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COGEM REPORT
CGM/141222-01

BUILDING BLOCKS FOR AN ASSESSMENT FRAMEWORK FOR THE CULTIVATION OF GENETICALLY MODIFIED CROPS

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

To the Minister of
Infrastructure and the Environment
Ms. W.J. Mansveld
P.O. Box 20901
2500 EX The Hague

DATE	22 December 2014
REFERENCE	CGM/141222-01
SUBJECT	Presentation of report 'Building blocks for an assessment framework for the cultivation of genetically modified crops'

Dear Minister,

I would like to present you with the report 'Building blocks for an assessment framework for the cultivation of genetically modified crops (CGM/141222-01).

SUMMARY

To break the deadlock in Europe surrounding the decision-making process on genetically modified (GM) crops, the European Union is working on an amendment to the legislation to provide member states with the competence to restrict or prohibit cultivation in their own territory on the basis of considerations other than safety. In this way the EU wishes to defuse the safety discussion and provide member states with the possibility of restricting or prohibiting cultivation. Since 2010 the EU has been working on a proposal to amend Directive 2001/18/EC to provide national cultivation competence for GMOs. On the basis of the proposal member states must determine how they will implement this in national legislation.

At the request of the then Minister of Housing, Spatial Planning and the Environment (VROM), COGEM published a report in 2009 which provided building blocks for a sustainability assessment framework for GM crops. In the context of the European proposal COGEM was requested by your Ministry in July 2014 to examine that report once more and update it where necessary to reflect the Dutch situation, also in the context of the national cultivation proposal. The original report was written on the basis of a worldwide perspective. This report looks at which building blocks may be relevant to the Dutch situation and to what extent these aspects are covered by existing legislation. A number of considerations were also identified concerning decisions that have to be made before an assessment framework can be arrived at. For the purposes of preparing this report, COGEM organised an international workshop 'A socio-economic assessment framework for GMOs' to exchange ideas, experience and insight with scientists and policy-makers from other EU member states.

The complete report is enclosed herewith as an attachment..

Yours sincerely,

Prof. dr. ing. Sybe Schaap
COGEM Chairman

SUMMARY

This report is an update of the nine building blocks identified by COGEM in 2009 for the sustainable use of genetically modified organisms (GMOs) in agriculture. These building blocks were formulated at the time on the basis of a worldwide perspective and irrespective of what had already been laid down or not in Dutch legislation. The present report looks at which building blocks may be relevant for the assessment of the desirability (or otherwise) of the cultivation of GM crops in the Netherlands.

The background to this report is the proposal by the European Commission (EC) to amend the legislation so that member states are given the opportunity to prohibit GM crops on their territories on the basis of considerations other than safety. The EC proposal provides an indicative list of seven elements on which basis member states can institute a restriction or prohibition. The member states must decide whether, and if so, how, they intend to implement the proposal at national level.

This report has produced a list of elements which may be relevant to the cultivation of GM crops in the Netherlands. These comprise a selection or combination of the nine building blocks from the 2009 report plus the seven aspects from the national cultivation plan. A number of the building blocks have already been fully or partially incorporated in the European and Dutch legislation and are therefore less relevant in the context of a supplementary Dutch assessment framework further to the EC proposal.

This report does not provide an assessment framework. Neither has the operationalization of the various potential building blocks been touched upon. A number of concerns and considerations have been identified, however, in relation to the decisions which will have to be made before developing a supplementary assessment framework. These concerns and considerations arise from the previous report and from the international workshop that COGEM organised for the purpose of this report. COGEM notes that the European and national debate on the interpretation and implementation of the compromise submitted to the Council and Parliament for approval was still in progress while this report was being updated. Based on developments and the results of this process, one or more points in this report could be further expanded upon on in the future.

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INTRODUCTION

In an attempt to break the deadlock in Europe surrounding the decision-making process on genetically modified (GM) crops, the European Union is working to change the legislation. The aim of this is twofold: to provide member states with the possibility of allowing GM crops which meet the set safety criteria to be cultivated in their own territory and to provide them with the competence to restrict or prohibit cultivation in their own country based on considerations other than safety. In this way the EU wishes to take the heat out of the safety discussion.
In 2010 the European Commission (EC) submitted a proposal for a regulation to amend Directive 2001/18/EC to the Council of Ministers of the European Union (hereafter Council) and the European Parliament (EP). This original proposal by the European Commission has been the subject of a long-drawn out debate in recent years. In a tripartite discussion[a] in December 2014 the Commission, Council and Parliament arrived at a political compromise on a final text. It appeared at the COREPER meeting on 10 December that the member states could agree to the compromise.[1] It is expected that the European Parliament will vote on the proposal early in January 2015,[2,3] followed shortly thereafter by the Council. If the proposal is adopted it can enter into force in the EU 20 days after publication in the Official Journal of the European Union. The member states must then decide whether, and if so, how, they will implement the amendment to the directive in the national context. The member states are free to decide whether or not they will implement the amendment in their own legislation.
During the writing of this report, the text of the amended Directive had not yet been formally adopted, nor was it publically available. Therefore in this report reference is made to the text of the proposal as discussed by the European Parliament on 23 July. Further in this report this will be indicated by the expression 'national cultivation proposal' or 'the EC proposal'.

The former minister of Housing, Spatial Planning and the Environment (VROM), Jacqueline Cramer, asked COGEM in 2009 to publish a report on the socio-economic aspects of activities involving the use of GMOs in agriculture, and sustaina-

a The tripartite discussion in the European context is an informal meeting at which delegations from the European Commission, the European Parliament and the Council of Ministers negotiate on proposed legislation.

bility in particular.[4] In the context of the national cultivation proposal COGEM was requested in July 2014 by the Ministry of Infrastructure and the Environment (IenM) to examine its report once more and update it to reflect the Dutch situation where necessary.
The original report was drawn up on the basis of a worldwide perspective in relation to both cultivation and import. This update looks at which building blocks may be relevant to the Dutch situation, i.e. the cultivation of GM crops in the Netherlands, and to what extent the aspects identified are covered by existing legislation. A number of considerations have also been identified in connection with the decisions which have to be made in the run up to a possible assessment framework. In preparation for this report, COGEM organised the international workshop 'A socio-economic assessment framework for GMOs' to exchange ideas, experience and insight with scientists and policy-makers from other EU member states.

Given the limited time frame and the complexity of the context in which updating the report from 2009 had been requested, it has by necessity been limited to a preliminary review of the applicability of the previously formulated building blocks to the Dutch situation in the light of the European proposal. Further round of refinement or development will be necessary to identify those elements which could actually be included as part of a supplementary assessment framework. In consultation with the ministry during the course of 2015 COGEM will consider whether it can make a further contribution to this process.

1.1 COGEM REPORT 2009

In its report "Socio-economic aspects of GMOs: Building blocks for an EU Sustainability Assessment of Genetically Modified Crops" COGEM identified and described nine building blocks which could play a part in assessing the contribution that GM crops could make to 'more sustainable' agriculture. The report was drawn up in the context of the European debate on the socio-economic impact of GM crops.[5] The members states were asked to provide input to identify both the positive and negative consequences arising from the cultivation of GM crops. Sustainability aspects referred to social, economic and ecological aspects. These aspects are closely interrelated and cannot be seen as separate from one another. The nine building blocks in this report were:

1. **Benefit to society**
   Elements: harvest security, food security, food quality, environmental benefit, cost saving, recreation.
2. **Economics and prosperity**
   Elements: employment, efficiency of the production process, productivity and profit.
3. **Health and welfare**
   Elements: human rights, the working environment and employment terms.

4. **Local and general food supply**
   Elements: food security and fair trade.
5. **Cultural heritage**
   Elements: local customs and traditions, autonomy of the local population
6. **Freedom of choice**
   Elements: GMO (or GMO-free) labelling of products, product information, co-existence and innovation, and research freedom.
7. **Safety**
   Elements: food safety and environmental safety.
8. **Biodiversity**
   Elements: agrobiodiversity, protected or vulnerable biodiversity, places of origin of agricultural crops.
9. **Environmental quality**
   Elements: emissions of hazardous substances to the soil, surface water and air, soil fertility and resilience.

The summary of the COGEM report 'Socio-economic aspects of GMOs: Building blocks for an EU sustainability assessment of genetically modified crops' (CGM/090929-01) has been included as **Annex B** to this update.

1.2 NEW CONTEXT: THE NATIONAL CULTIVATION PROPOSAL

The context in which the present report was prepared is quite different than that of the report from 2009 and was drawn up in relation to the national cultivation proposal that provides member states with the possibility of prohibiting GM crops on their territory on the basis of considerations other than the safety considerations.
The admittance of GM crops is regulated Europe-wide and based on an assessment of food and environmental safety. The desirability of GM crops however is also has national, regional and local dimensions to it, and is linked to land use, local agricultural systems and the protection or conservation of heritage landscapes. The European Commission's proposal to amend Directive 2001/18/EC was made to enable the decision-making on cultivation to take place in the individual member states on the basis of these aspects. The proposal is intended to:

- Facilitate the decision-making process in the area of GMO cultivation
- Maintain freedom of choice for consumers, growers and businesses
- Provide clarity to stakeholders concerned with the cultivation of GMOs in Europe
- Facilitate a properly functioning internal market

The EC proposal amended by the Council and Parliament provides for a possible 'opt out' in two steps in which EU member states can, in the first instance, request the

applicant or notifier (via the EC) to exclude its territory from the geographical scope of the permit application (Step 1: Article 26b.1 Adjustment of geographical scope). If the applicant/notifier opposes this, then on the basis of aspects other than safety considerations member states can adopt measures restricting or prohibiting the cultivation of the specific crop in all or part of its territory (Step 2: Article 26b.3 Compelling grounds for restrictions/prohibitions). A clause providing transition arrangements has been included for existing permits and pending applications.
The safety assessment remains an EU-wide assessment and therefore also the first requirement for the admittance of a GM crop. To ensure that the functioning of the internal market is not hindered, matters related to the market admittance and import of GMOs will continue to be regulated at EU level.
Step 1 requires no statement of reasons or legal basis. For a national decision (Step 2), under the EC proposal a statement of reasons is required in additional to a number of other requirements, as long as it does not contravene EU legislation. Furthermore, a national decision must rest on a competence which has been laid down in national legislation; the legal basis. Member states are themselves responsible for taking measures which are legally valid and in conformity with the WTO. The measures must be proportional, non-discriminatory and substantiated. They must also be based on a specific, case based assessment, i.e. targeted at one GM crop and for one area. In addition, the measure may not conflict with the EU environmental risk analysis. The EC proposal includes a non-exhaustive list of grounds on which member states may limit GMO cultivation.

1. Environmental policy goals other than those assessed under EC Regulation no. 1829/2003
2. Spatial (town and country) planning
3. Land use
4. Socio-economic impacts
5. Avoidance of GMO presence in particular products
6. Agricultural policy objectives
7. Public policy (only in combination with 1-6 or others)

To make use of Step 2 of the national cultivation proposal member states must on the basis of national legislation take a decision in which they 1) indicate that they do not wish to cultivate a crop and 2) stating on which non-safety related grounds their argument for this decision is based. Furthermore the European Commission must be informed of the intended decision in advance, which it may comment on, although this does not obligate the member state to take this commentary into account in the final decision.

1.3 INTERNATIONAL WORKSHOP

COGEM organised an international workshop on Thursday 20 November 2014 to gather input for this report. The aim of the one-day workshop was for scientific experts

and policy-advisors to exchange ideas, knowledge and experience about the elements which may be relevant for a supplementary assessment framework for the cultivation of GM crops. Attending the workshop were 42 participants from 11 different countries. The workshop consisted of a number of presentations and provided an opportunity for discussion on three main topics. Firstly, how member states view the possibility of restricting or prohibiting GMOs in their territory on the basis of the EC proposal. Secondly, the challenges surrounding the identification, qualification and quantification, operationalization and monitoring of non-safety considerations, and thirdly, experience with socio-economic evaluation frameworks in other fields. A report on this workshop is included in **Annex A** to this report.

1.4 FIRST: CONCERNS AND CONSIDERATIONS

This section will discuss a number of concerns and considerations which may be relevant to the development of an assessment framework for the evaluation of GMOs on the basis of other considerations than safety. These considerations were also derived from the previous report, and during the discussions at the 'International Workshop on a socio-economic assessment framework for GMOs'.

1.4.1 ASSESSMENT FRAMEWORK: PURPOSE, TYPE AND CONDITIONS

Socio-economic assessment frameworks are generally based on an analysis of the environmental or health risks, economic risks and risks to society which are then weighed against the possible benefits of a technology or development. The approach of the national cultivation plan is based on a situation in which no environmental or health risks have been identified, but member states still have recourse to other grounds for restricting or prohibiting the cultivation of a GM crop without weighing this against possible benefits. This provides those member states who wish to have it, with the possibility of shifting from a 'yes, provided (that a GM crop is safe)' to a 'yes, unless (there are reasons other than safety considerations for prohibiting a GM crop)' approach[b].

A 'yes, unless' or a 'yes, provided' approach requires an assessment framework with different considerations than a 'no, unless' approach as used in the Netherlands for biotechnology activities involving animals. With a 'no, unless' assessment framework there have to be (compelling) reasons for nevertheless permitting a biotechnological

b There are two distinct approaches to the assessment of activities: 'Yes provided that certain rules are met' or 'No, unless there are nevertheless compelling reasons to undertake the activity'. A third half-way option is 'Yes, unless' in which a 'Yes' is subject to additional criteria or conditions to be met. 'Yes, unless' essentially means: Yes, provided the rules have been met, but there may be additional grounds for saying no anyway.

activity, for example. Given the purpose and type of assessment framework for a supplementary assessment of GM crops, COGEM notes the following:

- In selecting an assessment framework it is necessary to look at whether the framework is more suitable for gaining insight into the impact of admitting a GMO crop or whether it is to play a key role in the decision-making process on GMO cultivation (i.e. a decision-making framework).
- A practical assessment framework must be proportional, non-discriminatory, case specific, legally tenable, understandable, transparent, efficient and workable.
- If considerations other than safety in the assessment of GM crops do not meet these conditions or a framework is selected which is unsuitable for the intended purpose, this can lead to an unworkable situation.

1.4.2 LEGALLY TENABLE: THE NETHERLANDS, EUROPE AND THE WTO

If an applicant (or notifier) does not agree with a request (Step 1) by a member state to be excluded from the geographical scope of the market application for the cultivation of a GM crop, a member state still has the possibility of prohibiting cultivation on its territory. It then has to provide reasons based on considerations other than safety indicating why it wishes to restrict or prohibit cultivation of the GM crop concerned. These reasons must be legally tenable in three areas:

1. The reasons must meet the amended Directive 2001/18/EC and other relevant EU legislation.
2. A national decision and the reasoning must be based on a competence which has been laid down in national legislation, i.e. the legal basis. The reasons must be legally tenable and able to withstand a judicial review in the event that:
   - Permit applicants challenge a national decision to prohibit cultivation.
   - Third parties turn to the courts if the cultivation of a GM crop is not prohibited.
3. The grounds must also be tenable in the context of international agreements and treaties which the EU has committed itself to, such as that of the World Trade Organisation (WTO). It should be noted that when a member state resorts to Step 2 of the amended directive, it is itself responsible for the legal tenability of the argumentation. This probably also means that if a complaint is submitted to the WTO, the member state itself will be a party to the conflict in any legal proceedings.

1.4.3 MEASURABILITY AND SPECIFICITY

The substantiation and quantification of the arguments in Step 2 of the national cultivation plan may be complex and will, among other things, depend on the data avail-

able. A pitfall may be that too much emphasis is placed on measurability and 'objectively' quantifiable factors and while factors which are more difficult to quantify are left out of the arguments or assessment framework. Existing assessment frameworks may offer useful insights for a supplementary evaluation framework for the cultivation of GM crops in the Netherlands. In should be noted however that the debate on genetic modification centres on fundamentally-held objections and beliefs. It is practically impossible to include such arguments in many of the existing assessment frameworks. COGEM notes the following:

- The results of studies on GMOs in general are regularly the subject of debate in which those concerned often do not agree on the conclusions and the consequences arising from these conclusions. COGEM published a report in 2013 on how this affects the public and scientific debate on GMOs.[6]
- Similar discussions will arise on the non-safety-related aspects of GMOs in which various studies, models, calculation methods and results concerning the impact of GM crops will be put forward. Those involved must at least be aware of the various pitfalls that these sorts of discussions bring.
- In relation to specificity the arguments must be based on effects as a result of the specific nature of the GM crop, and which have not yet been laid down in existing EU legislation. The rejection of a GM crop on the basis of arguments other than safety, while this applies to the same degree to conventional crops which are not assessed on the basis of these criteria, could encounter incomprehension or face legal examination.

Besides (essentially) quantifiable effects, less quantifiable effects also play a role in public opinion. The question is how to include these more qualitative effects in an assessment. Moreover, how can effects of different orders be compared with one another. COGEM notes that any national assessment framework, therefore, will also have to take into account:

- **Quantitative and qualitative effects.** Economic, social and physical effects are generally are both quantitative and qualitative in nature. Some economic effects, for example, can be expressed in monetary or other quantifiable terms (e.g. no. of employees, working hours, hourly pay rate in euros, revenue in euros/tonne), but others, such as innovative ability or competitiveness are much more difficult if not impossible to quantify. Social effects can be partially expressed quantitatively (e.g. in no. of unemployed, no. of people living in poverty or on social security benefits), but social exclusion, or happiness, for example, are much more difficult to quantify. The same applies in particular to personal values and standards, such as integrity, justice and equality. In the physical environment, for example, it is possible to count the number of trees in a field or birds in the air, but not the perceived value of such.
- **Reversible and irreversible effects.** Reversible effects come to an end when the activity which causes the effect stops (whether positive or negative). Irreversible effects are final and have more definitive costs or benefits.

- **Distribution of effects.** The benefits or drawbacks or a particular development can accrue to various stakeholders. The consequences can even differ within a group such that the benefits accrue to part of the group while the costs are felt by another part. A new market introduction inherently has concomitant micro-economic and competitive benefits and drawbacks. The distribution of the benefits and costs between growers, consumers, food manufacturers, retailers, and technology developers can make an assessment even more complex.
- **Uncertainties with regard to effects.** The qualification and quantification of various types of effects is complex, data is not always available and the analysis is often partly based on assumption which may be subject to change. With regard to quantitative analyses it should be noted that these are generally limited in scope/applicability and can only ever be as 'good' as the input data used. If the data is insufficient or based on incorrect assumptions, this also undermines the analysis.
- **The possibilities and limitations of ex ante or ex post assessments.** Empirical information is to some extent available for GM crops which have already been cultivated for some time, such as soy and maize. For new GM crops with different properties, the impact on aspects such as welfare, employment or local food production, will probably be more difficult to estimate or quantify. On top of which the impact of the cultivation of a particular crop also depends on the area where it is cultivated. Economic, environmental and social situations, too, can vary from one area to another. Ex ante provisions are particularly difficult because there is little experience with the cultivation of GM crops in Europe. Data analyses are therefore often based on the extrapolation of data from other countries. The results and applicability of such analyses are regularly contested.
- **The possibilities and limitations of various types of analyses.** The input for an assessment framework could be drawn from various analyses each of which has its own advantages and limitations. The following analyses, for example, could play a part in this: cost/benefit analysis, break-even analysis, multi-criteria analysis, compliance cost analysis, qualitative or quantitative impact evaluation, life cycle impact assessment, costs and benefits to society analysis (MKBA) or scenario analysis.
- **Value to society plays** an important part and is closely linked to sustainability which generally centres on the elements of 'people, planet and profit'. If these three elements are not linked developments will not be sustainable or lasting.

A questionnaire was developed in Norway which could be used to flesh out the aspect of 'value to society' (see text box: **Assessing value to society for the Norwegian Gene Technology Act**).[7]

ASSESSING VALUE TO SOCIETY FOR THE NORWEGIAN GENE TECHNOLOGY ACT

Based on the Norwegian Gene Technology Act (1993) the decision-making process concerning the import or cultivation of GMOs had to include an assessment of whether the GMO and its use makes a contribution to sustainable development, offers a benefit to society and whether the application is ethically permissible. This was expanded upon in a recent report by the Norwegian Biotechnology Advisory Board (NBAB).[8] The report sets out a series of questions which can aid in determining the contribution made by a GMO to sustainable development, value to society and accountability, such as:

- **What problem does the GMO intend to solve?**
- **Is there a need for the product?**
- **What alternatives are available for solving this problem?**
- **Is the GMO more suitable to solve the problems than existing alternatives?**
- **What problems could arise if this GMO fails to resolve the problem concerned?**
- **Will the product lead to more employment? (own country or abroad)**
- **Could admittance of the GM crop lead to problems with existing production?**

In the Netherlands too, there have been initiatives in this area, such as the costs and benefits to society analysis (see text box: Costs and Benefits to Society (MKBA).

COSTS AND BENEFITS TO SOCIETY ANALYSIS (MKBA)

An MKBA analysis identifies the positive and negative effects of a project or policy option on economic prosperity and welfare in the Netherlands.[9] This looks not just at the financial costs and benefits but also the impact on society of a project, e.g. noise nuisance or nature areas. Such a study can help to increase insight into the effects of a project and support decisions on whether or not to undertake projects. A costs and benefits to society analysis (MKBA) generally comprises the following steps:

- **Problem analysis: what problem is the 'project' intended to solve?**
- **A survey of the present situation: 'the baseline alternative'**
- **Comparing project alternative with baseline alternative by looking at physical impacts (e.g. on biodiversity, recreation and health, co-existence, pesticide use or damage due to crops diseases/pests).**
- **Monetizing the effects: expressing the effects from the previous step in monetary terms.**
- **Converting the costs and benefits to one base year.**
- **Drawing up an MKBA report which focuses not only on the results but also relevant quantitative or qualitative information which cannot be reliably expressed in monetary terms.**

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Distribution effects would also be described (i.e. effects on various actors, such as regions, municipalities or purchasing power groups). Future scenarios and sensitivity analyses can be used to reveal uncertainties surrounding effect estimates.

2

UPDATING OF THE BUILDING BLOCKS FOR AN ASSESSMENT OF GM CROPS IN THE NETHERLANDS

This chapter combines the building blocks in the COGEM report from 2009 where possible with the seven grounds provided for in the national cultivation proposal (see Table 1: **Integration of COGEM building blocks 2009 and national cultivation proposal grounds**). The building blocks in the report were wide-ranging and covered all aspects which a GM crop should meet to contribute to greater sustainability in agriculture. Some of these aspects have already been laid down in the existing legislation and regulations. Other aspects are partly provided for in the legislation or are less relevant to the Netherlands because of the nature of the agriculture and the crops grown. Based on the table, this chapter provides a description of each of the building blocks, their relationship to the grounds from the national cultivation proposal and the possible components which may touch upon these.

TABLE 1: INTEGRATION OF COGEM 2009 BUILDINGS BLOCKS WITH NATIONAL CULTIVATION PROPOSAL GROUNDS

Building blocks COGEM 2009	National cultivation proposal grounds	Non-exhaustive list of components
1. Benefit to society*		*Overarching: found in one or more of the other building blocks
2. Economy and prosperity	Socio-economic Agricultural policy objectives	☐ employment ☐ efficiency of production processes ☐ productivity ☐ income ☐ competitive position ☐ export (balance of trade) ☐ damage to reputation ☐ Intellectual Property Rights (IPR)
3. Health and welfare	Socio-economic	✓ human rights ✓ working conditions ✓ employment terms ☐ recreation ± food quality
4. Food supply & food security	Agricultural policy objectives	☐ ecological footprint
5. Cultural heritage	Spatial (town and country) planning Land use	☐ landscape changes ☐ changes in land use
6. Freedom of choice & co-existence	Preventing cross-breeding Agricultural policy objectives	✓ consumer freedom of choice: labelling ± manufacturers' freedom of choice: co-existence ☐ damage to reputation/conflicts ☐ regional food production
7. Safety		✓ food and environmental safety
8. Biodiversity	Environmental policy objectives Agricultural policy objectives	☐ agrobiodiversity ✓ protection of biodiversity
9. Environmental quality	Environmental policy objectives Agricultural policy objectives	☐ energy consumption ☐ emission of hazardous substances to soil, surface waters and atmosphere ☐ soil fertility, and resilience ☐ Integrated Pest Management (IPM)
	Public policy*	*Overarching: together with one of the other grounds

✓ Covered by legislation and regulations in force
± Partly covered by legislation and regulations in force

2.1 ECONOMY AND PROSPERITY

The production and use of GM crops contributes to the general and local economy and prosperity. Components: employment, efficiency of production process, productivity, income, competitive position of the Netherlands, exports (balance of trade), damage to reputation, Intellectual Property Rights (IPR).

National cultivation proposal: socio-economic, agricultural policy objectives

The factors under economy and prosperity in the report dating from 2009 were in the first instance associated with developing countries in relation to such elements as productivity and income. In the context of these building blocks for the Dutch situation the focus can be placed on the economic benefits and drawbacks in the Netherlands. This analysis should ideally look at the overall macro-economic impact on Dutch society. Micro-economic advantages or indeed disadvantages are inherent to any successful commercial market introduction. Bother the supplier (breeder) and the buyer (grower) must perceive a benefit, competitors on the other hand will perceive a successful market introduction to be a drawback. The same applies to all technological developments where the socio-economic effects are distributed over various stakeholders. Certain groups, for example, may find technological advances to be undesirable, because they generate less income as a result. Others, however, will judge that the introduction makes the production process more efficient and has a cost saving effect. This process is also referred to as creative destruction.

The influence on productivity (increase in yield) and income could play a role in the Netherlands. This will involve weighing up whether the GM crop concerned brings sufficient added value compared to the additional costs which will have to be incurred for its introduction into the agricultural system (such as the costs for co-existence). Some of the effects which could occur as a result of the introduction of GM crops would also apply to changes in conventional cultivation. Possible specific elements involved in the cultivation of GM crops are the costs for co-existence, the competitive position of the Netherlands, exports (balance of trade) and any damage to reputation as a result of cultivating GM crops (or not).

These building blocks can be linked to the grounds of 'socio-economic'[c] and 'agricultural policy objectives' in the EC proposal on national cultivation competence. With regard to this aspect, the EC proposal makes reference to a European report on the socio-economic implications of GM crop cultivation. This report was drawn up based on the input of various member states, including the COGEM report from 2009.[10]

c There are various definitions and interpretations of the term 'socio-economic'. This could refer to a mix of social and economic factors related to the welfare and prosperity of society, or a broader range of factors which includes sustainability.

2.2 HEALTH AND WELFARE

The production and use of GM crops contributes to the health and welfare of employees, the local population and consumers.
Components: human rights, working conditions and employment terms, recreation and food quality.

National cultivation proposal: socio-economic

Factors such as health and welfare in relation to agriculture were in 2009 primarily associated with developing countries and in relation to elements such as the working environment and employment terms, as well as food security. COGEM reported that, in general, these aspects were not (no longer) a topic of discussion in Europe and are covered by the comprehensive legislation and inspection authorities.
In the context of the Dutch situation the focus for this building block however could lie on other aspects related to health and welfare. Viewed from this perspective, for example, recreation (welfare) and food quality (health) may be relevant components.
As an example of food quality the incorporation of genes for the production of health omega-3 fatty acids could be mentioned, or a potato with a different composition as a result of which less acrylamide[d] is produced when it is fried.[11] The prevention of threats to health also falls into this category, such as the effects of mycotoxins[e]. Inhibiting the present of mycotoxins by reducing fungus resistance or insect damage (thereby reducing fungal attack) could make a contribution to health and welfare. Adverse consequences are also conceivable. For example, the presence of pesticide residues in food and food crops. Impoverishment of the landscape due to the introduction of GM crops which easily lend themselves to monocultures could have an adverse impact on perceptions of the landscape. This could also affect recreation and tourism (see Section 2.4 Cultural heritage).
This building block can be linked to the 'socio-economic' grounds in the EC proposal on national cultivation competence.

d Acrylamide is a substance which is produced when starchy foods, such as potatoes and grain are heated to above 100°C. Animal testing has shown that acrylamide can be carcinogenic in mice and rats, and therefore possibly in humans too. Source: Voedingscentrum (Dutch Food Authority for Consumers).

e Mycotoxins are natural toxins produced by soil fungi that occur on crops worldwide and form on batches of food even after harvesting. Mycotoxins in food can be damaging to health. Source: Voedingscentrum.

2.3 FOOD SUPPLY AND FOOD SECURITY

The production and use of GM crops will ensure that the food supply and food security of the country itself and beyond remains the same and could improve.
Components: ecological footprint

National cultivation proposal: agricultural policy objectives

This building block was formulated in the previous COGEM report as 'local food supply' and was linked to local food security, food traditions and the autonomy of local populations, particularly with a view to import also from developing countries. On this basis COGEM reported that in general this criterion is not (or no longer) the subject of discussion in Europe. In a broader and more international context, however, this building block is still relevant to the Netherlands' situation. The Netherlands imports products and raw materials from other countries. In particular the import of protein-rich raw materials such as soy for animal feed is important to the Netherlands. Many animals are fed with this that are, in turn, exported as animal produce. A GM crop which could increase the production of protein-rich crops in the Netherlands or a crop that is resistant to certain pests or diseases could in various ways have an indirect effect on the food supply and food security in the Netherlands and elsewhere, for example:

- Reduced dependence of the Netherlands on other countries
- Reduction of the Netherlands' ecological footprint
- More land for food crops for own population in production countries
- Less income for production countries and transport chain due to reduction in exports

This building block can be linked to the grounds of 'agricultural policy objectives' in the EC proposal on national cultivation competence. Food security is one of the areas which the Netherlands expects to be able to contribute to in the context of the Implementation of the Common Agricultural Policy (CAP).[12]

2.4 CULTURAL HERITAGE

The production of GM crops in the land or region concerned could, if so desired, provide room for the conservation and continuation of certain cultural heritage features in the context of spatial planning and land use.
Components: landscape changes, land use

National cultivation proposal: spatial planning (town and country planning) and land use

In the previous COGEM report this building block was mainly coupled with local applications and food traditions and the autonomy of local populations in relation to agricultural production in relation to export and import in the Netherlands. In the context of the national cultivation proposal however cultural heritage could be thought of in the form of landscape and landscape changes. A typically Dutch landscape could be viewed as cultural heritage, e.g. consisting of fields and wooded banks. The crops cultivated in the Netherlands, such as maize and potato, over the course of time, have had a significant impact on the landscape and its appreciation by those living in the area and visiting it for recreation. If as a result of the introduction of a GM crop, other crops were to be cultivated, or the same crop in a different form (e.g. colour, height, rotation) or density, this could affect the landscape and public perceptions of the landscape. These changes could also be induced by new strains or species which have not been genetically modified. Changes in cultivation also have an impact on the cultivation management, such as soil tillage, weed control and resistance management. In 2012 COGEM had a survey carried out of possible changes in cultivation management further to the introduction of a few species of GM crops.[13]

This building block can be linked to the grounds 'spatial planning' (town and country planning) and 'land use'. In the EC proposal spatial planning (town and country planning) refers, among other things, to the conservation of specific or natural landscape features, habitat or ecosystems and ecosystem functions. For land use sustainable agriculture and forestry management were given as examples. Spatial planning relates to the planning and development of local, regional or national land (see text box: **Spatial planning**). Land use types also affect the ecological footprint based on the characteristics of the land use.[14] The potential or actual productivity of farmland, for example, will be more than that of grassland and much greater than building land.

SPATIAL (TOWN AND COUNTRY) PLANNING

Spatial planning can be defined as the process by which land is allocated and developed in accordance with a complex set of rules. The purpose of spatial planning is to coordinate society and the use of space on the basis of both individual and public interests. Planning, landscape architecture, urban planning, the environment and the economy all play important parts in this.[15] Central government, provinces and municipalities weigh up the various interests under the Spatial Planning Act (WRO).[16] The spatial planning developments envisaged by the State, provinces and municipalities are set out in policy strategy documents. In these documents they also indicate how they intend implementing or steering these developments. Central government does this in the National Policy Strategy for Infrastructure and Spatial Planning (SVIR). The zoning plan is the most important instrument in spatial planning. A municipality lays down in a zoning plan who may build what and where. As well as the scale of the built structure and what purpose an area may be used for, e.g. residential building, agriculture or nature.[f]

2.5 FREEDOM OF CHOICE

That consumers' and manufacturers' freedom of choice concerning GMO (or GMO-free) is safeguarded in the production of GM crops.
Components: consumer freedom of choice (labelling), manufacturer freedom of choice (co-existence), damage to reputation/conflicts, regional food production.

National cultivation proposal: preventing inadvertent admixture, agricultural policy goals

Freedom of choice is important to both consumers and manufacturers. Freedom of choice is largely regulated by a labelling requirement, among other things, and rules on co-existence. In 2010 COGEM published a report in which it considered the background to and the role of freedom of choice in relation to GMOs in Europe.[17] In that report COGEM noted among other things that labelling is key to the operationalization of freedom of choice but is not the complete answer. There are other factors connected with freedom of choice, these being information, education and trust.

f In 2012 the Nijmegen municipality adopted the citizens' initiative 'Nijmegen GMO- free zone'. The zoning plan was used to create a GMO-free zone under the Spatial Planning Act (WRO). A letter from former State Secretary Joop Atsma of the Ministry of Infrastructure and the Environment stated that regional GM crops cannot be prohibited or restricted other than as provided for under the European legislation concerned with safety considerations and co-existence.

Freedom of choice for producers is about the co-existence of GM crops alongside conventional or organic agriculture. If admixture should occur in the field due to outcrossing then an organic farmer could suffer economic loss. The co-existence regulation must prevent cross-fertilization from occurring (e.g. through the use of insolation distances) which would cause serious commercial damage to organic farmers. COGEM has published several reports and research surveys in the past on co-existence.[18],[19] Rules on co-existence for maize, potato and sugar beet have been laid down in the Netherlands in the co-existence regulation (see text box: **Co-existence in the Netherlands**).

CO-EXISTENCE OF GM CROPS IN THE NETHERLANDS

The Dutch regulation 'Crop Co-existence 2005' falls under the remit of the Agriculture Commodity Board (Hoofdproductschap Akkerbouw, HPA) and arose out of the 'Covenant on Co-existence in the Primary Sector'. Due to the abolition of the Commodity Boards from January 2015 this regulation has been transferred to the Ministry of Economic Affairs. An important part of the regulation concerned the setting up of a residual damage fund. In September 2008 former Minister of Agriculture, Gerda Verburg, announced that agreement had been reached about the residual damage fund for maize, potato and sugar beet.[20] This damage fund will be funded by the suppliers of basic agricultural materials to compensate farmers, growers and horticulturists for the damage caused by inadvertent admixing with GM crops for which no one can be held liable. In the event of economic damage at a primary business (or farm) where someone can be held liable, the damages can be claimed from this individual under the Civil Code. This agreement covers only damage due to admixture on the farm itself. A separate route would apply for 'damage further along the chain'.

Some of the aspects related to freedom of choice of the grower or producer have therefore been arranged. Rules have been established for the co-existence of maize, potato and sugar beet, but not for all crops which are (or could be) cultivated in the Netherlands. The question is whether similar agreements could be made for all crops. As COGEM indicated in a previous report, it would be difficult, for example, to establish isolation distances to prevent the cross-fertilization of rapeseed.[21] The components related to co-existence are closely linked to economic impacts. The costs for co-existence could rapidly mount for the GM grower, owing to the necessity to maintain isolation distances or incur additional costs for cleaning machines, for example, which will therefore have to be carefully weighed against the benefits of a GM crop. These considerations will to some extent be taken care of by the market mechanism. Admixture however could also damage to the reputation of a business and lead to conflicts between adjacent businesses. This type of damage is more difficult to quantify.

With regard to freedom of choice COGEM would also like to point out the trend towards locally produced and organic food (known as regional produce). Some people

believe that these products fit better into a healthy, natural and environmentally-responsible diet and are therefore considered to be important and beneficial. Some people might consider the use of GMOs to be inconsistent with this trend and therefore perceive the cultivation of GM crops to be undesirable.

The building block freedom of choice contains elements from the grounds 'agricultural policy objectives' and 'avoiding the unintended presence of GMOs in other products with the exception of those matters which are already covered by Article 26a[g] of Directive 2001/18/EC. Many co-existence agreements are intended to operate at national level. When GMOs are cultivated in some member states and not in others, this could create problems in border regions. The national cultivation proposal refers to the recommendations of 13 July 2010 about the development of co-existence measures to include border regions for suggestions on how to deal with this.[22] It is indicated in the national cultivation proposal that member states can put forward these grounds when they consider it impossible to take co-existence measures due to specific geographical conditions, for example, or the need to prevent GMO presence in certain products, the need to protect the biodiversity of the agricultural production or the need to protect the purity of basic seed and plant growing materials.

2.6 SAFETY

The admittance and assessment of GM crops in terms of safety to humans and the environment takes place in the country concerned in accordance with the legislation, on the basis of the international agreements in force concerning human and environmental safety.
Components: food safety and environmental safety.

COGEM reported in 2009 that safety was the fundamental consideration in the present assessment of GM crops in Europe. Both the European Food Safety Authority (EFSA) and the national advisory bodies are involved in this. Even after the adoption of the amended directive, this will remain unchanged and therefore will not be further discussed in this report.

g Article 26a 'measures to avoid the unintended presence of GMOs' states that: Member states may take appropriate measures to avoid the unintended presence of GMOs in other products.

2.7 BIODIVERSITY

The production of GM crops does not lead to a) a reduction in the agrobiodiversity of the agricultural environment relative to the normal situation, and b) damage to protected or vulnerable biodiversity.
Components: agrobiodiversity, protected or vulnerable biodiversity

National cultivation proposal: environmental and agricultural policy objectives

COGEM reported in 2009 that protection of biodiversity is laid down partly in national and partly in European legislation. There are various EU initiatives (e.g. Natura 2000)23 aimed at protecting biodiversity and vulnerable nature areas. Even the present European Common Agricultural Policy (CAP) and its implementation in the Netherlands includes rules on biodiversity in farmland.[12]
It should be noted that there is a difference between agrobiodiversity and biodiversity in general (i.e. biodiversity on farmland such as fields or grassland). A reduction in biodiversity is inherent to an agricultural area relative to nature areas or reserves. Biodiversity also forms part of the present environmental safety assessment for GMOs, in which the direct impact of a GM crop on biodiversity is examined.
This building block can be linked to the grounds of 'environmental policy objectives' and 'agricultural policy objectives' in the EC proposal on national cultivation competence.

2.8 ENVIRONMENTAL QUALITY

The production and processing of GM crops ensures a) that the quality of the soil, surface water and groundwater, and atmosphere, does not deteriorate and, where possible, is improved and b) that the emission of greenhouse gases along the entire chain (development, production, processing and transport) remains neutral or declines relative to conventional agriculture.
Components: emissions of hazardous substances to soil, surface waters and atmosphere, soil fertility and resilience, energy consumption, Integrated Pest Management (IPM)

National cultivation proposal: environmental and agricultural policy objectives

The cultivation of agricultural crops can have an adverse impact on the environment. In Europe and many other countries, rules have therefore been drawn up to limit these harmful effects as far as possible. The use of crop protection products and artificial or animal fertilizer can impact the quality of the soil, water and groundwater. Tilling the

soil can lead to depletion and erosion. The clearing of areas with large above ground (vegetation) or underground (soil) carbon reservoirs can lead to the emission of greenhouse gases. The use of crop protection products, fertilizer and the CO_2 and particulate emissions of agricultural machinery, etc. also result in emissions to the air. Together these aspects can be considered the environmental impact of agriculture.
Crops which are more capable of withstanding pests and weeds can produce a higher yield and thus less farmland, less crop protection products and less fossil fuels are needed for the same level of production and thus reduce the environmental impact. This does not apply to all GM crops, however. It could be considered therefore whether a GM crop contributes to or fits within Integrated Pest Management (IPM).[h] COGEM reported in 2009 that some of the elements in this building block were already regulated under existing legislation in the Netherlands and Europe.

This building block can be linked to the grounds of 'environmental policy objectives' and 'agricultural policy objectives' in the EC proposal on national cultivation competence. This concerns environmental policy objectives other than those aspects already covered under the existing environmental risk assessment and food safety assessment (Directive 2001/18/EC (release into the environment) and Regulation (EC) no. 1829/2003 (GM food and feed). The text box **EU environmental policy objectives** provides a number of general examples of environmental policy objectives which may also be relevant in the context of GM crops.

EU ENVIRONMENTAL POLICY OBJECTIVES

The European Union has defined more than 130 environmental objectives which it wishes to achieve between 2010 and 2050. A report by the European Environment Agency (EEA) enumerates and describes a number of environmental policy objectives, including[24]:

- **reducing energy consumption,**
- **improving energy efficiency, increasing the share of energy from renewable sources,**
- **reducing greenhouse gases,**
- **improving air quality and reducing air pollution,**
- **reducing exhaust emissions in the transport sector,**
- **reducing waste generation, more effective recycling and reducing waste storage,**
- **management of water sources,**
- **sustainable manufacturing and consumption,**
- **reduction in the use of chemicals, including pesticides,**
- **reducing loss of biodiversity.**

h IPM aims to suppress pest organisms in agriculture on a sustainable basis, based on the principle of prevention rather than control.

2.9 OVERARCHING: BENEFIT TO SOCIETY AND POLICY OBJECTIVES

The production of GM crops leads to an increase in yield, contributes to harvest security or offers some other form of general benefit to society.
Components: harvest security, food security, food quality, environmental benefit, cost saving, recreation.

The building block benefit to society is very broad and will almost always be linked to one or more of the other building blocks. Harvest security and increase in yield, for example, could also fall under the building blocks of 'the economy and welfare' or 'food supply'. Environmental benefits or indeed drawbacks can be found under environmental quality, etc. Drawbacks are essentially about a lack of benefit to society. The 'policy objectives' grounds referred to in the proposed amendment to the Directive also have the same all-embracing (i.e. overarching) nature. Policy objectives in general tend to be periodic in nature. In the EC proposal the grounds of 'policy objectives' may only be invoked in combination with one of the other grounds.

TO CONCLUDE

COGEM wishes to emphasize that this report represents an updating of the nine building blocks provided in the report dating from 2009. As indicated, some of the building blocks have already been fully or partly covered in European or Dutch legislation. A number of them cannot be directly linked to the specific nature of GM crops. It should be noted that there are some reservations, including among some COGEM members, about whether all the building blocks referred to can be incorporated into a detailed assessment framework in terms of usability, applicability and legal tenability. Some believe that only some of the building blocks can be used in the context of the national cultivation proposal. COGEM shall refrain from making a judgment about which building blocks or elements should play a part in any supplementary assessment framework. It has limited itself to summarizing the relevant elements surrounding the cultivation of GM crops. Whether, how and which building blocks could play a part in the context of the implementation of the national cultivation proposal in the Netherlands will depend, among other things, on the legal possibilities, the type of assessment framework that is to be drawn up and political decisions.

In 2009 COGEM identified nine building blocks which could play a part in an assessment of the contribution which GM crops could make to making agriculture 'more sustainable'. These building blocks have been updated in this report in the light of a different context, that of the national cultivation proposal. This EC proposal may provide EU member states with the option of prohibiting GM crops on their territory on another basis than safety considerations.

The inclusion of considerations other than safety could have the effect of preventing technologies from being introduced which have insufficient public support. Furthermore, it may be possible to use them to determine the trade-offs between the costs and benefits to society. If not adequately or carefully implemented the inclusion of these aspects could have unintended side-effects in the decision-making, such as unclear legislation, further delays to admittance procedures and increase costs for compliance with the ultimate result that new technologies are not given a chance and developers become hesitant to further develop or commercialize them.[25]

COGEM notes that sustainable development is related not only to the product (the GM crop) but also its application and use in a particular agricultural system. The rejection of a GM crop on the basis of arguments other than safety, while these arguments will apply to the same extent to conventional crops that are not subject to these criteria, could be seen as (unjustly) creating an uneven playing field. New techniques in plant biotechnology are blurring the distinction between conventional and GM crops and

could therefore heighten the debate about the use of additional legalisation to regulate the market admittance of GM crops. The blurred dividing line could complicate both the justification for a supplementary assessment framework as well as its application.

With regard to future cultivation of GM crops in the Netherlands COGEM notes that given the diversity and differences in measurability and comparability of the various building blocks, there is a risk that a supplementary national assessment framework will not provide a clear 'yes or no' on the matter of GM crops. This raises the question of whether it is feasible to create an assessment framework which can be used as a 'decision-making framework'. Having said that, applying an assessment framework and making the considerations explicit could help to clarify and explain the grounds on which a sound decision can be based.

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ANNEX A

REPORT – INTERNATIONAL WORKSHOP ON A SOCIO-ECONOMIC ASSESSMENT FRAMEWORK FOR GMOS

20 November 2014

Organization workshop and workshop report by Ronald Zwart, Ckade.

Scientific advisory body COGEM[a] organized a one day international workshop on a socio-economic assessment framework for genetically modified organisms (GMOs). The initiative will support the drafting of a report by COGEM on this subject following a request by the Dutch government. This request pre-empts the adoption in the EU of a new Directive that will authorize EU Member States to restrict or prohibit the cultivation, in all or part of their territory, of GMOs[b].

The objective of the workshop was two-fold:

- To **learn**; by promoting the exchange of knowledge, insights and specific experiences between scientific experts and policy advisors,
- To **explore**; by identifying elements that may be of relevance for a socio-economic assessment framework for GMOs.

The workshop enjoyed the participation of 42 experts from 11 European countries. The program addressed three topics:

1. Perspectives and challenges towards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory.
2. Identification, qualification, quantification, operationalization and monitoring of socio-economic considerations.
3. Experiences with socio-economic considerations in other areas, including socio-economic criteria in sustainability frameworks for agricultural products.

This report is COGEM's reflection of the most relevant discussions and outcomes of the meeting.

a COGEM is the scientific advisory body to the Dutch 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.

b Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory.

1. PERSPECTIVES AND CHALLENGES

The introduction of a socio-economic assessment (SEA) framework will enable EU Member States to take into account other arguments but risks to human health and the environment to restrict or prohibit the cultivation of GMOs on their territories. The implementation of such a framework faces **two immediate challenges**: what is considered a socioeconomic (SE) impact and what methods can be applied for a sound evaluation of such impacts. The workshop identified several features that need to be taken into account when addressing these two challenges:

- Quantitative and qualitative impacts. Economic impacts often have a **quantitative** character as they are expressed in monetary terms, while social impacts more often have a **qualitative** character as they are based on values and cultural and behavioural norms.
- Reversible and **irreversible impacts**. Reversible impacts will be restored when the activity that causes the impact is stopped. Irreversible impacts, however, cause an effect (positive or negative) that cannot be overturned and will carry an absolute SE cost or benefit.
- **Distribution of SE impacts**. The SE impact can differ between, as well as within stakeholder groups. The impact of the cultivation of GMOs can e.g. be a benefit to one group of farmers, while it presents a cost to another group of farmers.
- The **uncertainties** of SE impacts. The quantification and qualification of SE impacts bring inherent uncertainties. This is due to the complexity of defining SE impacts and limited experience in measuring SE impacts. **Limited data** are available, esp. for social impacts, while the analysis of economic impacts often relies on mathematical models.
- The tasks, roles and responsibilities of **stakeholders** (scientific experts, policy advisors, industry, societal organizations, general public) in the design and use of an assessment framework for SE impacts.
- SE impacts will be associated both with a refusal and approval of GMO cultivation.

Another challenge is to carefully **manage the expectations** people may have from a SEA framework. Proponents of GMO cultivation expect that the introduction of a national SEA framework will improve the EU authorization procedure for commercial cultivation of GMOs. While critics of GMO cultivation expect it will provide better means to restrict or prohibit the cultivation of GMOs on their territories. The features listed above make clear that a SEA framework is unlikely to give a clear yes or no answer towards the socioeconomic performance of certain GMO cultivation. It was reiterated several times during the workshop that SEA, at this stage, can have an important function in the disclosure and **sharing of information** amongst stakeholders about possible SE impacts associated with the cultivation of a certain GMO. Today, SEA is not fit for decision-making on the cultivation of GMOs, due to the limited availability of data and the uncertainties and lack of methodologies for a sound evaluation of SE impacts.

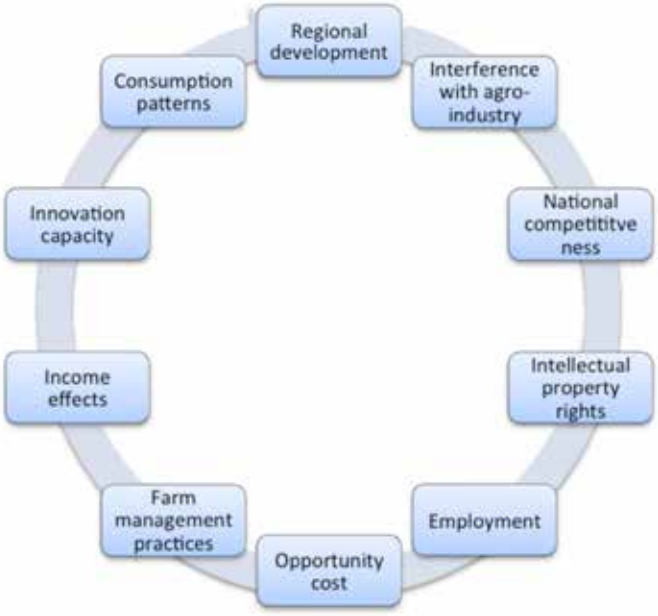
An evaluation of SE impacts is further complicated by conveying the outcomes to stakeholders and the general public. The inherent uncertainties and consideration of multiple SE impacts will present a complex and careful message, while people may only expect to hear a yes or no. Participants to the workshop thus argued to pay close attention to **communication** with stakeholders and the general public. It was suggested this should be done in a structural and transparent way and include an active outreach to, and involvement of, stakeholders already at the start of developing a SEA framework. A structural communication and interaction with stakeholders should i.e. contribute to developing a **shared language** to describe and discuss SE impacts and **take away potential conflicts** arising from interpretations and perceptions of uncertainties associated with SE impacts.

2. IDENTIFICATION OF ELEMENTS FOR A SOCIOECONOMIC ASSESSMENT FRAMEWORK

The different presentations and discussions highlighted a **diverse set of potential SE impacts** (see Figure 1 below). The workshop did not qualify these in terms of e.g. measurability, occurrence, relevance or priority/urgency. Economic impacts can be regulated until the benefits outweigh the costs, with the **irreversible impacts key** in any such analysis. However, not all impacts will be quantifiable and thus the overall SE impact may be expressed as a **threshold** level, rather than an absolute number to take into account the multiple impacts and their uncertainties.

The various SE impacts all face the challenges mentioned under 1., stressing the **need for guidance** in qualification and assessment of SE impacts. The European GMO socio-Economic Bureau (ESEB) is an initiative by the European Commission to identify possible SE impacts and to develop methodologies for the investigation of SE impacts. ESEB consists of scientific experts nominated by the EU Member States and experts from the European Commission. ESEB expects to publish a first general reference document shortly. It introduces **scenarios** to describe possible manifestations of SE impacts and it **differentiates between stakeholder** groups on the nature and extent of a given set of SE impacts. ESEB uses certain **criteria to select for SE impacts**: an SE impact should have at least one measurable indicator, there must be a plausible causal relationship with the GMO cultivation and a sound method must be available to assess the impact. These criteria are particularly challenging for social impacts that generally are more qualitative in nature and have been researched less exhaustively. As a result, the emphasis in the reference document is more on economic impacts.

Figure 1. Overview of possible social and economic impacts of commercial cultivation of GMOs. The circular presentation reflects the non-hierarchical and qualitative nature of the SE impacts.



3. EXPERIENCES WITH SOCIOECONOMIC ASSESSMENTS IN OTHER POLICY AREAS

The European Chemicals Regulation REACH includes an SEA to determine the costs and benefits of the restriction or continued use of specific chemicals. The REACH legal framework differs in three aspects from the proposed application of an SEA for GMO cultivation:

- The SEA applies to chemicals that are already in use.
- Only when a health or environmental risk exists for a certain chemical, the SEA will underpin the continued use or restriction.
- The public and policy discussions have a lower level of public sensitivity compared to the field of GMOs.

Still, experiences with SEA under REACH present valuable insights in the organization and operation of a SEA framework. First, the **availability of information** presents a true challenge. It is costly to identify and analyse relevant information and information on costs is more readily available than information on benefits. Also, the comparing and impact assessment of qualitative versus quantitative is difficult. Second, **no standard SEA** methodology is available. The approach taken is case-specific and depends also on available data. Third, a sound SEA requires **multidisciplinary exper-**

tise, including experts in economics, sociology, chemistry and risk assessment. At the same time, the SEA should be **proportionate**, unbiased and **transparent**, in particular with respect to the uncertainties enclosed in any SEA. This presents a very demanding situation for collaboration between experts and stresses the need for clear and trustful internal and external communication.

Biomass[c] is increasingly used for the production of energy and biobased products. Key condition for these applications is the sustainable nature of the biomass and the greenhouse gas performance of the overall value chain. Voluntary product standards and third party audited certification schemes are tools to account for the **sustainability**, measured against the 3Ps of People, Planet, Profit. Criteria for the People and Profit dimensions are partly based on existing regulatory frameworks and address e.g. labour conditions, land use rights, business practices (financial risk management, anti-corruption), competition (with natural resources like water, food security, existing use of raw materials) and contributions to local population. Besides **administrative controls**, auditing activities may include **interviews** with local stakeholders and on-site inspections. Also in this context, the availability and **reliability of information** present difficulties. In addition, it is challenging to determine whether a **causal link** exists between observed SE impacts and the activities of an economic operator.

OTHER CONSIDERATIONS

Mutual consent on adjustment of geographical scope of GMO cultivation

It is important to be aware that a first step in the proposed authorization procedure for the cultivation of GMOs provides an opportunity to EU Member States and the applicant to mutually agree on adjustment of the geographical scope (exclusion of territories) of the notification. Such an agreement would avert the execution of restrictive measures by Member States based i.a. on socioeconomic grounds. Serious concerns exist if such measure will hold in court when they were legally challenged. It may thus be worthwhile to consider institutional solutions that take due account of the mutual agreement provision.

GMOs as part of a broader bioeconomy context

Agriculture plays a crucial role in feeding a biobased economy, in which both food, feed and industrial applications like energy, chemicals and products are made from biomass and replaces our current use of non-sustainable fossil fuels. The discussions on a SEA framework centre on the cultivation of GMO crops in the EU. This scope implies

c Biomass includes raw materials from forestry and tree plantations, as well as agriculture products and –residues and organic waste.

certain arbitrary boundaries. One is the distinction it makes between the cultivation of GMOs and non-GMO (also often called conventional) crops. A second is disclosed with the introduction of new breeding techniques and what may be defined as genetic modification and what not. A third is the import of products that are made from GMOs cultivated outside the EU. And a fourth is the non-agricultural (or land-based) cultivation of GMOs and use as e.g. enzymes, additives and nutrients in food, feed and industrial applications. These considerations illustrate the potential reach and impact of a SEA framework, not just on the cultivation of GMOs but on the development of a biobased economy in general.

ANNEX B

SUMMARY COGEM TOPIC REPORT CGM/090929-01

SOCIAAL-ECONOMIC ASPECTS OF GGO'S

Building blocks for an EU sustainability assessment
of genetically modified crops

The minister of Housing, Spatial Planning and the Environment (VROM), Jacqueline Cramer, asked COGEM to draw up socio-economic criteria for the application of GMOs in agriculture. In her letter commissioning the assignment, the minister asks COGEM which socio-economic themes, including in any event, sustainability, play a part in activities involving GMOs in agriculture.

BUILDING BLOCKS FOR AN ASSESSMENT FRAMEWORK OF THE SUSTAINABILITY OF GM CROPS

COGEM has identified and describes in this report a number of building blocks which could play a part in assessing the contribution that GM crops could make towards 'more sustainable' agriculture. Where this report refers to sustainability aspects this relates to social, economic and environmental aspects. These aspects are closely inter-related and cannot be seen as separate from one another.
While drawing up this report COGEM aimed to involve a broad range of expertise to throw light on the differing approaches and perspectives. In arriving at this report, existing sustainability criteria were also looked at, such as those for palm oil, soy and biomass. The results of the Ministry of Agriculture, Nature and Food Quality (LNV) seminar on 9 June 2009 on re-evaluating the GMO assessment framework, have also been incorporated in this report and interviews were conducted with a number of experts in the area of agrarian development and sustainability.

SUSTAINABILITY CRITERIA SPECIFIC TO GMOS

Sustainable development is not a clear-cut, static concept but a dynamic one, and depends on the context (e.g. society, culture and religion) and the spirit of the age. What sustainable development means will also depend on what is considered to be acceptable from a socioeconomic point of view and this can evolve over the course of time. How sustainability is defined changes as society changes, and as our knowledge and technological capabilities increase. What form sustainable agriculture takes can thus also differ from one country or region to another because different cultural and other values may be involved or because it is at a different stage of development.
All forms of sustainable development, however, relate not so much to the product, in this case the plant or agricultural crop itself, but to its application and use at a certain time and place. Because in many areas there is little or no difference between the application (production, cultivation) and use (import, processing, end product) of GM crops and conventional crops, this could mean that criteria applied to sustainable agriculture could also be applied to GMOs, because these are the criteria which a crop must meet to be able to make a contribution towards a more sustainable form of agriculture. Unfortunately, sustainability criteria for agriculture have not yet been developed in a way which can be drawn upon here.
Furthermore, this would be to overlook the exceptional position which GMOs have in relation to conventional (agricultural) produce in Europe. The reason for this exceptional position is the ethical and public objections which have been raised by certain groups in society regarding the process by which GMOs are created: the use of genetic modification. This is why criteria for the application of GMOs in agriculture have been specially formulated.

COGEM notes here that the introduction of an assessment of the sustainability aspects of GM crops could raise questions concerning the sustainability of certain conventional crops and cultivation methods which at present, are not assessed in this way. COGEM notes also that the rejection of a GM crop on the basis of socio-economic arguments, while these equally apply to conventional crops that are not subject to such criteria, could be met with incomprehension.

CONVENTIONAL AGRICULTURE AS A FRAME OF REFERENCE

In the minister's letter to COGEM it is suggested that conventional agriculture be taken as a frame of reference. The term conventional agriculture does not refer to a form of agriculture which can be unequivocally defined and exists only in relation to so-called 'nonconventional' forms of agriculture, such as organic farming. What constitutes con-

ventional agriculture may also differ from one country to another depending on what stage of development they are at and what techniques are available.
Although there are major differences between existing agricultural systems (organic and conventional), there are also similarities. In all cases it is essentially a matter of controlling (or trying to control) biological processes. Agriculture can generally be defined as the entirety of economic activities in which the natural environment is modified for the production of plants and animals intended for human use. Depending on the product, the production method and the level of prosperity and underlying values, a wide range of techniques and types of solutions are used to deal with agricultural problems. Whatever form of agriculture is applied this generally has an adverse impact on the existing environment and ecosystem, depending on the crop and the cultivation method used. This impact is largely accepted because the business of farming directly or indirectly provides society with food and is therefore seen as a necessity. Both conventional and organic forms of farming aim for sustainability, but do this in different ways.

In this report conventional agriculture has been taken as a frame of reference because this form of agriculture is most common. A general principle in drawing up these criteria was that GM crops in agriculture should meet as well, if not better, the criteria which apply to the present non-GM variants in conventional agriculture.

NINE CRITERIA FOR THE SUSTAINABLE APPLICATION OF GM CROPS

COGEM has formulated nine themes and associated criteria which could serve as building blocks in an assessment framework on the socio-economic and sustainability aspects of GMOs:

The production and use of GM crops must contribute to more sustainable agriculture in the form of:

Benefit to society

1. The production of GM crops leads to an increase in yield, contributes to harvest security or offers some other form of general benefit to society.
Elements: harvest security, food security, food quality, environmental benefit, cost saving, recreation.

Economics and prosperity

2. The production and use of GM crops contributes equally to local and overall prosperity and the economy and, where possible, leads to an improvement.
Elements: employment, efficiency of the production process, productivity and profit.

Health and welfare

3. The production and use of GM crops means that the health and welfare of workers, the local population and consumers remains at the same level and, where possible, improves.
Elements: human rights, the working environment and terms of employment.

Local and general food supply

4. The production and use of GM crops means that the local food supply remains at the same level and, where possible, improves.
Elements: food security and fair trade.

Cultural heritage

5. The production of GM crops offers the country or region concerned, if so desired, room to conserve and continue specific cultural heritage aspects or other local applications (such as building materials, medicines).
Elements: local applications and traditions, autonomy of the local population.

Freedom of choice

6. The consumer and the manufacturer's freedom of choice regarding GMO (or GMO free) is safeguarded in the production and import of GM crops.
Elements: GMO (or GMO-free) labelling of products, product information, co-existence and innovation, and research freedom.

Safety

7. The admittance and assessment of GM crops in terms of safety to humans and the environment takes place in the country concerned in accordance with the legislation, on the basis of the international agreements in force concerning human and environmental safety.
Elements: food safety and environmental safety.

Biodiversity

8. The production of GM crops does not a) lead to a reduction in the agrobiodiversity of the agricultural environment and where possible strengthens it, and b) damage protected or vulnerable biodiversity.
Elements: agrobiodiversity, protected or vulnerable biodiversity, places of origin of agricultural crops.

Environmental quality

9. The production and processing of GM crops means that a) the quality of the soil, surface water and groundwater, and air, does not deteriorate and, where possible, is improved and b) the emission of greenhouse gases along the entire chain (development, production, processing and transport) remains neutral or declines relative to conventional agriculture.
Elements: emissions of hazardous substances to the soil, surface water and air, soil fertility and resistance.

PRACTICAL CONSIDERATIONS

Operationalization of the criteria drawn up goes beyond the scope of this report. In the preparation of this report COGEM has, however, indicated some points which should be taken into account when the criteria are further developed into an assessment framework at a later stage.

Measurable criteria

For the operationalization of the sustainability criteria it would be desirable that the indicators used to measure the criteria: a) are objectively measurable, and b) can be estimated in advance. Some of the aspects referred to will be more difficult to operationalize, such as the themes cultural heritage, or welfare. Welfare and prosperity are general terms which on further consideration may well differ per country, culture or even religion. Initially, a reporting requirement could apply for these aspects so that more information can be gathered. With the aid of this information a system can eventually be drawn up by which these aspects can be quantified. When European member states can decide individually about cultivation on their own territory, this step will be essential to limit major differences between the member states in the admittance of GM crops for cultivation.
To test the safety of GM crops, the EU and many countries outside Europe already have a risk assessment in which largely objectively measurable data are evaluated with regard to safety to humans and the environment. The results of these studies in terms of the impact of GM crops on the environment and the significance of the measured values in this research are still regularly the subject of discussion. This applies to various scientific studies which contradict one another as well as to any one study which can be interpreted in different ways.
COGEM notes that when people already cannot agree on measurable facts, in practice the introduction of socio-economic criteria will be a complex task in which wide differences of interpretation could arise between EU countries.

Besides this, it is open to question whether the impact of the cultivation of a GM or non-GM crop on social, economic and environmental aspects, the three essential elements of sustainability, can always be predicted in advance. In estimating risks to health or the environment it is, to a certain extent, possible to make use of scientific studies and research.
Other aspects, however, are more difficult to quantify in advance, particularly when they are closely connected, as with the three basic components of sustainability. Often assumptions have to be made with regard to one or more aspects of these elements. For GM crops which have already been cultivated for some time, such as soy and maize, there is already empirical data upon which such assumptions can be based. For new GM crops with different properties, the impact on socio-economic aspects, such as welfare, employment or local food production, will generally be much more difficult to

estimate or quantify. Furthermore, the impact of the cultivation of a particular crop will also depend on the region or area where this takes place.
The economic, environmental and social situation may vary per region. The present admittance procedure relates to permits for cultivation or import, irrespective of the location. The question is, therefore, whether a sustainability assessment for new crops can be carried out in advance or whether new applications must first be introduced on the basis of a qualitative estimate of the sustainability aspects in which monitoring of the socio-economic impact takes place to provide a more quantitative picture.

Distinction between import and cultivation

In this report a distinction has been made between those criteria which are mainly relevant to the cultivation of GM crops in Europe, and the cultivation of GM crops elsewhere in the world followed by import into Europe. The are several reasons for making this distinction. A particular theme may be less relevant because there is already legislation or regulations on that specific topic, as with safety for example, or because the theme is not (or no longer) a current topic of discussion, as with welfare and prosperity in Europe. The practical application of the criteria is another reason for making this distinction.

Criteria relevant to cultivation in Europe

The themes and discussion points which are most relevant to the debate on GM crops in Europe which have not yet been included in an assessment framework or regulated in any other way, are as follows:

- Benefit to society
- Economics and prosperity
- Cultural heritage

Safety, freedom of choice, biodiversity and environmental quality are also still topical and relevant to Europe. These aspects have already been laid down in legislation. Safety is the fundamental principle in the assessment of GM crops in Europe and will continue to be so. Freedom of choice is covered in the legislation through a labelling requirement, among other things. Biodiversity and environmental quality too, are largely laid down in the legislation. There are various initiatives on biodiversity, such as Natura 2000, which are intended to protect vulnerable areas of natural beauty in EU member states. The themes benefit to society, economics and prosperity, and cultural heritage are not covered in the legislation or regulations on GMOs. These can be further developed and operationalized if it is decided that they could play a part in the individual assessment by member states on the admittance of GM crop cultivation in their own territories. The themes health and welfare, and local food supply are generally no longer discussion topics in Europe.

Criteria relevant to cultivation elsewhere followed by import into Europe

All nine themes are relevant to cultivation outside Europe followed by import into Europe. The operationalization of a sustainability assessment for cultivation in Europe is less complex than the imposition of such requirements on countries outside the EU which export to Europe. In view of trade relations, as well as politically and legally, it is much more complex to draw up an assessment framework for sustainability for import, because other laws and rules apply outside Europe. A more ethical and political issue related to the introduction of an assessment framework for sustainability for countries outside the EU is the matter of whether this is actually desirable. Is the conservation of cultural heritage a choice to be made by the country itself or can it be used by importing countries as an argument?
In order to estimate the potential impact of the introduction of GM crops into the agriculture of other countries, the involvement of local stakeholders will always be very important. This is already done in a number of existing international initiatives such as the Round Table on Responsible Soy (RTRS) in which both experts and local stakeholders are involved. One option might be to support these initiatives and get involved in them until more experience has been gained within the European member states with regard to the use of sustainability criteria in the assessment of GM crops.

COGEM notes that if the various European member states were to gain experience in the operationalization of a number of sustainability criteria for crops cultivated in their own territories, this could be a useful step in the process of moving towards a broader assessment in which import is also assessed in terms of sustainability.

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