMOs feel that their opinions are not being heard and continue to pursue the debate with undiminished vigour. Such situations easily arise in discussions on topics about which there are scientific uncertainties (disagreement about the facts) and about which social values and norms vary widely (disagreement about values). They are called 'wicked problems': dynamic problems without no clear demarcation or definition and which are continually redefined and reproduced, making previous solutions no longer workable and throwing up new problems and questions.

Assessment by a scientific advisory body is itself no remedy

Alarming studies always make the news. They often lead to national or international debates about the safety of GMOs, and usually it is not possible to determine straight away whether the results and claims in such studies are valid or not. The credibility of the study will therefore always have to be investigated – but this does not resolve the issue.

The debate about GMOs involves several other important aspects, such as ethical and religious objections and soft concerns like the fear of monopolies controlling food supplies and the desire for a less industrialised form of agriculture, but the legislation on genetic modification in the Netherlands and Europe is concerned primarily with safety. The question of whether genetic modification is useful, ethical and socially acceptable is largely left to companies, scientists and consumers themselves to decide. The government's decision to limit its role to ensuring public safety and freedom of choice means that it hardly addresses these soft issues at all, whereas the public debate about genetic modification is largely concerned with just these issues. These other issues are not considered in the authorisation procedure for GM crops, which is based mainly on a risk assessment. As a consequence, the public debate about genetic modification out of necessity also focuses on the safety aspect, making the scientific research and risk assessment themselves the subjects of a critical public debate. The highly charged nature of the topic and the lack of attention to the social aspects in the GMO safety debate mean that scientific reviews and recommendations on alarming studies are not accepted by the public as the last word. Evaluations or reviews by risk assessment agencies and scientific advisory bodies are therefore not sufficient to resolve the ongoing debate about GM crops and their safety.

Advisory bodies must beware of rigid thinking and tunnel vision

Only a relatively small group of scientists publish on the alleged danger of GM crops. The more the publications of these scientists are criticised, the greater the risk that new studies will be dismissed as incorrect or not properly carried out. Risk assessors and scientific advisory bodies should therefore remain alert to the existence new findings and review new publications on their own merits. The ability to identify new risks depends on being open to different, sometimes unconventional research methods. Moreover, the highly polarised nature of the GMO debate makes it important that advisory bodies are aware of the public perception of their position and are careful to protect their image. International consultations between the various official bodies in Europe about the scientific value of an alarming publication can be useful in coming to a more discriminating judgement, but can also be considered as an orchestrated attempt to put down dissident opinions. The scope of such consultations should therefore be carefully defined and observed to ensure that each organisation can be shown to have come to its own independent judgement and the principles on which these are based are clear to all concerned.

Transparency is crucial for government, science and industry

Many consumers have little idea about how much of their daily diet consists of GMOs and they do not know about the legislation on the marketing authorisation of GM crops. It is therefore important that the government takes the trouble to explain openly, clearly and frequently what the procedures are for deciding about GMOs so there can be no doubt about how they will ensure public safety and freedom of choice, and why.

The issue of the burden of proof and availability of data and research materials is a recurring sticking point in the debate about the safety of GMOs. The government makes itself vulnerable by placing the burden of proof for the safety of GMOs entirely on the manufacturers. It sets the test conditions and criteria and assesses the results obtained. For some people the fact that manufacturers supply the data is reason enough to assume they cannot be reliable. To bolster confidence in the system, the government could commission random repeat studies or supervised inspections, as is customary for pesticides. This would give the government the opportunity to observe some safety experiments.

Visibility of political decision making an issue

By asking scientific advisory bodies for advice, the government is, in effect, doing little justice to the broader public debate about GM crops. It makes reducing scientific uncertainties the key issue, whereas in essence the debate is about the threat posed to social values and norms by new scientific developments. Under the authorisation

procedure, the government takes the final decisions about the safety of GM products, based on advice from expert committees. The government has chosen to safeguard the freedom of individual citizens by requiring GM foods to be labelled, but this does not mean it has no further part to play when faced with these choices. It is when science can provide no clear answers that political responsibilities and decisions become much more important. In such situations, a key challenge is how to deal with uncertainties. It is up to the government to state where the legislation and research into the safety of GMOs may be flawed and contain uncertainties, and how it will take decisions within the margins of uncertainty. It is up to politicians to decide at what point science provides a sufficient basis to take a decision and to accept responsibility for this.

Addressing the wider issues of biotechnology in a broader debate

A general point is that the government response to an alarming study must be balanced and give due consideration to both the specific and the contextual arguments. It is crucial that the different types of arguments in the debate are acknowledged and kept separate. This does not mean that addressing one type of argument invalidates the other argument, but that it may belong in another discussion.

The government has a role to play in addressing the contextual arguments and soft concerns about GMOs in agriculture. Many of these arguments are not specific, but belong in a broader debate about food production and food security. Facilitating a platform for discussion will give the government an opportunity to identify any fundamental context-related sticking points. The soft concerns and wider issues surrounding biotechnology must not be addressed in an ad hoc way in response to alarming studies, but during the normal course of research and development and as part of existing government policy. Monitoring scientific results and context-related aspects of biotechnology can deliver insights into the arguments and discussions about GMOs.

Promoting knowledge and competences in science communication will better equip the government to meet the information needs of the various stakeholders in the debate. By communicating directly with social stakeholders and non-governmental organisations (NGOs), the government can strengthen its position as a central point of contact.

When an alarming study about the safety of a GMO appears, a decision should be made on whether the new findings provide grounds for reviewing or revising the risk assessment already carried out on the GMO. In addition to the usual actions (obtaining advice from scientific advisory bodies), the government can consider the following:

- **Make it clear to all concerned that the political decision will be based on the scientific assessment, but that the final decision and the responsibility for this decision will lie unreservedly with the government.**
- **Consider whether additional expertise should be obtained, bearing in mind the advantages and disadvantages of this option.**
- **Define and carefully observe the scope of consultations between national and European advisory bodies in order to ensure an independent judgement.**
- **Continue to actively communicate policy decisions about the authorisation of GMOs (such as the decision to guarantee individual consumers the right to choose by requiring GM food to be labelled as such).**

Alarming studies also often give cause to reopen discussions about the wider issues. In this respect the government could consider the following actions in relation to its current policies:

- **Encourage monitoring of scientific research (e.g. by advisory bodies) and where necessary encourage further examination and review of alarming studies.**
- **Take a decision to include or exclude contextual arguments about GMOs in discussions and policy decision making by:**
  - **organising forums and 'thinking laboratories' or facilitating a broader and non-GMO-specific debate about food supplies;**
  - **monitoring contextual arguments and identifying fundamental sticking points (e.g. arising from new technological developments);**
  - **regularly re-examining and revising biotechnology policies based on output monitoring (possible policy tool: trend analyses).**
- **Carry out random repeat studies or supervised inspections of GMO safety studies by companies.**
- **Promote scientific research into the safety of GMOs by making it more attractive for researchers to carry out counter-studies and repeat studies (for example through the provision of funding and access to research materials).**
- **Ensure in-house knowledge and competences in specific areas of science and science communication within the ministries.**

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1

INTRODUCTION

In recent years a number of scientific journals have published articles on studies that dispute the safety of genetically modified (GM) crops. Several unpublished studies and reports have also led to discussion in the scientific and public domains. We call these 'alarming studies'. The recurring scientific and public debates about the value of these studies (are the conclusions justified or not?) and the consequences that should be attached to them is the subject of this report. We investigate how the government and advisory bodies can respond to the results of alarming studies on the safety of GMOs. The focus of this report is on the use of GMOs in agriculture (field trials, cultivation and consumption), because this is the most controversial form of biotechnology and most of the alarming studies are about these applications.

The research into and use of genetic modification and genetically modified organisms (GMOs) have been subject to regulation for quite some time. Companies, universities and research institutes around the world are looking into the possible risks and short- and long-term effects of existing and new GMOs on humans and the environment. The results of this research, whether published in the scientific literature or not, form the basis for the environmental risk assessments performed by licensing authorities. To date there have been no incidents confirmed by governments or competent authorities in which GMOs have caused direct harm to the environment or human health.

Although the vast majority of the research indicates that no significant adverse effects can be expected from the use of GMOs, studies concluding that certain GMOs can indeed cause harm to human and animal health or the environment do crop up occasionally. These alarming studies[a] provoke fierce debates in the scientific community and lead to considerable public disquiet and anxiety. Moreover, these debates are open-ended because those involved (scientists, risk assessors, companies, NGOs, citizens and consumers) cannot agree on the significance or value of these studies and the consequences that should be attached to them. For various reasons, some people

a In this report 'alarming study' means a scientific or other study, the results of which may or may not have been published in a peer-reviewed journal, from which it can be concluded that a technological innovation (such as a GM crop) poses a threat to human and/or animal health and the environment. The term 'alarming study' refers only to the claim made and does not say anything about the veracity or otherwise of the study.

are not prepared to accept the conclusion that GMOs authorised for marketing have been found to be safe by scientific advisory bodies. At the same time, governments and scientists become frustrated because the public will not accept 'the facts' about the safety of GMOs. As the Dutch and European authorisation procedures for GM crops only recognise those arguments that relate to potential risks, the public debate about genetic modification has been limited mainly to the safety aspects. As a consequence, part of the political decision-making process (which must be an informed and reasoned step between scientific knowledge and uncertainties, public opinion on ethics and people's perception of risk, and actual decision making) has been transferred to the scientific community and its assessment of GMOs.

1.1 ALARMING STUDIES

Alarming studies on the safety of GMOs are not new and have been appearing since the first GM crops were authorised for placing on the market. A few examples are discussed below.

Abnormalities in the digestive tracts of rats after eating GM potatoes – Pusztai (1998)

In 1998 Dr Arpad Pusztai, a researcher who was then working at the Rowett Institute in Scotland, claimed that the feeding experiments with GM potatoes he was conducting on rats had led to abnormalities in their digestive tracts. Before the results were published in a peer-reviewed journal, Pusztai announced his preliminary findings on British television in the *World in Action* programme. In an interview he said things like 'If you gave me the choice now, I wouldn't eat it' and 'very, very unfair to use our fellow citizens as guinea pigs'.[1] These pronouncements caused much commotion in England and several other countries. An internal audit of the results concluded that Pusztai's research data do not support his conclusions and he was suspended by his employer. Later that year he was dismissed.[2] But this did not end the discussion. Scientists, NGOs and politicians became embroiled in a heated debate that raised various arguments, accusations and conspiracy theories.[3]

A year later the results of the study were published in letter form in *The Lancet*.[4] Letters to the journal sent in reaction to the publication by research groups from various countries (including England and the Netherlands) criticised the study. The journal was also criticised and accused of publishing the study simply to generate publicity. The editor emphasised that the report had been subjected to a more extensive peer review than usual and said he stood by its publication. Pusztai and his co-author submitted a written reply to the responses defending their experimental design and criticising the tests carried out by commercial parties, arguing that they had severe shortcomings and were not suitable for revealing adverse effects.

In the Netherlands, parliamentary questions were raised on the issue and a moratorium was called for.[5,6] In answer to these questions, the Dutch government stated that it was not possible or desirable for the Netherlands to adopt a position on the results as long as they had not been published in an independent, peer-reviewed journal. As far as is known, since the publication of the letters in *The Lancet* this case has received no further political attention in the Netherlands. The debate eventually subsided, but to this day reference is still made to Pusztai's research and the reactions to his results.

Harmful effects of GM maize in aquatic insects – Rosi-Marshall (2007)

In 2007 Emma Rosi-Marshall, an ecologist, published an article in the journal *Proceedings of the National Academy of Sciences* (PNAS) in which she concluded on the basis of laboratory tests that feeding caddis-fly larvae Bt maize reduced their growth rate and increased their mortality rate.

The first reactions from other researchers came in almost immediately. Criticism was levelled not only at the research but also at Rosi-Marshall herself. A plant biotechnologist from her own university drew up a joint protest letter with several other scientists. In the letter they criticised six aspects of Rosi-Marshall's research and called it 'sloppy science'. The main criticism was of the extrapolation of conclusions from the laboratory tests to field conditions. The journal was also not spared: publication of the article was said to undermine its credibility. Monsanto, a biotechnology company, sent a letter to the US Environmental Protection Agency (EPA) criticising the research. The main complaint critics made against the research was that the findings did not justify the strident and definitive way the conclusions were stated in the summary. It was feared that the research results would lead to changes in policy and that anti-GMO activists would seize on the results to promote their cause ('When bad science is used to justify bad policies, we all lose' – Alan McHughen, Nature News).[7] Other scientists concluded that Rosi-Marshall's conclusions may have been premature and left certain questions unanswered, but that despite this the data were a valuable addition to the field. Rosi-Marshall and her colleagues replied to the criticisms in a letter to PNAS in which they said that they had expected the paper to be taken as a whole instead of being judged on all the detailed points. References to the article appear regularly in publications by anti-GMO groups to show that GM crops are damaging to the environment and biodiversity. The article was also used to justify a moratorium on MON810 maize imposed by France in 2012.[8] Rosi-Marshall has continued her research into the effects of Bt proteins on aquatic organisms and is currently occupied with field observations.

New pathogen from GM crops – Huber (2010)

In 2011 emeritus professor Don M. Huber, former professor of plant pathology at Purdue University in the United States, made the news with the announcement that he

had discovered a new pathogen from GM crops with tolerance for glyphosate-containing herbicides (Roundup ready crops). A scientific paper with data and supporting evidence for this conclusion has not been published. Huber sent an insistent letter to Secretary of Agriculture Tom Vilsack in which he made specific reference to the authorisation of Roundup Ready GM crops, saying this should be revoked immediately in the light of his findings.[9] The letter was leaked and spread like wildfire over the internet. Huber later also sent a letter to the European Commission. The US Department of Agriculture asked Huber to provide additional information supporting his claim (the exact contents of this letter are not public). Huber responded to this request by sending an extensive list of references on Roundup and repeated his demand for a moratorium on Roundup Ready GM crops in the US.[10]

Biotechnology firm Monsanto, the producer of Roundup Ready crops, declared in a statement that there were no underlying data to support Huber's claim and that his conclusion in fact contradicts many other studies on the safety of these GM crops.[11] Several of Huber's former colleagues at the University of Purdue distanced themselves from his assertions.[12] However, Huber did get support for his claims: about 800 sympathisers signed a petition supporting his research and expressing their concern about the adverse consequences of GM crops.[13] In the ensuing period Huber was frequently given the opportunity to state his case in the media and was invited to speak by non-governmental organisations (NGOs) in various countries in Europe and elsewhere. Questions were raised in the Dutch and European Parliaments in reaction to Huber's letter.[14,15] In both cases the answers referred to the lack of available data and pointed out that none of his research results had been published in a peer-reviewed journal. Until this was the case, there was considered to be no reason to look into the matter further or take any action. Three years later, no article has yet been published in a peer-reviewed journal or any other journal. Nevertheless, in the recurring debate about the safety of GMOs, Huber is often mentioned in the same breath as Pusztai.

Rats fed GM crops develop cancer – Séralini (2012)

In September 2012 the journal *Food and Chemical Toxicology* published the results of a study in which rats were fed GM maize for a period of two years.[16] The authors of the study belong to the research team led by Gilles E. Séralini, a professor at the University of Caen (France) and president of the Scientific Council of the Committee for Research and Independent Information on Genetic Engineering (CRIIGEN).[17] Séralini has been studying the impact of GMOs on human health and the environment for many years and has various publications on the subject to his name.[18,19,20] In the study published in 2012, rats were fed a diet that included the herbicide-tolerant GM maize NK603 and various concentrations of the herbicide Roundup. The aim of the study was to investigate the long-term toxicological effects of GMOs. The researchers concluded that the rats fed with NK603 and Roundup developed more and more seri-

ous tumours than the control group, and also developed the tumours earlier in their lives. The researchers said they were surprised to discover these carcinogenic effects. They also said that the rats fed with NK603 developed kidney problems. According to the authors, both Roundup and NK603 caused hormone imbalances. Publication of the article was accompanied by a book (Tous Cobayes? – All Guinea Pigs?) and a film with the same title which stresses the dangers of eating GM food. The results were presented in a more readily comprehensible and popular form on a special website and Facebook page.[21]

The publication led almost immediately to a vigorous international debate. The EFSA as well as various national authorities and scientific advisory bodies responded formally.[22,23,24,25,26,27,28,29] They concluded that the study contained so many methodological shortcomings that the conclusions could not be justified. A few NGOs also responded to the article,[30,31] arguing that repeated calls for more rigorous, long-term research into the effects of eating GM crops had so far been ignored. Moreover, they said there were undisputable close links between the European risk assessors and the industry, making it impossible for EFSA and other advisory bodies to give completely independent and reliable advice about GMOs. Questions were asked in the Dutch Parliament and the answers referred to the revised advice by the EFSA and the assessment agencies in the Netherlands. Although the study was dismissed as being unsound and incorrect by several advisory bodies and the EFSA, media interest and the public debate in Europe continue.

Pigs fed GM feed show harmful effects – Carman (2013)

At the beginning of June 2013 a new feeding study appeared in which the authors claimed that GM crops had caused harmful effects.[32] In this study, by an Australian research group led by Judy Carman, pigs were fed with conventional and GM maize and soy for several months. The researchers concluded that the pigs fed with GM feed developed significantly higher levels of stomach inflammation. A few sows in the study also developed an enlarged uterus. The results were published in the *Journal of Organic Systems*. As soon as the article was published, a website and Facebook page were launched for this study as well, containing easy-to-read information about the research and the subsequent media coverage.[33]

Again, the research was heavily criticised by the scientific community and industry as well as in news articles and blogs.[34,35,36,37,38,39] The main criticisms were that the experimental design was ill-defined, the statistical analysis was suspect and the general health of the pigs in both the GM and the conventional test groups was so bad that the reliability of the research had to be called into question. The food safety assessment authorities in Australia and New Zealand reviewed the study and found that the conclusions are not supported by the available data.[40] The researchers responded to the criticisms on their website.[33] As far as is known, the govern-

ments of various European Union member states have not formally reacted to the study.

1.2 RECURRING DISCUSSIONS PROMPT ANALYSIS OF THE DEBATE

The examples of alarming studies on the safety of GMOs described above have provoked heated debate in the scientific and public domains. Moreover, a reassessment by governmental and scientific bodies of the studies or the GMOs concerned does not seem likely to bring the debates to a satisfactory conclusion. The lack of consensus about the significance of these studies and their consequences makes the studies important catalysts in the recurring debate about GMOs. The dynamics and characteristics of the public debate on the safety of GMOs, however, are not unique; similar debates arise around other controversial technologies or developments which affect social values. Examples are shale gas, nuclear power, mega farms, culling wild animals in nature reserves and vaccination programmes.

Dutch and European policies on genetic modification are geared to safeguarding human, animal and environmental safety; the question of whether genetic modification is ethical and socially acceptable is largely considered to be one of individual choice.[41] The only valid arguments in the permit and authorisation procedures for most GMOs are those relating to the potential risks. This has limited the public debate about genetic modification largely to the safety aspects.

Under current policies the debate on the authorisation of GM crops concentrates mainly on demonstrating their safety and removing any scientific uncertainties. Although the existence of uncertainties is acknowledged, the government always asks scientists and advisory bodies to come up with definitive answers that can dispel these uncertainties.[42,43] This would suggest that the government assumes that uncertainties about risks lie at the heart of the public debate,[44] and it hopes that removing these uncertainties will settle the debate, leaving only individual choices regarding ethical and social acceptability. But besides personal principles, norms and values, the GMO debate is also about broader public issues like conflicts of interest, the quality of scientific research, government responsibility, the transparency of safety research, the influence of large biotechnology firms and monopolisation of farming practices (see also COGEM's 2007 topic report *Het gentech debat ontleed* [Dissecting the Gentech Debate]).[45]

Alarming studies on the safety of GMOs repeatedly cause concern and unease in society and frustration within the scientific community. This is because 1) science can never deliver absolute certainty about the safety of GMOs, and 2) other arguments besides safety are relevant but at the moment have no formal place in the debate. Partly as a

result of these tensions, the GMO debate has become highly repetitive. But can the debate be conducted differently, and if so, how?

This report investigates how the government and advisory bodies can respond to the results of alarming studies on the safety of GMOs.

1.3 STRUCTURE OF THE REPORT

Analysing the course of events surrounding the publication of an alarming study can establish whether this process is inevitable or whether there are opportunities to break through the deadlock and conduct the debate in another way, or even bring it to a conclusion. Chapter 2 examines the dynamics of scientific and social debates and the mechanisms operating in these debates. In Chapter 3 an argument analysis is made of the reactions to the publication of Séralini's article in 2012: What were the reactions to the studies and who responded? What arguments were used, by whom, and to what end? Chapter 4 discusses several policy options for dealing with these studies, along with their associated risks and pitfalls, and the lessons learned and points to consider. Finally, the findings are brought together in Chapter 5 and recommendations are made on how the government and its advisory bodies can respond to alarming studies on the safety of GMOs.

2

MECHANISMS AT WORK IN CONTROVERSIES

The debate about GMOs has the characteristics of a 'wicked problem': there is disagreement not only about the facts but also about the underlying values. In discussions about alarming studies several different viewpoints claim legitimacy and scientific knowledge alone is not enough to provide a solution. These types of wicked problems have no clear demarcation or definition and are dynamic; they are continually redefined and reproduced, making previous solutions no longer workable and throwing up new problems and questions. When participants are so convinced by their own opinions they are no longer prepared or are incapable of considering other ideas, the debate can easily become polarised and escalate. If an institution with authority or decision-making powers then gives advice or intervenes, this is not accepted and even viewed with suspicion and mistrust. This type of problem and discussion occurs regularly in what is called 'post-normal science', which is characterised by a greater degree of scientific, technical and ethical uncertainty and a lack of consensus about the prevailing paradigm. In such situations political decision making acquires increasing importance.

The cases described in the Introduction are about complex issues in which those involved disagree with each other to varying degrees, both about the facts and about the values and norms in question. This chapter examines the characterisation of these types of problems and some mechanisms that can influence the course of the debate.[46]

2.1 DEGREE OF CONSENSUS ON FACTS, NORMS AND VALUES IS A MEASURE OF COMPLEXITY

Problems can be divided into categories according to the degree of consensus on the facts and the norms and values at issue in the debate (see Table 1). A problem for which there is consensus on the facts and on the norms and values at issue can be considered to be a simple or technical problem, whereas a problem for which there is no consensus on both points is a politically, administratively and technically complex problem. For complex problems in particular, the various stakeholders and other parties involved in the debate often do not agree on the 'status' of the problem, which makes

it much more difficult to find a solution. Some see the problem of the alarming studies discussed in this report as a disagreement about the facts (a technically complex problem), whereas others point to underlying problems caused by differences in the norms and values held by those involved in the debate (a politically and administratively complex problem).

TABLE 1: CHARACTERISATION OF PROBLEMS ACCORDING TO CONSENSUS ON FACTS AND NORMS & VALUES

Source: Hoppe R and Hisschemöller M (1996). Coping with Intractable Controversies: The Case for Problem Structuring in Policy Design and Analysis. Knowledge and Policy 8.4 (1996): 40–60.

		FACTS	
		Consensus	No consensus
NORMS & VALUES	Consensus	Simple problem	Technically complex problem
	No consensus	Politically/administratively complex problem	Politically/administratively and technically complex problem

2.2 FROM CONTROVERSY TO WICKED PROBLEM

A controversy is a problem on which there is disagreement about the facts or the norms and values at issue, or both. In the latter case, the controversy can develop into a 'wicked problem'.[46] A wicked problem can be described as a complex and dynamic problem with no consensus about its precise definition and no consensus about avenues for solutions. Wicked problems are not static, but are continually being redefined and reproduced, making previous solutions no longer workable and throwing up new problems.[47] Examples of this type of problem include some debates about biotechnology, climate change and shale gas.

It is difficult to draw a firm line between a controversy and a wicked problem, but there are some indicators of the transition from a controversy to a wicked problem. An example is whether the debate is under control or out of control.[4849] In a debate that is under control, the parties involved are, in principle, open to a participatory process in which there is no doubt about who is participating in the debate and there is room for dialogue and negotiation. Despite the differences in opinion about the facts or values/norms, the participants have faith in the process and see a sufficient basis for discussion. In a situation that is under control the participants also accept the assumption of

decision-making powers by a higher body (for example, by elected representatives). They trust them to use the right means (for example, by enlisting expert advice) to come to an appropriate decision to bring the debate to a resolution. An example is the legislation on labelling foods containing GM ingredients, which resulted from discussions between consumer organisations, industry and government.
In a situation that is out of control, the participants in the debate feel that no-one is listening to them and so they eventually stop listening to others as well. The participants are so convinced by their own arguments and visions they have difficulty in taking stock and interacting with others. They are locked into their own 'configuration'. Configurations arise when people develop a shared opinion, but sometimes also when they have a similar background and subscribe to the same values and norms.[50] People within a configuration develop the same interaction mechanisms, take part in the same discussions and use similar language. Actors within a configuration also tend to value information from their own network more than external information.[51] When information is supported by other information the actor already has, it is more readily considered to be authoritative.[52] This process makes interaction with other configurations more difficult and encourages a tendency to exclude other perspectives and visions. When participants are no longer able to reflect on their own opinions and are preoccupied with confirming their own principles and views, they become fixated and this in turn strengthens their resolve to maintain their own position. Discussions are characterised by cynicism rather than realism and participants who base their arguments on the facts are increasingly ignored. The intervention of an institution with authority or decision-making powers is no longer accepted and even viewed with suspicion and mistrust.

2.3 POLARISATION AND ESCALATION MECHANISM

Polarisation and escalation play an important role in the transition from a controversy to a wicked problem. The polarisation mechanism is characterised by (apparently) irreconcilable points of view. Both sides develop a certain (negative) view of the 'opponent', making it increasingly difficult or even impossible to conduct an open and transparent dialogue. Participants disqualify each other from the discussion on the basis of personal attacks rather than substantive arguments, which can easily lead to the participants adopting positions in direct opposition to each other. This effect can be magnified by an increase in the scale of the problem (loss of control and comprehensibility) and by the amplifying effect of the media (internet hypes and social media).

The escalation mechanism is usually a reaction to the measures taken to solve a complex problem, but a failure to take action may also lead to escalation. Two phases can be distinguished in the escalation mechanism. The first phase is commissioning further research or advice in order to clarify the problem and possibly indicate appro-

priate solutions. This is a very common strategy. In a situation in which positions have started to become polarised or have become entrenched, the introduction of more facts can actually lead to increasing uncertainty, new questions and new arguments and counter-arguments.[53] And doing more studies often brings in additional actors, which can make the debate less manageable. If the new information does not solve the problem, it may trigger a growing feeling of mistrust among the participants, not only of the information itself, but also of each other. The escalation mechanism then moves into the second phase. In this phase the arguments and discussion become less concerned with the substance of the debate and have more to do with style: the focus shifts to making criticisms, accusations and recriminations. This phase is characterised by a negative interpretation of new information and a determination by the participants to stick to their positions as a matter of principle. Provocation and conspiracy theories easily take root, precipitating a spiral of mistrust and increasing stalemate in the discussion.

2.4 *WICKED* PROBLEM CHARACTERISTIC OF 'POST-NORMAL' SCIENCE

The debate about the safety of GMOs is typical of debates in post-normal science or 'mode 2 science'. It can relatively easily degenerate into a wicked problem because the basic conditions for this (uncertainty about knowledge and values) are present.[54] The COGEM topic report 'The Farm Scale Evaluations Evaluated' contains an analysis of the relation between the various 'types' of science and the use of this knowledge in policy development for complex problems (based on Funtowicz and Ravetz's concept of post-normal science).[55] That report looked at the Farm Scale Evaluations (FSE) as a case study. The FSE was a major four-year programme of research in the United Kingdom to study the effect of the cultivation of GM crops on farmland biodiversity. The research itself and the results were used by both proponents and opponents of GM crops to back up their arguments in the debate. This showed that in the debate about genetic modification in agriculture, scientific information provides an insufficient basis to form a consensus and formulate unambiguous and transparent policies. It illustrates how new facts in complex situations lead to further discussion and new questions.

About 20 years ago Funtowicz and Ravetz drew a distinction between normal and applied science, professional consultancy and post-normal science (see Figure 1). In normal and applied science problems are solved within the prevailing, undisputed paradigm and advice given by scientists provides a solid basis for policy making. When government and scientists are trusted, normal science can adequately provide answers to questions from policy makers, and applied science can provide the answers when the problems to be solved require routine technical expertise. Science supports and provides evidence for policy development, decision making and the enforcement of

policies and decisions. The normal science paradigm may include developments that involve uncertainties and require expert judgement about the latest scientific insights. In such cases professional consultancy provides an important platform for policy development. Most of the advice given by COGEM, for example, falls into this category. Use of the case-by-case approach in the risk assessment of specific cases is an effective way of filling in knowledge lacunas within the prevailing paradigm.

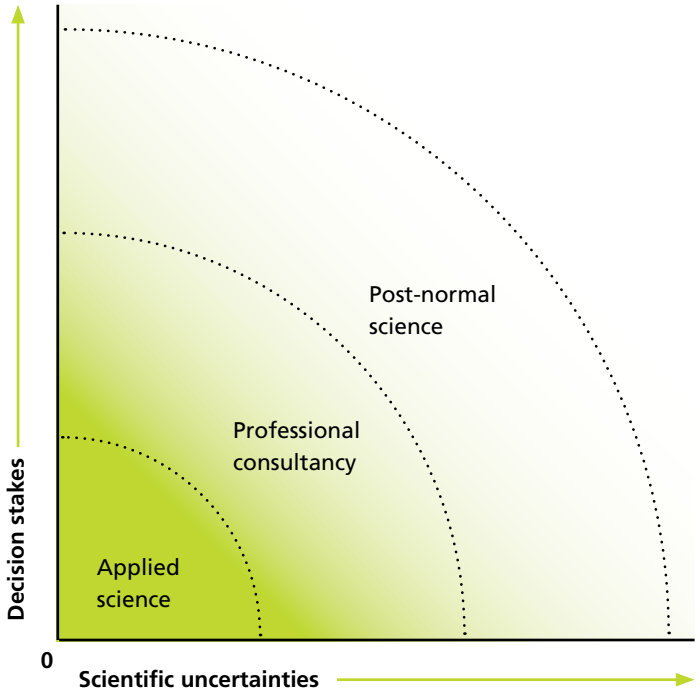

FIGURE 1:
RELATION BETWEEN DIFFERENT SORTS OF KNOWLEDGE AND THE INTENSITY OF THE PUBLIC DEBATE.
Source: after Funtowicz SO and Ravetz JR (1993). The emergence of post-normal science. In: René von Schomberg, ed. Science, Politics and Morality. Scientific Uncertainty and Decision Making. Dordrecht: Kluwer Academic Publishers, p.100.

In post-normal science there is a much greater degree of scientific and technical uncertainty, there are ethical doubts and there is no consensus about the prevailing paradigm. Various different points of view claim legitimacy and scientific knowledge alone is not enough to understand the situation or provide answers to problems. In these

situations, professionals and experts do not have answers that can satisfy everyone. Moreover, dissatisfaction with scientific input can lead to the scientists and experts themselves being called into question.
This effect can also be seen in the debates about alarming studies on the safety of GMOs. The various stakeholders and other interested parties in the debate make use of scientific data to justify their own convictions. Opponents of GMOs concentrate on emphasising the uncertainties surrounding the safety aspects in order to pull the debate into the realm of post-normal science, whereas scientists tend to stress the factual and quantifiable aspects in order to keep the discussion within the bounds of normal science. In situations in which science does not provide a solid foundation or the stakes are so high that science cannot play an effective part in the discussion, social analysis and political decision making become much more important.

A number of policy lessons relevant to post-normal science derived from the FSE research are about dealing with biotechnological innovations. They include the need to involve as many stakeholders and experts as possible (extended peer review), to address the wider issues, set common goals and evaluate and steer technological trends in order to achieve these goals. In addition, COGEM formulated several conditions for holding a constructive debate. Among these are that stakeholders must be committed to joint learning and moving forward, participants must seek common ground and be prepared to compromise, and a methodology or working procedure must be established that enables verifiable agreements to be made. However, COGEM concluded that these provide no guarantee of the social robustness of biotechnological innovations and that further thought needs to be given to how stakeholders and experts can be brought into the process. Increasing the number of those involved is only advisable if the reason for this is clear and criteria for success are drawn up to verify whether the objectives have been achieved.

The ways in which post-normal science works are still developing. Over the years various studies have been done on how to conduct debates in post-normal science and various publications have appeared.[56,57,58,59] COGEM has also commissioned research into biotechnological issues and post-normal science. The report *Governance van biotechnologie, de veranderende rol van wetenschappelijke adviescolleges* [Governance of biotechnology, the changing role of scientific advisory boards] (2006) examines in more detail how advisory bodies can operate in the context of post-normal science.[57] The report distinguishes between the various types of issues and the roles an advisory body can have, from advice, review, evaluation and reflection for structured problems to monitoring trends and pointing out opportunities and risks within a broad social context for unstructured issues.

A recurring insight in the various studies is that scientific facts can resolve only part of the issue. Stakeholder participation and communication are repeatedly mentioned as a strategy, with an emphasis on transparency and openness about certainties and

uncertainties. Political decision making and responsibility can make a big difference in overcoming and dealing with uncertainties – but that is easier said than done.

3

ARGUMENT ANALYSIS OF THE GMO SAFETY DEBATE

The debate about GMOs involves a range of stakeholders, such as scientists, risk assessors, NGOs, citizens, companies and politicians and policy makers, as well as different types of arguments. These arguments can be broken down into publication-related arguments, contextual arguments and arguments attacking personal credibility. In response to alarming studies, different stakeholders articulate the same arguments but in different ways. And although a theoretical distinction can be made between these different types of argument, in practice many of the arguments used actually consist of a mix of various types. Some arguments work well together in constructive discussions, whereas others attract increasingly negative feedback or act to weaken or disqualify each other, which in turn leads to a hardening of attitudes, polarisation and escalation of the debate. Awareness of how the different arguments affect the dynamics of the debate can be helpful when trying to build more constructive and effective communication.

Scientists, risk assessors and citizens may fundamentally disagree about risks because they define, estimate and interpret them differently. This is also the case for the consequences of risk assessments or the measures that should be taken in response to them. Various factors, including the backgrounds of groups or individuals (gender, age, social status, world view, background knowledge and experience), influence how people appraise and perceive risk.[60] These differences in how people perceive, respond to and experience risk are one of the reasons why stakeholders tend to use different types of argument when discussing the safety of GMOs. They also use arguments unrelated to risk, either on purpose or unconsciously. The combination of different views, perspectives and arguments does not necessarily to lead to a wicked problem, but a lack of reflection and unwillingness among participants to revise their own points of view can seriously hamper the discussion.

3.1 THE IDEAL DEBATE

Various frameworks and models have been developed to provide a theoretical reference for effective communication or dialogue and different characteristics and prin-

ciples have been identified as the preconditions for effective communication. In *The Theory of Communicative Action* (1981) the German philosopher and sociologist Jürgen Habermas argued that in a discussion several validity claims can be made regarding truth, moral rightness and authenticity.[61] Ideally, these validity claims will be met when the following conditions are met:

- All the participants in the discussion use certain linguistic terms in the same way.
- Absolutely no relevant arguments are suppressed or ruled out in advance by the participants.
- All individuals are authentic in their participation in the discussion: they genuinely want to reach a consensus.
- All participants in the discussion are equally capable of proposing topics for discussion.
- Communication is domination-free (herrschaftsfreie Kommunikation): no single power relation may have an influence on the course of a discussion, apart from that flowing from a good argument.

However, in practice, communication is an intractable process and discussions about controversial topics like GMOs are often far removed from the ideal discussion environment mentioned above. This chapter describes various types of arguments that emerged during the public debate on the article 'Long-term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize' by Séralini et al., published in 2012.

3.2 THE DEBATE IN PRACTICE: A CRITICAL EXAMINATION OF ARGUMENTS IN THE SÉRALINI DEBATE

The Séralini case is one of the most recent and topical examples of an alarming study on the safety of GMOs. Moreover, the debate that followed publication of the article was international, wide-ranging and diverse, and is thus illustrative of the various types of arguments which also play a role in the other cases.

The arguments can be broken down into three broad categories: specific arguments about the alarming study or publication; contextual arguments relating to the underlying discussion; and arguments attacking personal credibility, which are not related to the topic itself, but are directed at the discussion partner. In this chapter the arguments are illustrated by quotes from the scientific literature, news articles and discussion forums. Many quotes contain elements from different types of arguments and these are categorised according to the degree to which they are representative of a certain type of argument. The list of quotes given in this chapter is not exhaustive, but provides an indication of the various arguments that play a role in the debates on alar-

ming studies on the safety of GMOs. This is further illustrated in Appendix 1 by a list of quotes from the other cases mentioned in the Introduction.

3.3 ARGUMENTS ABOUT PUBLICATION

Specific arguments are about the alarming study or publication that got the debate going. The arguments are not only about the design of the experiment, the hypothesis and methods used, but also the scientific and administrative procedures surrounding the publication of research results in (peer-reviewed) journals.

3.3.1 METHODOLOGICAL ARGUMENTS: THE EXPERIMENTAL DESIGN

We have replicated, extended and thus improved the experiments conducted by Hammond and colleagues…by measuring outcomes from 3 instead of 2 feed doses and more crucially for a period 8 times longer in duration…with 11 blood and urine measures of around 50 parameters, 34 organs instead of 17, etc., in order to ascertain if the statistical findings…were biologically relevant or not in the long term.

Séralini GE et al. (2013), Food Chem Toxicol. March 2013, Vol. 53, pp 476–83

The Séralini article claims to address the toxicity of herbicide-tolerant GM maize in the diet, with or without Roundup herbicide, and of Roundup alone when administered in drinking water at levels equivalent to 50 ng/l, 400 and 2,250 mg/l of glyphosate. Since the water consumption was not measured it is not possible to calculate the real exposure to glyphosate from these concentrations.

Arjó G et al. (2013), Transgenic Research, April 2013, Volume 22, Issue 2, pp 255–267

The scientific debate surrounding Séralini's publication is mainly about the study design, in particular the details of the experiment and the hypothesis behind the study. The quotes above are from Séralini's research group and a research group at the Spanish biomedical institute which conducts research into safety and human health.

Complexity and experiments on laboratory animals

Animal experiments are awkward because of the biological variability in the population of the laboratory animals, even in genetically near identical inbred lines.[b] It is difficult to distinguish a potential effect from the natural variation. In short-term experiments the variability is smaller than in experiments that run for a long period, which is why larger numbers of animals have to be tested in long-term experiments than in short-term experiments.[62] Toxicity studies on rats usually last for 90 days. Longer test periods are used when investigating carcinogenicity or chronic toxicity. Toxicologists and regulatory authorities hold different opinions about the effectiveness of the standard tests.[63,64] In feeding tests to determine toxicity or carcinogenicity a purified substance is usually used so that the difference between the control group and test group is limited to their exposure to the substance being investigated. International guidelines for this have been drawn up by the *Organisation for Economic Co-operation and Development* (OECD).[65,66] Animal experiments with food or plant material are difficult to carry out and interpret because the material being tested is a mixture of a large number of different components rather than a single purified substance or component. This makes it inevitable that the food given to the control group will differ from the food given to the test group in several ways, which introduces greater variability into the results and makes the tests less sensitive. This is one of the reasons why in standard food safety assessment practice tests of acute toxicity are limited to short-term (90 days) animal experiments only and further assessment is based on comparative compositional analyses. In 2013 the EFSA published guidance on two-year feeding tests that makes the composition of the diet a crucial consideration.[67]

Séralini's group argues that because in theory a person can eat GMOs for human consumption during their whole life, a study lasting 90 days has inadequate predictive value. They think that GM food should be tested for chronic toxicity or carcinogenicity and so they conducted an experiment in which rats were tested for a period of two years. Scientists who criticised Séralini's research claim that several aspects of the experimental design were faulty (e.g. the test period was too long, the wrong test animal was used, and the test and control groups were too small) and that the study did not meet international standards, reducing the reliability of the results and increasing the likelihood of erratic or extreme values. In response to the critics, Séralini said that the design of his experiment was unique, but in many other respects was no less valid than the experiments carried out by the industry for marketing authorisation.

b Inbred lines are used in animal tests and are obtained by long inbreeding of mice or other laboratory animals: brothers and sisters or parents and offspring are mated together until the inbreeding coefficient is 98.4% (the F factor); this means that almost all alleles are identical in the animals of the inbred line.

Statistical arguments

The methodological arguments include criticisms of the statistical analysis of the results. It is argued that a correct statistical analysis would show no significant differences between the group of rats fed with GMOs and the control group.

We have applied the most modern statistical methods…for multivariate data analysis of approximately 50 parameters measured 11 times for 200 rats. This allowed, in a blinded manner, to obtain results significantly discriminant at 99% confidence levels.
Séralini GE et al. (2013), Food Chem Toxicol. March 2013, Vol. 53, pp 476–83

The Séralini article therefore suffers from all the problems of an underpowered statistical fishing trip.
Arjó G et al. (2013), Transgenic Research, April 2013, Volume 22, Issue 2, pp 255–267

Critics of the study argue that the lead researcher used unconventional statistical methods to demonstrate an effect, but he defended his choice of statistical tools saying they were better able to demonstrate correlations between the datasets than the conventional methods.

Statistics is the art of modelling (mathematically describing) situations in which chance plays a role and drawing conclusions from data obtained in these situations.[68] The primary function of statistics in experimental research is to demonstrate the clarity, accuracy and objectivity of the results presented and interpreted by researchers.[69] A thorough statistical analysis is always necessary before valid conclusions can be drawn from complex experiments involving numerous variables, such as animal feeding tests. Pitfalls include using a method unsuitable for the experimental design and testing too many end points or variables, which increases the likelihood of a statistical correlation being found in the absence of an actual biological or causal connection. Although statistics are the standard and accepted way of demonstrating irrefutable facts, in the case of alarming studies it is the substantive aspects of the scientific research that fuel the debate. But statistics and the choice of certain statistical methods are also subject to criticism, and not everyone considers the outcomes of statistical tests to be decisive. In these cases the statistical analysis itself becomes part of the polarised debate.

Methodological arguments in the debate

The aim of the methodological arguments is mainly to verify the scientific validity of the results and evaluate and confirm or refute the scientific credentials of the research and lead researcher. In complex studies such as long-term animal feeding tests, however, this is not an easy matter, especially when methods are used that are difficult to compare. In a written response, Séralini said that his research did contain a few methodological errors, but emphasised that the study was unique

because it was the first to investigate the real long-term health effects of GMOs. He called for the research to be continued and the experiments to be repeated to confirm the results. Other researchers disagree with him, saying that repeating the study would just repeat the same methodological errors and again lead to unreliable outcomes. In other cases too, arguments about the experimental design and method are an important element in the initial debate following publication (see Appendix 1).

3.3.2 *PEER REVIEW* ARGUMENTS: SCIENTIFIC QUALITY

More than 26 international scientific peer-reviewed papers by the team with the lead author on the topic in the last 5 years, and 11 in toxicological journals on the same period only in PubMed.…None of the papers was considered as flawed by the scientific community.

Séralini GE et al. (2013), Food Chem Toxicol. March 2013, Vol. 53, pp 476–83

It is appalling that such work should appear in a respected Elsevier Journal.…we would also like a comment from you as editor-in-chief as to how this paper passed peer review successfully.

Maurice Moloney, Director of Rothamsted Research, Reuters article, 30 November 2012

The Editors and Publisher wish to make clear that the normal thorough peer review process was applied to the Séralini et al. paper. The paper was published after being objectively and anonymously peer reviewed, with a series of revisions made by the authors and the corrected paper then accepted by the Editor.

Journal Statement, Journal Food and Chemical Toxicology, November 2012

Responding to the methodological and other arguments, supporters of Séralini pointed out that the article published in the journal *Food and Chemical Toxicology* was peer reviewed and therefore found to be of sufficient scientific merit. Other scientists acknowledge that peer review is an important seal of approval for quality, but in this case conclude that the article should never have passed the peer review process. They protested to the journal and some demanded that the article be withdrawn. The editor of the journal responded by affirming his confidence in his journal's peer review system, stating that he did not intend to retract the article. However, he did ask Séralini to respond to the substance of the criticisms in a subsequent issue of the journal. In the societal domain, the peer review argument is presented as a barometer for the reliability and accuracy of information. Citing the peer review system as the undisputed measure of reliability has led to disagreement and discussion in the other cases as well (see Appendix 1), which clearly indicates that there are several difficulties inherent in the peer review system (see text box).

Peer review no guarantee of accuracy

Peer review is intended to be an initial and provisional test of scientific quality, but it is also presented as a hallmark for the correctness of research findings. However, peer review is a 'minimum quality requirement' and not a guarantee of accuracy.[70] In other words, the fact that an article has been peer reviewed does not automatically imply that the conclusions are correct; it means that a selection of scientists with relevant expertise consider the results to be of sufficient quality and interest to be worth sharing with the rest of the scientific community. Conversely, information published without having been peer reviewed (such as tacit knowledge) is not necessarily untrue or inaccurate.[71]

The thoroughness and quality of the peer review process can vary from journal to journal.[72] It depends to a great extent on the individual reviewers, their specific expertise (and the choice of the editor), the time available to them, etc. An authoritative journal like *Nature* receives more than 10,000 submissions each year. Of these, 60% are immediately rejected by the editors and only 7% of the remainder pass the peer review system and are eventually published (2006 data).[73] Following rejection by one journal it is common practice for authors to submit their articles to another journal in an attempt to get them published. Despite the peer review system, articles regularly have to be withdrawn (4% of the total written) because of fraud, data manipulation or errors (see the Retraction Watch website[74]). There are about 900,000 'scholarly' journals, but it is not certain how many operate a peer review system.[75] In addition, in recent years several 'predatory publishers' have appeared on the scene.[76] These are publishers that exploit the open access model for their own commercial ends. Some are known to have launched hundreds of predatory journals.[77] Although it is not unusual to charge authors for open access publication of their articles, the problem with predatory journals is that their editorial and publishing services and their status are ambiguous at best, or even fraudulent. Some predatory journals and publicists claim to operate an extensive and strict peer review system, whereas in fact this is bogus.[78] An example is the article by Mezzomo et al. about the presence of Bt toxins in the blood of mice. The article was originally published in the *Journal for Food and Chemical Toxicology* in November 2012, but was later withdrawn.[79] It then appeared again in March 2013, this time in the first issue of the new *Journal of Hematology & Thromboembolic Diseases*.[80] There are websites that publish lists of suspected predatory journals or bogus journals, such as Beall's List of Predatory, Open-Access Publishers.[81,82]

The peer review arguments appear to be used mainly to emphasise, verify or evaluate the scientific quality of a publication. However, the quotes show that this argument is used in different ways, in many cases making the peer review system itself part of the debate. Moreover, reading between the lines it is apparent that other arguments, such as those attacking personal credibility (tu quoque and authority arguments), are also sometimes used. These are discussed later in this chapter.

3.3.3 EARLY WARNING ARGUMENTS: THE SERIOUSNESS OF THE FINDINGS

Study linking GM maize to cancer must be taken seriously by regulators. Trial suggesting a GM maize strain causes cancer has attracted a torrent of abuse, but it cannot be swept under the carpet.

John Vidal, Environment editor, The Guardian, 28 September 2012

...taking note of the recent study by professor Séralini in Toxicology in which rats fed glyphosate (Roundup) maize and pesticide in two-year tests developed cancer at high rates...requests the government furthermore to actively resist, in the Netherlands and Europe, any new authorisation of crops that will further the use of glyphosate until their safety has been demonstrated in long-term tests lasting several years...

Motion by Van Gerven (SP) Plenary Session, Netherlands House of Representatives, 12th sitting, 11 October 2012

This is the main cause of your and your kids health problems and the monstrous obesity in the country. So if we do not start educating ourselves on GMO and do not demand our government now to stop pretending that they have no idea about what is going on with the notorious biotech industry, which is exterminating the US citizens as they do with their masterpieces super-weeds or super-bugs, then your kids and your grandchildren lives are in the greatest danger ever in the entire history of the planet Earth.

Marta Tereshchenko, reaction on website GMOseralini.org, visited 2 October 2013

In both the political and social domains, Séralini's findings are said to indicate such a serious threat to human health that urgent measures need to be taken in response. Although the scientific article by Séralini et al. is difficult for non-experts to comprehend, the many photographs of rats with enormous tumours leave little to the imagination. The same goes for the explicit photographs in the study on pigs by the Australian researcher Carman.

The seriousness of the findings has a major impact in the social domain in particular, unlike the scientific domain, where (theoretically) as much if not more emphasis is placed on the methodological underpinnings and validity of the claims. The seriousness of the findings are also politically important in terms of policy response, as ignoring potentially severe effects could have major political consequences. A common policy measure in such cases is to ask an advisory body to review the issue and investigate the validity of the claims. Effect arguments create a sense of urgency. By stressing the seriousness of the situation (and broadening its scope by generalising the results) the sense of urgency to take action can be heightened.

3.3.4 ARGUMENTS ABOUT DATA AVAILABILITY: TRANSPARENCY

At this level, a full debate is biased if the toxicity tests on mammals of NK603 and R obtained by Monsanto Company remain confidential and thus unavailable in an electronic format for the whole scientific community to conduct independent scrutiny of the raw data.

Séralini GE et al. (2013), Food Chem Toxicol. March 2013, Vol. 53, pp 476–83

Following a written request by Professor Gilles-Eric Séralini, EFSA has today given the researcher access to all available data relating to the Authority's evaluation of genetically modified (GM) maize NK603 carried out in 2003 and 2009.

EFSA News, EFSA provides Séralini et al with data on GM maize NK603, 22 October 2012

To set an example, we are arranging the formal delivery of the raw data of our last study to a notary. We will make these public as soon as the regulatory agencies or Monsanto do the same for their data, or when governments consent to publish the industry data.

CRIIGEN press release: Raw data released to a notary, 14 January 2013

Reducing uncertainty is important both in science and in risk assessment. In the scientific domain access to the raw data on which results are based is needed to validate the research. Some, but not all, journals oblige authors to make their raw data available on publication. One criticism of the study by Séralini is that some of the raw data are not included in the publication, which means that risk assessors and scientists cannot repeat the analyses ('Member States also generally highlighted the incomplete, fragmentary and selective presentation of data' – final review EFSA). Critics of Séralini also argue that certain conclusions cannot be drawn from the results without being able to examine the underlying data.[27]

One of the aims of the arguments about the availability of data is to remove as much uncertainty as possible and to validate the conclusions of the research. The availability of data is also an issue in the debate in the other cases (see Appendix 1). It is ostensibly a factual discussion, which suggests that the solution can be found by making the missing data available, but there may also be an implicit accusation that the owner of the data has something to hide and does not want the data to be checked by third parties.

In the polarised debate about GMOs, however, the data discussion is also about something else: the transparency and reliability of the data. It is standard practice for companies that want to introduce a GMO onto the market to demonstrate that their product is safe. To protect their intellectual property rights, they make the authorisation documentation available to the assessment agencies and advisory bodies, but not to

the public. This is a source of dispute, as illustrated by the Séralini quote in which he asks for the raw data from the authorisation documentation for Monsanto's GM crops so that he can carry out an independent reanalysis. Using data as a bargaining chip in the debate is also related to the tu quoque arguments: 'if they (companies) do not make their data available, then I won't either'.[83] It should be noted that assessment agencies such as the EFSA and relevant scientific advisory bodies do have access to the raw data from tests carried out by the industry.

3.3.5 LONG-TERM EFFECT ARGUMENTS: UNQUESTIONED

Séralini's is the first long-term peer-reviewed toxicity study on the health impacts of GM NK603 maize and the commercial herbicide formulation it is engineered to be grown with....This shows that the 90-day tests routinely done on GM crops are not long enough to detect serious health effects that take time to develop, such as cancer and organ damage.

Frequently asked questions: website GMOseralini.org – visited 2 October 2013

A point that I keep bringing up...is that every research animal in the US has been eating GMOs for well over a decade. These animals are closely monitored in animal colonies by trained professionals that include veterinarians and pathologists and biomedical researchers. If there were problems in their food, that would be obvious.

'Memsomervile', response to the article by Tim Worstall, Forbes magazine, 20 September 2012

The long-term effect argument is a recurring argument in the debate and is theoretically irrefutable. These arguments are more or less a given in the debate: long-term research is useful and important because it can help to provide more certainty about the safety and/or risks of a new technology or application. The European Network of Scientists for Social and Environmental Responsibility (ENSSER), the German TestBiotech and others have complained that repeated calls for more rigorous and long-term research into the effects of eating GM crops have so far been ignored.[31,84] They argue that long-term studies into the possible effects of GMOs on human health are badly needed and view Séralini's study as a step in the right direction.

The aim of the long-term effect argument is to point out the shortcomings of current safety research or emphasise the importance of long-term research. But it can also be used to disqualify the results of mainstream studies (with a standard test period of 90 days), as in the first quote, because it casts doubt on the value of existing findings (see quotes from other cases in Appendix 1). Like other arguments, the issue of what long-term studies are, how they should be conducted and how the results can contribute to the risk analysis and evaluation is not limited to the facts, but also encompasses things like scientific and social visions, norms and values.

3.4 CONTEXTUAL ARGUMENTS

Contextual arguments are not about specific cases or publications, but about related themes, such as the safety of GMOs in general and other, broader and more fundamental issues relating to GMOs.[44] The contextual themes may also include 'soft concerns'[c] based on the political, cultural and moral consequences of a technology. These say something about the direction in which society should be heading and are therefore subject to personal preferences. Soft concerns include topics like sustainability and naturalness, but also monopolisation of the food supply chain and the power of big biotechnology companies. In the debate, these topics are often privatised and placed in the realm of individual responsibility (see Introduction).[85] For the most part, these arguments cannot be addressed in the legislation, but they are reflected in the positions taken by political parties. Contextual arguments and soft concerns broaden the scope of the debate and the pool of participants, but at the same time make it more difficult to find a solution to the initial issue of the significance and consequences of an alarming study.

3.4.1 GENERALISATION ARGUMENTS: BEYOND THE DETAIL

Séralini's findings revealed that industry and regulatory claims of biological irrelevance of effects found in 90-day tests are invalid. They showed further that the regulatory system for GM foods is inadequate and cast into question the safety of all commercialized GM foods.

Claire Robinson - Journal of the Canadian Association of Naturopathic Doctors, spring issue 2013

…that concluded the opposite about the effect of GM foods on animals: that such food was as safe, or safer, than regular non-GM food and feed.

Alan McHughen - C2C journal, 21 January 2013

From a scientific perspective, an individual study on a GM crop only says something about that specific crop, or at most something about GM crops which contain the same inserted genes. The results and conclusions of such studies are therefore not representative of all GMOs. However, both proponents and opponents frequently draw opposite conclusions from the same results – that all GM crops are good/bad or safe/unsafe. In the social domain it is even more difficult to make a distinction between specific and generic conclusions, in part because news reports already include an element of generalisation, and sometimes even stretch the implications of research findings beyond

c The consequences of a technology can be divided into those that can be considered 'soft' and 'hard'. In contrast to risks which are generally considered to be 'hard impacts' (in other words, objective, rational, neutral and factual), other impacts are defined as 'soft concerns' (in other words, subjective, emotional and interest-driven).

their original context. Some people immediately extrapolated the results of Séralini's study with rats to effects on humans and assumed that the effects would be the same for all GM crops and not just the GM maize variety in the study (see Appendix 1). The scientific data are thus lifted out of the modelled context of science where they were generated and dropped into the everyday world. In the process, the findings are stripped of some or all of the context in which they were valid.[86] Generalising the results blows the issue up and increases the number of those affected by the problem, and thus its urgency. The debate itself becomes less focused, which further diminishes the prospects of reaching a consensus or solution.

3.4.2 RISK-BENEFIT ARGUMENTS: BROAD CONTEXT

But my bigger concern is the well established environmental downside of GMO crops. Biodiversity is damaged and pesticide resistance increases. Far from enabling us to produce more food with less environmental damage the opposite is proving to be the case.

'John Bying', response to the article by John Entine - Forbes Magazine, 30 September 2012

As for genetic manipulation – that's got lots of potential benefits for food and feed production. The number of mouths to feed is increasing rapidly and the capacity to feed them, given climate change, is dropping.

'SouT', response to the article by John Vidal - The Guardian, 28 September 2012

The risk/benefit argument stresses that it is not only the safety risks that count, but the benefits as well. People are generally prepared to accept greater risks when the benefits are greater and less prepared to take risks for something they believe has little benefit. This is also true for the control people have over risks: despite the well-known risks, many people choose to travel by car because they have control over some of the risk. This feeling of control is much less when making choices about what food to eat because people have little or no idea of its quality or the associated risks. It should be noted that people do not automatically accept a technology simply if the advantages are big enough or they have enough control. Both the pro- and anti-GMO camps suggest that the advantages, or lack of them, are crucial for public acceptance of GMOs. However, research indicates that freedom of choice, transparency and provision of information are at least as important as direct advantages.[44]

People use risk/benefit arguments to point out the wider consequences and the balance between risks and benefits. Often selective use is made of scientific reports on GM crops to demonstrate the benefits or the lack of them. These arguments are often linked to the generalisation argument: either the benefits and safety of GMOs in general are emphasised, or all GMOs are said to be unsafe and pose risks to humans and the environment (see for example the other cases in Appendix 1). These argu-

ments are based on the soft impacts of technology and can be traced back to the question of what sort of society we want to live in and the appropriate technologies needed to get there. Drawing on risks/benefit arguments when discussing alarming studies broadens the debate and makes it more difficult to reach a consensus on the significance and consequences of the research results in question. On the other hand, it does not mean that these arguments are unwarranted or invalid. The question is whether they belong in this debate or in a broader debate about how we want to feed ourselves in future.

3.4.3 BURDEN-OF-PROOF ARGUMENTS: INDEPENDENT RESEARCH

We recall that in the regulatory assessment of GMOs, chemicals and medicines, tests are conducted by the applying companies themselves, often in their own laboratories. As a result, conflicts of interest exist in these cases.

Séralini GE et al. (2013), Food Chem Toxicol. March 2013, Vol. 53, pp 476–83

EFSA had recommended approval of Monsanto's NK603 Roundup-tolerant maize in 2009 without first conducting or insuring any independent testing. They admitted in their official journal that they relied on 'information supplied by the applicant' (Monsanto)….

F. William Engdahl, Global Research Canada, 19 December 2012

These arguments are about the question of who should bear the burden of proof for demonstrating the safety or risks of GMOs. It was a political decision to make the person or organisation wanting to place a product, such as a GMO, on the market legally responsible for demonstrating that it is safe. This has proved to be contentious, because the company or organisation given this responsibility also has an interest in the product being found safe. At the same time, it is argued that companies have nothing to gain by putting an unsafe product on the market, because there is a good chance they will eventually receive claims for damages. Nor would everyone be in favour of the taxpayer footing the bill for safety studies of GMOs.

Specific conditions and restrictions on the sale and use of most commercial GM crops further complicate the burden of proof issue. For one thing, to protect their intellectual property rights many companies require purchasers of GM seed to sign a contract stating the purposes for which the seed may be used. Some companies go further and include a provision in the contract stating that the seeds may not be used for independent research, and may only be used for research and publication purposes if the company gives prior consent.[87] The burden-of-proof argument is not only used against companies, but also against scientists who are perceived as being anti-GMO. Various articles imply that Séralini's research is unreliable because he is a well-known opponent of GMOs.[88,89]

These arguments are used mainly to disqualify the opposition as a transparent and reliable discussion partner and trusted supplier of information, and can therefore overlap with arguments attacking personal credibility. The question of the burden of proof in safety studies of GMOs will not go away and it seems to be a fundamental sticking point in the debate. But at the same time these arguments do not take the debate about alarming studies any further forward.

3.5 ARGUMENTS ATTACKING PERSONAL CREDIBILITY

Arguments directed at individuals address the background and intentions of the opponent with the aim of discrediting the discussion partner and their arguments. It should be noted that it can sometimes clarify the issue to make the background and motives of a participant in the discussion explicit, but attacking the opponent's personal credibility in most cases simply provokes a counter-attack, which only leads to further polarisation of the discussion.

3.5.1 TU QUOQUE ARGUMENTS: 'YOU TOO'

The omission in this case is not Séralini's but that of industry and regulators. Industry has failed to carry out carcinogenicity studies on GMOs or complete herbicide formulations like Roundup before releasing them onto world markets, and regulators have failed to require them.

Website GMOseralini.org: Critics answered – visited 2 October 2013

Séralini responded that six is the OECD recommended protocol for GM food safety toxicology studies and he had based his study on the toxicity part of OECD protocol no. 453….Monsanto used 20 rats of each sex per group in its feeding trials but only analysed 10, the same number as Séralini.

John Vidal, Environment editor, The Guardian, 28 September 2012

If we argue that Séralini's study does not prove that the GM food tested is dangerous, then we must also accept that industry studies on GM foods cannot prove they are safe.

Website GMOseralini.org: Critics answered – visited 2 October 2013

Tu quoque arguments do not address the substance of a criticism, but are directed at the behaviour of the opponent. Séralini's research group argues that their publication gives grounds to ban GM maize. When confronted with criticism of the quality of the research, they said that the industry used the same experimental design and strain of rats and so the safety studies performed for the authorisation of the maize suffered from the same shortcomings. In other words, either the Séralini study is correct and GM maize is harmful, or the Séralini study is flawed, in which case the safety

tests performed for the authorisation of the maize are also flawed. This tu quoque argument says little about the accuracy of the Séralini's own publication. Similar arguments are made about the availability of data and Séralini's publication strategy. The EFSA and others asked Séralini to release the raw data on several aspects of his publication. Séralini replied that the biotechnology companies do not make their data public either and that he would release his data only if these companies released their data as well.[83] Similar arguments are also found in the other cases (see Appendix 1).

Tu quoque arguments are used to bring the opponent down to the same level by pointing out that they have acted in the same way and are therefore no better or worse. These arguments avoid discussing the substance of the issue and seek to disqualify the discussion partner. Such tit-for-tat accusations exacerbate the polarisation and uncompromising nature of the debate.

3.5.2 AUTHORITY ARGUMENTS: EXPERT OPINION

The journal, one of the best toxicological journals, did not retract the study, despite relentless pressure to do so.

CRIIGEN press release: Raw data released to a notary, 14 January 2013

He (Moloney) is not a toxicologist and hasn't studied or published any papers on the health effects of GMOs, so I am not sure how he is qualified to comment on a study by Séralini's team, who have published many such studies.

'Dusha100', repsonse to the article by John Vidal, The Guardian, 28 September 2012

Authority arguments invoke the authority of a person, group, organisation or journal. For example, a reference might be made to 'one of the best toxicological journals' or someone may put themselves forward as an expert by pointing to their qualifications or experience in the field (both proponents and opponents). Referring to expertise or authority in the debate is regularly criticised, often in combination with ad hominem arguments (see Appendix 1).

In complex and controversial studies it is usual to ask experts to give their views and clarify certain issues. These experts may come from different backgrounds and positions and their expertise may not necessarily be in the specific subject in question (for example, biochemists may be asked to comment on the statistical methods used in a toxicological study). A general claim to authority is problematic in the scientific community because expertise in one field does not imply authority in another field, which is why advisory committees almost always consist of members from various fields. In debates on issues involving different fields of expertise, the question of authority may still arise as an area of disagreement. An example is the question of how far animal

models in toxicological research are representative of the effects to be expected in humans. From the social perspective, a claim to authority based on someone's academic qualifications can be problematic because the differences between university doctoral degrees are generally not apparent. Moreover, the diversity of fields of expertise in biotechnology means it is not easy to draw a line between one area of expertise and the next.

The aim of the authority argument is to increase the value of an opinion given by a person or organisation by referring to their expertise or authority. In some debates this can be used to parry awkward questions. However, an inherent problem with the authority argument is that discussions should first and foremost be about *what* someone says and not *who* says it (see also the Habermas's validity claims in section 3.1). On the other hand, the authority or experience of experts in a certain field most definitely does play a role in the debate. Their views deserve to be given more weight and recognition in the public debate than those of others, not only because they have relevant qualifications or experience, but because they can demonstrate that they deserve this authority and respect in their daily work.[90] If a debate is already polarised, however, it will be almost impossible to invoke authority unchallenged, and these arguments are then usually employed to improve one's own stature or to dispute the authority or expertise of someone else.

3.5.3 AD HOMINEN ARGUMENTS: 'PLAYING THE MAN'

Towards the end of September, shocking headlines ricocheted around the world, claiming eating GM food caused cancer. But the truth is much darker: an anti-GM scientist overtly manipulated scientific process and the media to get those headlines.

Elizabeth Finkel, Cosmos magazine, 9 October 2012

Since Moloney is tied in closely with GM corporations he is not an impartial judge of Séralini's study.

'Dusha100', response to the article by John Vidal - The Guardian, 28 September 2012

GMWatch is one of the most rabidly anti-GM sites out there, so I don't think they're anyone to be pointing fingers and accusing people of not being 'impartial judges'.

'Shoe' , response to the article by John Vidal, The Guardian, 28 September 2012

Playing the man, not the ball and casting suspicion on stakeholders, scientists and scientific and other assessment agencies plays a big part in the debate about GMOs. It is an umbrella argument and is often woven into other types of arguments, from methodological arguments and peer review arguments to burden-of-proof and authority arguments. Ad hominen accusations are made by both proponents and opponents and are used in several domains (see Appendix 1).

These arguments do not address the substance of the criticisms being made, but are meant to cast doubt on the right of the other party to make any comment at all. This is described as a disturbing trend in a recent article.[91] The aim of ad hominem arguments is to disqualify the opponent as a discussion partner and to divert attention from the matter at hand. The effect of these arguments is to encourage tit-for-tat accusations, leading to a harder and more polarised debate. Nevertheless, ad hominem arguments can sometimes be helpful, for example when used in combination with authority arguments to put a position held by one of the parties into perspective. In situations of uncertainty, the status of one of the participants in the debate can sometimes be a decisive factor.

3.5.4 CONSPIRACY THEORY ARGUMENTS: DISTRUST THE SYSTEM

It is much better for the economy to have both GMO and GMO chemical sales AND the cost of curing the impact from the GMOs. That becomes the sticky issue in all this because German & Swiss pharmaceutical giants are heavily invested in cancer technology. Almost a conflict of interest.

Dr. Richard Lasker, repsonse to an open letter by various authors, Independent Science News, 2 October 2012

This revolving door of corrupt ties between powerful private industry lobby groups and the EU Commission was in full view recently with the ruling of the European Food Safety Administration (EFSA) trying to discredit serious scientific tests about the deadly effects of a variety of Monsanto GMO corn.

F. William Engdahl, Global Research Canada, 19 December 2012

Conspiracy theories are generally defined as attributing an event to the actions of powerful people or organisations who are said to be trying to hide their involvement from the outside world.[92] The characteristics of a conspiracy theory include the following: attributing special powers to people/organisations to influence and control others, the absence of chance (everything is planned in advance) and branding knowledge institutions as untrustworthy. In addition, these arguments are bolstered by referring to conspiracy theories from the past (such as the tobacco industry lobby) that appeared far-fetched at the time but which eventually turned out to be partly or wholly true (and therefore, of course, can no longer be considered to be conspiracy theories).

The accusations of orchestrated attacks and such like are also often linked to ad hominem arguments. Recurring GMO conspiracies, for example, tend to have the following scenario (see Appendix 1): employees, ex-employees or stakeholders of large biotechnology companies are said to have infiltrated the assessment agencies and govern-

ment advisory bodies long ago in order to smooth the way for the authorisation of GM crops and cover up studies that indicate adverse effects. Biotechnology companies try to manipulate the whole food supply chain in order to earn even higher profits at the expense of public health. Conversely, conspiracy theories can be found that assert the opposite: Séralini is a fierce opponent of GMOs and manipulates his studies to demonstrate adverse effects. He is said to be financed by big French supermarket chains with the aim of keeping GMOs out of supermarkets.[93] Conspiracy theories are found mainly in the social domain. Although it cannot be excluded that some actors have coordinated their activities, there are often no direct sources to confirm this and commentators tend to repeat each other's claims and refer to each other in blogs and the social media. Raising conspiracy theories diverts attention from the social, scientific and political issues and generates mistrust of the parties involved.[94]

3.6 THE SAME ARGUMENTS FROM A DIFFERENT PERSPECTIVE

Although a theoretical distinction can be made between the various arguments, in practice 1) many arguments contain a mix of elements from several types, and 2) similar arguments are used by different parties to the debate. Four domains can be identified within which arguments can be exchanged: the scientific domain; the social domain; the risk assessment domain; and the political and policy-making domain. Ideal-typical descriptions of these domains are given below:

- ***Science:*** In the natural sciences a single publication is usually insufficient to convince other scientists of the validity of a claim. Following the publication of an article containing unusual results, further research (confirming or refuting the original results) and published articles containing contradictory results are a fundamental part of the normal scientific discourse. Each study that confirms previous results adds to the growing body of evidence. Science investigates existing and new truths through carefully planned and designed research that can be reproduced by others to make it possible to confirm or refute the findings. Uncertainties and risks are an inherent part of this because scientific research can be difficult and unpredictable, and studies may take many years to complete. The scientific domain consists mainly of discussions between scientists in scientific journals and during scientific conferences and workshops. Even scientists themselves do not always agree on what 'good science' is.

- ***Risk assessment:*** The risk assessment domain arose in response to the desire to understand and manage the dangers and uncertainties in life. Risk assessors (such as EFSA and COGEM) walk a knife-edge between early warning and false alarm. They generally follow fixed methods and procedures to identify potential adverse effects and determine the probability that any such effects will occur. However, risk assessments sometimes require expert judgements in which the experts concerned

weigh up the merits of various scientific publications based on their expertise and experience. Risk assessments are not based on science alone, because uncertainties are involved and the final judgement is informed by norms and values.[95] Risk assessors must be able to explain and justify their decisions to the scientific community as well as policy makers, politicians and the general public. According to the well-known psychologist Paul Slovic, the identified potential effects and the probability of their occurrence depend on the methodology used. One of his main points is that although risk assessments seem to be objective, in practice they contain subjective elements and the outcome can be influenced by the chosen method.[96] He emphasises that risk assessors should be aware of this.

- ***Society:*** Social actors include civil society organisations and companies that announce their opinions in the media and political parties and interested citizens who base their opinions on what they find in the media (mainly newspapers, magazines, blogs and social media) and take part in the debate. From the social perspective, scientific and other developments are mainly of relevance to the question of what sort of society we want to live in, how a new development or discovery can contribute to this (the 'soft impacts' mentioned earlier), and also what level of risk we are prepared to accept, what the benefits are, and who benefits. Science has a lot to do with these questions, but not in the same way as for scientists. Society, to the extent that it can be seen as a collective whole, has its own ideas about science and risk. Some argue that the assumption that social issues involving risk are in fact risk issues is incorrect.[97] At root, these issues are about ethical, economic and social values and cannot be answered by science alone.[98] Social actors form their opinions not only on the basis of individual knowledge, but also on matters of principle, moral and ethical convictions and the degree to which the reader is interested in the topic. In the social domain, the seriousness of the effect found in a study is often of greater importance than the body of evidence. In the popular media a single publication is easily elevated to the status of conclusive evidence, which in turn can fuel the idea that a finding should meet with an immediate policy response.

- ***Politics and policy making:*** Politics and policy making are not the same, but both lie within the domain where decisions are made that affect the society as a whole. That is why they are described together here. Civil servants working in a specific policy field try to identify and review the technical and social costs and benefits and the opportunities and risks of various policy options as best they can. In doing so they often consider and assess information provided by scientists and other consultants (the risk assessment). The policy options are then presented to the relevant government minister for a political judgement (the risk evaluation). This judgement is based not only on the information put forward, but also on a consideration of policy lines set out in the past (what does the legislation say; what does the coalition agreement or relevant policy document say; should we follow the judgement of the EFSA or proposal by the European Commission?) and the political affiliation of the

minister and the political colour of the Government. In addition, a judgement has to be made about the likely reaction in Parliament and the country. It is then up to the minister to make a political decision based on the proposed alternatives and considerations. This may mean that for political reasons a decision is made to depart from a previously established policy, either temporarily or sometimes for the long term. The decision may also be postponed due to unresolved uncertainties or to avoid unnecessarily heightening political tensions.

In response to alarming studies like Séralini's, the same arguments are stated and used in different ways in the various domains. In the scientific domain, the debate and arguments about the article by the Séralini group focus on the content of the publication (the peer review process) and how it compares with other research in the field. In the social domain, the debate and arguments focus mainly on the effects observed in the study and their translation into consequences and soft impacts on consumers and the public in general. Contextual arguments about benefits and risks and burden-of-proof arguments are also important. In the risk assessment domain, the debate and arguments focus mainly on making the right appraisal of the risks and the likelihood of an effect occurring. With regard to substantive issues, the emphasis is on reducing uncertainties (to improve the accuracy of the risk assessment) and taking action to avoid or manage the risks. Some of the arguments in the risk assessment domain overlap with those in the scientific domain, such as specific arguments about the experimental design and severity of the effects. In the political and policy-making domain, the tensions and discrepancies between the different domains and arguments are themselves an issue. It is the job of politicians to weigh up and appraise these arguments and make a decision about any action to be taken based on the appropriate expertise, but also on concerns raised in the social domain.

4

GOVERNANCE: LESSONS AND PITFALLS

More scientific research and more facts on their own do not resolve recurring debates about the safety of GMOs. Coming up with more facts can even provoke new questions that further fuel the debate. There is no single (best) strategy for dealing with wicked problems, because both the diagnosis and the solution are looked at from different perspectives. Nevertheless, the risks and pitfalls of various types of response can be described and a number of lessons and pointers can be identified to inform government and advisory bodies of the possible consequences of various actions. The lesson and pointers include remaining alert to the dangers of rigid thinking when making judgements and establishing a platform where contextual arguments (wider issues) can be properly discussed. Falling back on procedural issues and arguments that seek to undermine personal credibility are pitfalls that must be avoided to prevent the debate escalating.

In Chapter 3 we have seen how debates arising from alarming studies about the safety of GMOs are not limited to the scientific and safety aspects alone. Although the scientific merits of such studies are discussed, much of the debate is about the underlying norms and values of scientific research and the context-related or wider issues surrounding GMOs. The mix of different types of argument has a big influence on the course of the debate, which in the case of GMOs easily becomes uncompromising and polarised and can soon escalate. Each new alarming study appears to make the process even more intractable and it seems that simply providing more scientific research and more facts will not resolve these recurring debates.[99],[100,101] The desire among the policy-making community to remove uncertainties by commissioning scientific research ignores the fact that a decision to put a technology onto the market or not is partly a value judgement. As long as there is no consensus on the values and norms that should inform these decisions, further scientific research will not help to bring about a consensus.[102] The government will have to find a solution that is both scientifically and socially robust and which lends itself to the formulation, implementation and enforcement of appropriate policies.

There is no single (best) strategy for debating issues arising from alarming studies on GMOs. When problems are complex, those involved will have different ideas about the knowledge and actions needed to solve the problem, depending on their world view or

configuration.[103] However, experience gained in earlier cases throws light on the effects of various options for action open to government and advisory bodies. This chapter examines the risks and pitfalls associated with several options as well as the lessons learned from past experience so that advisory bodies and policy makers can be aware of these and get an impression of the possible consequences of their chosen actions. The chapter is divided into the periods before, during and after the appearance of alarming studies.

4.1 PREPARATION: MONITORING

Benefit:	Learn to recognise alarming developments; rapid response possible.
Risk / pitfall:	Evidence that goes against the scientific consensus is not picked up as quickly after repeated false claims.
Lesson:	Remain open to new developments (and unconventional research methods).

By monitoring scientific developments and the discussions surrounding them, governments and advisory bodies can prepare themselves for a potential controversy or escalation of a debate involving scientists, risk assessors and the public. This is no easy task, given the huge number of publications in numerous scholarly and other journals published worldwide. Nevertheless, it is important that the government is fully up to date on developments in the field. Monitoring can be done by civil servants, assessment agencies and advisory bodies, such as COGEM. Through their work and their national and international networks they are kept informed of new research results and ongoing research, and it is their job to know about the existence of any alarming publications about the safety of GMOs. Monitoring can also reveal other scientific developments. To assess the social impact of scientific developments the government must also be aware of any public discussions about GMOs. Monitoring can deliver useful tools for policy making in the form of trend analyses.

By monitoring scientific developments, the government can avoid being unexpectedly confronted with an alarming study and may be able to respond more rapidly. Monitoring can also provide evidence to support a process of learning to recognise emerging discussions. A possible pitfall for agencies interpreting monitoring results is that evidence that goes against the scientific consensus will not be picked up as quickly after repeated false claims. This makes it important to remain open to new developments and unconventional research methods. A recent study by the Public Administration and Policy Group at Wageningen University, in which researchers Termeer and Dewulf make a case for strengthening a number of capabilities for observing situations and managing or avoiding controversies, is one of several studies offering pointers for observing developments associated with wicked problems.[104] Anther possibility is that the researchers themselves inform government about their results at an early stage. As far as is known

this only happens in exceptional cases and mainly on a voluntary basis. The early warning responsibility for notifying relevant research results could be given a more formal character through the Netherlands Code of Conduct for Scientific Practice (Gedragscode Wetenschapsbeoefening) for researchers, universities and research institutes.[105]

4.2 FIRST RESPONSE: TIMING AND OPENING GAMBIT

It is the task of government to safeguard human, animal and environmental safety, which also means that society expects government to respond to reports that one or more of these is in danger and to adopt an appropriate standpoint. It is important that the government's response is visible to the public at large. How and to what extent the government should react to alarming research results depends on each individual case, and each case will have its own risks and pitfalls. The government's response will depend on various factors, such as the status of the research (has it been published in a peer-reviewed journal or not?), the nature of the debate (specific or context-related?) and the stage it is in. A further question is whether the government should take urgent measures as a precaution or wait for the outcome of further research. This is addressed in the next section.

4.2.1 RESPOND OR IGNORE

Benefit:	Respond: visible action by government; bolsters public confidence. Ignore: media hype dissipates more rapidly following a false alarm.
Risk / pitfall:	Respond: heightens public concern, possibly unnecessarily. Ignore: may lead to public mistrust, especially if it turns out there is a real cause for concern.
Lesson:	Government must explain how it is ensuring safety and freedom of choice and why it is, or is not, taking action to investigate an alarming study or introduce appropriate measures.

If questions are raised in Parliament, the government should at the very least respond to these questions. Any letters or emails sent to the government by individuals or organisations should also be answered.[d] In both cases, however, this response does not have to explicitly acknowledge the problem or promise that any measures will be taken. In the first instance, the government can limit its response to explaining the situation and initiating standard procedures, mentioning that decisions to authorise GMOs take all the available knowledge and expertise into account. Measures such as changing exis-

d General Administrative Law Act (AWB), 4 June 1992

ting procedures or declaring a moratorium can only be taken when there are grounds for justifiable concern for human, animal and environmental safety.

It is more difficult to know how to respond when there are uncertainties and no formal questions have yet been asked, but there is national or international disquiet about the publication of an alarming study. Ignoring an alarming study or responding too late can lead to suspicion and dissatisfaction with the conduct of government, but a direct response from government will give the impression that the situation must be serious, which can easily lead to an escalation of public concern. This is not the complete picture, though, because there is a range of possible options between issuing a simple statement and taking urgent measures. The government could begin by clearly stating what the rules are for the authorisation of GMOs and how these were arrived at. The Dutch and European authorities are obligated to maintain safety standards and uphold freedom of choice, and they must be able to clearly show which information and instruments they are employing to ensure these standards and conditions. Government transparency and disclosure of the actions it is taking and why gives structure to the debate and can be informative, certainly in situations in which the public has little idea of the relevant legislation and licensing procedures. This is supported by a recent meta analysis of worldwide questionnaire surveys on consumer attitudes to GM food. Among other things, this looked at the communication of the benefits of GMOs compared with explaining the measures taken to control the risks. The results support the idea that providing clear and convincing information about managing the risks of a technology is more effective in increasing public acceptance than promoting the benefits.[106]

4.2.2 ALARMING STUDY IN PEER-REVIEWED OR NON-PEER-REVIEWED JOURNAL

Benefit:	Peer-reviewed: filters out most incorrect assertions and methodological mis takes – solid justification for response and follow-up actions. Not peer-reviewed: early warning potential – early response reinforces public confidence.
Risk / pitfall:	Peer-reviewed: no definitive, objective proof of correctness – waiting for peer-reviewed results can be time-consuming – permit applications for GM crops also contain unpublished information. Not peer-reviewed: more often than not a false alarm – undermines public confidence – claims for damages as a result of unnecessarily restrictive policies – indications of alarming situations lose potency.
Lesson:	Monitor both peer-reviewed and non-peer-reviewed alarming research results and maintain effective communication between scientists and government – provide professional support to government ministers for the communication of scientific developments.

In the examples of alarming studies in this report an important issue was whether the results were published in a peer-reviewed journal or not. Peer review is considered by both proponents and opponents of specific studies to be a hallmark of good research, but they draw different conclusions: proponents say the research was good, whereas opponents say the peer review process was flawed. In addition, studies that may provide good cause for alarm about GMOs raise the question of whether the government should respond only to peer-reviewed studies or to unpublished research results as well. An advantage of peer-reviewed articles is that most incorrect assertions and methodological errors will have been filtered out and the government can respond to scientific data that have already been critically examined. This gives the government a powerful justification for its reaction and any follow-up actions. However, alarming reports about the safety of GMOs have so far seldom been published in prestigious or other peer-reviewed journals. If the government only considered peer-reviewed results when formulating policy, the number of reports it would have to respond to would be limited, which can be considered to be an advantage – but also responding to non-peer-reviewed results has the benefit of early warning potential, which the government can use to strengthen its position and gain greater public trust (if the warnings prove to be correct).

Nevertheless, the supposed benefits of the peer review process contain a hidden danger. Peer review is an initial and provisional test of the scientific quality of a study, but it does not provide proof of the correctness of any claims made in the study. Often further research is needed to demonstrate whether, and to what degree, the findings are correct. Responding to non-peer-reviewed results is also potentially risky: responding to unpublished results incurs a greater risk of raising a false alarm than responding to peer-reviewed results, and early warning can cause considerable public unease, which is difficult to dispel, even if it later becomes clear that it was a false alarm. In discussions characterised by polarisation, the government may feel under pressure to respond to unpublished results, particularly when these results are very worrying. When restrictive measures are taken on this basis, they can have adverse effects on science and industry. Should at a later date these measures prove unnecessary, the government may even receive claims for damages.

Peer-reviewed results may be a long time in coming, making it difficult for the government to respond quickly and diligently. Dismissing an alarming study by arguing that the results have not been peer reviewed can damage public confidence in the government if the results are published and later confirmed. The government will then appear to have been indifferent to an early warning. Another pitfall is related to the question of the burden of proof. Applications for marketing authorisation of GM crops also contain unpublished and non-peer-reviewed information, which suggests that different criteria apply to different stakeholders and opens the door to arguments in the tu quoque category, making the government come across as biased. It should be noted that the studies submitted in support of permit applications also

undergo a type of review in the form of appraisals by the competent authorities and advisory bodies.

There are advantages, risks and pitfalls associated with responding to peer-reviewed and to non-peer-reviewed results. It is not possible to draw a firm line between studies the government should and should not respond to. A quality model for selecting non-peer-reviewed information could be useful, but would still raise questions in the GMO debate. There is something to be said for the government always reacting to an alarming study about the safety of GMOs when there is public unease. For the general public and the media, peer review is partially a non-issue because most people do not know which journals are peer-reviewed and which are not, or what it entails; this distinction has little or no influence on the level of public unease about the conclusions of an alarming study.

4.2.3 MORATORIUM

Benefit:	Moratorium: decisive action by government – bolsters public confidence. No moratorium: less (unnecessary) unease as long as the status of the research is uncertain.
Risk / pitfall:	Moratorium: unease; claims for damages when restrictive policies prove to have been unnecessary. No moratorium: public confidence in government is damaged if the alarming study proves to be correct.
Lesson:	Clearly communicate the arguments for and against a moratorium – have a step-by-step plan of action available for after a moratorium.

In addition to the question of whether the government should formally respond to an alarming publication, there is the question of whether (as a precautionary measure) urgent measures should be taken. Such measures may include a moratorium on the import and/or cultivation of the GMO, taking specific products off the market, or even a moratorium on research. There are various sorts of moratoriums, such as voluntary and imposed moratoriums. Voluntary moratoriums are the only option when there is no legislative or legal basis for imposing a moratorium. Examples of voluntary moratoriums are the moratorium on GMO research introduced following the Asilomar conference in 1975 and more recently the moratorium on research into the H5N1 influenza virus.[107,108] In 2012 France and other EU member states imposed a moratorium on the cultivation of the GM maize MON810.[8] Finally, there are implicit or de facto moratoriums when a policy leads to the ending of an activity without it explicitly being prohibited. An example is the de facto moratorium on the authorisation of GM crops from 1999 to 2003, which was

brought about by the European Commission not taking any decisions on the permit applications.[109]

A moratorium on a GM crop would appear to be justified when a study indicates an acute and significant risk to public health or the environment. But in the early stages of a study that goes against the scientific consensus, or when such a study is published, there may still be uncertainties about the seriousness of the situation. Given the body of evidence about the safety of GMOs that have been approved for marketing, a single alarming study or publication on one of these GMOs will seldom be indisputable evidence of an acute risk that justifies immediate action.

The decision to introduce a moratorium or not depends on the question of whether the GM crop in question is grown in the Netherlands or Europe or imported, and in what quantities. A further question is whether the GM crop is used for human or animal consumption. A moratorium is not a simple measure and entails the risk of causing public unease and, if it proves to be a false alarm, the negative consequences for public confidence in the government. Moreover, a moratorium can have far-reaching consequences for political relations and commerce. For these reasons, the various interests at stake and the risks involved must be carefully considered before introducing a moratorium. In addition, it is important that plans are in place for follow-up actions during and after the moratorium: the end of a moratorium does not automatically mean that a consensus has been reached. Protocols for decision making and information provision during crises such as the outbreak of animal diseases could provide a basis for developing an appropriate approach.[110,111]

The measures to be taken in response to an alarming publication must be proportionate to the identified risk, and this means that they must be carefully tailored to each specific case. In most cases the government will only be able to make a decision about any measures to be taken after establishing with sufficient certainty that the study really does justify taking action and amending existing policies. This is usually done by having the study critically reviewed by experts and specialist advisory bodies.

4.3 OBTAIN ADVICE: EXPERTISE AND DATA

Before governments (EU, NL) take measures in response to an identified safety risk associated with a GMO, the study is assessed by the relevant scientific advisory bodies.

4.3.1 CHOICE OF ADVISORY BODIES

Benefit:	Established advisory body: experience and expertise in house – available resources – contribution to confidence in and recognition of the advisory body. Different advisory body: avoid the appearance of bias – possible to match expertise to a specific issue.
Risk / pitfall:	Established advisory body: rigid thinking when making judgements – reluctance to revise previous advice in the interests of maintaining consistency – appearance of bias. Different advisory body: damage to the reputation of the established advisory body – long lead-in time – appearance of cherry-picking expertise – lack of experience due to variable composition.
Lesson:	Keep options open and establish criteria for a second opinion in addition to the advice from the formal responsible bodies.

Various national and European advisory bodies have been appointed to assess the environmental and food safety aspects of GMOs and provide advice to governments. It is therefore only natural to ask these advisory bodies to investigate alarming studies about GMOs. However, asking the same bodies that have previously advised on the same GMO can incur resistance because of the possibility of bias or prejudice. This is why in the Séralini case the Belgian Biosafety Council chose to form an ad hoc advisory committee to critically examine the study.[22] The decision to go with a new advisory body or ad hoc committee has various advantages and disadvantages.

The advantage of using existing advisory bodies is that they possess relevant expertise and experience and have the resources to respond quickly. Theirr visibility and raison d'être are enhanced in the process, which in turn imbues them with an aura of trust and distinction in the eyes of the public. But the provision of advice by the established advisory bodies also has its risks and pitfalls. The ability to assess new risks or uncertainties depends in part on being alert to new, sometimes unconventional research methods. This ability to remain open to new research methods may be constrained because established bodies always work with specific research protocols and methods. Moreover, in the interests of consistency and reliability, professional organisations may be reluctant to retract earlier advice too soon,[e] given that their reputation and credibility is an important factor in how their advice is regarded and received. Another related factor is that professional organisations operate within certain networks that

e Scientific knowledge is subject to change, whereas a certain degree of consistency is important in risk assessment and evaluation. Constantly changing the risk assessment can lead to a loss of confidence among companies (legal certainty) and the public, whereas waiting too long to make changes can also damage confidence.

may not be trusted by outsiders. For example, some people accuse the EFSA of not being independent, because of alleged connections with interested parties (companies applying for permits), and this means that their assessments are also not always trusted. When advisory bodies become (or are seen to be) part of the established system that represents a dominant but disputed paradigm, their advice may not have any useful input, and may even exacerbate the controversy.

Asking a different advisory body or ad hoc advisory committee to advise on an alarming study can deliver a fresh perspective and may be more easily accepted by the public. Another advantage of an ad hoc committee is that the members can be selected to match the nature of the specific conflict. However, by establishing an ad hoc committee the government risks putting the value of the acknowledged advisory bodies in doubt, and it would also to a certain extent disqualify them. Putting together an ad hoc committee can be a time-consuming business and there is a risk that the government will be accused of cherry-picking from the pool of available expertise. If the expertise held by the members of an ad hoc committee is in a different, probably related field, this will also raise questions, mainly in the scientific domain. Moreover, an ad hoc committee will not be able to draw on an accumulated body of experience because its composition will vary each time. A possible pitfall is to establish an ad hoc committee with too narrow a range of expertise, with the danger that the members will not fully recognise or consider the contextual nature of the problem. The decision to consult an established, acknowledged advisory body or a new or ad hoc advisory body is namely a political one.

4.3.2 AVAILABILITY OF THE RAW RESEARCH DATA

Benefit:	Wait for the data: less chance of mistakes – confirmation of the soundness of the judgement. Do not wait for the data: rapid and easy.
Risk / pitfall:	Wait for the data: delay to the assessment of the research – public discontent if the data do not lead to greater clarity. Do not wait for the data: insufficient evidence base for the conclusion – vulnerability to mistakes.
Lesson:	Know what you do not know à what data are essential to form a conclusive judgement.

Evaluating the research results and underlying data from a GMO safety study is the job of the advisory bodies or experts responsible for the assessment. In some of the cases examined in this report, some of the raw research data were not available. This made it more difficult to assess the studies, for example because the statistical analyses could not be checked or replicated. Not making the raw data available when publishing

an alarming study can lead to considerable delay in the assessment of the research, depending on the willingness or not of the author to provide the data on request. Advisory bodies are faced with the choice of making an initial assessment based on the data available or first asking for the underlying raw data to be released and then preparing their advice.

Assessing the available data at an early stage can quickly lead to manageable conclusions, but there is a risk that the conclusions may not be sufficiently substantiated. This will make the assessment agency vulnerable to mistakes, whereas with hindsight the public will have little appreciation of the pressure to act at the time. Waiting for information has the advantage of making it possible to come to a more informed judgement. It should be borne in mind that the more exceptional the claim, the more convincing the evidence has to be, but there is also a risk that too much importance will be given to the missing data. Interpreting third-party raw data is difficult and time-consuming and if, after all the hold-ups and delays, this does not lead to a definitive judgement, the public may not be forgiving (given the sense of urgency and concern they feel). An important consideration is which data are needed to come to a definitive and well substantiated judgement ('knowing what you do not know'). After all, focusing on raw data ignores the contextual aspects of the discussion about GMOs, and this can be a pitfall in the debate.

4.3.3 REQUIRING BIOTECHNOLOGY COMPANIES TO RELEASE THEIR DATA

Benefit:	Industry data made public: all the cards are on the table – bolsters confidence. Data are confidential: focus on the alarming study instead of contextual discussion about the data.
Risk / pitfall:	Industry data made public: conflicts about the confidentiality of company data – reputation damaged by submitting to pressure – interminable wrangling about the data. Data are confidential: continuing deadlock – reputation damaged by submitting to pressure.
Lesson:	Be aware of the persuasive power and limitations of data – availability of raw research d**ata (commercial and scientific).**

A complicating factor in the discussion about missing data from alarming studies is the issue of the transparency of the research data produced by biotechnology companies. In the Séralini case, the fact that he did not make his raw data public was used as a way to pressure the biotechnology industry to release the authorisation data. The requests from both sides for transparency and for the underlying raw data led to an impasse in the debate about the safety of the GM maize NK603. Companies regard information

as a capital good and so they are not prepared to simply give it away. To protect their information, they make authorisation documentation on GM crops available to the assessment agencies and advisory bodies, but not to the public. The advantage of authorities, companies and researchers agreeing to exchange information is that it they can claim to have revealed all the relevant known facts and uncertainties. A risk is that conflicts could arise about the confidentiality of the information.

It is important that those involved in this discussion are aware of the limitations of the persuasive power of data. The data debate suggests that making missing data available will lead to a solution and that there is a single truth waiting to be uncovered. The question, however, is whether data conflicts can be satisfactorily dispelled if there is no basic trust in the organisations responsible for assessing and authorising GM crops. There is a risk of descending into interminable wrangling about the availability or validity of the data, whereas the disagreement is actually partly about the interpretation of the relevance of the data. Moreover, by allowing themselves to be caught up in the discussion and the tu quoque game surrounding the exchange of data, assessment agencies themselves run the risk of being branded as unreliable.

An important consideration is whether researchers may release data conditionally, especially when a researcher claims there is a serious risk to human and animal health as a result of consuming a GM crop. Scientific journals also have a responsibility in the discussion about data. They can make an important contribution by pointing out the moral responsibility of researchers to make their raw data available. Although the discussion about making raw data available is confined mainly to researchers, companies and the assessment agencies, ministers could make their concerns known in Parliament and to the public about the way the data transparency discussion is conducted with little regard for the safety aspect of the debate.

4.3.4 COORDINATION WITH NATIONAL AND EUROPEAN ADVISORY BODIES

Benefit:	European: diversity of available expertise – broadens support. National: quicker – advice especially pertinent to the national debate.
Risk / pitfall:	European: tendency to compromise – minority opinions less visible – lack of relevance to national GMO debate – collective rejection leads to a hardening of the debate. National: position at variance with EU policy – isolation of member state – lack of expertise at national level.
Lesson:	Ensure the consultation process is transparent to the public – integrity and aut hority of negotiators – retain own identity in final advice.

Where food and environmental issues surrounding GMOs have international ramifications it is usual to consult with national advisory bodies and with international advisory bodies like the EFSA. Whether and to what extent it will be necessary to consult and coordinate with other advisory bodies can vary from case to case. The advantage of extensive international consultation is that use can be made of a wide variety of available expertise. If it is possible to come to a common position, the advantages of this coordination are that it increases public acceptance and support and, in particular, that there is international consensus. On the other hand, coordination at the national level will probably be quicker and will be more relevant to the national debate.

A risk of international coordination is that the agreements made will tend to be a compromise. Given the different positions within Europe about the authorisation of GM crops, some points will be subject to negotiation because they will take on a different significance depending on the national context: the evaluation and measures to be taken may be too cautious for some and too rigorous for others. Presenting a consensus document may be a selective form of transparency in which minority opinions are less visible, although this may be a conscious decision in the interests of avoiding mixed signals to the outside world. To the public, international coordination is often an obscure process, making it easy for critics to dismiss it as a conspiracy or orchestrated response. Moreover, when national or international advisory bodies and governments set their sights on the authors of an alarming study, there is a risk they may respond to criticism by adopting an increasingly defensive position, making it more difficult to have an open and fruitful discussion. International coordination and the formulation of a common position can heighten this effect and there is also a risk of tunnel vision among those in agreement. In response to coordinated recommendations, the authors of the alarming study may appeal to their 'us against everyone else' position. This pitfall can be raised in the discussion in an attempt to disqualify the outcome of the consultation and coordination process. The integrity and authority of the negotiators should therefore be given careful consideration during international coordination. A risk of limiting consultations to national coordinating is that the final outcome may not be in agreement with current EU policy or that a member state may become isolated in the international debate. Another pitfall may be lack of expertise at the national level. As international borders fade, international orientation and coordination is often essential (or obligatory within the EU), but it does not relieve national governments of the duty to form their own judgement.

4.4 RESPONSE: COMMUNICATION AND FOLLOW-UP ACTIONS

Once the assessments by scientific advisory bodies have been obtained, it is the government that has to come to a decision on the value of the alarming study and any consequences that should be attached to it. But the scientific assessment is just a part of

the political and public debate about the safety or desirability of GMOs and does not cover all its aspects, as we have seen in the analysis of arguments in Chapter 3 of this report. The question, then, is what arguments, if any, the government should consider and what channels should the government use to effectively communicate its views on alarming studies.

4.4.1 ATTUNE COMMUNICATION TO STAKEHOLDERS

Benefit:	Reactive & specific: (theoretically) comprehensible and rational discussion – focus on the immediate cause: the alarming study. Active & in context: recognition of contextual problems.
Risk / pitfall:	Reactive & specific: an illusion of value-free science – procedural reaction does not do justice to the contextual discussion about GMOs. Active & in context: (unmanageable) broadening of the debate – reduces the chance of reaching a consensus on the alarming study.
Lesson:	In addition to responding directly to an alarming study, pay attention to the broader communication of contextual arguments – meet the information needs of the stakeholders – make decision-making procedures transparent – strengthen position as information provider by paying due regard to contextual arguments.

A general point is that government responses must be balanced and give due consideration to both the specific and the contextual arguments. It is crucial that the different types of arguments are acknowledged and kept separate – but addressing one type of argument does not mean that the other is invalid, and this must be made clear in the communication. It is essential to always indicate which arguments will be considered in the decision making on GMOs and which will not. It could also be made clear where these other arguments may contribute to policy making, for example in a broader debate on agriculture and food production. In this section a distinction is made between specific communication in response to an alarming study and the broader government communication on contextual arguments.

General pitfalls in the area of communication include focusing on procedures, generalising outcomes and disqualifying participants in the discussion due to their position, background or knowledge.[60] In the debate about the safety of GMOs, arguments attacking personal credibility appear to be gaining the upper hand in both the scientific and the social domains. These arguments divert attention away from the substantive issues and are almost always geared to disqualifying the opponent as a discussion partner. They do not take the discussion any further forward and lead to polarisation, a hardening of attitudes and escalation of the debate.

Communicating an alarming study: reactive & specific

In the first instance, alarming studies about the safety of GMOs have a bearing on safety policy. Government often responds to this by asking its advisory bodies to investigate whether the results of the study are accurate. In such situations, the government will at least have to provide a reason why it will or will not take measures in response to the alarming study.

Differences in scientific opinions can be a reason to initiate research to provide answers that will settle the issue. In theory, a strictly scientific discussion should keep the debate about alarming studies both rational and manageable. Alarming studies are published in the scientific literature and advisory bodies assess the quality of the research. The research results are then confirmed, refuted or corrected and the government takes measures appropriate to the study outcomes. But values also play a role in scientific discussions – although this does not mean that science 'is also just one opinion'.[112] When there is disagreement about the quality of the experiments, the correctness of the data and who has the right expertise or authority to make valid statements, scientific discussions can also escalate and become deadlocked. This process is intrinsic to science, but can be made more difficult by the intrusion of contextual arguments and arguments attacking personal credibility.

Focusing on specific details of scientific research can unhinge the discussion or encourage tunnel vision. This is a risk, for example, when criticism of the statistical analysis, the test animals used or the experimental design is used to dismiss the whole study. A strong focus on the early warning argument (the seriousness of the effect found in the study) can serve to escalate the debate and therefore makes little or no constructive contribution to the discussion. What it can do, though, is link into the contextual arguments, which attract attention mostly in the social domain. This also applies to the argument about the availability of data and the discussion about the burden of proof in marketing authorisation procedures. The arguments about the availability of data and burden of proof raise a more fundamental, underlying problem, but do not belong in the specific discussion about an alarming study. The government could play a coordinating role in pulling together specific and contextual arguments by addressing these and indicating in which domain the debate can be conducted. Government also plays an essential role in translating scientific results and evaluating alarming studies. It is up the government to explain why the alarming study does or does not justify taking further measures.

Communication of GMO-related aspects: active & in context

Because the government consults scientific advisory bodies it can be accused of hiding behind procedures and the opinions of advisers, which makes the position of advisory bodies part of the debate. The public feel their views are not being taken seriously

because only safety-related arguments are taken into account in the decision making. In its topic report 'Farm Scale Evaluations Evaluated', COGEM concluded that scientific knowledge must be not only scientifically but also socially robust if it is to be useful for the formulation, implementation and enforcement of appropriate policies. Government should be aware that the broader discussion about GMOs cannot be resolved solely by arguments from the scientific discourse. This means that the government has to take a decision about what to do with the wider issues, soft impacts and context-related aspects if it wants to get the debate on the right course.

Contextual arguments are often not GMO-specific and are part of the wider debate about the type of society we want and the policies and technologies we need to get there. The types of questions in this debate include the relation between GMOs and sustainability, the power of the multinationals over food supplies, the desirability of widespread industrialisation of agriculture, as well as questions about focusing on technology to solve problems instead of behavioural changes in society. These arguments broaden the discussion and heighten the sense of urgency, but they cannot be seen in isolation from the specific arguments. If there is to be a constructive debate, contextual arguments must also have a factual basis, or it must at least be possible to examine them against the background of how the world actually works.[113,114] However, when deployed in a discussion about a specific alarming study, a contextual argument can frustrate the dialogue because a solution to the wider problem cannot be found within the specific situation. In only a few cases does the generalisation argument (all GMOs are safe and useful or all GMOs are dangerous and undesirable) make a constructive contribution to the debate, because it precludes any further discussion or zooming in on specific examples.

Ad hoc situations, such as the appearance of an alarming study in which the safety of a specific GMO is questioned, are by definition unsuitable vehicles for these arguments. As a result, socially engaged people looking for ways to use their contextual arguments feel ignored, and that leads to frustration. The government usually limits its communications to pointing out the relevant procedures (we have asked our advisory bodies to assess or reconsider the study) and issuing a press release on the findings of these advisory bodies. This is important information, but it all too easily comes across as saying 'these are the facts and you'll have to accept them'.[115] The government can also choose to take further steps in its public information and communication strategy, such as opening a telephone line, taking an active part in discussions and forums and organising meetings. Such communication tools are usually only used in emergency situations, for example when an alarming study is recognised and confirmed.

The choices the government makes in response to alarming studies are in many cases implicit or largely unknown to the public. It could explain more openly, clearly and frequently which procedures are used to assess GMOs and why. The government limits its role mainly to ensuring certain requirements are met, such as safety standards and

freedom of choice, and must continue to explain which instruments it uses to do this. It is advised by expert committees and is responsible for taking decisions about the safety of GM products under the authorisation procedure. It has decided to safeguard the freedom of individual citizens and consumers to choose whether or not to buy or consume products made with the use of genetic modification by requiring GM foods to be labelled as such.

The government can reinforce its position as the public's source of information on GMOs by establishing a platform where contextual arguments regarding GMOs can be aired. There are different views on the form this platform should take, such as forums, 'thinking laboratories'[116] (a cross between closed expert committees and open public debates) or a broader national or international debate on food production. However, addressing the wider issues involves more than simply setting up a discussion forum; facilitating a platform for wider issues gives the government a chance to identify structural obstacles.

A further point to consider in the communication about alarming studies is adjusting the intensity of communication to the degree of scientific and social unease surrounding the conflict. The media are an important link between government and the public and a gauge of public opinion, but they can also act as catalysts to escalate the debate (see text box).

The effect of the media

The media can play a part in escalating public debates because they focus on the conflict frame (conflicts and controversies are more interesting than consensus and confirmation of the existing order), dramatisation (discriminating and factual news reports do not sell as well as dramatised versions of the same stories) and bandwagon journalism (journalists, consciously or not, tend to pick up on other journalists' stories, intensifying total media interest). These effects are intensified by the rise of social media, making it more difficult to estimate the impact a story will have in society: an incident can easily be blown up, for example by rapid dissemination via Facebook ('going viral'). Moreover, research has shown that negative comments and tu quoque arguments posted online under news reports also have a negative effect on other readers. This was the reason why the website *Popular Science* decided to stop hosting these comments.[117] Media attention is unpredictable and can disappear as quickly as it came when another interesting topic comes along (issue attention cycle). These characteristic vagaries of the media can disrupt the clarity of what is being communicated via these channels. On the other hand, science journalists are key agents in making scientific information accessible to the public.

The government can strengthen its position as prime information provider by passing information directly to social stakeholders and NGOs representing the voice and inte-

rests of specific groups. For this to work, the public sector must have in-house expertise on science and science journalism to ensure that it can meet the information needs of the various stakeholders in the debate. A recent report published by the public information and communication office of the Ministry of General Affairs, which sets out 37 trends in government communication, may contain useful pointers for government communication.[118] The report reviews trends in society and the work of communication professionals, including government participation, expectation management and accountability.

4.4.2 FOLLOW-UP ACTIONS: FURTHER RESEARCH

Benefit:	Further research: refute or confirm results – consistent with scientific practice – a clear signal to society. No further research: rapid response possible – confirms body of evidence.
Risk / pitfall:	Further research: time and costs – discussion about independence and methodology – temporary delay damages research community and industry. No further research: appearance of government indifference and inflexibility.
Lesson:	Select researchers with care – need for transparent management and coordination.

Alarming studies present new results that go against the existing consensus on the safety of GMOs. The options for responding to this are commissioning or facilitating further research or repeat studies, or referring to existing research results. The usual response to contradictory results is to establish whether they can be confirmed, refuted or matched by existing studies or conducting new experiments. But if the experimental design and method differ from standard tests, or are even controversial, it can be difficult to find comparable studies to compare results with.[119] Moreover, when the majority of scientists in the field consider a controversial study to be methodologically flawed or incorrect, repeat studies will always lead to further discussion or argument. But if no repeat studies are done and no comparable results can be found, the study will remain unique and, despite the criticisms, references to the results of the study will remain. The reasons for doing further research or not do not necessarily have to be scientific; the existence of a controversy or highly charged emotions may be reason enough. In such cases it may be advisable to repeat studies to overcome the limitations of a previous study, but there is a fine line between a study with weaknesses or constraints and a study with an incorrect or biased experimental design. A biased or methodologically dubious safety study (accidentally or on purpose) should, from a scientific point of view, not be an incentive to do further research financed by government. In such cases, the responsibility should lie first with the researchers themselves to rectify their study. However, this can be problematic because it is not always unequivo-

cally clear whether a study is sound or not. Moreover, it must be stressed that scientific research, including safety studies and repeat studies, always involve a certain degree of uncertainty. It is ultimately up to the politicians to decide at what point science provides a sufficient basis to take a decision and to accept responsibility for this.[120]

If further research or repeat studies are carried out, the alarming study will no longer be unique and may be partially or entirely refuted or confirmed. Undertaking further research shows that the issue is being taken seriously and can bring an element of calm to the situation, at least temporarily. However, commissioning further research may also cause a public stir, because there is then 'apparently' reason for concern. Doing further research may also be time-consuming and costly. A risk is that during the course of the research, further development and commercial activities will be put on the back burner as a precaution. Government funding for replicating a study branded by the scientific community as being methodologically very weak can meet with incomprehension and resistance from the field. Counter research into safety studies of GMOs found to be safe and authorised for placing on the market is not very interesting for most researchers because of the high costs and limited publication potential (see text box). The compulsory post-market monitoring is generally seen as sufficient to bring to light any unanticipated adverse effects following marketing authorisation.

Scientific value of safety studies

Scientific progress is based on confirming, refuting and adding to research results. From this perspective, controversial results are also useful because they keep scientists on their toes. Publications are not only the product of research, but are part of the scientific process. This model also has its limitations, though. Scientists are judged by the number and impact of their publications, which is why scientists attempt to publish as many articles as possible, preferably in journals with a high impact factor, which influences how many references are likely to be made to an article. This impact may be simply be scientific impact (citation score) or also translate into opportunities to turn the research into private (commercial) or public activities (valorisation). 'Safety studies' generally receive low scores for scientific impact and only in exceptional cases are they published by high ranking journals, such as the study into gene therapy which showed that treated patients later developed leukaemia.[121] If repeat studies find no safety risk, the results are unlikely to be accepted for publication, because they contain little in the way of new scientific insights and no possibilities for valorisation.71 Research replication in which a study is repeated in exactly the same way is rare. Such studies are virtually unpublishable. Funding organisations are also dismissive of repeat studies. This may be different for research carried out in response to publications that have generated scientific and/or public debate. Studies refuting those results may be easier to publish because of their newsworthiness. In June 2013, in response to the Séralini study the European Commission opened a tender for a two-year feeding test of the GM maize NK603 on rats.[122]

Given the polarised discussion about GMOs, there is a risk that when the results of additional research are published, the debate will escalate further or start up again, whatever the results. Various stakeholders will try to influence the design of the additional studies and the composition of the research team, and may withdraw support during the process if they think that the results will not back their own views. If so, support for the final outcome of the research will crumble. Things that require attention when carrying out or commissioning further research include the choice of researchers and the transparency of the decision-making process. The fact that just a limited group of researchers are involved in GMO safety studies can be problematic. Given the polarisation of opinions on the subject, one or other of the parties involved will be easily inclined to mistrust researchers that have previously worked with GMOs. More researchers could be encouraged to carry out repeat studies or further research by providing funding and access to research materials. Another point to consider is ensuring that the coordination of the process is transparent, so that the conditions under which the research is carried out are clear to everyone. Those involved will have to agree how the research can be conducted in a reliable and accountable manner.

Referring to existing and repeatedly confirmed research results is quicker and can confirm the existing body of evidence. But because comparable research results are few and far between, there is a risk that the government and its advisory bodies will be accused of cherry-picking the results that suit them. And because study designs differ to varying degrees, a similar discussion may arise about the study design, the methods used, the execution of the study and the value of the results. The paradigmatic and contextual aspects mentioned previously have much to do with this. Points to consider when referring to previous research results include identifying clear criteria or a quality model for selecting alternative studies to refute or confirm the alarming study.

4.5 OPTIONS FOR CASE-BY-CASE ADAPTATION TO THE NATURE AND INTENSITY OF THE DEBATE

When authorising GMOs the government has the responsibility to safeguard human, animal and environmental safety. Although it can be considered a government task to prevent the escalation of public debates, this does not mean that every form of discussion must be suppressed. Actions designed to control and contain discussions can in fact cause them to escalate. A sophisticated reaction model (activating or deactivating the discussion) attuned to the nature and intensity of the scientific and social unease could offer government a framework for managing the dynamics of the situation. This chapter has discussed the various options for dealing with alarming studies and raised relevant lessons or points to be considered, the risks involved and pitfalls to be avoided. It has shown that there is no 'magic formula', but that each option has its own pros and cons.

Recent examples show that the debate about alarming studies can become broad and international in scope in a very short time, considerably increasing the numbers of people involved. Scientists, risk assessors, companies, NGOs, concerned citizens, politicians and policy makers all compete for attention in a welter of different arguments expressed in statements, news reports, blogs and forums. In this situation it does not seem likely that the various types of arguments can be completely separated. What is possible is to make a distinction between the information and communication needs of the different stakeholders, which will help the government and advisory bodies to devise appropriate communication strategies for these groups. This communication will not begin when an alarming study is published, but beforehand. Analyses of the dynamics of past debates, as in this report, can identify lessons, pointers, risks and pitfalls, and help the government prepare for and anticipate future situations. Government must continue to monitor social trends and developments and remain cognisant of the contextual arguments about GMOs.

5

CONCLUSION

This chapter draws on the argument analysis and the various options for action open to government and advisory bodies and presents an overview of the main points to be considered when responding to alarming studies. In addition, several recommendations are made for consideration.

Debates about the safety of GMOs have a history of complexity and controversy because there is disagreement not only about the facts but also about the underlying norms and values. Alarming studies[f] which conclude that GMOs are damaging to human health and the environment appear regularly. The debates that arise as a result follow a familiar pattern and do not come to a resolution or a consensus. Debates about alarming studies usually begin with scientific arguments, but eventually degenerate into generalisations, a broadening of the debate and the use of arguments attacking personal credibility (such as ad hominem and tu quoque arguments) to disqualify the discussion partner. Drawing on several case studies, this report has analysed the dynamics of debates about alarming studies on the safety of GMOs. It also explores the advantages and pitfalls of the various governance options for dealing with these studies.

On alarming studies, COGEM makes the following observations:

- Alarming studies will always provide an excuse to reignite the national or international scientific and public debate, and therefore also the political debate.
- It is not possible to determine immediately whether the results are valid or not, and so the value of the results will have to be investigated.

On the dynamics of the debate, COGEM makes the following observations:

- The debate involves not only specific scientific arguments, but also contextual arguments and attacks on personal credibility.

f In this report 'alarming study' means a scientific or other study, the results of which may or may not have been published in a peer-reviewed journal, from which it can be concluded that a technological innovation (such as GM crops) poses a threat to human and/or animal health and the environment. The term 'alarming study' refers only to the claim made and does not say anything about the veracity or otherwise of the study.

- No clear-cut distinction can be made between scientific actors with their scientific arguments and social actors with their social arguments, but the same arguments are made from different perspectives.
- Some arguments lead to constructive discussions, whereas others attract increasingly negative feedback or act to weaken or disqualify each other. The mix of different types of argument can make discussions more uncompromising and polarised and lead to an escalation of the debate.
- By pointing to scientific uncertainties as the core of the problem and asking scientists to remove these uncertainties, political decision making shifts towards the scientific domain, making it part of the public debate about GMOs.

On GMO safety studies, COGEM makes the following observations:

- Scientific research, and thus also safety studies, will always involve uncertainties; it is up to politicians to decide at what point science provides a sufficient basis to take a decision and accept responsibility for this.
- Government makes itself vulnerable by placing the burden of proof for the safety of GMOs entirely on the manufacturers. Government sets the test requirements and assesses the results obtained via its advisory bodies. This means that the manufacturer carries out the safety tests (such as laboratory experiments, field trials and food tests) or contracts them out, and that risk assessors use these data for their safety assessment. For some people the fact that manufacturers supply the data is reason enough to assume that they cannot be reliable. This idea is strengthened by a general mistrust of multinationals that market GMOs. To bolster confidence in the system, the government could commission random repeat studies or introduce supervised inspections, as is usual practice for pesticides. This would give the government the opportunity to observe some safety experiments.
- Counter research into safety studies of GMOs are not interesting for most researchers because of the high costs and limited publication potential. The polarised climate of the debate also means that the relatively small group of institutes, companies and NGOs that do do this type of research become easy targets for accusations of conflicts of interest, which in turn does not help the debate. This type of research should be made more attractive for a larger group of scientists.
- Scientific journals and scientists have their own responsibilities in the debate. If a journal accepts an article which states that the safety of humans, animals or the environment are at risk, it should point out the moral responsibility of the authors to make the underlying (raw) data available to other scientists and risk assessment bodies.
- When researchers obtain alarming results, they themselves could inform the relevant government authorities. For example, the early warning responsibility for notifying relevant research results could be made more formal by including it in the Netherlands Code of Conduct for Scientific Practice (Gedragscode Wetenschapsbeoefening) for researchers, universities and research institutes.

On the appropriate response to alarming studies, COGEM makes the following observations on the role of risk assessors and scientific advisory bodies:

- They should remain alert to new findings. Risk assessors should review new publications on their own merits. The ability to identify new risks depends on being open to new, sometimes unconventional research methods.
- They should be careful to avoid adopting a rigid view when making judgements and be alert to the danger of tunnel vision among like-minded colleagues when consulting nationally or internationally.
- They should be aware of public perceptions. Consulting official bodies in Europe about the scientific value of a publication can be useful in coming to a more discriminating judgement, but it can also be considered as an orchestrated attempt to suppress dissident opinion. The scope of such consultations should therefore be carefully defined and observed to ensure that each organisation can be shown to have come to its own independent judgement.
- They will not be able to end the public debate about the safety of GM crops simply on the basis of a scientific assessment of the alarming study. If risk assessors and scientific advisory bodies come to the conclusion that an alarming publication is of insufficient scientific quality to justify its conclusions, it is then up to the government to take a definite decision and state why the study provides no reason to reconsider the authorisation of the GM crop.

On the appropriate response to alarming studies, COGEM makes the following observations on the role of government:

- The government responds primarily in a procedural way to each alarming study by referring it to scientific advisory bodies and asking them to assess or reassess the quality of the study.
- Taking such a procedural approach gives de facto decision-making powers over the authorisation of GM crops and their products to the bodies that assess their safety.
- When deciding which bodies to ask to assess a new study, the government should consider whether they should ask the same bodies that have previously assessed the same GMO or not. The heavily polarised nature of the debate about GMOs means that even the hint of bias or prejudice presents a real danger. Choosing a different body may be seen by opponents as a victory and could damage the reputation of the original risk assessment body. However, enlisting the aid of a different agency can be seen as a request for a second opinion by the government, and if this confirms the advice of the first advisory body it can strengthen its authority in the eyes of the public.
- The government can decide to commission further research. Although this may be seen by opponents of GMOs as proof that something is wrong with the safety of GMOs, additional research can also serve to show the public that the government

takes alarming publications seriously, even if they are of insufficient scientific quality to justify taking urgent measures.

- By emphasising measurable and quantifiable effects, the government only helps to overshadow other aspects of the debate about GMOs, which can lead to frustration among the public. Contextual arguments, wider issues and soft concerns, such as ethical and religious objections, the fear of monopolies controlling food supplies and the desire for a less industrialised form of agriculture, play no role in the decision making on GMO crops. The government should be aware that these discussions cannot be resolved by appealing solely to arguments from the scientific discourse.
- The government should therefore explain more openly, clearly and frequently which procedures are used to assess GMOs, and why. The government restricts itself to safeguarding various requirements such as safety standards and freedom of choice and must continue to explain which instruments have been deployed to do this.
- The government has decided to safeguard the freedom of individual citizens and consumers to decide whether or not to buy or consume products made with the use of genetic modification by requiring that GM foods must be labelled as such, but this does not mean that the government has not further role to play.
- The government always remains open to dialogue with all stakeholders by continuing to communicate (talking and listening) and taking contextual arguments and soft impacts seriously in discussions and when weighing up policy options. Options open to the government to facilitate this include the following:
  - Continual monitoring (instead of ad hoc investigations in response to alarming studies) of both scientific developments and context-related aspects of biotechnology; this can provide government with valuable information and lasting insights into the arguments about GMOs, making it possible to identify any structural problems at an early stage.
  - Regularly reviewing policy to test whether it is still in line with developments in society. Trend analysis can be a useful policy-making tool.
  - Establishing a platform where contextual arguments can be discussed, for example via a forum or 'thinking laboratory', or by facilitating a broader and non-GMO-specific debate (local, national or at the European level) about how our food is produced and the power of major companies.
- The government must enhance its in-house knowledge and competences in science and science journalism to ensure that it can meet the information needs of the various stakeholders in the debate.

APPENDIX 1

ARGUMENT ANALYSIS QUOTATIONS

METHODOLOGICAL ARGUMENTS: THE EXPERIMENTAL DESIGN

PUSZTAI

...with just six rats in each group, the sample size was very small; and the monotonous diet had made all the rats protein-starved—not a good basis to assess a substance's toxicity...

Martin Enserink, science journalist for Science Magazine: The Lancet Scolded Over Pusztai Paper - 22 October 1999

...points out that the diets were comparable in protein and energy content and that a sample size of six is perfectly normal in studies like this.

Martin Enserink, science journalist for Science Magazine: The Lancet Scolded Over Pusztai Paper – 22 October 1999

ROSI-MARSHALL

The goal of our feeding experiments was to determine whether trichopterans were at all susceptible to the effects of Cry1Ab protein, not to determine a safe level of exposure in a toxicological context.

Rosi-Marshall EJ et al. (2008). Reply to Beachy et al. and Parrott: Study indicates Bt corn may affect caddis flies. PNAS 19 February 2008 vol. 105 no. 7 E11

CARMAN

Carman et al. used adequate sample sizes, appropriate statistical tests and generated reliable findings.

Reaction to Monsanto statement by website GMOjudycarman – 13 June 2013

PEER REVIEW ARGUMENTS: SCIENTIFIC QUALITY

PUSZTAI

The society rightly says that research scientists should expose their new results to peer review before releasing them.

Brunner E, Millstone E (1999). Correspondence: Health risks of genetically modified foods. The Lancet Volume 354, Issue 9172, 3 July 1999, Pages 71

ROSI-MARSHALL

The points above illustrate sloppy experimental design and interpretation that should have been detected by even a cursory peer review.…We are at a loss to explain how qualified reviewers and editors could be unaware of flaws of this magnitude.

Alan McHughen et al. (2007). Letter by scientists to the editor of PNAS – November 2007

HUBER

However, evidence to support these claims has neither been presented to nor evaluated by the scientific community.

Statement by scientists at Purdue University: Glyphosate's Impact on Field Crop Production and Disease Development – 24 February 2011

CARMAN

The journal is a peer-reviewed journal. The paper was reviewed by three expert, anonymous, reviewers who did not even know who the authors were.

Judy Carman, repsonse to criticisms in the media via website GMOjudycarman – June 2013

EARLY WARNING ARGUMENTS: THE SERIOUSNESS OF THE FINDINGS

PUSZTAI

He (Pusztai) told Granada's World in Action that he would not eat the GM food and said it was 'very, very unfair to use our fellow citizens as guinea pigs'.

BBC News, Friday, 12 February 1999. Sci/Tech Fears erupt over genetic food

ROSI-MARSHALL

Stream insects are important prey for aquatic and riparian predators, and widespread planting of Bt crops has unexpected ecosystem-scale consequences.

Rosi-Marshall EJ et al. (2008). Toxins in transgenic crop byproducts may affect headwater stream ecosystems. PNAS 9 October 2007 vol. 104 no. 41 16204–16208

HUBER

This is highly sensitive information that could result in a collapse of US soy and corn export markets and significant disruption of domestic food and feed supplies. On the other hand, this new organism may already be responsible for significant harm.

Letter by Don M. Huber to State Secretary Tom Vilsack – February 2011

CARMAN

If you have stomach problems or gastrointestinal problems, a new study led by Dr. Judy Carman may help explain why: pigs fed a diet of genetically engineered soy and corn

showed a 267% increase in severe stomach inflammation compared to those fed non-GMO diets.

Mike Adams (2013). Natural News. GMO feed turns pig stomachs to mush! Shocking photos reveal severe damage caused by GM soy and corn

ARGUMENTS ABOUT DATA AVAILABILITY: TRANSPARENCY

PUSZTAI

For the intraepithelial lymphocyte counts, one essential group—rats fed with potatoes spiked with Galanthus nivalis lectin (GNA)—was omitted on the grounds that the authors claim to know that 'dietary GNA or other lectins do not induce lymphocyte infiltration'. This omission is improper and those data should have been provided.

Lachmann P (1999). GM food debate. The Lancet, Vol 354 – 13 November 1999

ROSI-MARSHALL

Similarly, the authors do not disclose quantitative measurements of tissue sampled, e.g. 'Leaves were added…as needed'. This lack of detail precludes others from replicating their study.

Alan McHughen et al. (2007). Letter by scientists to the editor of PNAS – November 2007

HUBER

No data was provided nor cited, and no collaborators were identified.

Monsanto: Statement About Alleged Plant Pathogen Potentially Associated with Roundup Ready Crops – 22 February 2011

CARMAN

There is a lack of information on the composition of the control (non-GM) and GM diets. This does not allow the impact of other dietary factors, unrelated to the GM trait, to be excluded.

Australia New Zealand Food Standards: Detailed comment on Carman et al (2013): study design and conduct – July 2013

LONG-TERM EFFECT ARGUMENTS: OBVIOUS RESULTS

PUSZTAI

The immune system takes about 10 days to get in top gear. So, if we do a short-term trial, we wouldn't have seen the end result.

Dr Arpad Pusztai: transcript of the World in Action TV show – October 1998

ROSI-MARSHALL

With regard to biodiversity, there have been too few long term, properly controlled studies of the effects of GM crops to make much comment.

Jeanette Fitzsimons, head of New Zealand's Green Party. speech: Genetic Modification Revisited – NZIAHS convention at Lincoln University, Canterbury, 1 July 2009

CARMAN

Can you explain your comment, for example on pigs living for only 22 weeks and this claimed as their full life? To find harm from even poisonous or toxic food at small levels in this time is frightening to me.

'John Fryer', comment on Blog Biology Biofortified: Lack of care when choosing grains invalidates pig feeding study

GENERALISATION ARGUMENTS: BEYOND THE DETAIL

HUBER

GMOs are good but we must watch for and be prepared to respond to damaging unintended consequences.

'Bob S', comment on the article by Capital Press: Delays pile up in investigation of biotech woes – 21 July 2011

CARMAN

Pigs fed a GMO diet exhibited heavier uteri and a higher rate of severe stomach inflammation than pigs fed a comparable non-gmo diet. Given the widespread use of GMO feed for livestock as well as humans this is a cause for concern.

Carman JA et al. (2013). A long-term toxicology study on pigs fed a combined genetically modified (GM) soy and GM maize diet. Journal of Organic Systems 8 (1), 2013

RISK-BENEFIT ARGUMENTS: BROAD CONTEXT

ROSI-MARSHALL

We argue that the wise use of any new technology requires a full understanding of both the benefits and the potential costs.

Rosi-Marshall EJ et al. (2008). Reply to Beachy et al. and Parrott: Study indicates Bt corn may affect caddis flies. PNAS 19 February 2008 vol. 105 no. 7 E11

HUBER

Ohio producers, as well as those worldwide, need to double the world food supply within the next 20 years due to predicted changes in the world population.…We will need every single tool, approach and tactic to make this happen and in my opinion includes genetically modified strategies.

'Anne Dorrance', comment on the Crop Observation and Recommendation Network newsletter: Glyphosate Effects on the Occurance and Development of Soybean Diseases – 18 March 2011

CARMAN

There are a lot of things that are wrong with GMOs, but not on a biological level. Rather, it's the question of intellectual property and patent laws that are a huge disadvantage to small farmers.

'Alia', comment on David Gorski in Science-Based Medicine: More bad science in the service of anti-GMO activism – 17 June 2013

BURDEN-OF-PROOF ARGUMENTS: INDEPENDENT RESEARCH

PUSZTAI

There is a real problem for us here, and that is that you say that it is not right to discuss unpublished work; as I understand, all of the evidence taken by the advisory committee in that report comes from the commercial companies, all of that is unpublished.

Dr. Williams, UK Parliament – Committee on Science and Technology Minutes of Evidence – 18 March 1999

HUBER

Monsanto…has cynically blocked truly independent research into the lifetime and multi-generational effects of GM feed. In that company's obsession with 'efficiency' health and safety issues have been shunted out into the long grass – and they have also worked tirelessly to vilify those honest scientists who have had the courage to point out that animals which consume GM crops (and the Roundup residues that come with them) are actually HARMED.

'Brian John', comment on the article by Dr Mae Wan Ho: Emergency! Pathogen New to Science Found in Roundup Ready GM Crops? Institute of Science in Society website – 21 February 2011

CARMAN

The result has been that Monsanto has NEVER found 'relevant' differences in any of their studies so of course, no follow-up research is ever done. Any differences are always deemed irrelevant simply due to statistical manipulation, and NOT due to any further consideration due to toxicological relevance.

'Saijanai', comment on David Gorski in Science-Based Medicine: More bad science in the service of anti-GMO activism – 17 June 2013

TU QUOQUE ARGUMENTS: 'YOU TOO'

HUBER

We hear a lot of criticism about the self driven studies made bio 'Big-Ag', yet this is accepted by the same people without question. Why aren't we hearing a call for 'independent studies' here?

'Pdiff', comment on Anastasia Bodnar: Extraordinary claims…require extraordinary evidence – 27 February 2011

CARMAN

If you're looking for bad science on GMOs, you can start with Monsanto.

'StanMrak', comment on David Gorski in Science-Based Medicine: More bad science in the service of anti-GMO activism – 17 June 2013

So I looked at the sponsors of this journal. They include the Organic Federation of Australia, which seemed odd for a journal presumably aiming to be independent. Imagine the hullaballoo if Nature Biotechnology was sponsored by Monsanto!

Mark Lynas blog: GMO pigs study – more junk science – 12 juni 2013

AUTHORITY ARGUMENTS: EXPERT OPINION

PUSZTAI

Our table 1 clearly gives the statistical methods used and the number of comparisons. These methods were approved by independent statisticians.

Ewen SWB, Pusztai A (1999). GM food debate – authors' reply. The Lancet, Volume 354, Issue 9191, Pages 1726–1727, 13 November 1999.

The Royal Society also abandoned the normal protocols of choosing a review team with specific scientific qualifications to evaluate the study in question. Their members clearly did not have the relevant experience to review such a nutritional study.

Jeffrey Smith in The Huffington Post: Anniversary of a Whistleblowing Hero – 9 August 2010

HUBER

For the past 40 years, I have been a scientist in the professional and military agencies that evaluate and prepare for natural and manmade biological threats, including germ warfare and disease outbreaks. Based on this experience, I believe the threat we are facing from this pathogen is unique and of a high risk status.

Letter by Don M. Huber to State Secretary Tom Vilsack – February 2011

CARMAN

Unlike you or I, the participants in these consensus statements are true experts, real scientists who live and breathe and understand the specifics of the biochemistry, the importance of methodology and the true relevance of each study.

'WilliamLawrenceUtridge', comment on David Gorski in Science-Based Medicine: More bad science in the service of anti-GMO activism – 17 June 2013

Most developed countries do not consider that GMOs are safe. In more than 60 countries around the world, including Australia, Japan and all the countries of the European Union, there are significant restrictions or outright bans on the production and sale of GMOs.

'Ashraf Farouk', comment on David Gorski in Science-Based Medicine: More bad science in the service of anti-GMO activism – 17 June 2013

AD HOMINEN ARGUMENTS: 'PLAYING THE MAN'

PUSZTAI

Lachmann had been one of the co-signers on the Royal Society's open letter attacking Pusztai. He also had extensive financial ties to the biotech industry.

Jeffrey Smith in The Huffington Post: Anniversary of a Whistleblowing Hero – 9 August 2010

ROSI-MARSHALL

The letter attacking the study is from the 'usual suspects' – Alan McHughen, Henry Miller, Klaus Ammann, C. Kameswara Rao, Ingo Potrykus, Piero Morandini, Chris Leaver, S. Shantharam, Mark Sears, and C. S. Prakash. With the exception of Sears, none seems to have any especial expertise in the area they're commenting on, and nearly all can be found in the GM Watch profiles of ardent GM promoters.

GMWatch.org, News report: Letter attacking PNAS study 'misleading' – 19 November 2007

HUBER

It's a classic example of several tactics used by biotech PR companies, which I describe on pages 252–253 in Genetic Roulette (see below). I'm not suggesting that this professor is lying, rather that he has been the victim of a well-crafted campaign that leaves him closed to the real evidence of harm.

Jeffrey Smith, comment on his article: Monsanto's Roundup Triggers Over 40 Plant Diseases and Endangers Human and Animal Health – Institute for Responsible Technology – 14 January 2011

CARMAN

In brief, Carman appears to be an anti-GMO activist who, along with another anti-GMO activist, Professor Jack Heinemann at the University of Canterbury's Centre for Integrated Research in Biosafety, made some truly nonsensical claims about GMOs.

David Gorski in Science-Based Medicine: More bad science in the service of anti-GMO activism – 17 June 2013

Citing conflict of interest in this experiment is like the pot calling the kettle black.... Tune into Ag research at universities across the United States, monies from GMO and chemical manufacturers rule the day.

'Drake Larsen', comment on the article by David Tribe (GMOpundit): Pigs in the real world – feed them different diets, measure many health parameters, some will show differences – but what does it all mean? – 12 June 2013

CONSPIRACY THEORY ARGUMENTS: DISTRUST THE SYSTEM

PUSZTAI

'This raises questions about the extent to which the biotech industry seeks to permeate every level of government,' says Labour MP (Member of Parliament) Alan Simpson.

Martin Enserink for Science Magazine; News of the week: Preliminary Data Touch Off Genetic Food Fight - Science 19 February 1999: Vol. 283 no. 5405 pp. 1094-–1095

HUBER

They can't kill people have enough with bullets and bombs and using nukes and plagues are to overt and dangerous. Therefore, attacking the food supply is a more effect and subtle means for going after populations. Here's are some terms of reference: 'quiet weapons for silent wars,' 'codex alimentarius,' 'eugenics,' 'vaccinations,' etc.

'Joe', comment on the article by Dr Mae Wan Ho: Emergency! Pathogen New to Science Found in Roundup Ready GM Crops? Institute of Science in Society website – 21 February 2011

CARMAN

These companies (MONSANTO) don't merely set the policy and interpretation for their own workers, but set the guidelines that the FDA, EUSA, etc follow, and help devise the textbooks that researchers learn from.

'Saijanai', comment on David Gorski in Science-Based Medicine: More bad science in the service of anti-GMO activism – 17 June 2013

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