STATUS REPORT
2008 - 2011

EVALUATION COGEM 2011

MARCH 2011

Colofon

Ontwerp: Avant la lettre

PREFACE

The purpose of this status report is to provide background information on the Netherlands Commission on Genetic Modification (COGEM), and its activities in the past three and half years for the benefit of the external review process 2011. The information in this report is gathered from different documents published by COGEM, internal (non-published) documents, correspondence and procedures. The report is chiefly aimed at providing an accurate description of the facts. The report does not offer an extensive interpretation of facts or general conclusions about COGEM or its activities in the past few years. This is up to the Evaluation Committee.

CONTENTS

1. TERMS OF REFERENCE

The Environmental Management Act (§ 2.3) states that every four years the Netherlands Commission on Genetic Modification (COGEM) will issue a report in which the role, structure, constitution and procedures of the commission are evaluated and proposals made for improvement (Annex 1). This report, together with the opinion of the State Secretary, is sent to parliament. No specific instructions or criteria are listed concerning the form or manner in which the evaluation has to be carried out.

Previous evaluations of COGEM took place in 2003 and 2007. Hence the next evaluation has to take place in 2011 and covers the period 2008-2011. The organisation and results of the previous evaluations are described in Chapter 12 of this report.

As described in the Management Act, the evaluation of the commission is the responsibility of COGEM and the evaluation report is sent to the State Secretary of Infrastructure and the Environment. As with the previous evaluations, for reasons of transparency, thoroughness and objectivity, the Executive Board of COGEM has decided to involve external reviewers for the 2011 evaluation.

The Executive Board of COGEM (acting on behalf of the commission) commissions the evaluation process. The external Evaluation Committee will draw up the evaluation opinion which will be presented to the Board of COGEM. The Board will send the opinion, accompanied by a letter setting out its response to the findings of the Evaluation Committee, to the State Secretary.

FOCUS OF THE EVALUATION

As in the previous evaluations, the main questions in 2011 are "has the COGEM done the right things?" and "has COGEM done these things right". COGEM's mission can serve as the starting point for the evaluation:

> *"COGEM has the duty to advise the government on the risks of genetically modified organisms and to report on the ethical and societal aspects of genetic modification (Environmental Management Act §2.3)"*

COGEM operates in a complex field which is defined by public debate, scientific and technical developments and advances, policy choices, judicial decision processes, and the growing influence of the EU on regulations, scientific assessment procedures, policies and decision processes. Therefore, an evaluation should take into account whether the organisation, structure and procedures of COGEM can deal with these changing conditions. It also raises the question of whether COGEM's role and remit as a national advisory body are still well-matched.
Other possible elements in the evaluation concern scientific quality and the degree to which COGEM's publications and activities are attuned to policy-making processes.

EVALUATION PROCESS

This status report has been compiled to facilitate the evaluation by the Evaluation Committee. It gives an overview of the organisation and structure of COGEM, its main publications and activities in the past three and half years, the highlights of recent years, and any controversies surrounding COGEM or its publications, activities and relevant procedures. Moreover, the evaluation committee has full access to all COGEM publications, documents, procedures, and minutes of meetings, etc.[1]

1 Nearly all the documentation concerning COGEM and its procedures and activities is in Dutch. If it is felt necessary a translation can be provided. However, the resources of COGEM and the capacity of its secretariat do not allow for all internal documents to be translated in advance.

1. TERMS OF REFERENCE

The evaluation will be carried out on the basis of the report and other relevant publications. The Evaluation Committee will also have the opportunity to interview relevant stakeholders, representatives of the ministry (the client), COGEM members and staff, etc. The evaluation committee will asses the scientific quality of COGEM on the basis of COGEM's advice and reports.

The Evaluation Committee will convene for two days in the Netherlands. Approximately three weeks before this meeting, the status report will be sent to each member of the committee. On the first day of the meeting the committee will hold interviews with representatives of organisations deemed relevant by the Evaluation Committee. On the second day the committee will draw its final conclusions. A report containing these conclusions will be sent to the COGEM Board within one month of this meeting. This evaluation report will be finalised and approved by e-mail.

The Evaluation Committee will be supported by the secretariat of COGEM. They will assist with writing the report, providing relevant documentation and carrying out other relevant tasks.

2. STATUTORY ROLE OF THE NETHERLANDS COMMISSION ON GENETIC MODIFICATION

The Netherlands Commission on Genetic Modification (COGEM) is an independent scientific advisory body that provides advice to the government on the risks to human health and the environment of the production and use of GMOs, and informs the government of ethical and societal issues linked to genetic modification.

Permits for the production of GMOs and experiments with GMOs are granted by the Ministry of Infrastructure and the Environment (IandM). Consequently, COGEM is primarily an advisory body to this Dutch government ministry. COGEM advises and informs both independently and at the request of the minister.

COGEM's remit covers all fields from agriculture to medicine, and from contained use to deliberate release of GMOs. COGEM advises on environmental risks but not on feed or the food safety of GMOs, animal welfare or patient safety (e.g. in relation to gene therapy). [2]

The foregoing means that COGEM advises (among other things):
- at the request of the Ministry on specific permit applications (notifications) and the safety measures which should be in place to guarantee safety;
- on the classification in risk groups of pathogens, or specific experiments and techniques involving GMOs (on request or unsolicited);
- on amendments (or interpretation) to the regulations in the event of new technological developments.

COGEM provides information (on request or unsolicited):
- to the government on ethical or societal aspects linked to genetic modification, without taking a standpoint.

COGEM is therefore sometimes part of the permit application process on the one hand, and also advises and informs on more general issues, on the other hand.

The tasks and organisation of COGEM are laid down in the Environmental Management Act (Annex I). The COGEM Rules of Procedure (*'Reglement van Orde'*; Annex II) provide further details of § 2.3 of the Environmental Management Act, e.g. procedures concerning voting, appointments, meetings, minority views, etc.

2 Food safety in the Netherlands is covered by the independent research institute RIKILT - Institute of Food Safety. Patient safety forms part of the ethical medical assessment. In the Netherlands local Medical Review Ethics Committees conduct the reviews of research protocols involving human subjects (i.e. patients). However, for gene therapy this review is carried out by the Central Committee on Research involving Human Subjects (www.ccmo.nl).

3. ORGANISATION OF COGEM

3.1 SUBCOMMITTEES, MEMBERS AND ASSOCIATED MEMBERS

The Minister of Infrastructure and the Environment appoints the 20 members of COGEM. As it turned out to be impossible to cover COGEM's entire field of activity with 20 members, the commission also has associated members. The Executive Board of COGEM appoints the 20 associated members. Since the rights and duties of the associated members are almost the same as those of the members (Annex II), no further distinction will be made between members and associated members in this document.

All members are selected for their scientific expertise and do not represent any organisation. The members have expertise in different fields, such as ecology, bacteriology, virology, genetically modified plants and animals, zoology, public perception and ethics. The members and their fields of expertise are listed in Annex III.

The members of the COGEM Executive Board are the chairman of COGEM and the chairs of the various subcommittees. The Chairman of COGEM is appointed by the Minister of IandM following consultation with the members of COGEM.

COGEM has four scientific subcommittees:
- Agriculture
- Medical and Veterinary Aspects
- Contained Use
- Ethics and Societal Aspects

COGEM publications, like its advice and reports, are prepared by the subcommittee concerned. If specific expertise is lacking among the COGEM members, external experts are consulted. All publications are submitted for approval to all COGEM members (by e-mail). Consequently, all publications are published and endorsed by COGEM and not by a specific subcommittee.

The first three subcommittees carry out risk assessments and prepare scientific advice on risk aspects and measures for controlling environmental risks. The subcommittee Contained Use focuses more on general issues related to GMO legislation and does not deal with specific applications for permits. It acts like a working group; it has no permanent members and its makeup is tailored to the subject matter of each specific study. The subcommittee Contained Use has not convened in the last three years.
The subcommittee Ethics and Societal Aspects informs the minister by means of topic reports ('signaleringen'), about ethical and societal aspects related to genetic modification, in particular when GMOs are deliberately released or placed on the market. COGEM does not pass judgement on these matters. The commission systematically sets out all the various arguments to facilitate a balanced decision-making process.

Each subcommittee meets six times a year. General issues, advice and topic reports are discussed at these meetings. Advice on notifications is discussed in the meetings if possible given the statutory deadlines (see chapter 4). Otherwise they are dealt with by e-mail.

3.2 CONFLICTS OF INTEREST AND INTEGRITY

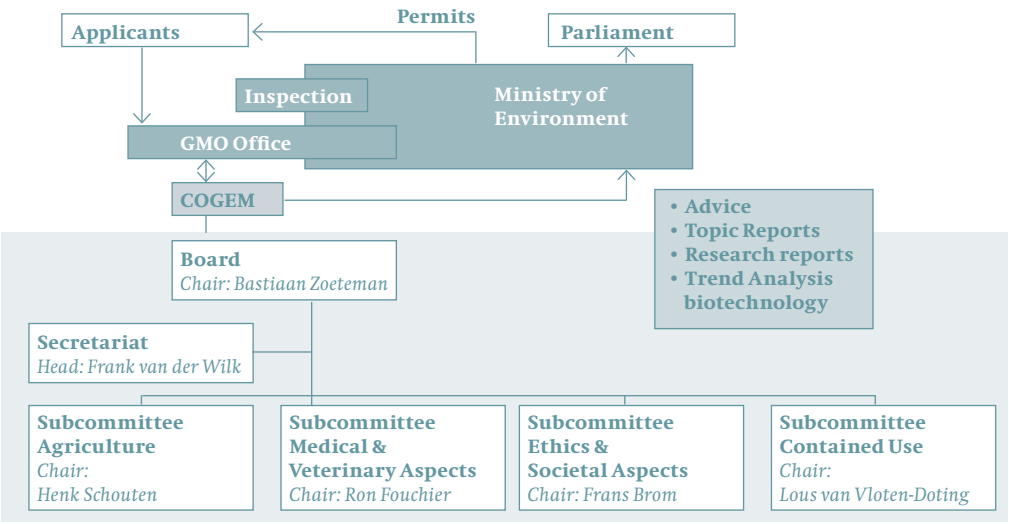
The members of COGEM are appointed in a personal capacity and they do not represent organisations or institutions. However, due to the fact that COGEM is a scientific advisory

body, it is inevitable that members of COGEM will also be active in the field of genetic modification. This is a potential source of conflict of interest. Rules have been established to prevent this. The procedures are listed on the COGEM website.
Firstly, transparency is required concerning any potential conflict of interest. All members have to fill in a form declaring their interests. These declaration forms are updated annually. The chairman of COGEM discusses the interests of a member at the start of membership and later if there are any reasons for concern. If necessary the chair makes specific arrangements with relevant members to avoid conflicts of interest. Furthermore, the declarations of interest are circulated among the members of each subcommittee and the Executive Board so that they are all aware of each others' interests. The forms are held by the secretariat and the register is open to inspection by the Ministry of IandM. Secondly, to prevent possible conflicts of interest, members refrain from taking part in decision-making on advice given by COGEM on subjects relating to their own interests. This applies to both the considerations in meetings of subcommittees and the completion of the written advice. This is supervised by the COGEM chair and the chairman of the subcommittee, supported by the secretary of COGEM. It was recently decided that it will be clearly stated in the advice which members have refrained from taking part in the decision-making process.
Thirdly, COGEM members have to sign a declaration of integrity, to raise their awareness of potential pitfalls.

3.3 SECRETARIAT

The work of COGEM is supported by a professional secretariat of 8 full-time equivalent (FTE) positions (including administrative staff). Every subcommittee is supported by a coordinator. The coordinator is a specialist in the field of its subcommittee. Besides preparing the meetings and taking minutes, the coordinator acts as the 'ears and eyes' of the subcommittee.
Besides the coordinators there are three staff members employed on projects which are in hand. They are generalists and not allied with specific subcommittees. Both coordinators and staff members are involved in preparing advice and reports. The secretariat is supported by administrative staff (1.2 FTE). The secretariat is headed by the 'executive director' or secretary. Among other things, he is in charge of assigning duties, preparing the budget estimate and monitoring the budget, the research programme and supervision of the advisory process. He is also secretary to the COGEM Board.

Figure 1: COGEM, organisation and position



4. COGEM PUBLICATIONS: ADVISORY AND TOPIC REPORTS

4.1 ADVICE

As indicated above, COGEM issues both unsolicited advice and advice at the request of the minister. Advice issued in response to a ministerial request is often linked to specific cases or notifications.
There are three different notification categories: contained use, deliberate release into the environment, and placing on the market of a GMO. 'Contained use' involves the use of GMOs in laboratories, production facilities, greenhouses or animal housing. 'Deliberate release' means any intentional introduction of a GMO into the environment for which no specific containment measures are used to limit contact of the GMO with the environment. These are mainly field experiments with GMOs, such as field experiments with genetically modified plants or clinical gene therapy experiments. 'Placing on the market' (Market authorisation) means making GMOs available to third parties, whether for payment or free of charge.

> All notifications or permit applications in the Netherlands are handled by the GMO Office, under the auspices of the Ministry of IandM, which holds final responsibility. The GMO Office is part of the Expertise Centre for Substances (SEC) of the National Institute for Public Health (RIVM). Granting permits and the classification of experiments is done according to the rules laid down in the Ministerial Order on GMOs (GMO order) which is linked to the Decree on GMOs *('Regeling genetisch gemodificeerde organismen bij het Besluit GGO')*.

COGEM's advice is not binding and the minister can decide to deviate from the content of the advice. However, this has only occurred once in the past four years (see chapter 11).

Advice on notifications are subject to strict time limits. Since the subcommittees meet six times a year, in most cases it is not possible to consider the advice in the subcommittee meetings. Therefore, the issues involved and the processing of the advice is discussed and handled predominantly by e-mail.

CONTAINED USE

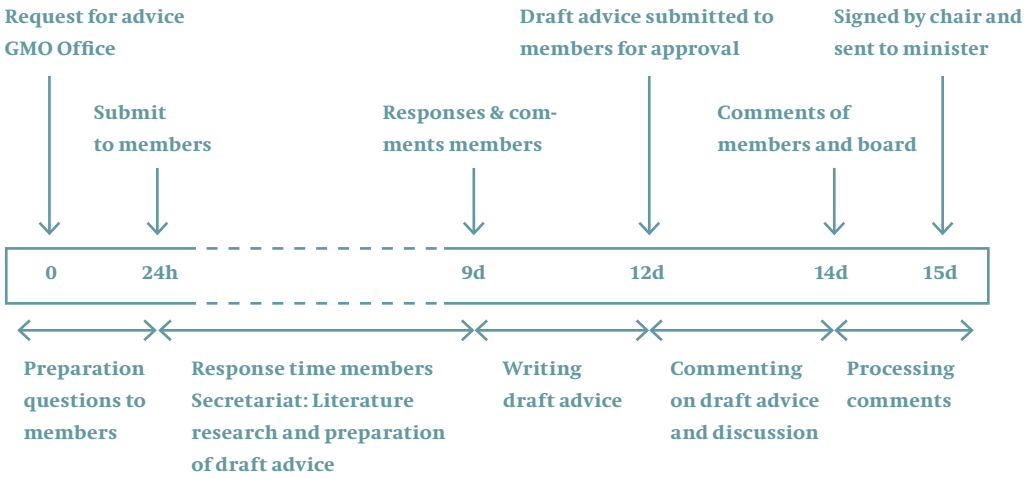
In the Netherlands a permit is needed for all contained use experiments with GMOs. These permits are specific to the type of experiments and organisms involved. Consequently, approximately 100 new permits or major revisions to existing permits are issued a year by the GMO Office / Ministry of IandM, in addition to approximately 700 minor or other amendments to existing permits.
On a case by case basis, COGEM may be requested by the GMO Office and the Ministry to advise on new permit applications or major revisions to permits. This will be at the discretion of the GMO Office. No formal criteria have been laid down on when COGEM will be asked for advice. Usually, it involves permit applications with highly pathogenic organisms, or types of experiments or organisms that are new to the notification process and not previously assessed, or where the applicant wants to deviate from the rules set in the 'GMO order'. On average COGEM issues advice on contained use notifications 22 times a year, usually for new permit applications or major revisions.

4. COGEM PUBLICATIONS: ADVISORY AND TOPIC REPORTS

Table 1: Contained use permits issued by the ministry and COGEM advice

	2002	2003	2004	2005	2006	2007	2008	2009	2010
Contained use permits. Total	**772**	**701**	**693**	**718**	**785**	**829**	**732**	**827**	**739**
New notifications	303	191	209	139	131	150	97	103	97
Minor and major revisions	468	509	484	579	654	679	635	724	642
COGEM advice on contained use	**33**	**26**	**14**	**19**	**29**	**25**	**21**	**19**	**21**

It should be noted that the time limit for advice on contained use is rather short. COGEM has to issue its advice within 15 days, which puts considerable pressure on the advisory process. A diagram showing the advisory process and time table is given below. The application file is sent to four COGEM members or external experts. On the basis of their comments and a literature review, the COGEM secretariat formulates a draft advice document which is subsequently submitted to all members for comments and approval. After all the comments have been incorporated and the chair of the subcommittee concerned has agreed to the text, the COGEM chairman signs the advice and sends it to the minister.



DELIBERATE RELEASE

COGEM is requested by the ministry to advise on the environmental risks in all cases of notifications of deliberate release of GMOs. Notably, COGEM is requested to advise during the 'public consultation period', after the ministry has issued a draft permit. This means that the ministry / GMO Office carries out a risk assessment prior to COGEM. In exceptional cases COGEM will be asked to advise at an earlier stage in the notification process. Generally, this occurs where the potential environmental risks are deemed to be high, for instance in clinical experiments with replicating modified viruses and field experiments with flowering GM plants with wild relatives.

The advisory procedure differs from the 'contained use procedure' in that the application file is sent to all members of the subcommittee involved and COGEM has a 6 week deadline.

4. COGEM PUBLICATIONS: ADVISORY AND TOPIC REPORTS

MARKET AUTHORISATIONS

Placing GMOs on the market is regulated under a central European procedure. However, the member states are given the opportunity to carry out their own risk analysis. In the case of notifications for cultivation it is even mandatory that the initial environmental risk analysis is carried out by a member state. In the Netherlands COGEM is requested by the Ministry of IandM to advise on every market authorisation, for import and processing, as well as cultivation. Up until January 2008 COGEM carried out a risk analysis which included the risks of incidental consumption. Since then, however, COGEM no longer gives advice on the potential risks of incidental consumption where a food/feed assessment has already been carried out by other organisations, which is the case for nearly all market authorisations.

The advisory procedure is similar to that for deliberate release with a deadline of approximately 6 weeks.

4.2 TOPIC REPORTS

As previously mentioned, COGEM has a legal task to inform the government on ethical or societal issues involved in genetic modification. It states in the Environmental Management Act that COGEM has to inform the ministers concerned of those issues which the commission deems to be important. The information is provided to the government by means topic reports ('signaleringen'). In recent years COGEM has analysed the GMO debate, reported on the societal consequences of new technological developments, and inadequacies in the GMO regulations. COGEM also issues reports at the request of the minister. In 2009 the minister of the former Ministry of Housing, Spatial Planning and the Environment (VROM) asked COGEM to draw up socio-economic criteria for assessing the contribution that GMOs could make to more sustainable agriculture. The minister used the COGEM report as a basis for the Dutch contribution to the European discussion. An overview of COGEM reports published over the past four years is given in Annex IV.

4.2.1 TREND ANALYSIS BIOTECHNOLOGY

As part of its informative task, COGEM has the lead role in drawing up a trend analysis on developments in biotechnology. It is compiled for the Dutch House of Representatives with the aim of informing politicians about major new biotechnological developments and applications in the Netherlands and further afield, the discernable trends, the associated chances and opportunities and the ethical and societal aspects related to these developments.
The Trend analysis biotechnology was commissioned by the former Minister of VROM, also on behalf of her colleagues in the former Ministry of Agriculture, Nature and Food Quality and the Ministry of Health, Welfare and Sport. It is a joint publication of the Commission on Biotechnology in Animals (CBD), the Health Council of the Netherlands and COGEM. The trend analysis covers the whole field of biotechnology and is not limited to genetic modification. A joint project committee consisting of members of the three organising bodies draws up the Trend Analysis. The project committee is supported by a working group of staff members of the three organisations, headed by the secretary of COGEM. During the process, stakeholders are invited to put forward trends and developments. Stakeholders are further offered an opportunity to comment on the draft trend analysis. However, the Trend Analysis is a product of the organising committees and it is up to the joint project group to weigh the comments and arguments of the stakeholders and to decide whether or not they will be incorporated in the final Trend Analysis.

4. COGEM PUBLICATIONS: ADVISORY AND TOPIC REPORTS

In 2009 the third Trend Analysis was published. Previous Trend Analyses were published in 2004 and 2007. The 2009 report identified five trends deserving particular attention by politicians and policymakers:

- Medical biotechnology: in search of the meaning of the human genome;
- Medical biotechnology: potential applications in healthcare;
- Industrial biotechnology: the road to a bio-based economy;
- Plant biotechnology: the gap between the EU and the world;
- Animal biotechnology: the advance of cloning.

Due to the cabinet crisis in 2010, the Trend Analysis 2009 has not yet been discussed by the Dutch parliament. An English summary of the Trend Analysis 2009 is available.

4.3 OUTPUT OF COGEM

In the past four years COGEM has, on average, published 60 advice (topic) reports and (advisory/topic) letters to the minister a year. The output of COGEM depends largely on the number of requests for advice by the ministry or GMO Office. Unsolicited advice and reports usually involve larger projects. The number of these projects COGEM can handle is limited. Therefore, the bulk of the output is advice on specific notifications. Because requests for advice are bound by legal time limits, they take priority over unsolicited projects.

4.3.1 BREAKDOWN OF THE OUTPUT IN CATEGORIES AND BY SUBCOMMITTEES

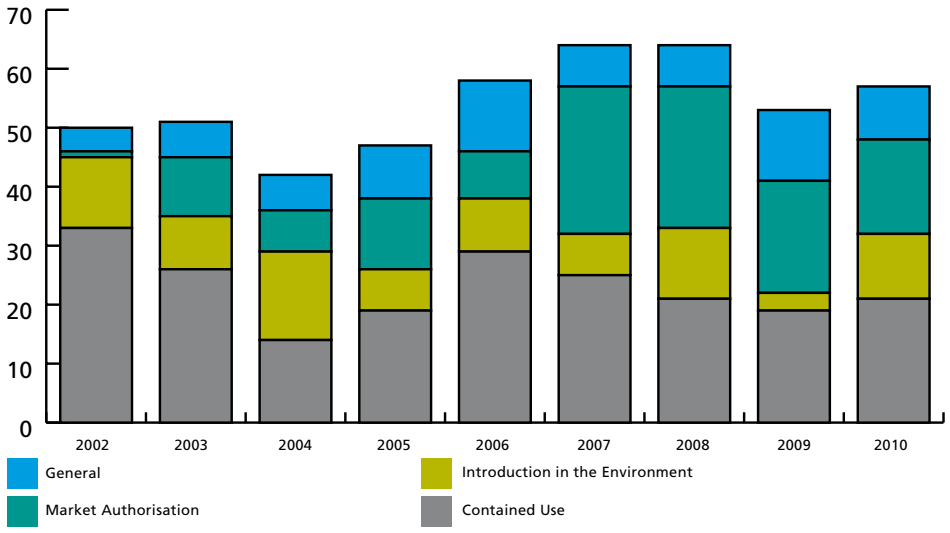
In 2007 and 2008 the COGEM output peaked at 64 publications. This workload posed a major challenge to both the secretariat and the members of COGEM. The commission was working at full capacity and stretched its limits. There were serious concerns about whether the commission would be able to assess all notifications without compromising standards, if the workload were to continue at such a high level.
The peak in 2007 and 2008 was mainly caused by a major increase in market authorisation notifications (Figure 2). Apparently, a backlog of notifications had been building up under the European authorisation procedure. After 2008 the workload gradually became more manageable, for three reasons. Firstly, the number of notifications started to decline. Secondly, some outstanding discussion points in COGEM were settled, like the criteria for molecular characterisation and the criteria for testing non-target organisms.[3],[4] Thirdly, most of the notifications deal with the import of the same crops with similar traits, and as a result a certain routine has been developed.

3 Heroverweging criteria voor de moleculaire karakterisering bij markttoelatingen van gg-gewassen. COGEM topic report CGM/081219-01.

4 Charleston DS & Dicke M (2008). Designing experimental protocols to investigate the impact of GM crops on non-target arthropods. COGEM Research Report CGM2008-01.

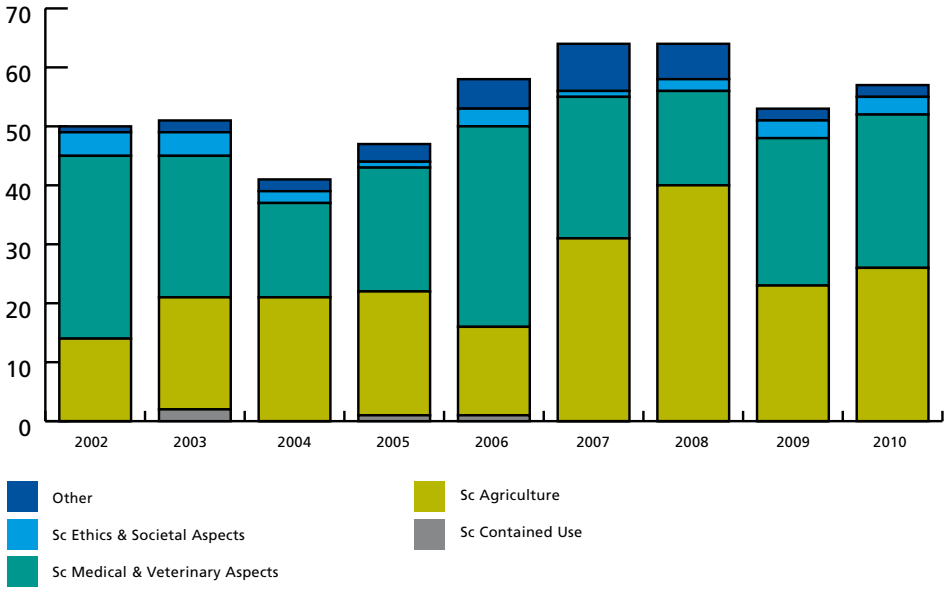
4. COGEM PUBLICATIONS: ADVISORY AND TOPIC REPORTS

Figure 2



The volume of advice issued on contained use has varied over the years, with a long term average of 23 reports, documents and letters a year, altogether. Advice on Introduction in the Environment permit applications mainly involve field experiments with GM plants. The number of notifications for clinical experiments (gene therapy) fluctuates between 2 and 4 a year.

Figure 3



In 2009 the number of advisory reports handled by the subcommittee Agriculture dropped significantly (Figure 3). This was due to a reduced demand for advice on permit applications for experiments with GM plants in laboratories and greenhouses, and noti-

4. COGEM PUBLICATIONS: ADVISORY AND TOPIC REPORTS

fications for field experiments with GM crops. It is believed that this was caused by the decision of the Council of State, the country's highest administrative court, to annul all permits for field experiments issued by the Ministry of the Environment. To discourage activists from destroying GM field trials, the ministry decided that the exact location of these fields would no longer have to be made public. However, the Council of State decided that the public's right to information is more important than preventing damage to farmers and industry, and rescinded the permits. This led to a temporary halt in permit applications. However, the number of applications recovered in the course of 2010, which was further stimulated by positive decisions by the Council of State on other permits for field experiments.

In view of the fact that so many permits for field experiments were annulled by the Council and the COGEM advice provided on all permit applications for field experiments, in 2010 COGEM commissioned an external legal expert, Professor Somsen of the University of Tilburg, to examine the Council rulings. The objective of this study was to gain a better understanding of the Council's legal arguments and to investigate whether COGEM's advice held up in court. Professor Somsen analysed the Court decisions of the past ten years. As indicated above, the permits were rescinded mainly due to infringement of the public's right to information. Permits have never been rescinded because of a faulty environmental risk analysis or objections concerning elements in COGEM's advice. In its judgements the Council never questioned the task and role of COGEM and carried out only a limited judicial review of the COGEM advice issued in each case.

The majority of the advice requests on contained use notifications dealt with the classification of pathogens and GM experiments. For recurring questions COGEM can decide to issue general advice which can be used by the GMO Office in the future to deal with such notifications without involving COGEM. In recent years COGEM has published general advice several times on the classification of GMOs or experiments with GMOs, including on the classification of experiments in laboratories and animal housing with so-called second and third generation lentiviral vectors.

It should be noted that COGEM classifies pathogens into risk groups. This classification is a prerequisite for the environmental risk analysis and essential for the permit procedure. Although the (wild-type) pathogens are classified into four categories, this classification only applies to GM experiments. Experiments with wild-type pathogens do not fall within the scope of the GM regulation or COGEM's remit. These experiments are regulated under legislation to protect workers from risks related to exposure to biological agents at work (ARBO), without the need for a specific permit. The COGEM classification of pathogens can differ from the classification under the ARBO legislation. The latter classification system is based on European Directive 2000/54/EC and best practices as laid down in the lists of the Dutch Society for Microbiology (NVvM).[5] COGEM commissioned a research project to classify fungal and bacterial species. One of the objectives of this project is to harmonise both classification systems as much as possible by involving members of the NVvM.

5 NVvM BioSafety Booklet "Veilig werken met micro-organismen, parasieten, en cellen in laboratoria en andere werkruimten: theorie en praktijk" (2009).

4.3.2 TOPIC AND GENERAL ADVISORY REPORTS

Over the past four years COGEM has focused in its general advice and topic reports on the implications of new technological developments, the shortcomings and possible improvements in the GMO regulations, and the GMO debate and policy-making.
COGEM had already published a topic report on the new and exciting field of 'synthetic biology' in 2006. Prompted by this report, the Rathenau Institute[6] started a project on synthetic biology which included a public discussion, and resulted in a report to parliament. In response to the media interest and parliamentary questions, the Minister of VROM asked COGEM for further advice. This included questions about whether the current risk analysis method and the assessment framework for GMOs will be suitable for assessing future developments in synthetic biology. The minister also enquired how government can best facilitate the public debate on synthetic biology.
Analogously, the Minister of Education, Culture and Science requested the Royal Netherlands Academy of Arts and Sciences (KNAW), the Advisory Council on Health Research (RGO) and the Health Council of the Netherlands to draw up a position paper on synthetic biology, including the opportunities that synthetic biology offers the Netherlands and the requirements for exploiting these opportunities. In a joint meeting the advisory reports were presented to the minister of and the Minister of Education, Culture and Science in 2008. In its report COGEM concludes, among other things, that the Dutch GMO legislation is fully applicable to synthetic biology. The potential risks of working with synthetic organisms can be adequately assessed and managed in the short term under the current risk policy and using the current risk analysis method. The report further examined the role of the government in controversial technological innovations or 'technology hypes'.

New technological developments and their effects on society and the GMO legislation is one of the focal points of COGEM. In a follow up to its report on new techniques in plant breeding (2006), COGEM organised a symposium and published a report in 2009 on the GMO legislation in the EU.[7] The report asked for a rethink of the European legislation. It was concluded that the EU legislation on GMOs is no longer in step with scientific developments in plant biotechnology. As a result it is no longer clear what should be considered to be GMOs and this has led to an uneven playing field for the European plant breeding industry compared with their colleagues in North America, for instance. It also undermines consumer choice and strains the government's credibility.

At the request of the Minister of VROM, in 2008 COGEM issued a topic report on the prospects for GM crops in sustainable agriculture.[8] This topic report draws no conclusion about whether genetic modification as such is compatible with the concept of sustainable agriculture. Instead, it was investigated how GM crops are related to a number of aspects of sustainability, such as reducing environmental impact, and the economic feasibility of new applications. As a follow-up to this report and in view of the discussions in the Dutch parliament, the Minister of the Environment asked COGEM to develop criteria for sustainability and GM crops. This report was issued in 2009 and served as the basis for the Dutch contribution in the EU.

6 The Rathenau Institute encourages public debate and assists political decision-making with regard to the social, ethical and political impact of modern science and technology. It further studies the organisation of the science system and how that system responds to scientific, social and economic developments. The Rathenau Institute is an autonomous organisation which is funded by the Ministry of Education, Culture and Science, with responsibility for governance falling to the Royal Netherlands Academy of Arts and Sciences (KNAW).

7 Should EU legislation be updated? Scientific developments throw new light on the process and product approaches. CGM/090626-01.

8 Perspectieven van gg-gewassen voor een duurzame landbouw. CGM/080201-01.

4. COGEM PUBLICATIONS: ADVISORY AND TOPIC REPORTS

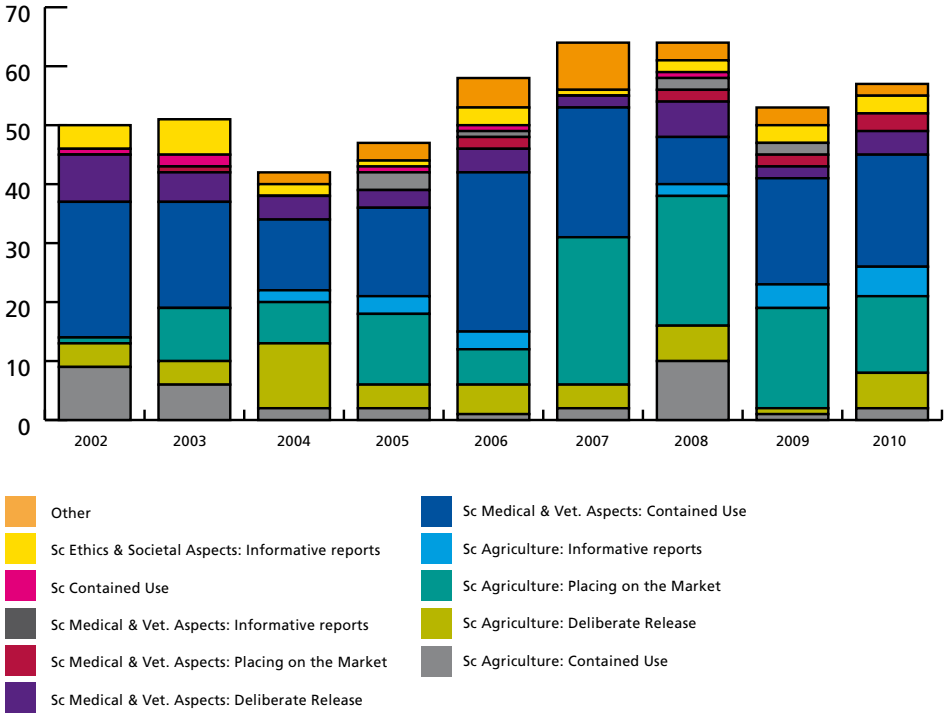
At the end of 2010 COGEM published a topic report on freedom of choice and labelling. This report analysed the bottlenecks in the current policy on freedom of choice and GMOs. Freedom of choice is the cornerstone of Dutch and European policies on GMOs. However, the report concludes that freedom of choice is increasingly under pressure. This is caused not only by technical, economic or judicial issues, like admixture, different innovation rates and differences in GMO regulations between countries, but also due to a lack of knowledge and trust on the part of the consumer. In the report COGEM points out that stricter and broader requirements for labelling will not solve the existing problems, but most likely further contribute to them. Labelling is the tailpiece of a policy on freedom of choice. The necessary conditions for freedom of choice are information, education and trust. In this respect it is important that policy-makers communicate that it is not safety reasons but freedom of choice which underlies the labelling of GMOs. Moreover, the report stresses the importance of international agreements concerning the exact nature of a GMO, suggests restricting labelling to detectable entities, and focusing on certification of the supply chain rather than the labelling of an end product afterwards.

Besides issues in GM agriculture, COGEM also published several topic and general advisory reports dealing with contained use or clinical experiments. In the autumn of 2008 COGEM presented several proposals to the minister to simplify and reduce the Dutch GMO legislation for contained use. The Dutch ministry is in the process of revising the GMO Act. COGEM's proposals are aimed at reducing the rules and administrative costs by converting from a permit system based on individual experiments, to organisation-based permits for the lowest categories of contained use. In 2011 the matter of deregulation was revived in an accompanying topic letter with the COGEM research report "Survey on the implementation of Directive 2009/41/EC: regulations in Europe on the contained use of genetically modified organisms". It was concluded in this report that the present Dutch contained use regulation is among the strictest in the EU.

In a follow-up to two advisory reports on market authorisations for two GM medicines in 2008, COGEM informed the Dutch government about the implications of 'off-label use' of GM medicines. In the Netherlands (like many other EU countries) doctors sometimes prescribe medicines to treat diseases for which the medicine is not registered. This off-label use is an important and indispensable part of healthcare. However, no risk assessments have been carried out for off-label uses of GM medicines. In a topic letter to the environment and health ministers, COGEM took stock of all the different aspects of off-label use of GM medicines and urged the Dutch government to take appropriate measures to safeguard the effectiveness of the healthcare services and to minimise possible risks. To communicate this issue directly to the field, an informative publication in a scientific journal is in preparation.

4. COGEM PUBLICATIONS: ADVISORY AND TOPIC REPORTS

Figure 4: The output of COGEM broken down into all categories. A full overview of all the publications of COGEM in the last four years is given in Annex IV.



5. RESEARCH PROGRAMME

COGEM has a modest budget to commission research to support and improve its advisory role. The focal points of the research programme are developments in the deliberate release of GMOs, improving the methodology of risk analysis, identifying and categorising ethical and societal issues relating to gene technology, and identifying new scientific developments and trends. In 2009 the budget for the research programme was halved (to 200,000) and it became a joint research programme shared by COGEM and the GMO Office. The Board of COGEM and the head of the GMO Office control the programme, its budget and contracts.

More than 19 research reports have been issued since 2007. Most of the reports were published in English. All research reports are sent to the minister. In the accompanying advisory or topic letter COGEM comments on the report, highlights the main findings, and identifies the important issues for policymakers.
The subjects of the various research reports reflect COGEM's broad field of activity. Research reports range from the use of bacteriophages as therapeutic anti-bacterial agents, and the spread of pollen in greenhouses, to politics in converging technologies. Most of the research projects involve short-term desk research. However, there are a few exceptions.

An example of this is a project dealing with the admixture of GM and non-GM products in the transport chain and on the field. This project was carried out by Leiden University and constituted four studies. The first two studies provide a general picture of transport chains, the import of GM and non-GM crops, etc. The last two studies focus on rape (*Brassica napus*; koolzaad) because at the moment rape is the only GM crop that can run wild and has wild relatives in the Netherlands. The findings of part three of the project were surprising. In contrast to the general notion and the data available in flora and databases, *B. rapa* (raapzaad) proved to be much more common in the Netherlands than *B. napus*. Very likely *B. napus* was confused with *B. rapa* in the past, due to difficulties in identification. *B. napus* typically occurs in highly disturbed habitats and can often be traced back directly to seed spillage through human activity. The potential for weediness of *B. napus* appears to be very limited. In the fourth part of the project the gene flow from *B. napus* to *B. rapa* was investigated. This sub-project showed that although gene flow from *B. napus* to *B. rapa* occurs in the Dutch situation, it is very limited. These findings offer further substantiation of the environmental risk analysis of GM rapeseed.

Another interesting project in the field of agriculture concerned an inventory of unexpected adverse effects after release on the market of a GM crop. As there is only limited experience with monitoring unexpected environmental effects of GM crops, the project focused on the unexpected environmental effects observed in countries where GM crops have already been grown on large areas in the last 10 to 15 years. Information was gathered by performing a literature review and by interviewing representatives of the authorities responsible for releasing GM crops and scientists, mainly during a study visit to the USA. The objective of this inventory was to find clues for developing protocols for monitoring environmental effects during post-release growing of GM crops. Most of the adverse effects (like resistance development and herbicide tolerant weeds) observed in GM cultivation were anticipated at the release of the GM crop, and only minor unexpected effects were identified. However, it has to be noted that post-release monitoring of a GM crop in the USA is performed primarily in relation to agronomic aspects and only to a lesser degree in terms of the environmental effects. Notwithstanding this, one main conclusion of the research was that the observed effects (expected or unexpected) were no different from those observed in non-GM cultivation and not caused by the genetic modification itself.

Other projects commissioned by COGEM in the field of agriculture and GM plants focused on new developments and the efficacy of containment measures. In a report by Wageningen University and Research Centre, the consequences of new plant breeding techniques

were described for the environment, and food and feed safety. Novel plant breeding techniques are high on the European agenda due to past COGEM publications. The report concluded that in most cases the plants obtained by the implementation of novel techniques are as safe as traditionally bred plants. The research report confirmed and underpinned the conclusions of the earlier COGEM advisory report of 2006 on novel plant breeding techniques.
With possible future developments and notifications in mind, COGEM commissioned a review of the efficacy of the various biological containment strategies to prevent transgene spread from GM plants. A desk study was also commissioned, aimed at providing an overview of the ongoing developments in crop modification to enhance or preserve yield, and the identification of aspects important to the environmental risk assessment of such crops. Furthermore, research projects were carried out to gather empirical data on pollen escape from greenhouses and to propose ecologically relevant experimental protocols for laboratory experiments to investigate the impact of GM crops on non-target organisms. The results of these projects were used to enhance the scientific basis of the advice COGEM issues.

In the field of gene therapy, studies were commissioned on the development of gene therapy in China, international medical tourism from the Netherlands for gene therapy, and the use of oncolytic viruses. In past years information reached COGEM that Dutch patients had gone abroad to undergo gene therapy. This would involve experimental therapies, without proven effectiveness or safety. In theory, this can lead to risks due to the spread of the administered gene therapy products from patients who return from abroad to third persons in the Netherlands. It proved to be difficult to find out if any, and how many, patients were treated outside the Netherlands. Many hospitals and companies are unwilling to share information for privacy reasons. There are also considerable differences in the registration of clinical trials and patients, even between the EU countries. In many countries no registration takes place. A few cases could be retrieved. However, there was little detailed information provided on the nature of the virus used in the treatment, or on the results of monitoring viral shedding in the patients' excreta. COGEM concluded that improvement was needed in the exchange of information between health institutions, patient associations and national authorities. Furthermore, an international system of registration would be advisable.
The issue of medical tourism is linked to the project on gene therapy in China. China is the only country in the world which has approved gene therapeutics for clinical use, with large numbers of patients being treated there. However, little data is available in the international scientific journals or other international literature on the effectiveness or safety of the treatments. The project was initiated by COGEM to retrieve information from Chinese sources, including the scientific literature relating to gene therapy, with a special focus on the possible risks to the environment. The report concluded that the clinical activities in China are increasing faster than worldwide. More companies are active than were so far known and covering a broad spectrum of activities. China has the potential to become the country with the most clinical data from gene therapy patients. The recording and publication of these data, including shedding data, should be further improved to enable future risk assessments. Shedding data have so far only been reported in scientific articles to a limited extent. Interestingly enough, an overall increase in publications by scientists from China was observed and a shift from Chinese to Western literature databases. All things considered, this means that the output from Chinese gene therapy research is growing and becoming more readily accessible to those not familiar with the Chinese language.
An inventory has been drawn up on the use of non-human viruses as therapeutic oncolytic agents in humans. The administration of non-human viruses (either systemically or intratumoral) to humans may have an associated risk of adapting the virus to increase replication in humans. Theoretically this could result in horizontal transfer of adapted viruses to

the recipient's relatives or medical personnel. Twenty-seven virus species were identified that have been evaluated pre-clinically or clinically. Surprisingly, no environmental risk assessment is required for the clinical use of wild-type viruses in the Netherlands.

Other projects in the field of the COGEM subcommittee Medical and Veterinary Aspects included a study of the available evidence on the effectiveness of measures aimed at protecting man and the environment against the risks of working with GMOs and non-GMO pathogenic micro-organisms. Data on the containment effectiveness of equipment and laboratories proved to be scarce and fragmented, and limited mainly to technical specifications. Although when taken together the measures for assuring the biosafety of pathogenic micro-organisms and GMOs appear to be largely effective, it is unknown to what extent specific measures contribute to the overall level of biosafety. The authors concluded that strengthening the evidence base of biosafety practice (where feasible) is needed: by defining criteria to evaluate effectiveness, by acquiring further data on the effectiveness of containment measures, and by optimising the monitoring of laboratory-acquired infections.

Projects aimed at deregulation involved a project on the possibility of deregulating gene therapy using 'naked DNA' and a project on Contained Use regulations in the EU member states. The latter report involved a survey conducted in 11 EU member states, which aimed to identify the commonalities and differences in the implementation of EU Directive 2009/41/EC on Contained Use in terms of procedures, administration, substantive requirements and enforcement. The survey showed that there are many shared aspects as well as some significant differences in the procedural, administrative and technical implementation of the Directive in the 11 EU member states surveyed. The Netherlands appears to be among the group of EU member states with stricter regulations than the Directive requires. A main conclusion of the report is that further clarification, updating in line with technical advances, and/or further European harmonisation is needed on issues like the definition of terms such as 'GMO', 'inactivation', and 'accident'; the relation to rules for non-GM pathogens; exemptions; fees; application formats; Internal Biosafety Committees and Biosafety Officers; risk assessment; and differentiated containment requirements for class 2 activities. The main recommendation is to restart the competent authorities meetings at EU level, in order to take stock of the experience gained over the past few years in the various member states and to further harmonise the implementation of the Directive.

The research projects dealing with ethical or societal issues linked to genetic modification were varied in nature. Two projects dealt with economics and GMOs. The first project compared the costs of obtaining approval for a GM crop in the EU and the USA. The report also gives a breakdown of the costs for each of the different elements in the approval dossier. The costs for approval are approximately 25% higher in the EU than in the USA. The total cost estimations for approval of a 'new' GM crop range between 4.4 and 13.0 million euros.
The second project investigated what role biotechnology and genetic modification play in the ongoing consolidation taking place in the seed industry, and the consequences of this consolidation. The research focused on three US seed markets where GM seeds have been broadly used: cotton, soy and maize. The report gives an extensive overview of the history of the global seed industry, the interplay between science, government and business strategies and an economic analysis of the three markets. It concluded that GM is one of the drivers of consolidation in the seed industry. Although high levels of concentration were found in the three seed markets, this had not had a negative impact on innovation and only limited market power had been achieved. However, there are concerns about under-investment in the public sector R&D plant breeding of minor crops, the survival of the organic seed market, the role of patents, and impediments to the emergence of a market for generic GM/biotech seeds after the expiry of a patent.

Another project involved a preliminary study exploring the extent to which biotechnological solutions to problems of global change are realistic and feasible. In the report the authors conclude that biotechnology is certainly not the 'silver bullet' solution to global change but it can make a contribution, in some fields more than in others.
In two reports the media interest in biotechnology in different parts of the world was analysed. This analysis is of interest to policymakers as it provides insight into the attitude towards biotechnology in various parts of the world and, more importantly, the gradual changes in these positions over the years.
Convergence of technologies can lead to promising new technologies and scientific fields. However, the new opportunities also bring new societal and ethical questions. COGEM therefore commissioned a study to identify the characteristics of converging technologies, to enable the detection of convergence at an early stage.

6. SYMPOSIA AND MEETINGS

COGEM organises both symposia and workshops. These can be used to gather information or input for COGEM activities or publications, to put an issue on the agenda, to create (public or scientific) support for COGEM advice or reports, and as a communication tool. The meetings may be aimed at policymakers and politicians, but also at stakeholders or the scientific community. COGEM aims to organise at least one symposium a year. In addition, COGEM can organise smaller workshops or meetings on specific topics.

In September 2008 a small scientific meeting, concerning the risk analysis of the insertion of small DNA inserts in the plant genome, took place under the auspices of COGEM. Prior to this, COGEM had issued advice on the risk analysis of cisgenic plants. Briefly, COGEM concluded that the risks to the environment associated with cisgenic plants were essentially similar to those of plants derived from conventional plant breeding. In its advice COGEM pointed out that, besides the plant-derived sequences, small t-DNA borders of bacterial origin were also inserted in most 'cisgenic' plants. COGEM was of the opinion that these insertions did not lead to environmental risks but that it was up to experts on food safety to determine whether these border insertions generate a risk to food safety. At the request of the former Ministry of VROM, COGEM organised a meeting to discuss these matters with Dutch food safety experts. During the meeting it transpired that the food safety evaluators took a different view of cisgenesis than COGEM and that they were of the opinion that 'cisgenic' products should undergo the same risk assessment procedure as 'regular' GM products. The outcome of the meeting was communicated to the ministry.

In October 2008 COGEM organised the international symposium "The new GMO debate: a clash between legislations", in The Hague. The symposium was aimed at raising awareness of the forthcoming problems and gathering information for a report. The symposium can be regarded as a continuation on the COGEM topic report "New techniques in plant biotechnology". In this report it was concluded that new techniques developed in plant breeding had outgrown the EU GMO legislation. The distinction between genetic modification and other techniques is fading and it is unclear whether or not the products resulting from these techniques should be considered genetically modified. Legislation on GMOs is complex and different regulatory frameworks have been developed in different countries to assess the safety of GMOs and the products derived from them. The USA and Canada have adopted approaches differing from those in the EU. The approach adopted by Northern America is usually referred to as a product-based approach while in Europe more of a process approach has been implemented. COGEM organised the symposium to discuss the merits and demerits of process based and product based legislation. A broad overview of these differences was presented to provide insight into the pros and cons of the two approaches and possible adaptations in the two approaches to overcome discrepancies. The results of the symposium were incorporated in the COGEM topic report "Should EU Legislation Be Updated? Scientific developments throw new light on the process and product approaches".

In 2009 COGEM, together with the Rathenau Institute, organised an expert meeting to investigate whether scenarios could be developed for the adaptation of genetic modification in agriculture in the Netherlands and Europe. The aim of the meeting was to identify the key uncertainties which determine the introduction of genetic modification in agriculture in Europe, to outline the different scenarios or future worlds which could arise and to identify the important policy questions in these scenarios. With the help of a Group Decision Room system, two drivers for the possible future developments were identified: 'societal acceptance of GM food' and 'external urgency'. Four different possible 'future' worlds can be distinguished by changing the two drivers from low to high. These 'European' scenarios take place in a world setting in which GM is widely accepted outside of Europe. The results

of the scenario workshop have been incorporated in a joint publication[9] of COGEM and the Rathenau Institute which was presented to the State Secretaries of IandM, and Agriculture in early 2011.

In January 2010 the "Trend analysis biotechnology 2009" was presented to the then Minister of VROM, Ms. Jacqueline Cramer, during a symposium at the Nieuwspoort international press centre in The Hague. At the well-attended meeting the contents and main findings of the trend analysis were discussed by the authors and scientists involved in compiling the report with an audience of stakeholders and other interested listeners, including journalists. The symposium was organised by COGEM as the lead organisation in drafting the Trend Analysis.

In January 2011 COGEM organised an international symposium on the new and exciting field of the use of (conditional) replicating viral vectors or GM viruses to fight diseases. The first promising results have been achieved in clinical trials and the actual use of replicating viral vectors as a regular treatment modality for cancer patients appears to be within reach. In view of these developments, COGEM organised the international symposium "Genetically modified viruses as medicine: Panacea or Pandora's box" in the science museum NEMO in Amsterdam. Besides providing insight into the latest scientific developments and the opportunities for cancer patients, the symposium also looked at risk assessment of the use of replicating GM viruses, and the possible concerns in society about treatments with viruses. The symposium was visited by approximately 110 scientists, policymakers, representatives of non-governmental organisations, and other interested parties.

9 Mondiale motivatie of Europese eigenheid. Vier scenario's voor ggo's in de Europese landbouw. (2010). Joint publication by COGEM and the Rathenau Institute.

7. COMMUNICATION

The world in which scientific advisory bodies operate has changed considerably since COGEM was established. Whereas 30 years ago the scientist's word was sufficient basis for an irrefutable final judgement, nowadays this is not enough because the authority of scientists is increasingly being undermined. This can be explained by several related factors.

Internet has made scientific information accessible to all and so scientists do not have exclusive access to their fields of knowledge. The fact that non-scientists lack the know-how to properly evaluate and interpret all this information only makes it more difficult. Moreover, authority in general is mistrusted more than it was in the past, and anyone who appeals to authority (in this case scientific authority) will be regarded with suspicion. In the same vein, policymakers, politicians and interest groups are also increasingly selective in their use of scientific or pseudoscientific data. If scientific results support their own thinking or objectives, they are embraced, but if not, they will call for further research or try to find a scientist with a different opinion. The media also play a part in this. In their search for newsworthy controversy they highlight differences in scientific understanding. The new social media allow individuals and social groupings to rapidly organise and quickly secure a position alongside established governmental and civil society organisations. Today's media coverage no longer draws a clear distinction between scientists who have made a subject their life's work and self-proclaimed experts who, after a day's googling, pitch their opinions as scientific fact. Another important aspect is that scientists often have commercial interests at stake, not least because government demands that research results are put to commercial or other use. This puts scientists in a vulnerable position in the debate. 'Opponents' as well as journalists know this and exploit it by pointing to possible interests or by accusing scientists of defending certain perceived or actual interests. All this means that scientific advisory bodies have to operate in a totally different context than in the past and can no longer simply prepare an advisory report and drop it off at the client.

In this context communication is of paramount importance to COGEM. To function effectively, COGEM must be seen to be credible by the public, politicians and the scientific community. If COGEM is no longer considered credible by the public at large, but is seen as an interest group or as purveyors of 'just another scientific opinion' comparable to that of a concerned citizen or activist, its usefulness to the client will be severely curtailed. COGEM's advice is used in the implementation of policy and contributes to political and policy decision-making. As soon as COGEM and its advice are in dispute or challenged, COGEM will lose its value in political discussions.

The credibility of COGEM depends heavily on four aspects: 1) COGEM must strive for scientific excellence (scientific quality); 2) COGEM's integrity must be beyond any possible doubt (integrity and transparency); 3) because COGEM's image is crucial to its functioning, COGEM must take action to manage this image by clearly demonstrating its scientific quality and integrity (pro-active communication); and 4) COGEM must anticipate and be conversant with new topics under public discussion (monitoring). The measures COGEM has in place regarding aspects 1 and 2 are dealt with elsewhere in this report.

COMMUNICATION AND COGEM

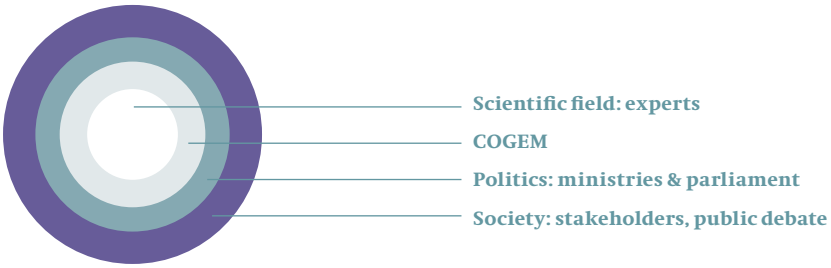
COGEM believes that scientific advice must be open to rigorous public scrutiny. Therefore, COGEM has a responsibility to provide all relevant information concerning its activities for the public in an open, transparent and readily accessible manner. To achieve this goal, all meetings of the subcommittees are publicly accessible and all the publications of COGEM, and the research reports commissioned by COGEM, can be found on the internet (http://www.cogem.net). Moreover, the COGEM policy to avert potential conflicts of interest is published on the website.

7. COMMUNICATION

In recent years, COGEM has invested in communication. A new communication strategy has been developed with the help of external consultants. They underlined that the emphasis of the communication activities should be on the independence of COGEM. It is recognised that COGEM has different roles and is present in different domains. Therefore, its communication activities have to vary. In this strategy three different target groups have been identified: the scientific field, politics (policymakers, ministries and parliament) and the stakeholders. The scientific field is of a twofold nature: the members of COGEM are scientists and therefore, COGEM is part of the scientific field, on one hand while COGEM's credibility depends on its support among scientists, on the other.

Several steps were taken to facilitate effective communication. Staff members have taken courses on writing press releases, on the media and media training. Criteria have been established for issuing press releases (Appendix V).

Figure 5: COGEM: its audience



At the moment COGEM makes use of the following communication tools:
- press releases,
- an e-newsletter (sent to subscribers),
- twitter,
- columns by the chair (published on the website and in the e-newsletters),
- annual reports,
- mailing lists to bring to COGEM publications under the attention of specific target groups,
- the website.

In its communication activities COGEM takes a cautious approach and operates as an information source (or disseminator), by providing scientific facts and information. COGEM enters into discussions only in exceptional cases. Consequently, communication tools like twitter or e-newsletters are used to notify people of COGEM activities and publications and not to disseminate opinions or viewpoints. Press releases are issued sparingly.
In addition, communication about COGEM revolves around imparting the higher goal of the organisation: "the socially responsible use of GMOs" or COGEM's mission. Therefore, COGEM's mission is stated in generic advisory and topic reports and on COGEM's website, staff business cards, and press releases.

The COGEM website (www.cogem.net) is in the process of being overhauled. It is planned that the revised website will be on line April 2011. The previous COGEM website was directed mainly at biological safety officers, licensing authorities, permit holders and scientists. Its

main function is as a database of all COGEM publications since around 2000. In the light of the recently developed communication strategy, the new website is directed at the three defined audiences; 1) the home page is intended for the general public, with underlying layers of information for 2) policymakers, NGOs and government bodies, and 3) scientists and licensing authorities.
There are, on average, 333 visits a week to the COGEM website with an average page view of 1125. Typically, 95% of the visits occur on weekdays, with hardly any visits at the weekend. In holiday periods the number of visits is also significantly lower. This indicates that the website is mainly used by professionals.

COGEM intends to publish public versions of important advisory and topic reports on its website (for a trial period of one year). Public versions will differ from press releases in being less focused on news value and more concerned with explaining the content of the publication for interested members of the public.

MONITORING

Monitoring 'old' and 'new media' may be a valuable means of identifying at an early stage the topics and issues that will be the subject of public debate. These may relate to COGEM's remit or to COGEM publications. Therefore the COGEM secretariat monitors news alerts, newsletters, blogs, etc. However, the scope of these activities is restricted because of the limited number of staff available.

8. NATIONAL AND INTERNATIONAL COOPERATION

One of COGEM's objectives is to strengthen its international contacts. Like other national scientific advisory bodies, COGEM operates in an increasingly international context. Legislation and regulations on genetic modification and GMOs is increasingly decided by the European Union, while international treaties like the Cartegena Protocol also dictate national laws and regulations.

Although placing on the market of GMOs is regulated under a central European procedure, the national advisory bodies have an important role in the notification process. The national scientific advisory bodies are dealing with the same notifications, problems and questions; however, the contact between the national scientific advisory bodies appears to be limited. In the case of COGEM the international contacts are probably more limited than for most of its European counterpart organisations. Many of these national scientific advisory bodies are supported by a staff employed by ministries and competent authorities. The staff of COGEM are not linked to the ministry and, therefore, not present at meetings of competent authorities, etc.
With this in mind, COGEM and the Swiss Expert Committee for Biosafety (SECB) organised the first meeting for biosafety advisory committees in Europe in January 2006. The meeting was for committees dealing with releases to the environment of genetically modified organisms (under Directive EC2001/18). The two-day meeting took place in Amsterdam and was attended by representatives from 20 advisory committees in 18 European countries and delegates from the European Food Safety Authority (EFSA). This initiative was a success and followed by meetings in the following years in Slovenia, Germany, and Belgium. The next meeting takes place in May in Bern.

The Board of COGEM has expressed its intention to strengthen international cooperation. COGEM's capacity is a limiting factor and, therefore, it was decided that there is no room for specific projects on international cooperation. Any efforts in this field take place as part of the regular activities of the commission. COGEM staff members have attended EFSA public consultation meetings. The COGEM secretary is an invited member of the newly-formed EFSA Scientific Network for GMO risk assessment'. As a substitute of a GMO Office representative he also attended a competent authorities meeting in 2010.
Several of the symposia organised by COGEM were held in English with invited international speakers. Furthermore, the COGEM website has an English section, and advice and topic reports deemed interesting for an international audience are translated into English. It should be noted that several COGEM publications initiated or played a role in the European discussion, like the advice on new techniques and the topic report on socio-economic criteria for the assessment of GM crops.

In the national context, COGEM cooperates with the Health Council of the Netherlands and the Committee on Biotechnology in Animals (CBD) on the Trend analysis biotechnology. COGEM further works closely with the Rathenau Institute for a project on synthetic biology. In the second half of 2011 a jointly-organised expert meeting will take place on biosafety and synthetic biology.

9. SCIENTIFIC QUALITY: PROCEDURES AND SAFEGUARDS

Various safeguards have been built into COGEM's working methods and procedures to ensure its scientific quality. First of all, COGEM strives to have the best possible scientists among its ranks. The challenge is to recruit experts with a proven scientific stature who can still make time for the work of the commission. Promising young scientists who have not yet been appointed professor (with all the concomitant obligations) and older scientists approaching retirement fulfil these requirements the best. Of the present members of COGEM seven have been appointed professor during their membership. COGEM further works to strike a balance in the composition and expertise of the members of its subcommittees.
COGEM publications are based on the scientific literature and the expert judgement of its members. This is specifically mentioned in its advisory reports and topic reports.
The secretariat oversees the drafting of reports for consistency and where necessary substantiates or verifies the expert judgement of the members with information from the scientific literature. To provide internal quality control one of the other staff members plays a 'buddy' role for the preparation of draft texts in the secretariat.
A file is maintained for every advice or topic report, including all the comments made by the members. A cover page is present in every dossier, with a checklist of a number of attention points like the scientific underpinning with publications or expert opinions. Before advisory or topic reports are published, all the members are asked to read and comment on them. The secretary and chair of COGEM also review all draft advisory and topic reports. Moreover, the members of the Board are expected to give their opinion on all advisory and topic reports, including those which are not in their field of expertise. If they are not able to respond within the set time limits, their comments will be considered in view of later advice or reports. A procedure has also been put in place for dealing with minority opinions which can be included in the advice if they are based on scientific arguments.

FUTURE ACTIONS

COGEM recently decided to include in advisory reports a more explicit statement of the key viewpoints, the discussions that have taken place on these and how the final judgements have been reached within COGEM. It is felt that it is essential that this is clearly stated to prevent any ambiguity or confusion in the reader's mind about the evidence base and the tenor of the advice.
Moreover, it was decided that when preparing generic advice or topic reports that consideration will be always given to whether it is necessary to hold a scientific meeting. This is especially important when dealing with advice on issues on which there is little scientific consensus or with topic reports on publicly highly controversial issues. The aim of these meetings is to assemble as many scientific insights as possible and to provide an accurate representation of the scientific debate, or to collect arguments on controversial issues. This to avoid the danger that the current composition of COGEM has too much influence on the content of the advice or report.

10. HIGHLIGHTS

- COGEM was able to issue all advice within the set time limits in recent years, despite the heavy demand for advice from the ministry and the GMO Office, and the high workload involved. Only in five cases was a formal request for respite made.
- COGEM has been successful in enlisting new members. Although membership demands a considerable commitment in terms of time, the vast majority of the scientists approached agreed to take a seat in COGEM. This is an indication that COGEM is regarded as authoritative and that its activities are appreciated in the scientific field.
- The requests from the then Minister of the Environment for topic reports on subjects like socio-economic criteria for the assessment of GM crops, synthetic biology, and the Trend analysis biotechnology show that COGEM is regarded in the political arena as a useful and authoritative scientific advisory body. These reports served as a basis for policymaking on these issues.
- The symposia organised by COGEM were well attended and the discussions at the end of the symposia were lively. Apparently, the topics were relevant and the speakers well chosen. Besides this, the symposia yielded input for topic reports and placed the issue involved on the agenda of policymakers. The symposia were also effective communication tools in bringing COGEM and its publications to the attention of stakeholders and other interested members of the public.
- In past years COGEM has made several suggestions for deregulation. These proposals covered issues like cisgenesis, contained use, and the use of naked DNA in gene therapy. The COGEM advice provided an important impetus for the forthcoming revision of the GMO Decree by the ministry.
- In the application and authorisation of GM licenses, lists of pathogenic and non-pathogenic organisms play a crucial role. COGEM has taken the revision of these lists or annexes in hand. At present, not all these lists are a formal part of the GMO Decree. The ministry has indicated that all the lists will be included in the Ministerial Order on GMOs ('Regeling ggo bij het Besluit ggo') in the forthcoming revision.
- COGEM placed a number of new and important issues on the agenda of stakeholders and policymakers. These issues concerned a wide variety of different subjects, such as the putative risks involved with the clinical use of replicating viruses and the public risk perception of the use of these viruses, the off-label use of GM medicines, and the widening gap between the GMO regulations and scientific developments in biotechnology, which call for a revision of the EU regulation.
- The discussion initiated by COGEM in 2006 on new techniques in plant biotechnology has led to an EU working group to advise the competent authorities on which techniques fall under the scope of the GMO regulation. COGEM has been following the discussions closely and made further contributions to the discussion and decision-making process with a topic report on zinc fingers, and a research project and advisory letter on novel plant breeding techniques.
- The COGEM research programme yielded results which were of considerable interest and clarified outstanding questions. More importantly, some of the results obtained were directly applicable in the permit application process or environmental risk analysis. For example, experimental protocols were developed to investigate the impact of GM crops on non-target arthropods. Other projects dealt with issues such as the actual cost of market releases of GM crops in Europe and the US, admixture of GM and non-GM crops, and the ecology of rapeseed.
- In anticipation of future developments and to avoid being taken by surprise by new permit applications, COGEM pro-actively monitors the latest developments in strategies for biological containment of GM crops, the environmental risk analysis of crops modified to enhance or preserve yield ('second generation' GM crops), synthetic biology, gene therapy in China and medical tourism for gene therapy.

10. HIGHLIGHTS

- A highlight in terms of the environmental risk analysis was the advice issued by COGEM on a notification concerning a clinical trial with a replicating virus. This was the first time that a replicating virus was used for clinical purposes in the Netherlands. To carry out a risk analysis COGEM had to leave the beaten track and forge new territory.

11. CONTROVERSIES AND POINTS OF INTEREST

In the past three and half years COGEM has encountered some controversies or difficulties:

- As indicated, 2007 and 2008 proved to be difficult years for COGEM. Its output peaked, but this put a considerable strain on the organisation. The capacity of the organisation was stretched to its limits. Organisations like COGEM appeal to their members who work for COGEM out of a sense of public spiritedness or community involvement. They are not employed by the commission, nor do the fees cover the amount of time involved. Therefore, they have to find the time in addition to their normal occupations. In 2007 and 2008 it became increasingly difficult for the members of the subcommittee Agriculture especially, to respond within the set time. COGEM still managed to issue all its advice within the time limits. However, COGEM staff had to put considerable effort into reminding the members to respond.
- In the past three and half years COGEM has made five formal requests for respite of the time limit for advice on notifications. These involved requests for advice in holiday periods with too many members absent and complicated notifications for which COGEM deemed discussion in a subcommittee meeting to be necessary. In two cases COGEM judged the information present in the notification dossier insufficient to be able to make an environmental risk analysis. The requested additional information did not arrive in time to allow COGEM to make a sound assessment. Curiously, it involved the same applicant and dossier. On the first occasion (in 2009) it concerned experiments under contained use and the second time (in 2010) introduction in the environment.
- COGEM aims to organise two symposia or workshops a year. Lack of capacity has meant that COGEM has been unable to do so in recent years.
- COGEM's advice is issued on the basis of consensus among its members. In 2009, for the first time in at least eight years, it proved to be impossible to reach a consensus. A minority opinion had to be included in advice issued on a notification concerning the classification of contained use experiments with Human metapneumovirus (hMPV). The majority of the members held the opinion that experiments with chimerical metapneumoviruses should be classified at safety level ML-II. However, three COGEM members made a different scientific assessment and were of the opinion that these experiments should take place at the higher safety level of ML-III. The ministry decided to issue the permit at ML-III. The possibility of a minority opinion is established in the Environmental Management Act and the COGEM Rules of Procedure. However, at the time it occurred, it became apparent that no procedures or criteria for a minority opinion had been put in place. Consequently, a guideline or procedure for minority opinions has been drafted and established (Annex II). The central element of this guideline is that a minority opinion has to be based upon scientific arguments.
- The ministry is not bound by COGEM advice, but in almost all cases the ministry or the GMO Office follows the COGEM advice issued. In 2010 the rare occasion occurred that the ministry deviated from the COGEM advice. COGEM advised that experiments with genetically modified kalanchoë plants be allowed in the lowest safety level pK-I greenhouses. The ministry decided to classify kalanchoë at the higher safety level pK-II. Based on the facts that kalanchoë is highly biologically contained as it has no relatives in the Netherlands and, due to the climatological conditions, it cannot survive outside greenhouses in the Netherlands, COGEM was of the opinion that there was no need to prevent pollen escaping from greenhouses. In its advice COGEM described a number of theoretical possibilities including cross pollination with kalanchoë plants in window sills. The chance of seed formation in such an unlikely event is theoretical. However, based on these theoretical eventualities the ministry decided to put measures in place to prevent the escape of pollen, based on the precautionary principle. The invocation of this principle was questioned by COGEM. In its opinion there was no scientific uncertainty warranting the use of the precautionary principle. Moreover, it appears that COGEM and the ministry take different views on what is considered 'contained'. Thirdly, this case also shows the potential difficulties with the recent decision

made by COGEM - which was made also at the request of the ministry - to list the different theoretical possibilities or risks in its advice, to provide more insight into its scientific reasoning and in the elements considered. This means that COGEM must carefully word its deliberations, on the one hand, and that the ministry or GMO Office has to be prudent in the conclusions drawn based on the contents of the advisory text, on the other hand. COGEM and the ministry are still in discussion on these issues.

- In 2009 the then Minister of VROM, Ms. Jacqueline Cramer, asked COGEM to develop criteria for sustainability and GM crops. This report would serve as the basis for the Dutch contribution to the debate in Europe later that year on the socio-economic assessment of GM crops. Publishing a socio-economic assessment of GM crops had wide support in the Dutch parliament. However, a member of parliament for the labour party, Mr. Harm Waalkens[10], questioned whether COGEM was the appropriate organisation to establish these criteria. On at least at two occasions he raised this point with the minister in parliament during the debate. From his statements the impression was created that he considered COGEM a technical and scientific advisory body without expertise on societal or ethical issues. COGEM responded by sending him a letter explaining the legal role and organisation of COGEM, and the expertise of its members. This did not change his opinion, however. The minister disregarded his objections and requested COGEM to issue the report.
- COGEM seeks to have all the relevant expertise within its ranks, without any over-representation of certain areas of expertise or specific views. COGEM also strives to have the best possible gender balance. However, this can be difficult. Female scientists are underrepresented in technical areas above the level of post-doctorates in the Netherlands. Moreover, female professors are greatly sought after by all kinds of commissions and other organisations, and consequently their schedules are overfull. An even gender representation is also a policy requirement. In June 2008 the former Minister of VROM refused to appoint the nominated candidates for COGEM, because female scientists were underrepresented. COGEM acknowledged this fact and stepped up its efforts to attract female experts. At the moment COGEM has 9 female members among a total of 39 members.
- In 2006 COGEM reported for the first time on new techniques in plant biotechnology. In its advice on new techniques COGEM concluded that the distinction between genetic modification and other plant biotechnology techniques is gradually blurring, and that the European GMO legislation is no longer in step with the latest scientific advances and developments in biotechnology. Over the next few years this issue became a focal point in COGEM's activities.
- In 2010 the Ministry of IandM asked COGEM to advise on the question of whether an oligonucleotide is a recombinant nucleic acid. This question is important in deciding whether plants developed using site-directed mutagenesis should fall under the current GMO regulations. COGEM was of the opinion that oligonucleotides (in the context of site-directed mutagenesis) should not be considered a recombinant nucleic acid. It was also concluded that the request underscored the notion that the frameworks and assumptions of the current European GMO legislation have been overtaken by technological developments. Increasingly, improvised assessments are becoming necessary, involving ever more elaborate descriptions of the context and conditions for an exception. Another example of such an assessment was the request for advice on the subject of plants produced by cell fusion in 2010. A cell fusion product of plants able to naturally hybridise is exempted from the GMO regulation. The ministry asked COGEM what evidence has to be submitted to unequivocally demonstrate that a plant is a hybrid and to define the moment when a hybrid embryo can develop into a mature plant.

10 Mr. Waalkens did not stand for re-election to parliament in 2010.

11. CONTROVERSIES AND POINTS OF INTEREST

These types of requests for advice or improvised assessments involve an inextricable tangle of legal considerations, scientific descriptions and policy considerations that lack a scientific basis. A possible way out would be to adjust the basis of the EU legislation (from a process to a product-based approach) or at least to come to a re-interpretation of the current legislation on basis of the definition of a GMO in the Cartegena Protocol, as mentioned in the COGEM topic report on EU regulation in 2009. Until the EU regulations are adjusted, COGEM will be confronted with more and more of these types of requests. They pose an inherent risk to COGEM because of the mixture of legal, policy and scientific aspects involved. COGEM's stronghold is its scientific base, which can be undermined if arguments other than scientific ones seep through into its advice.

12. EVALUATION OF COGEM: PREVIOUS FINDINGS

12.1 EVALUATION 2003

The previous evaluations of COGEM were carried out in 2003 and 2007. The 2003 evaluation was carried out by an independent consultant (Twynstra Gudde) and was mainly based on interviews with stakeholders. The evaluation took place in the context of a restructured organisation. In the years prior to 2002, COGEM had run into difficulties due to heavy workloads, understaffing, and differences of opinion between the commission and the ministry about its role and mission. In 2002 COGEM underwent major changes. A new chair was appointed, the secretariat was expanded to 8 FTE positions and all staff members were newly hired. The COGEM membership was also rejuvenated. The evaluation took into account that although COGEM was legally founded in 1990, at that time it was actually a young organisation. Procedures and good practices still had to be developed. The evaluation focused on answering the following questions: "Is COGEM doing the right things" and "Is COGEM doing the things right?". The main conclusions of Twynstra Gudde were:

- COGEM was seen as independent and authoritative;
- The technical and scientific advice issued by COGEM was unanimously considered to be the most important task;
- However, it was felt that COGEM should act in a more pro-active manner especially in issuing scientific-technical alerts about trends in the long term;
- There was confusion among the stakeholders about the informative task concerning ethical and societal issues. Many of the people interviewed mistakenly thought that COGEM passed an ethical judgement;
- There was satisfaction with the quality of the technical and scientific advice;
- Opinions on the quality of the ethical and societal reports were divided, but this was most likely due to the confusion about the purpose of this task;
- The number of requests for advice had decreased in recent years while the number of permit applications had increased. There was no obvious reason for this apparent discrepancy;
- It was noted that COGEM has no contact with permit applicants. Some applicants and members of COGEM would however like to liaise with one another.

The following recommendations were made:

- To pay more attention to the justification and explanation of the scientific reasoning in the advice issued;
- To establish rules and criteria on which contained use permits COGEM will issue advice;
- To formulate and communicate (both internally and externally) a mission statement;
- To enhance the communication with stakeholders;
- To communicate the different roles of COGEM (technical-scientific advice, and ethical and societal information) to the stakeholders;
- To further optimise the cooperation between COGEM and the GMO Office;
- To further step up the contacts with counterpart organisations in the Netherlands and abroad.

COGEM drew up an action plan in response to these conclusions and recommendations. A mission statement was formulated, the communication was strengthened, among other things, by improving the website and introducing an e-newsletter. Agreements were also established with the GMO Office concerning procedures, the ministry agreed to improve its feedback to the subcommittee meetings, and COGEM staff received training on relevant topics.

12. EVALUATION OF COGEM: PREVIOUS FINDINGS

12.2 EVALUATION 2007

The evaluation of COGEM in 2007 was a combination of a self-evaluation and an assessment by an external visitation committee. Two COGEM staff members interviewed stakeholders in COGEM's field of interest and carried out an e-questionnaire survey of a broad group of interested parties. The external committee under the direction of Professor Wiel Hoekstra assessed both the self-evaluation and the manner in which COGEM carries out its assignment.

OUTCOME OF THE EVALUATION

The results of the evaluation were predominantly very positive. Since the evaluation in 2003 COGEM had made considerable improvements and was considered well on track. The evaluation made a distinction between the two tasks of COGEM: 1) to provide scientific advice on risk assessment, and 2) to bring ethical and societal issues linked to genetic modification to the attention of the ministers concerned.
Its technical and scientific advisory role was highly appreciated by both the ministry and the scientific stakeholders. The quality of its advisory reports was widely rated as high. However, there was still some confusion regarding the Commission's informative role. A relatively large number of stakeholders were unfamiliar with the fact that this is a statutory task. Moreover, a number of the respondents mistook the informative role for making an ethical judgement on biotechnical applications, although COGEM never passes ethical judgement and has no intention of doing so. The quality of the topic reports was considered up to the mark, but the ministry noted that they could tie in better with the ongoing policy cycle.

The main recommendations of the 2007 evaluation were that:

- COGEM had to strengthen its communication, profile and visibility in the public debate;
- COGEM had to broaden its support especially in the scientific community, given an observed weakening of support for the GMO regulations in the scientific field. Incidents with GMOs, like escapes from contained areas, are rare to non-existent and many scientists feel that the actual risks of working with GMOs are not reflected in the current measures. Although the ministry and not COGEM is in charge of the GMO regulation, a weakening of support for regulation would directly affect COGEM. As a scientific advisory body the authority of COGEM is based on its role of 'giving science a voice' in policy-making. Therefore, the support of the scientific community for COGEM, its activities and publications, is of paramount importance;
- It was furthermore concluded that COGEM needed to put more effort into the dissemination of its publications. It was felt that many of COGEM's publications were of broader interest than only to policymaking officials in the ministry;
- Another matter was the need to strengthen international contacts. The review board concluded that the international meetings of advisory bodies initiated by COGEM were a first step towards better international cooperation, but that continued efforts were required;
- The evaluation also concluded that the boundaries between genetic modification and other science fields are dissolving due to the emergence of converging technologies like synthetic biology or bio-nanotechnology. It was recommended that COGEM include monitoring of these new developments in its programme of activities.

ACTION PLAN

The findings of the evaluation were discussed in COGEM and with the minister. Again an action plan was put in place and the following steps were taken:

- COGEM agreed that it had to strengthen its communication. A consultant agency was commissioned to review the communication strategy. A project to revise the website and

12. EVALUATION OF COGEM: PREVIOUS FINDINGS

e-newsletter was started. Procedures for press releases and other communication activities were updated, e.g. on the dissemination of general advice, topic reports and research reports;
- COGEM felt that its views on deregulation had been confirmed by the conclusion of the evaluation. The Board decided that one of COGEM's focal points in the coming years would be a critical review of the regulations and containment measures for working in laboratories. If appropriate, COGEM would make recommendations for deregulation.
- With respect to the monitoring of new technological developments and new science fields, COGEM pointed out that a delimitation had to be made. New technologies encompass a wide field and in most cases the putative risks involved differ from those linked to genetic modification. Therefore, COGEM decided to monitor only technologies which deal with organisms (in the broadest sense) that are able to replicate.

Not all of the recommendations of the evaluation committee were fully adopted. It was concluded that COGEM already had more than a full workload and could not reserve extra manpower to improve its international contacts and cooperation. Therefore, it was decided that expanding international contacts and cooperation had to be incorporated as part of COGEM's normal operations.
COGEM did not agree with the review board that the commission had to be more active in the public debate. COGEM is of the opinion that in order to be seen as an independent authoritative advisory body it is imperative that the commission does not become party to the public debate with its own standpoint or interests.

13. CONCLUDING REMARKS

The higher goal of COGEM can be defined as the socially responsible use of GMOs. To achieve this goal COGEM issues technical-scientific advice on the use and production of GMOs to ensure the safety of the environment and human health. The COGEM advice also helps to fill in the blanks in the Dutch Decree on GMOs and the interpretation of the requirements for new scientific developments and techniques.
Socially responsible use goes beyond the mere question of the risks and safety involved with GMOs. It also deals with public support for a controversial technology and whether the arguments and interests of both the opponents and proponents are heard and taken into account in policy decisions. The informative role of COGEM is aimed at supporting a well-balanced decision-making process by policymakers and politicians.
The scientific developments in the field of genetic modification and biotechnology are still advancing rapidly. The boundaries between genetic modification and other techniques in biotechnology are fading, raising the question of which techniques fall under the scope of the GMO legislation and why they are regulated and others not. Moreover, the boundaries between scientific disciplines are disappearing. There is a convergence of technologies and scientific fields in new 'sciences' like bio-nanotechnology or synthetic biology. These new developments bring great promise and opportunities, however, they also raise ethical dilemmas or provoke social concerns and fears.
Meanwhile, the ongoing globalisation also extends to science. Aside from the traditional scientific superpowers, Europe and the United States, new countries, especially in Asia, have become active players in biotechnology. Outside Europe, however, quite different considerations regarding biotechnology applications are becoming apparent. The products of applications which are deemed unwanted or unethical in the Netherlands and Europe, like genetic modification of animals, will be offered for import. These developments have implications for the Netherlands and the EU and will put pressure on national and European policy.
Over the past few years COGEM has worked to pro-actively take stock of the new developments and their consequences. In both advice and topic reports issues were addressed like synthetic biology, new techniques in biotechnology, the need for revision of the GMO legislation, limitations on and threats to the freedom of choice of consumers and producers, etc. The Trend analysis biotechnology played an indispensable role in bringing these issues to the attention of the politicians involved in the decision-making process. Moreover, several of the issues raised by COGEM are now on the agenda of the EU.

ANNEXES

ANNEX I: THE ENVIRONMENTAL MANAGEMENT ACT (§ 2.3)

§ 2.3 THE COMMITTEE ON GENETIC MODIFICATION

SECTION 2.25

For the purposes of this Division, genetically modified organisms shall be understood to mean organisms whose genetic material has been altered in a manner not possible by natural means such as reproduction or recombination and which are able to replicate or transmit that genetic material.

SECTION 2.26

There shall be a Committee on Genetic Modification.

SECTION 2.27

1. The task of the Committee shall be:
   a. to advise Our Minister on notifications and applications for a licence relating to the production of or activities involving genetically modified organisms and on safety measures to be taken in that connection to protect man and the environment;
   b. to advise the administrative authority authorised to grant licences pursuant to section 8.1 on applications for a licence relating to establishments designated by order incouncil in so far as the applications relate to the production of or activities involving genetically modified organisms;
   c. to advise the administrative authority authorised to monitor the production of oractivities involving genetically modified organisms on matters related to its monitoring tasks.
2. At the request of Our Minister or Our Minister whom it may concern, or on its own initiative, the Committee shall inform Our Minister concerned if the production of or activities involving genetically modified organisms have ethical or social implications which the committee considers to be important.

SECTION 2.28

Our Minister and Our other Ministers whom it may concern shall ensure that the Committee is kept informed of policy on the production of or activities involving genetically modified organisms.

SECTION 2.29

Within a period of four years, the Committee shall issue a report to Our Minister in which at least its tasks, composition, organisation and procedures are reviewed and any necessary changes may be proposed. Our Minister shall send this report, together with his opinion, to both houses of the States General.

SECTION 2.30

1. The Committee shall consist of a chair and between fifteen and twenty other members.
2. The chair and the other members of the Committee shall be appointed on the basis of their expertise in the field of the production of or activities involving genetically modified organisms and the potential consequences thereof for man and the environment, including the ecological consequences and the necessary safety measures.

SECTION 2.31

1. The chair of the Committee shall be appointed by Our Minister. Our Minister shall hear the Committee before appointing the chair.
2. Our Minister shall appoint between fourteen and nineteen other members of the Committee.
3. The chair and the members shall be appointed for a period of four years. They may be reappointed immediately.

4. The chair and the members may resign at any time by giving written notice to Our Minister.
5. In special cases, Our Minister may suspend and discharge the chair and the other members.

SECTION 2.32

1. The Committee shall appoint a deputy chair from among its own members.
2. The deputy chair may resign at any time by giving written notice to the chair.
3. In special cases, the committee may suspend and discharge the deputy chair.

SECTION 2.33

1. The Committee shall be assisted by a secretary. A deputy secretary may be appointed.
2. The secretary and deputy secretary shall be appointed, suspended and discharged by Our Minister, having heard the Committee.
3. The secretary shall not be a member of the Committee.
4. The secretary shall be accountable solely to the Committee for the performance of his duties.
5. Our Minister may provide an office for the Committee, which shall be run by the secretary.

SECTION 2.34

1. The Committee may set up subcommittees for certain issues.
2. The chair of a subcommittee shall be appointed by the Committee from among its own members.

SECTION 2.35

1. The Committee and its subcommittees may be assisted in their work by persons who are not members of the committee.
2. Our Minister and Our Ministers of Social Affairs & Employment, of Health, Welfare & Sport, and of Agriculture, Nature Management & Fisheries may designate officials from their own ministry who are authorised to attend the meetings held by the Committee and its subcommittees, provided that no more than one official from each ministry is present at the meetings of the Committee.

SECTION 2.36

1. The meetings of the Committee shall be public. In the decision referred to in section 2.40 the Committee shall lay down rules on public access to the meetings of the subcommittees.
2. A meeting or part thereof shall not be public in cases as referred to in section 10, subsection 1 of the Government Information (Public Access) Act and in cases where the importance of public access does not outweigh the interests referred to in section 10, subsection 2 of that Act.

SECTION 2.37

1. The recommendations of the Committee shall be made in accordance with the views of the majority of the meeting.
2. Minority positions put send at the meeting shall be stated in or attached to the recommendations.

SECTION 2.38

The Committee shall ensure that the preparatory documents relating to the recommendations issued by it remain at the disposal of Our Minister and the administrative authorities referred to in section 2.27, subsection 1 (b and c).

SECTION 2.39

1. The chair of the Committee shall hold consultations with Our Minister at least once a year on the activities planned by the Committee for the next twelve months. The Committee shall then finalise its programme of activities and send it to Our Minister.

2. In preparation for the consultations referred to in subsection 1, the Committee shall draw up an overview of its planned activities and submit it to Our Minister in good time. The Committee shall enclose with the overview an estimate of the costs associated with the implementation of the activities.
3. The Committee shall perform its activities within the framework of the funds placed at its disposal each year under the Budget Act.

SECTION 2.40

The Committee shall draw up further rules concerning its own procedures and those of its subcommittees and shall send them to Our Minister.

ANNEX II: THE COGEM RULES OF PROCEDURE

Having regard to sections 2.25 to 2.40 of the Environmental Management Act (Wet milieubeheer), the Commission on Genetic Modification has adopted its Rules of Procedure as follows:

ARTICLE 1 INTERPRETATION

1. In these rules the following words have the meanings ascribed to them:
   - decree: Genetically Modified Organisms Decree (Bulletin of Acts and Decrees 1993, 1994);
   - Commission: Commission on Genetic Modification, as referred to in section 2.26 of the Environmental Management Act;
   - the Minister: the Minister of Housing, Spatial Planning and the Environment;
   - member: member of the Commission on Genetic Modification appointed by the Minister of Housing, Spatial Planning and the Environment, as referred to in section 2.30 of the Environmental Management Act;
   - outside member: an expert with voting rights who assists the Commission on Genetic Modification in their work and is appointed by the executive board of the Commission, as referred to in article 2.35 of the Environmental Management Act;
   - majority vote: a voting proportion in which a simple majority of the number of votes cast is sufficient for a binding decision, unless otherwise stipulated, and which includes any votes cast in writing;
   - quorum: a majority of the members and outside members of the Commission or a subcommittee who have voting rights, including members voting in writing or electronically. A quorum is reached when more than half the members entitled to vote cast their votes and the number of voting members exceeds the number of non-Commission members with voting rights.

ARTICLE 2 THE MEMBERS AND OUTSIDE MEMBERS

1. The members and outside members of COGEM are appointed in a personal capacity based on their expertise.
2. The members and outside members receive a remuneration for their work for the Commission, as laid down in 'het Besluit vaste beloning COGEM' (dd 31 mei 2007).
3. There is no employment relationship between COGEM or the Ministry of Housing, Spatial Planning and the Environment and the members or outside members of COGEM.

ARTICLE 3 THE CHAIR

1. The chair, as referred to in section 2.31, subsection 1 of the Environmental Management Act, is appointed by the Minister following consultation with the Commission.
2. The tasks of the chair are:
   - setting the dates and agendas of the meetings of the executive board and the meetings of the Commission;
   - chairing the meetings of the executive board and the plenary meetings of the Commission;
   - determining which meeting documents referred to in article 10, paragraph 1f are treated in confidence until the Commission has decided whether those documents are confidential or not;
   - determining which parts of the meeting are confidential;
   - issuing advice on urgent matters, should it not be possible to consult the other members of the executive board on these matters;
   - representing the Commission externally;
   - maintaining an ongoing dialogue and communication with the secretariat;
   - supervising the allocation of the Commission's budget.

ANNEX II: THE COGEM RULES OF PROCEDURE

ARTICLE 4 THE VICE-CHAIR

1. The members of the executive committee shall appoint a vice-chair from among their number by majority vote for a period to be determined by those present.
2. In the absence of the chair, the vice-chair shall assume the responsibilities of the chair.

ARTICLE 5 THE EXECUTIVE BOARD

1. The Commission has an executive board consisting of the chair, the vice-chair and at least as many other members as required to represent all the subcommittees. These members, who may or may not be nominated by the executive board, shall be appointed by the Commission from among its own members by a majority vote of the Commission members with the right to vote for a period to be determined on appointment.
2. The members of the executive board chair the meetings of the subcommittees.
3. The executive board shall adopt the advisory reports and topic reports referred to in article 8 of these rules after consulting with the members, and if requested explain its decision to the Commission.
4. The executive board may delegate responsibility for adopting advisory reports and topic reports to the chair.
5. Each year the executive board shall adopt the Commission's budget and submit it to the Minister for approval.
6. The executive board nominates candidates for membership of the Commission. When making nominations the executive board shall have regard to the task of the Commission as laid down in the Environmental Management Act and the Biotechnology Policy Document (Integrale Nota Biotechnologie).

ARTICLE 6 SUBCOMMITTEES

1. The Commission, through the executive board, may establish one or more subcommittees and shall determine the responsibilities and working procedures of the subcommittees.
2. The Commission, through the executive board, shall appoint the members of the subcommittees from among its own members. A subcommittee may be assisted in its activities by persons who are not members of the Commission. The subcommittees propose these persons, by majority vote, to the executive board, who decide on the nominations. When nominating a person, the subcommittee shall state whether the nomination is for appointment as a member of the subcommittee with the right to vote (outside member) or as a consultant without the right to vote. No more than twenty non-Commission members with the right to vote may be appointed. The number of members of a subcommittee who are Commission members must be at least equal to the number of non-Commission members of the subcommittee with the right to vote.
3. The non-Commission members (outside members) referred to in article 6, paragraph 2, shall be appointed for a period of no more than four years. This appointment may be extended by the executive board.
4. The Minister shall be notified of the appointment of outside members.

ARTICLE 7 MEETINGS

1. The meetings of the Commission and the subcommittees are public meetings.
2. Meetings of the Commission and subcommittees, or a part of these meetings, are not public in cases within the meaning of section 10, subsection 1 of the Government Information (Public Access) Act (Wet openbaarheid van bestuur) and in cases where the interests of public access do not outweigh the interests referred to in section 10, subsection 2 of the Act.
3. Members of the subcommittees may decide, by majority vote, that one or more meetings shall, for other reasons, be partly or entirely closed to the public.

ANNEX II: THE COGEM RULES OF PROCEDURE

4. The Commission and each of the subcommittees shall hold meetings at least once a year.
5. Meetings of the Commission and each of the subcommittees shall be convened by the chairs, either on their own initiative or at the request of at least three members or outside members of the executive board.
6. The chair, or the secretary on behalf of the chair, shall send notices of meetings, accompanied by the agenda and the meeting documents, to the members and outside members, and to the government officials authorised to attend Commission meetings under section 2.35 subsection 2 of the Environmental Management Act, in a timely manner so that the participants of the meeting receive the documents no later than the weekend prior to the date of the meeting.
7. In urgent cases a chair, or the secretary on behalf of the chair, may deliver the meeting documents at a date later than that stipulated in article 6, paragraph 6, stating the reasons for doing so.
8. Items not included in the meeting agenda shall be discussed only with the approval of a majority of the members present at the meeting.
9. Should both the chair and vice-chair of the Commission not be present at a Commission meeting, one of the other members of the executive board shall assume the responsibilities of the chair. If the other members of the executive board are also absent, the members and outside members present at the meeting shall appoint a member by majority vote to chair the meeting for the duration of the absence of the members of the executive board.
10. If the chair of a subcommittee is absent during a meeting of the subcommittee, the responsibilities of the chair shall be assumed by one of the members of the subcommittee, who shall either be nominated by the chair or chosen by a majority of the members of the subcommittee present at the meeting.
11. At the start of the meeting, and as often as necessary, the chair shall discuss with each member and outside member in turn their additional activities that could compromise the independence of COGEM in forming its opinions. The secretariat shall maintain a register of all the additional activities of the members. This register shall be updated each year before 31 January. The register shall contain at least the following information: the main position held by the member, the administrative responsibilities of the member, and any patents held by the member. The Minister may ask to inspect this register where appropriate.
12. Members and outside members are required to abstain from the process of forming an opinion on matters where there may be conflicts of interest, and in such cases must inform the chair of the relevant subcommittee.
13. The chair shall ensure that members and outside members who can be considered to have an interest in a topic to be discussed do not take part in the meeting.
14. The meeting of the Commission or a subcommittee shall only take a decision if the members present make a quorum.
15. Unless otherwise stipulated, other decisions by the Commission and the subcommittees shall be taken by majority vote.
16. If the votes are equally divided, the chair's vote shall count as double.
17. Votes on matters of a personal nature are cast in writing, unless the Commission or a subcommittee decides by a unanimous vote that roll-call voting is acceptable.
18. The meeting can at any time decide to conduct its deliberations in writing or through the use of electronic means of communication.
19. If the members present at a meeting do not make a quorum, the necessary decisions shall then be made through written correspondence, or another meeting, in which the presence of a quorum is not required for binding decision making will be held as soon as possible.
20. The secretary shall ensure that for each meeting the minutes and a decision list are drawn up and sent to those invited to the meeting within three weeks of the date of the meeting.

ANNEX II: THE COGEM RULES OF PROCEDURE

ARTICLE 8 THE COMMISSION'S ADVISORY REPORTS AND TOPIC REPORTS

1. For advice on notifications and applications for licences based on the decision, the executive board, or the secretary on behalf of the board, can nominate one or more members or outside members of the Commission to prepare an advisory report or topic report.
2. When preparing advisory reports and topic reports, the Commission may be assisted by experts who are not members of the Commission.
3. The published advisory reports and topic reports shall reflect the majority opinion of the members and outside members of the Commission. The members and outside members shall be given the opportunity to respond in writing to draft advisory reports and topic reports.
4. Minority opinions submitted in writing or at a meeting shall, if required, be stated in or attached to the Commission's advisory reports.

ARTICLE 9 RESEARCH PROGRAMME

1. The Commission may appoint third parties to carry out research projects in support of its tasks.
2. The executive board shall adopt the Commission's research programme and submit it to the Minister for approval.
3. Research projects shall be commissioned through a public tender procedure.
4. The executive board shall decide on the award of contracts for research projects. The executive board may delegate this task to the chair or secretary.

ARTICLE 10 CONFIDENTIALITY

1. Information shall always be treated as confidential if it concerns one or more of the following:
   a. information provided in relation to a notification or an application for a licence based on the decision and which is marked as confidential by the competent authority;
   b. opinions about individuals;
   c. information for use in internal consultations;
   d. information that could damage national interests;
   e. information which, if published, would lead to a disproportionate disadvantage or benefit to the legal entity or third parties involved in the matter under consideration;
   f. other meeting documents which the Commission or a subcommittee has decided should be treated as confidential;
   g. draft documents from third parties.
2. In these cases, individuals shall be granted access to the closed parts of meetings of the Commission or subcommittees only when they have declared in writing to the chair that they will not disclose any of the information marked as confidential or deemed to be confidential.

ARTICLE 11 AMENDMENTS TO THE RULES OF PROCEDURE

1. These Rules of Procedure may be amended by the Commission by a two-thirds majority of votes, including votes cast in writing.
2. An amendment as referred to in article 11, paragraph 1 shall not come into force until it has been approved by the Minister.

ARTICLE 12 SITUATIONS NOT COVERED BY THESE RULES

1. In urgent cases not covered by these rules, the chair shall take a decision and inform the Commission or subcommittee of this decision.
2. In other cases, the Commission or subcommittee shall take a decision by majority vote, or decide to delegate this responsibility to the chair or the executive board.

ANNEX II: THE COGEM RULES OF PROCEDURE

ARTICLE 13 COMMENCEMENT

These rules shall enter into force on 1 March 2006.

The chair of the Netherlands Commission on Genetic Modification,
Prof. dr. ir. Bastiaan C.J. Zoeteman

ADDENDUM: GUIDANCE ON MINORITY OPINIONS

1. COGEM publishes topic reports and advisory reports. As stated in the Environmental Management Act (section 2.37, subsections 1 & 2) the published advisory reports and topic reports reflect the majority opinion of the members and outside members of the Commission (1), and minority opinions submitted in writing or expressed during a meeting are, if required, stated in or appended to the Commission's advisory reports (2).

2. The purpose of this guidance note is to set out the framework and procedural arrangements for dealing with minority opinions within the Commission.

3. Minority opinions may arise during the preparation of advisory reports. In its topic reports COGEM reviews all the relevant arguments and information related to the subject, without itself adopting a position. This means that for topic reports there can seldom be different opinions that are not properly covered in the argumentation, because they should be included in the review.

4. A minority opinion must be based on technical/scientific grounds. Ethical, social or policy considerations may never be part of the technical/scientific advice. Where appropriate, they may be mentioned in a topic report appended to COGEM's advice/ recommendations, but they are never part of the advice itself.

5. Advisory reports and topic reports are prepared by one of the Commission's subcommittees (or in some cases by more than one subcommittee) and then submitted to all the members for comment. Members and outside members of the other subcommittees or members of the executive board may only adopt or highlight a minority opinion if they can justify this on the basis of scientific arguments.

6. If members/outside members of the Commission have differences of opinion about a scientific risk assessment that go beyond what can normally be expected during such deliberations, the chair of the subcommittee (when alerted by the secretariat) will contact the members involved to compile a list of all the arguments and try to find a standpoint they can all support. If the chair of the subcommittee cannot perform this role (because, for example, the chair has an interest relevant to the subject matter), the vice-chair of the subcommittee will take on this task.

7. If it does not prove possible to formulate a consensus, the COGEM chair will be informed. If appropriate, the COGEM chair can then try to play a mediating role.

8. The guiding principles for trying to reach a consensus are 1) the force of scientific argument, and 2) the fact that the Commission applies the 'precautionary principle' in its technical/scientific advice. When there are empirical grounds for doubts about, or a lack of sufficient evidence for, the absence of risks to human health and the environment, the Commission will usually advise the adoption of extra safety measures (or containment measures), or if that is not possible, issue a negative advice.

9. Should it prove impossible to agree on a unitary advice or set of recommendations, a minority opinion will be included in the advisory report. The members of the executive board will be informed of this. With a view to the executive board's duty to formally adopt the advisory reports and topic reports (Rules of Procedure, article 5, §3), the board members will assess whether the minority opinion meets the requirements set out in this guidance note.

10. Discussion of minority opinions will preferably take place in a meeting of the relevant subcommittee. However, given the brief time period within which requests for advice have to be answered, it will not always be possible to discuss the issues at stake during a meeting. In these cases, the situation giving rise to the minority opinion will be retrospectively discussed during the next meeting of the relevant subcommittee.

11. Minority opinions are always discussed by the executive board. Should it not be possible to do this during a meeting before the publication of the advisory report, because the statutory period for submitting advice expires before the meeting can be held, a round of written or telephone consultations will be held. In such cases, the minority opinion will be discussed at a later date during the next meeting.

ANNEX III: COGEM MEMBERS AND THEIR EXPERTISES

EXECUTIVE BOARD

CHAIR
Prof. dr. B.C.J. Zoeteman, University Tilburg, Sustainable policy in international perspective

VICE-CHAIR
Prof. dr. R.A.M. Fouchier, Erasmus MC, Virology

MEMBERS
Prof. dr. F.W.A. Brom, Rathenau Institute / University of Utrecht, Ethics
Dr. H.J. Schouten, Wageningen University & Research Centre, Plant breeding
Prof. dr. L. van Vloten-Doting, Kenniscoöperatie

SUBCOMMITTEE AGRICULTURE

CHAIR
Dr. H.J. Schouten, Wageningen University & Research Centre, Plant breeding

MEMBERS
Prof. dr. G.C. Angenent, Wageningen University & Research Centre, Developmental biology
Prof. dr. F.P.M. Govers, Wageningen University & Research Centre, Molecular phytopathology
Dr. T.J. de Jong, Leiden University, Plant Ecology
Dr. J.C.M. den Nijs, University of Amsterdam (retired), Biodiversity and Ecosystem dynamics
Ing. A.J.W. Rotteveel, Plant Protection Service, Plant pathology / Weed science

ASSOCIATED MEMBERS
Dr. P.M. Bruinenberg, AVEBE, Plant breeding
Prof. dr. H. van Dijk, Université de Lille, Ecology
Prof. dr. J.D. van Elsas, University of Groningen, Soil microbiology
Dr. W.J. de Kogel, Wageningen University & Research Centre, Entomology
Dr. J.M. Kooter, VU University Amsterdam, Genetics
Prof. dr. N.M. van Straalen, VU University Amsterdam, Animal ecology

SUBCOMMITTEE MEDICAL AND VETERINARY ASPECTS

CHAIR
Prof. dr. R.A.M. Fouchier, Erasmus MC, Virology

MEMBERS
Prof. dr. R.C. Hoeben, Leiden University Medical Centre, Molecular Virology
Dr. G.A.P. Hospers, University Medical Centre Groningen, Physician / Oncology / Gene therapy
Dr. T.G. Kimman, Central Veterinary Institute, Virology
Dr. C. van Maanen, Amimal Health Centre Deventer, Animal virology
Dr. B.P.H. Peeters, Central Veterinary Institute, Virology

ASSOCIATED MEMBERS
Dr. R. de Groot, University of Utrecht, Virology
Prof. dr. P.W.M. Hermans, Radboud University Nijmegen Medical Centre (RUNMC), Molecular Infectiology

ANNEX III: COGEM MEMBERS AND THEIR EXPERTISES

Prof. dr. M.D. de Jong, Academic Medical Centre, Medical microbiology
Dr. N.A. Kootstra, Academic Medical Centre, Virology / Immunology
Prof. dr. J.P.M. van Putten, University of Utrecht, Infectiology
Dr. M.W. Weststrate, Dutch Vaccin Institute, Vaccine production

SUBCOMMITTEE CONTAINED USE

CHAIR

Prof. dr. L. van Vloten-Doting, Kenniscoöperatie

SUBCOMMITTEE ETHICS AND SOCIETAL ASPECTS

CHAIR

Prof. dr. F.W.A. Brom, Rathenau Institute / University of Utrecht, Ethics

MEMBERS

Prof. dr. J.J.M. Dons, BioSeeds, Biotechnology
Prof. dr. R.A.M. Fouchier, Erasmus MC, Virology
Prof. dr. E.T. Lammerts van Bueren, Louis Bolk Institute / Wageningen University & Research Centre, Organic plant breeding
Prof. dr. P. Osseweijer, Kluyver Centre for Genomics of industrial Fermentation / Technical University Delft, Biotechnology and society, science communication
Dr. H.J. Schouten, Wageningen University & Research Centre, Plant breeding
Ir. H. de Vriend, LIS Consult, Life sciences, Innovation and Society

ASSOCIATED MEMBERS

Dr. S. van der Burg, Radboud University Nijmegen, Medical ethics
Prof. dr. M.J.A Margadant-van Arcken, Nature and environment education
Prof. dr. G. Meester, Agricultural economy
Drs. L. van den Oever, Netherlands Institute of Biology (NIBI), Biology
Prof. dr. S. Roeser, 3TU centre for ethics and technology, Twente University / TU Delft, Political philosophy and ethics,
Prof. dr. G.T.P. Ruivenkamp, Wageningen University & Research Centre / VU University Amsterdam, Sociology
Dr. J.A.A. Swart, University of Groningen, Ethics and societal aspects of life sciences
Drs. T.J. Wams, Association of Nature Reserves, Nature conservation

FORMER COGEM MEMBERS (STEPPED BACK 2008-2010)

Prof. dr. dr. A. van Belkum, Erasmus MC, Medical microbiology and Infection diseases
Prof. dr. W. van Delden, University of Groningen (retired), Population genetics
Prof. dr. M. Dicke, Wageningen University & Research Centre, Insect-plant interactions
Prof. dr. C.D. Dijkstra, VU University Medical Centre, Neurobiology
Prof. dr. P.J.J. Hooykaas, Leiden University / Delft University of Technology, Molecular genetics
Dr. W.R. Gerritsen, VU University Amsterdam, Physician / Molecular virology
Prof. dr. F.W.J. Keulartz, Wageningen University & Research Centre / Radboud University Nijmegen, Applied Philosophy
Dr. B.A. Uijtewaal, Nunhems BV, Plant breeding
Prof. dr. J.A. van Veen, The Netherlands Institute of Ecology, Soil microbiology

ANNEX III: COGEM MEMBERS AND THEIR EXPERTISES

Dr. D. van Zaane, Wageningen University & Research Centre, Virology / Biochemistry
Prof. dr. H.A.E. Zwart, Radboud University Nijmegen, Ethics / Philosophy of sciences

SECRETARIAT COGEM

Dr. M. Bovers, coordinator Subcommittee Agriculture
A.T.A. Box BASc, staff
B. Erkamp, MSc, staff
E. Bardakci, secretary
F.G. Koning MSc, staff
R. Mampuys MSc, coordinator Subcommittee Ethics and Societal Aspects
Dr. F.H.E. Schagen, coordinator Subcommittee Medical and Veterinary Aspects
M. Scholsz, office coordinator
Dr. F. van der Wilk, executive director

ANNEX IV: COGEM PUBLICATIONS AND ACTIVITIES

(Titles translated)

1. ADVICES LINKED TO NOTIFICATIONS

2008

CGM/080121-04	Experiments with genetically modified Hosta spp
CGM/080122-01	Large scale field trial with the genetically modified (low amylase) starch potato AV 43-6-G7
CGM/080122-02	COGEM opinion concerning the information on the location of a field trial necessary for the environmental risk analysis
CGM/080131-04	COGEM opinion on the French report 'Project dávis sur la dissémination du MON810 sur le territoire français'
CGM/080205-01	Classification of Equine infectious anemia virus (EIAV)
CGM/080131-05	Classification of five fungal species
CGM/080207-02	Cultivation of genetically modified maize 59122 (reapplication)
CGM/080207-03	Classification of experiments with genetically modified cow parsley
CGM/080215-01	Small scale field trials with genetically modified maize DP-98140-06
CGM/080215-02	Small scale field trials with genetically modified maize NK603
CGM/080219-03	Revision of the containment measures for Boechera spp.
CGM/080310-01	Classification of a non-SIN lentiviral vector in combination with the Lenti-X production system
CGM/080313-05	Classification of experiments with genetically modified Rift Valley fever virus (RVFV)
CGM/080325-02	Cultivation of genetically modified maize line 1507x59122
CGM/080328-01	Import and processing of cotton MON88913 x MON15985
CGM/080328-03	Market release of Advexin as a treatment for patients suffering of the Li-Fraumeni syndrome
CGM//080414-01	Renewal application cultivation of genetically modified maize MON810
CGM/080417-01	Import and processing of maize Bt11xGA21
CGM/080416-01	Import and processing of soybean line 305423x40-3-2
CGM/080509-01	Import and processing of cotton GB614
CGM/080507-01	Classification of experiments with genetically modified Aspergillus vadensis
CGM/080509-01	Import and processing of genetically modified cotton GHB614
CGM/080519-01	Classification of experiments with genetically modified Tanacetum cinerariifolium
CGM/080521-01	Renewal application import and processing of soybean line 40-3-2
CGM/080521-02	Import and processing of maize MIR604xGA21
CGM/080521-03	Import and processing of maize Bt11 x MIR604
CGM/080522-02	Clinical study 'Allovectin-7 and melanoma'
CGM/080523-02	Renewal of authorization for import and processing of maize Bt11
CGM/080602-03	Appendix 1 of the Ministerial Regulation on GMOs: classification of 14 bacteria
CGM/080623-02	Classification of experiments with genetically modified Abyssinian mustard
CGM/080702-01	Classification of experiments with genetically modified dandelion
CGM/080710-02	Experiments involving genetically modified duckweed species
CGM/080721-03	Classification of experiments with NYVAC-C mutants
CGM/080729-01	A clinical study to the treatment of critical limb ischemia (CLI) using the plasmid NV1FGF
CGM/080806-02	Renewal application cultivation of maize T25
CGM/080806-01	Classification of Lactobacillus rhamnosus
CGM/080821-01	A phase 2a clinical study to the effect of treatment with L. lactis AG011 of patients suffering of ulcerative colitis

ANNEX IV: COGEM PUBLICATIONS AND ACTIVITIES

(Titles translated)

CGM/080827-01	Molecular characterisation of soybean MON89788
CGM/080827-02	COGEM opinion on the additional questions concerning the exemption of cisgenic plants from gmo-regulations
CGM/080918-02	Import and processing of soybean line A5547-127
CGM/080929-06	A clinical study involving vaccination of patients suffering of melanoma by tattoo with the plasmid pDERMATT
CGM/080930-03	Classification of experiments with genetically modified Jatropha curcas
CGM/081017-03	Import and processing of maize Bt11xMIR604xGA21
CGM/081020-01	Import and processing of MON15985 cotton
CGM/081027-02	Import and processing of cotton MON15985xMON1445
CGM/081106-01	A phase II clinical study to the use of a genetically modified vaccinia virus as a vaccine against HIV-B
CGM/081111-01	Classification of experiments with genetically modified Talaromyces emersonii
CGM/081112-01	Classification of genetically modified Clostridium phytofermentans
CGM/081112-02	Cultivation of genetically modified maize line MON88017
CGM/081125-01	Market release of Contusugene ladenovec as a treatment of head and neck tumors
CGM/081126-01	Classification of experiments with Blue tongue virus
CGM/081205-01	A small scale field trial with genetically modified poplars
CGM/081215-01	Classification of tamiflu resistant gm-influenza A (H1N1) viruses
CGM/081219-01	Cultivation of herbicide tolerant maize line GA21

2009

CGM/090116-01	Import and processing of genetically modified maize line 98140
CGM/090119-04	Classification of experiments with the flaviviruses CFA en YokV
CGM/090126-01	Molecular characterization of maize MON89034
CGM/090202-03	Classification of in vitro experiments with a Mycobacterium tuberculosis phoP mutant
CGM/090227-03	Classification of experiments using recombinant human coronaviruses
CGM/090310-01	Renewal of authorization for import and processing of maize Bt11: additional information
CGM/090317-03	Classification of experiments using the vaccin stam Bacillus anthracis Sterne
CGM/090324-03	Marketing authorization of the novel drug 'Cerepro'
CGM/090407-08	Import, distribution and retail of gm-carnation 'Moonshadow'
CGM/090414-01	Classification in risk groups of four bacteria species
CGM/090416-01	Lowering of the containment level for experiments with a Rhodococcus equi vaccin strain
CGM/090428-12	Import and processing of genetically modified maize line MON89034x1507xMON88017x59122
CGM/090429-04	Assessment of a clinical study with a conditional replicating adenoviral vector
CGM/090429-01	Import, distribution and retail of GM-carnation IFD-25958-3
CGM/090504-06	Import, distribution and retail of GM-carnation IFD-25958-2
CGM/090512-07	Classification of containment levels in green houses of four GM plants
CGM/090602-01	Classification of a lentiviral production system with heterologous surface proteins
CGM/090603-01	Classification of experiments with VEE virus based replicons
CGM/090619-03	Marketing authorization of 'Hiprabovis IBR Marker Live' vaccine to prevent infectious bovine rhinotracheitis
CGM/090731-01	Flow cytometric analysis of van retroviral transduced mouse cells

ANNEX IV: COGEM PUBLICATIONS AND ACTIVITIES

(Titles translated)

CGM/090907-02	Genetically modified Rhipicephalus microplus ticks
CGM/090917-04	Import and processing of genetically modified maize Bt11xMIR162x GA21
CGM/090917-05	Import and processing of genetically modified maize Bt11xMIR162xMIR604xGA21
CGM/090921-01	Import and processing of soybean BPS-CV127-9
CGM/090922-02	Experiments employing naked mice with lentiviral transduced xenografts
CGM/090930-01	Import and processing of genetically modified MON89034x1507xNK603 maize
CGM/091019-01	Classification of the yeast Zygosaccharomyces bailii
CGM/091019-02	Import and processing of maize Bt11xGA21
CGM/091020-01	Additional advice on the import and processing of MON89034xNK603
CGM/091021-02	Advice on additional information regarding a clinical study with conditional replicating adenovirus
CGM/091026-01	Cultivation of genetically modified sugar beet H7-1
CGM/091118-01	Revised molecular characterization of RF3 oilseed rape
CGM/091124-04	Petition for lowering the containment level for experiments with Human metapneumovirus
CGM/091127-01	Freedom from the GMO legislation: GM E. coli harbouring GFP
CGM/091130-05	In vivo experiments with a adenoviral based vector
CGM/091208-01	Cultivation of maize line MON89034xNK603
CGM/091216-03	Classification of the containment level for large scale production of Infectious pancreatic necrosis virus VP2 antigen
CGM/091222-02	Cultivation of maize line MON89034xMON88017

2010

CGM/100126-02	A small scale field experiment with genetically modified potato plants less susceptible to Phytophthora infestans
CGM/100122-02	Classification of experiments with genetically modified Candida lusitaniae
CGM/100202-01	Import and processing of genetically modified soybean MON87701 x MON89788
CGM/100225-01	Proof of hybridisation between related plant species (confidential)
CGM/100304-08	Classification of the Chikungunya virus
CGM/100310-01	Market authorization of a recombinant canarypox vaccine against rabies in cats (confidential)
CGM/100330-01	Import and processing of genetically modified maize line MON87460
CGM/100407-01	Classification of the fungal species Neosartorya fischeri
CGM/100414-01	Import and processing of genetically modified soybean MON87769 expressing two desaturase genes
CGM/100421-02	Additional advice on the import and processing of MON89034x MON88017
CGM/100426-01	Market authorization of an adeno-associated viral vector encoding lipoprotein lipase (LPL) for LPL deficient patients
CGM/100503-01	Large scale production of monoclonal antibodies in a Single-Use Bioreactor
CGM/100512-01	Market authorization of a recombinant combination vaccine against myxomatosis and rabit hemorrhagic disease in rabbits
CGM/100517-01	Classification of the yeast Lachancea kluyveri
CGM/100526-02	Classification of experiments with the GM potato Solanum tarijense
CGM/100608-01	Additional advice on import and processing of genetically modified maize MIR604xGA21
CGM/100608-02	Additional advice on import and processing of genetically modified maize Bt11xMIR604

ANNEX IV: COGEM PUBLICATIONS AND ACTIVITIES

(Titles translated)

CGM/100614-01	An isolation distance is not necessary for category 2 field experiments with genetically modified starch potato plants with a reduced amylose content
CGM/100616-01	Classification of Canine distemper virus
CGM/100701-03	The status of oligonucleotides within the context of targeted mutagenesis
CGM/100706-01	Classification of experiments with genetically modified Hepatitis B virus
CGM/100707-01	Classification of experiments with genetically modified Hepatitis delta virus
CGM/100708-01	Introduction in the enivironment of a Rhodococcus equi vaccine strain
CGM/100712-05	Classification of experiments with recombinant Orbiviruses
CGM/100810-01	Import and processing of insect resistant soybean line MON87701
CGM/100813-01	Classification of Monascus ruber
CGM/100813-02	Classification of six bacteria species
CGM/100820-01	Market authorization of a recombinant canarypox vaccine against West Nile disease in horse
CGM/100830-02	Classification of experiments with genetically modified influenza A/Udorn/307/72
CGM/100920-01	Classification of experiments with genetically modified EIAV transduced chicken
CGM/101013-03	Import and processing of genetically modified soy MON87705
CGM/101014-02	Vaccination of dogs with naked DNA
CGM/101019-04	Import and processing of genetically modified maize MIR162
CGM/101028-03	Large scale culture of genetically modified animal cells in a Single-use bioreactor
CGM/101028-04	Classification of five alphaviruses
CGM/101109-03	Classification of three lyssaviruses
CGM/101117-01	Green house facilities for Kalanchoe blossfeldiana
CGM/101123-01	Classification of Streptococcus suis
CGM/101126-01	Experiments with genetically modified Macrostomum lignano flatworms
CGM/101213-02	Import and processing of genetically modified maize NK603xT25
CGM/101214-01	A field experiment with genetically modified apple trees

2011

CGM/110110-02	Commercial production of genetically modified animal cells in a single use bioreactor under MI-I conditions
CGM/110112-01	Request for amendment of a notification of a phase I/II clinical study with a conditional replicating adenovirus
CGM/110113-01	Additional advice on the renewal of the authorization for import and processing of genetically modified soybean 40-3-2
CGM/130111-02	Classification of the tropical plant Parasponia andersonii
CGM/110202-01	A small scale field experiment with potato plants with reduced susceptibility to Phytophthora infestans
CGM/110221-01	Classification of Escherichia coli strain W
CGM/110321-01	Classification of experiments with Crimean-Congo hemorrhagic fever virus
CGM/110322-01	Classification of the production of genetically modified Rift Valley fever virus
CGM/110325-01	Import and processing of cotton GHB614xLLCotton25
CGM/110330-01	Cultivation of genetically modified potato AV43-6-G7

ANNEX IV: COGEM PUBLICATIONS AND ACTIVITIES

(Titles translated)

2. GENERAL ADVICES (NOT LINKED TO SPECIFIC NOTIFICATIONS)

2008

CGM/080205-01	Classification of Equine infectious anemia virus (EIAV)
CGM/080923-01	Proposals for deregulation and to revision of the Dutch GMO Act
CGM/081107-01	Supplementary advice on the deregulation proposals
CGM/081125-02	Revision of the classification scheme for field trials with genetically modified plants

2009

CGM/090217-02	Advisory letter concerning the standardization of laboratory experiments to assess effects on non-target
CGM/090331-03	Laboratory experiments with lentiviral vectors
CGM/090625-03	Revision of the risk group classification of Hepatitis C virus
CGM/090709-03	Revision of the risk group classification of Bacillus anthracis
CGM/090818-03	Advisory letter 'Wind pollination in green houses'
CGM/091222-01	Advisory letter 'Novel plant breeding techniques'

2010

CGM/100225-02	Verification of the evidence for hybridisation between plant species
CGM/100323-01	Isolation distances and field experiments with genetically modified potato plants
CGM/100701-03	The status of oligonucleotides within the context of site-directed mutagenesis
CGM/100930-01	Developmental stages and viability of hybrid plants
CGM/100429-05	Response to the public consultation on the draft Scientific Opinion of the EFSA GMO Scientific Panel on the environmental risk of GM plants
CGM/101026-06	Gene therapy with naked DNA

2011

CGM/110114-01	Comments on the European Food Safety Authority draft guidance on selection of comparators for risk assessment of genetically modified plants
CGM/110124-01	Comments on the European Food Safety Authority revised 'Guidance on the risk assessment of genetically modified micro organisms and their food and feed products'
CGM/110214-02	Comments on the 'Guidance on the environmental risk assessment of GM plants' and on the 'Scientific opinion on the assessment of potential impacts of GM plants on NTO's
CGM/110311-03	Opinion on the 'Guidance on risk assessment of living modified organisms' of the Convention on biodiversity

3. TOPIC REPORTS & LETTERS

TOPIC REPORTS

2008

CGM/080201-01	Genetically modified crops and a sustainable agriculture
CGM/080925-01	Biological machines? To anticipate on the future developments in the synthetic biology
CGM/081219-01	Revision of the criteria for the molecular characterisation of genetically modified plants (market release notifications)

ANNEX IV: COGEM PUBLICATIONS AND ACTIVITIES

(Titles translated)

2009

CGM/090616-02 Zinc finger on the pulse. Developments and implications of zinc finger technology
CGM/090626-03 Should EU Legislation Be Updated? Scientific developments throw new light on the process and product approaches
CGM/090929-01 Socio-economic aspects of GMOs. Building blocks for an EU sustainability assessment of genetically modified crops
CGM/091214-01 Off-label use of GM-medicines: a mixed blessing?

2010

CGM/100226-01 General Surveillance
CGM/101230-01 Captivated by freedom of choice: an exploration of the development and role of freedom of choice on GMOs in Europe

TOPIC LETTERS

2008

CGM/080613-01 Presentation of and considerations to the research report 'Evidence-based biosafety'
CGM/080625-01 Presentation of and considerations to the research report 'ggo-beoordelingsregimes'
CGM/080627-04 An analysis of the gmo-debate in the EU'
CGM/081007-04 Presentation of and considerations to the research report 'Analyse Mediaberichten'
CGM/081028-04 Cisgenics and food safety risk analysis

2009

CGM/090224-02 Presentation and considerations to the research report 'Global Change and Biotechnology'
CGM/090312-01 Presentation and considerations to the research report 'Costs for marketing authorization of GM crops in the EU and the USA'
CGM/090626-01 The need for research to shedding during gene therapy experiments
CGM/091216-04 Presentation and considerations to the research report 'Admixture of GM and non-GM crops at import. Overview, insight and supervision'

2010

CGM/100225-03 Exemption of the GMO legislation: societal aspects
CGM/100311-01 COGEM opinion on the research report 'Efficacy of strategies for biological containment of transgenic crops'
CGM/100407-02 COGEM opinion on the research report 'Transport chains and seed spillage of potential GM crops with wild relatives in the Netherlands'
CGM/100428-01 COGEM opinion on the research report 'Politics in converging technologies'
CGM/100628-01 COGEM opinion on the research report 'A baseline study of the distribution and morphology of Brassica rapa L. in the Netherlands
CGM/100929-01 COGEM opinion on the research report 'Anticipating the Environmental Risk Assessment of crops modified to enhance or preserve yield'
CGM/101129-01 COGEM opinion on the research report 'International medical tourism from the Netherlands for gene therapy'
CGM/101223-03 COGEM opinion on the research report 'Inventory of observed unexpected environmental effects of genetically modified crops'

ANNEX IV: COGEM PUBLICATIONS AND ACTIVITIES

(Titles translated)

2011

CGM/110112-02 Topic letter with the research report 'Replication-competent non-human viruses for use in clinical gene therapy: an inventory study'

CGM/110302-02 Topic letter with the research report 'Survey on the implementation of Directive 2009/41/EC: regulations in Europe on the contained use of genetically modified organisms'

4. OTHER PUBLICATIONS

Trendanalysis biotechnology 2009, jointly published with the Health Council of the Netherlands and CBD
Trendanalysis Biotechnology 2009. Mondial momentum

Mondial motivation or European individuality? Four scenarios for GMOs in the European agriculture (2010)
Scenario study jointly published with the Rathenau Institute

5. RESEARCH REPORTS COMMISSIONED BY COGEM

2008

CGM 2008-01 Designing experimental protocols to investigate the impact of GM crops on non-target arthropods
D. S. Charleston & M. Dicke (Laboratory of Entomology Wageningen University and Research Centre)

CGM 2008-02 Evidence-based biosafety: a review of the effectiveness of microbiological containment measures
T.G. Kimman, E. Smit & M. Klein (National Institute of Public Health and the Environment (RIVM))

CGM 2008-03 Bacteriophages: therapeuticals and alternative applications
R.A.A. van der Vlugt & M. Verbeek (Plant Research International)

CGM 2008-04 Posities van Wereldblokken inzake Biotechnologie
H. de Vriend, Y. Heldens, R. Nijskens, C. Pan & W. Vos (LIS Consult)

CGM 2008-05 Dossierkosten markttoelating gg- gewassen in de Verenigde Staten en de Europese Unie
P. Schenkelaars (Schenkelaars Biotechnology Consultancy)

CGM 2008-06 Global Change and biotechnology
H. van den Belt, A. Jansen, F.W.J. Keulartz, F. Valkema & C.N. van der Weele (Wageningen UR & Schuttelaar en Partners)

2009

CGM 2009-01 Pollen flow out of greenhouses for wind-pollinated species, in the context of current GM containment regulations in the Netherlands
T. van Hengstum, D.A.P. Hooftman & P.H. van Tienderen (University of Amsterdam)

CGM 2009-02 Novel plant breeding techniques. Consequences of new genetic modification-based plant breeding techniques in comparison to conventional plant breeding
J.G. Schaart & R. G. F. Visser (Wageningen University and Research Centre)

CGM 2009-03 Admixture of GM and non-GM crops at import. Overview, insight and supervision
A. Jansen & D. Thelen (Schuttelaar en Partners)

ANNEX IV: COGEM PUBLICATIONS AND ACTIVITIES

(Titles translated)

2010

CGM 2010-01	Efficacy of strategies for biological containment of transgenic crops *R.A. de Maagd & K. Boutilier (Wageningen Universiteit en Researchcentrum)*
CGM 2010-02	Transport chains and seed spillage of potential GM crops with wild relatives in the Netherlands *W.L.M. Tamis (CML, Universiteit Leiden) & T.J. de Jong (IBL, Universiteit Leiden)*
CGM 2010-03	A baseline study of the distribution and morphology of Brassica napus L. and Brassica rapa L. in the Netherlands *S.H. Luijten & T.J. de Jong (IBL, University Leiden)*
CGM 2010-04	Politics in converging technologies *G. Ruivenkamp & J. Jongerden (Wageningen Universiteit)*
CGM 2010-05	Anticipating the Environmental Risk Assessment of crops modified to enhance or preserve yield *P.L.J. Rüdelsheim & G. Smets (Perseus BVBA)*
CGM 2010-06	Gene therapy with naked DNA: Potential steps towards deregulation *J.H. van den Berg & J.B.A.G. Haanen (The Netherlands Cancer Institute)*
CGM 2010-07	International medical tourism from the Netherlands for gene therapy *Schenkelaars Biotechnology Consultancy*
CGM 2010-08	Inventory of observed unexpected environmental effects of genetically modified crops *L. van den Brink, C.B. Bus, A.C. Franke, J.A.M. Groten, L.A.P. Lotz, R.D. Timmer & C.C.M. van de Wiel (Wageningen UR)*
CGM 2010-10	Replication-competent non-human viruses for use in clinical gene therapy: an inventory study *D. Koppers Lalic & R.C. Hoeben (Leiden University Medical Center)*

2011

CGM 2011-01	Drivers of consolidation in the seed industry and its consequences for innovation *P. Schenkelaars (Schenkelaars Biotechnology Consultance), H. de Vriend (LisConsult) & N. Kalaitzandonakes (University of Missouri)*
CGM 2011-02	Survey on the implementation of Directive 2009/41/EC: regulations in Europe on the contained use of genetically modified organisms *(Ameco Adviesgroep Milieubeleid & Horizons Consultancy bureau)*
CGM 2011-03	Gene Therapy in China. From a Dutch perspective *L.C.M. Kaptein, Yuedan Li & G. Wagemaker (Erasmus MC)*
CGM 2011-04	Hybridisation and introgression between Brassica napus and Brassica rapa in the Netherlands *S.H. Luijten & T.J. de Jong (Institute of Biology Leiden, University Leiden)*

6. SYMPOSIA AND WORKSHOPS

02-10-2008	The new GMO debate: a clash between legislations, The Hague
13-05-2009	Workshop forecast study 'GMOs in Dutch Agriculture', The Hague
19-01-2010	Presentation of the Trendanalysis biotechnology 2009, The Hague
20-01-2011	GM virus as medicine. Panacea or Pandora's box?, Amsterdam

ANNEX V: CRITERIA FOR PRESS RELEASES

- The basic reason for issuing a press release is that it will contribute to positioning COGEM as an independent scientific advisory body.
- COGEM does not express any political, social or other opinions, but bases its statements on 'facts', research results and its topic reports and advisory reports.
- COGEM only issues press releases about its own publications and does not react to publications by others. Press releases focus on the content of COGEM publications.
- An exception to this can be made when false information about COGEM is disseminated which damages COGEM's reputation and functioning. In these cases, COGEM responds to the substance of such allegations and does not take a position against third parties.
- Press releases are not issued with the aim of attracting as much media attention as possible or to maximise the number of times COGEM is mentioned. Substance is paramount. It is on or through the substance of debates that COGEM seeks to profile itself.
- COGEM must be able to explain or comment on the information presented in its press releases (in response to queries by journalists) and provide background information.
- Before any press release is issued, ask why it is being issued and what COGEM wants to achieve. There must be a clear reason and objective for bringing out a press release.
- Press releases must be of interest to the press; they must newsworthy. Issuing as many press releases as possible is counterproductive. In addition, press releases must satisfy the usual requirements (the 'who, what, where, when, why and how' criterion.
- The procedure to be followed when issuing COGEM press releases is:
  - The press release is drafted by the secretariat (whose members have been trained in writing press releases).
  - The draft press release is then submitted to the members of the Executive Board for comments.
  - The final version of the press released is decided by the COGEM chair.
  - No later than one day before the press release is issued, copies are sent to the Ministry of Infrastructure and the Environment for information.