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DATUM	29 april 2010
KENMERK	CGM/100429-05
ONDERWERP	Reactie op EFSA conceptrichtsnoer milieurisicoanalyse van gg-planten

Geachte mevrouw Huizinga,

Op 4 maart heeft de EFSA het conceptdocument ‘Guidance on the environmental risk assessment of genetically modified plants’ gepubliceerd en opengesteld voor commentaar. Gelijktijdig heeft de EFSA een ‘scientific opinion’ over het testen van effecten van gg-gewassen op zogenaamde niet-doelwitorganismen gepubliceerd. Het is de intentie dat dit laatste document later in het ‘guidance document’ (richtsnoer) zal worden geïncorporeerd en de huidige sectie over testen op niet-doelwitorganismen zal vervangen. Commentaar op de documenten kan uiterlijk 30 april bij de EFSA worden ingediend. Gezien de beperkte tijd voor reactie heeft de COGEM er voor gekozen om haar commentaar op beide documenten gelijktijdig zowel aan u, via dit advies, als direct aan de EFSA te doen toekomen.

Samenvatting
De COGEM waardeert de poging van de EFSA om een richtsnoer voor de milieurisicoanalyse van gg-planten op te stellen. Echter, het conceptrichtsnoer kan sterk verbeterd worden.
De te beoordelen risico’s betreffen onder andere indirecte effecten, zoals het gebruik van bestrijdingsmiddelen. Omdat bij de indirecte effecten een heel scala aan effecten kan worden betrokken, die steeds meer gaan overlappen met de sociaal-economische aspecten die in een eerdere signalering zijn benoemd, raadt de COGEM aan in de toekomst de door de EFSA in kaart te brengen indirecte effecten, waaronder zowel negatieve als positieve, duidelijker dan nu in richtlijn 2001/18/EC is gebeurd, in te kaderen.
De COGEM onderschrijft de onderliggende methodiek van risicoanalyse die de EFSA hanteert. Echter, het conceptrichtsnoer lijkt meer op een discussiedocument dan een richtsnoer. Onduidelijk is welke informatie de vergunningaanvrager daadwerkelijk moet overleggen. Van veel van de informatie die gevraagd wordt, is daarbij onduidelijk hoe deze toegepast kan worden in de risicoanalyse. Ook geeft het richtsnoer onvoldoende duidelijkheid over de ‘baseline’ waartegen eventuele effecten van gg-gewassen moeten worden afgezet.
De COGEM beoogt met haar commentaar de kwaliteit van het richtsnoer te verbeteren. Dit is met name van belang omdat eerder in de EU Milieuraad besloten is dat het richtsnoer bindend zou moeten worden verklaard voor alle lidstaten.

De door de COGEM gehanteerde overwegingen en het hieruit voortvloeiende advies treft u hierbij aan als bijlage.

Hoogachtend,

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c.c. Drs. H.P. de Wijs
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Comments on the EFSA draft guidance for environmental risk assessment of genetically modified plants and the EFSA opinion on effects on non-target organisms

COGEM advice CGM/100429-05

Introduction

Recently, the EFSA GMO Panel published a draft guidance document for the environmental risk assessment of genetically modified plants for public consultation of the European member states and stakeholders.
The document 'Guidance on the environmental risk assessment of genetically modified plants' provides the most recent guidance document for the Environmental Risk Assessment (ERA) of genetically modified (GM) plants submitted within the framework of Regulation (EC) No. 1829/2003 on GM food and feed or under Directive 2001/18/EC on the deliberate release into the environment of GMOs. EFSA states that the document aims to provide guidance to applicants as well as risk assessors for assessing potential effects of GM plants on the environment and the rationale for data requirements in order to complete a comprehensive ERA of GM plants.

COGEM welcomes the initiative of the EFSA to renew its guidance and considers this an important step towards harmonization of risk analysis in the EU. COGEM appreciates the extensive amount of effort that is being made to realize this document and acknowledges the difficulties in the task to draw up a guideline which has to cover all aspects of the ERA. However, after assessing the guidance document, COGEM is of the opinion that the document is inadequate in providing clear criteria and methods for the ERA. A series of important discussion points remains unanswered. Given the short time available for commenting on the guidance document, COGEM has focused on major concerns, which are discussed below.

General comments

Indirect and socio-economic effects overlap and are part of a political process

In the guidance document, a distinction is made between direct and indirect effects on the environment. Direct effects include aspects such as persistence and invasiveness of the GM plant, effects on NTOs and biochemical processes. Indirect effects include, amongst others, the impact of specific cultivation, management and harvesting techniques and greenhouse gas emissions.

In the guidance document, it is stated that an assessment is required of the possible immediate and/or delayed direct and indirect environmental impacts of specific cultivation, management and harvesting techniques. COGEM agrees that the introduction of a GM plant can lead to changes in production systems (line 66) and that these changes can affect the environment.

However, in the current guidance document, no limits are set to the scope of these indirect effects in the assessment of the GM plant. COGEM is of the opinion that a decision on the boundaries of the indirect effects that should be taken into account in the ERA of GM plants, should be put forward at the political level.

COGEM noticed that the mentioned indirect environmental impacts show overlap with the socio-economic aspects of GM crops which are currently under discussion in the EU. These socio-economic aspects are not part of the risk assessment and could also include positive effects of GM crops on agriculture and/or the environment.

If these indirect effects on the environment are taken into account in the ERA of GM plants, COGEM is of the opinion that potential positive effects should not be left out. The inclusion of both positive and adverse effects in the assessment of GM plants, facilitates a balanced evaluation. The extent to which indirect effects of the GM plant should be part of the ERA, requires a political decision. COGEM suggests that such a decision could be made in the EU environmental council when the guidance document is discussed.

Nature of the ERA guidance leans toward a discussion document

The basic principles of the ERA correspond to the internationally accepted methodology, which is also used by COGEM, of hazard identification, hazard characterisation, exposure characterisation, risk characterisation, risk management strategies and overall risk evaluation. The objective of this document was however, to identify clear criteria and methods which can be used as guidance for applicants and risk assessors in the ERA of GM plants (see line 147-184). An effective guidance document reduces uncertainties and increases the consistency in the ERA, while maintaining some flexibility for a case by case evaluation for GM plants. Unfortunately, the document seems not to fully fulfil these criteria. This new guidance document extends the information the applicant has to provide to a considerable degree. However, it is not clear how much of this information is useful for the ERA or the decision making process. Ideally, the ERA should be a checklist that, once completed correctly by the applicant, should lead to an almost automatic decision of the EFSA board or another competent authority. The nature of the ERA guidance leans more toward a discussion document than a guidance document.

Unclear distinction between obligatory and facultative data

The formulation of criteria and data requirements in the ERA guidance document are in many cases confusing and vague. For example, a clear definition of the baseline, environmental harm (line 570), standard farming practices (line 573) and valued flora and fauna remains absent, although the applicant has to provide detailed information and data to demonstrate the absence of an adverse effect of the GM plant.

Furthermore, in many cases it remains unclear whether data on certain aspects are obligatory or not. Throughout the document different terms are used: ‘The applicant should provide detailed information…’ (line 581), ‘the applicant should discuss…’ (line 592), ‘…may be taken into

account' (line 623), 'the applicant should explain…' (line 660), '…is recommended …' (line 564), '…data may be required' (line 1170), '…should be assessed' (line 1883), 'the applicant is encouraged to...' (line 2715). This leaves room for interpretation and discussion among the applicant, different stakeholders and member states whether data requirements are obligatory or not. The current formulation of certain data requirements remains shrouded and without obligations. COGEM is of the opinion that a guidance document should be as clear and unambiguous as possible in relation to data which is voluntary (nice-to-know) and obligatory (need-to-know).

Specific comments per paragraph

The comments in this chapter are listed according to the texts in the EFSA guidance document or opinion on NTOs they refer to. Numbered paragraph headings refer to the exact paragraph as found in the EFSA documents. When a paragraph heading refers to the EFSA opinion on NTOs, this is indicated. Otherwise, the paragraph headings refers to the guidance document.

2.3 Cross cutting considerations

The EFSA recognizes the importance of the use of baselines important for environmental risk assessment, as stated in e.g. line 451: 'The magnitude of each potential adverse environmental effect should be evaluated and is to be seen in relation to defined comparative baselines and assessment endpoints.' The COGEM agrees with the EFSA on this. However, the guidance document does not give a clear definition of a baseline. COGEM considers this to be a major flaw in the document.

Throughout the guidance document, the applicant is requested to determine or define baselines for, amongst others, the receiving environment (line 381), target organisms (line 1712), non-target organisms (line 2216) and biogeochemical processes (line 2525). These baselines will be used to evaluate changes in indigenous biota and their interactions, ecological effects, production systems, etcetera. Although some indications are given for an approach to define a baseline (see e.g. line 1712), these descriptions are not accompanied by concrete criteria (see 2.3.2. and 4.4.3). The guidance document does not address what is considered to be a 'relevant baseline' in a certain environment or for a certain crop. Neither does the guidance document point out or discuss the fact that a single baseline does not exist, only a certain flexible bandwidth.
Therefore, COGEM considers a separate paragraph under '2.3 Cross cutting considerations', dedicated to the definition of and requirements for baselines used in the ERA of GM plants, necessary for the guidance document. Existing texts and discussion on baselines (like in 2.3.2 and 4.4.3) could for instance be incorporated in this paragraph. In addition, the paragraph should give examples of a baseline used for known GM crops and specific transgenes when these exist, or should give criteria on how the applicant should determine the baseline.

2.3.1 Choice of comparators

The EFSA states in paragraph 2.3.1 that effects of genetic modification should be estimated in relation to a conventional counterpart. Also, potential risks arising from the genetic background of varieties which might include the GM event should be discussed (line 592). This is requested because the environmental risk assessment concerns the GM event, not a specific GM variety. The GM event will be crossed into different varieties of the crop, which will subsequently be placed on the market in Europe. A variety usually has a range of environmental and climatic conditions under which the growth is optimal and therefore serves specific regions within Europe.
COGEM points out that variation in overall gene expression and metabolome profile is high when two plants of different genetic lineages are crossed.[1] This implies that the genetic make-up of the progeny of a cross of a GM event with another variety, will be largely unknown. Therefore, it will be impossible to discuss risks of the genetic background of crop varieties into which the GM event will be crossed beforehand.
Furthermore, it remains unclear what effects or variations should be analyzed and what predicting value detected changes will have for the ERA. COGEM underlines that information, related to the genetic background of crop varieties into which the GM event will be crossed, should be requested only when relevant. For e.g. GM plants with modifications in metabolic processes, information on the genetic background of crop varieties might be relevant. Such modifications might theoretically result in changes in secondary metabolites and subsequent plant defence processes, possibly leading to an effect on the environment.

2.3.2 Receiving environments

According to the guidance document, one of the characterizing components of a receiving environment is a 'geographical zone' (line 606). Examples are given concerning the elements of a geographical zone. However, the geographical zones itself are not defined. In appendix A of the guidance document (and in the NTO document, par. 1.3.4) examples are given of zoning concepts for geographical regions. COGEM is of the opinion that more guidance is needed on this subject and that the EFSA should take a position on which zoning concept should be used in an ERA.
COGEM is of the opinion that a limitation to three zones (as in 'Plant protection product' regulation) does not cover European environments and their biogeographical variations adequately. COGEM suggests the use of the formal biogeographic/phytogeographic zoning concept which is based on climatologic gradients in Europe and leads to four regions: Atlantic, Central European, Illyrian and Mediterranean provinces. In addition, the word 'biogeographical' would better describe zones as meant by EFSA than 'geographical'.

The applicant has to submit a description of the range of relevant biotic and abiotic interactions likely to occur in the receiving environment (line 684). This request involves vast amounts of data and literature and is formulated vaguely. Moreover, it is unclear how most of this

[1] *Kogel K.H., Voll L.M., Schäfer P. et al. (2010). Transcriptome and metabolome profiling of field-grown transgenic barley lack induced differences but show cultivar-specific variances. PNAS 107, 6198-6203*

information can be used in the environmental risk analysis. Also, since in most cases information on the baseline will not be present, the information supplied by the applicant will not be useful for the ERA. Therefore, COGEM stresses the importance of clear and precise requests for information, limited to data directly applicable in the ERA.

2.3.3 General statistical principles

Paragraph 2.3.3, amongst others, describes the experimental design and statistical analysis of field experiments. Field experiments have to be carried out over a period of at least two years, at three different sites. In line 697 it is mentioned that this section does not apply to field trials described in the food/feed guidance documents designed to compare phenotypic, agronomic and compositional characteristics of the GM plant with its conventional counterpart. Surprisingly, the requirements are also not applicable for field trials aimed at the assessment of putative effects on non-target organisms (line 858). Besides the fact that there is no explanation given for this exception, it opens up the question to which field experiments these requirements do apply.

When many studies on non-target organisms are supplied, there is a serious problem in integrating information. COGEM agrees (line 721) that meta-analysis would be useful to put studies into perspective. COGEM also agrees that effect size and standard errors should be reported in addition to substantiate the statistical significance of the results (line 959).

EFSA recommends using equivalence analysis, a method previously used in medicine for drug analysis. COGEM acknowledges that equivalence analysis can be applied to a comparison of GM and non-GM plants, but remarks that the method is not well known in the field of plant biotechnology. COGEM wonders whether this method has any added value as compared to describing type I and II errors for different effect sizes, which is the standard for good statistics in the biosciences.

In addition, equivalence analysis requires a statement of ‘limits of concern’, i.e. a delimitation of the boundaries within the GM and non-GM crop are considered equivalent. EFSA should state these limits of concern beforehand. Apparently this matter is left entirely to the applicant in the guidance document (line 771), leaving him in the blank of what is expected.

2.3.3.3 Power analysis

COGEM agrees with the idea that laboratory studies should be supported by power analysis. Such tests are standardized, are performed under highly controlled conditions, and because typical standard deviations within treatments are known before the experiment, these can be used to plan the experiments and compute statistical power, which depends on the number of replicates.

However, COGEM has serious reservations in applying this idea to field studies for two reasons. Firstly, the effects found in the field test will strongly depend on the scale of the set-up, the time that the experiment lasts and the surrounding landscape. Field tests are carried out on a small scale and it is not clear whether scaling-up to crops will produce similar results. A small plot of corn in a landscape dominated by potato fields is likely to attract different non-target organisms (mainly those that move a few meters from a potato to a corn plant) than a large corn crop. Also

many non-target organisms will take years to find a crop and build up significant populations. It is well known that plants can escape from herbivores by being non-apparent. This has the consequence that results of field tests are much more variable then those of laboratory tests and will be strongly context dependent. This point should be addressed in the guidance document.
Secondly, for computing power the standard deviation should be known before the experiment starts (as acknowledged in the guidance document line 801-2). In field testing, it is simply not possible to estimate standard error in a variable (like e.g. the number of ladybirds) beforehand. This will depend on the surrounding landscape, previous weather conditions and unknown factors (like the fraction attacked by parasites). Because of build-up of populations it would even be very difficult to estimate standard deviation in year 2 from that in year 1. Many insect populations, bumblebees included, show large variation over time.
The guidance document appears to partially acknowledge these problems. In line 793 a level of 80% is given for acceptable statistical power. In line 794 however, 'it is recognized that for ecological field trials, this is an aspiration that may only be achievable in exceptionally well-resourced and extensive experiments' and the final conclusion is that power should be 'as high as possible'. However, there is no specification of how large the ecological effect of a GM plant should be before there is reason for concern. Calculating statistical power for field experiments presents a practically impossible task for the applicant, while it is not clear beforehand which level of detail is required for a positive evaluation of the ERA.

2.3.4 Long-term effects

According to the ERA, an analysis of the long-term effects of the release of a GM plant has to be carried out by the applicant. Due to the complexity of analysis of long-term effects, it is understandable that the guidance document does not give clear criteria for the analysis. Still, the applicant is required to make an estimate whether long-term effects are expected to occur and how the monitoring plan for cultivation should be adjusted accordingly. In line 1117 EFSA states that applicants should propose indicators and reference databases for EU-wide surveillance of long-term effects. Each member state has its own regulations for monitoring environmental effects outside the field. It is questionable that the applicant is supposed to have knowledge on the subject of indicators and reference databases and is asked for specific information, while the guidance document does not clearly specify criteria for an analysis of long-term effects.
Since the analysis of long-term effects is closely connected to general surveillance, COGEM is of the opinion that this analysis should be incorporated into the post-market environmental monitoring plan.

3.1 Persistence and invasiveness including plant-to-plant gene flow

3.1.1 Problem formulation

In this paragraph, a flowchart (figure 4) is presented which intends to clarify the different stages of information requirements to test formulated hypotheses concerning persistence and invasiveness of a GM plant itself, or of its wild relatives as a result of vertical gene flow.
COGEM values the effort that has been put into making the process of problem formulation as practical and concrete as possible. Decision trees are helpful as a guidance to applicants and risk

assessors. However, it is very important that these flowcharts are correct and based on the right assumptions. In the opinion of COGEM, according to the problem formulation regarding possible gene flow, question 11 has been positioned too late in the flowchart. The question whether a transgene can cause outbreeding depression should be asked at least before question 8 & 9. The assumption that seemed to have been made in this flowchart is that only a GM plant with an increased fitness could cause environmental harm. However, if question 8 and 9 are answered negatively, no further data is required while there is a (theoretical) risk of a GM plant causing a fatal outbreeding depression.

3.1.2 Hazard characterization

The word 'fitness' is used more or less casually throughout the guidance document (e.g. lines 1212, 1151, 1373). COGEM points out that a clear definition of 'fitness' is needed for a clear description of requirements made in the guidance document.

3.1.2.1. Stage 1 info requirements

b) Seed germination characteristics. COGEM acknowledges that for evaluating the potential weediness of species and their persistence in the environment, it is relevant to have information on the ability of a species to form a seed bank in the field and whether they germinate at a time that is favourable for seedling survival. Field observations as well as growth chamber experiments can give information on seed germination. COGEM would like to stress, however, that seed germination characteristics do not automatically follow from standard laboratory tests, like the ones listed in lines 1305-1311. For instance, many species for which the seeds have no dormancy when they are ripe (e.g. *Brassica napus* or *B. rapa*) still build up considerable seed banks when seeds reach micro-sites unfavourable for germination. The problem is discussed at length in Baskin & Baskin (2001).[2] Field trials can be performed by placing seeds in small experimental plots in the field and either retrieving seeds after different time periods or disturbing the soil at regular intervals and count the new recruits.

3.2 Plant to micro-organism gene transfer

In this paragraph it is stated that horizontal gene transfer is a rare event (line 1561). COGEM points to the fact that although horizontal gene transfer from plant to bacteria can be provoked under laboratory conditions, it has never been described under field conditions. The problem formulation should focus, amongst others, on (line 1575-1577) the 'presence of recipient micro-organisms for transgenic DNA in the receiving environments' and 'selective conditions enhancing the probability of dissemination and maintenance of the genetic material from GM plants in natural microbial communities'. The terminology in these descriptions is unclear, hampering hazard identification.

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[2] *Baskin C.C. & Baskin J.M. (2001). Seeds; ecology, biogeography, and evolution of dormancy and germination. Academic Press.*

Furthermore, COGEM is of the opinion that problem formulation should also focus on persistence of plant material after harvesting, until complete degradation of the material has occurred. Persistence of plant DNA in receiving environments may drive future gene transfer events.

In addition to addressing those aspects concerning horizontal gene transfer as listed under paragraph 3.2.1, the applicant is required to make an analysis of the overall risk (line 1630). Potential effects should not only be regarded in view of potential adverse effects on human health, but also for possible effects on biogeochemical cycles. Any uncertainties may trigger the need for appropriate monitoring.
It is unclear to COGEM what kind of information the applicant has to provide for an ERA of plant to micro-organism gene transfer. It seems to range from a full description or characterization of the entire soil community to the statement that horizontal gene transfer is unlikely. The latter is useless and the first hardly possible. In addition, it is not clear how the information provided fits in the risk assessment. The envisaged methodology is obscure.

3.3 Interactions of the GM plant with target organisms
This section focuses on the development of resistance of the target organism. In the view of COGEM, resistance development is an agronomical or economical problem and not an environmental issue. Resistance of the target organisms renders the GM plant useless. It can lead to crop losses and damages for farmers. However, this problem occurs also in pest resistant conventional crops. Therefore, COGEM is of the opinion that this subject should be removed from the guidance document. Resistance development in target organisms could be discussed in the context of economical aspects of GM crops, apart from the ERA.

3.4 Interactions of the GM plant with non-target organisms
Two documents have been published for public consultation by the EFSA GMO Panel. Firstly the draft guidance document for the environmental risk assessment of genetically modified plants (referred to as the guidance document) and secondly the scientific opinion on the assessment of potential impacts of genetically modified plants on non-target organisms (further referred to as NTO document).
Since the potential impact on NTOs is also part of the ERA of GM plants, it would be expected that both documents are consistent, taking into account that the specific NTO document might be more detailed. This is confirmed in the guidance document at lines 1772-1773 which states that ‘Guidance to applicants as outlined in that (NTO document) opinion has been inserted in the present guidance document. However, comparing these two documents leads to the conclusion that there is at least one significant difference. Because of the limited time span for public consultation, a complete comparison between the two documents could not be made.

2.2 Hazard identification (NTO opinion)
The NTO document states that hazard assessment should consider possible effects at different ecological scales (e.g. organizational level, population level) (NTO document, page 43, par. 2.2).

In this document it is also emphasized that 'both lethal and sub-lethal effects are relevant in the assessment of a possible hazard for a given NTO species (NTO document. page 24, par. 1.7.2). The relative fitness is considered an appropriate measurement endpoint for NTO testing (NTO document, pg.25).
In the ERA document these measurement endpoints for NTOs are not defined. The hazard identification on page 61 only mentions that 'Once specific measurement endpoints are chosen, appropriate methods and criteria of measurements should be selected and described' (lines 2041 - 2042). This leaves the interpretation of these endpoints to the applicant. COGEM points out that sub-lethal effects are not covered in any of the current market applications. COGEM is of the opinion that sub-lethal effects can have a severe adverse effect on a population and should thus be assessed in the ERA of GM plants. In 2008, COGEM issued a report in which experimental protocols to investigate the impact of GM crops on non-target arthropods are discussed in detail.[3] Population growth measurements are suggested in this report as an alternative to simple mortality tests because they combine lethal and sub-lethal effects. This report is cited in the NTO document, but not mentioned in the guidance document. COGEM is of the opinion that this report by Charleston & Dicke presents useful and concrete guidance on the assessment of NTO effects of GM plants.

3.4.1.2 Definition of assessment endpoints considering exposure pathways to NTOs

In par. 3.4.2.1 on the definition of assessment endpoints considering exposure pathways to NTOs, attention is being paid to the identification of functional groups being exposed directly or indirectly to the GM plant. Except for a table with examples of functional groups (pg. 53, table 4, line 1833), no concrete guidance is given on which (combinations of) NTO species are recommended or which amount of NTOs should be used for a statistically robust assessment of NTO effects. COGEM points out that a report issued by Scholte & Dicke (2005) gives a more concrete indication of specific NTO groups per crop and event which could be used as a starting point for guidance to applicants and risk assessors.[4]

In par. 3.4.1.2 (lines 1869 – 1876), it is stated that in case of import, the ERA has to focus on indirect exposure to products of the GM plant (e.g. through manure and faeces from the gastrointestinal tracts of animals fed the GM plant, and other by-products of industrial processes). Further concrete guidance on how specific testing on this aspect should be executed remains absent. COGEM is of the opinion that this exposure route could only be relevant in very specific cases like pharmaceutical crops (which will most likely not be used as feed) and should be determined on a case by case basis.

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[3] *Charleston D.S. & Dicke M. (2008) Designing experimental protocols to investigate the impact of GM crops on non-target arthropods*

[4] *Scholte E. & Dicke M. (2005) Effects of insect-resistant transgenic crops on non-target arthropods: first step in pre-market risk assessment studies*

Further on, EFSA describes another indirect route of exposure of GM plants to NTOs. In case gene flow to cross-compatible wild/weedy relatives and feral plants inside or outside the areas of cultivation is likely to occur, then exposure of NTOs over life cycles and seasons should be assessed **(**lines 1882 - 1884**).** It remains unclear whether data on this subject is obligatory or not. Furthermore, COGEM partially agrees with this aspect, but underlines that indirect exposure via this route should be investigated only when relevant. NTOs that are relevant for the crop should be tested in the lab. In most cases, these NTOs will also be relevant to cross-compatible wild/weedy relatives. COGEM is of the opinion that unless there is a reason to assume a deviation in cross-compatible wild/weedy relatives, NTO tests with the GM plant will also provide sufficient information on the possible effects on NTO's in case gene flow occurs.

3.4.1.4 Specific hypothesis-driven investigation

COGEM is of the opinion that decision trees and flowcharts can be really helpful for applicants and risk assessors to provide guidance on the required data and risk assessment. However, COGEM underlines the importance of these decision trees to be completely correct. Unfortunately, some of the figures in the guidance document at hand seem to be incorrect or at least indistinct (see also figure 4 in paragraph 3.1.1).

In figure 6 (pg 58, par. 3.4.1.4) a decision tree is presented which can be used by the applicant to carry out a hypothesis driven assessment. This figure indicates that tier 1 tests are always necessary, even if there is no reason to assume an effect on NTOs based on the characteristics of the transgene. This would mean that for instance events with a herbicide tolerance gene or potatoes with an altered amylose content have to be tested for NTO effects in the laboratory. COGEM is of the opinion that NTO lab tests should only be required when the transgene gives reason to assume an effect on NTOs.

Furthermore, COGEM suggests that the order of the questions in the second box in figure 6 should be changed. The second box containing questions 3 till 5 should be split in two parts. If question number three is answered negatively (Does the GM plant produce toxic substances?), questions 4 and 5 are no longer relevant.

3.4.1.5 Generic hypothesis driven investigation

In paragraph 3.4.1.5, the EFSA considers generic hypothesis driven investigation of unintended or unanticipated effects. In this paragraph, it remains unclear which NTOs should be tested when there is no hypothesis. If EFSA recommends NTO testing without a specific hypothesis, then more concrete guidance on how these unanticipated effects should be tested and on which (group of) NTOs is desirable**.**

Field testing should be done in a relevant environmental setting for the specific application. EFSA states that field generated data from outside the EU may be informative, if the applicant justifies this choice (lines 1977 – 1979). COGEM is of the opinion that field testing data from outside the EU can never be sufficient to conclude that possible adverse effects on NTOs are absent within the EU, since non-target organisms in the EU differ from those outside the EU.

Therefore, field generated data should be collected from field testing in EU relevant agricultural areas.

3.4.2.1. Laboratory studies

COGEM emphasizes the importance of a relevant baseline in NTO testing. In the ERA document, it is stated that when the aim is to demonstrate the equivalence of the GM plant to the isogenic / near-isogenic comparator, the standard tests should include the near-isogenic line as a negative control […] as well as a positive chemical control to prove the functionality of the experimental setup, as advised in the pesticide test guideline (lines 2114 – 2117). No further details of the choice of comparators are given in this section. In the opinion of COGEM, the (near)isogenic control should include typical conventional management, as stated in line 570 on the baseline choice.

Furthermore, the ERA document does not further specify which type of positive chemical control should be used to prove the functionality of the experimental setup. In the opinion of COGEM, a relevant pesticide is most appropriate to be used as a positive control.

3.4.2.2 Field trials

From figure 6 on page 58 it can be concluded that if Tier 1 and 2 tests show no significant adverse effects, then Tier 3 testing (field trials) is not required. COGEM agrees with this.

However, the importance of field trials is underlined in par. 3.4.2.2 (lines 2135 – 2141). COGEM wants to emphasize that field testing is essential to investigate trait versus environment interactions when laboratory tests give reason to assume an adverse effect in the field.

3.5 Impacts of the specific cultivation, management and harvesting techniques

In this paragraph it is rightfully stated that the introduction of a GM plant can lead to changes in production systems (line 66) and that these changes can affect the environment. Therefore, it is claimed that an assessment is required of the possible immediate and/or delayed direct and indirect environmental impacts of the specific cultivation, management and harvesting techniques. The applicant should perform a scenario analysis.

As mentioned in the ‘General comments’, no limitations have been specified for the evaluation of indirect effects of GM plants. If environmental impacts of changes in management would be included in the ERA, then any positive effects on the environment of the introduction of a GM crop, such as reduced pesticide use compared to conventional farming, should be taken into account in the overall environmental risk assessment. If positive effects of GM on the environment due to cultivation changes cannot be part of the ERA, then the assessments of cultivation effects are more suited in an overall socio-economic evaluation.

Most importantly, this paragraph neglects the fact that agriculture is dynamic and subject to changes in e.g. crops, crop varieties and cultivation processes. It opens questions with regard to the baseline or comparator, which are not adequately addressed in the guidance document. For example, the market release of a GM maize variety can lead to a substantial increase of acreage

of maize at the cost of other crops. It is known that cultivation of maize has a negative effect on biodiversity (e.g. insects) compared to other crops, like rapeseed. Should the negative effects on biodiversity prohibit the market release of such a GM maize? Or should the effects of cultivation of GM maize be compared with those of conventional maize?

3.5.5 Step 5: Risk management strategies

Throughout the chapter 5.5 the focus appears to be on the herbicide regime of GM herbicide tolerant plants. EFSA acknowledges that registration and the ERA of herbicides falls under the scope of the Directive 91/414 or Plant Protection Product Regulation. However, irrespective of this fact, it is stated that the potential environmental impact of the management of GM herbicide tolerant plants should be discussed. This position ignores the interplay between the plant protection product regulation and Directive 2001/18, and will fuel any differences of opinion between the GM competent authorities and the competent authorities involved in the registration of herbicides. In the opinion of COGEM, the possible inclusion of the assessment of the effects of the application of herbicides in the present guideline, depends on the outcome of a political decision process on the harmonization of both directives involved.

3.6 Effects on biogeochemical processes

This paragraph discusses the assessment of the effects GM plants have on biogeochemical processes in e.g. soil, natural water bodies or the atmosphere, for example the emission of carbon dioxide. Cultivation of GM plants may indeed affect these biogeochemical processes, but it is questionable if changes to biogeochemical processes due to the cultivation of GM plants will lead to environmental risks, or are within range of natural variation, when compared to the cultivation of equivalent non-GM plants.

In addition, the current knowledge of all types of biogeochemical processes is not sufficient to specify a baseline for comparison (line 2525). Soil communities and abiotic processes in the soil, water and atmosphere are very dynamic and will respond to changes in e.g. cultivation practices and seasonal influences. Without a sound baseline, COGEM is of the opinion that a comparison of the effects of a GM plant and its conventional counterpart on biogeochemical processes can not be made. The applicant will in many cases be requested for information on biogeochemical processes that will not contribute to the ERA, due to the absence of a baseline.

The applicant is requested for information on ‘losses of production sites or systems’ to air or water like greenhouse gas emissions (line 2541). This also includes the loss due to operations that occur outside the GM plant production site, like manufacture and transport of fertilizer. These processes indeed affect the environment, but these should not be included in an ERA of GM plants. Agriculture is associated in general with the use of e.g. fertilizer, insecticides and biocides and resulting environmental effects. The subject of ‘losses of production sites or systems’ goes beyond the scope of the ERA of GM plants.

4. Post Market Environmental Monitoring Plan

Recently, COGEM formulated criteria for General Surveillance plans concerning applications for import and cultivation of GM crops. Although COGEM agrees with most points made in the EFSA guidance document concerning the post market environmental plan, she is of the opinion that some of the requirements set by EFSA should be improved.

On page 83, line 2919, EFSA states that independent audits have to be established to ensure the independence and integrity of all monitoring data. In addition, COGEM is of the opinion that all observations collated by the authorization holder must be retrievable. If all the recorded observations can be retrieved by the Member States or competent authority, the correctness of the conclusions drawn by the authorization holder from these observations can be verified.

On page 83, lines 2937 - 2940, EFSA states that farm questionnaires should be distributed, completed and collated annually via an arranged reporting system. These should be analysed by the applicant and reports submitted at the agreed time intervals (usually annually) to appropriate Competent Authorities. However, it is hard to predict if and how many distributed forms will actually be completed and returned. In order to detect potential unanticipated adverse effects, sufficient observations have to be made. COGEM is of the opinion that this could be achieved by the obligation to fill in the distributed farm questionnaires and by setting a minimum percentage or number of questionnaires needed for proper analysis.

In paragraph 4.4.4, page 84, lines 1958 – 1960, EFSA states that the design of the monitoring program will influence the quality and usefulness of resulting data, hence efforts should be made to ensure that data from all monitoring systems used can be statistically analyzed. COGEM is of the opinion that a thorough statistical analysis of the information collected by general surveillance is not possible, due to the nature of General Surveillance. Therefore, COGEM considers General Surveillance to be an early warning system for observing significant unanticipated adverse effects. When an unanticipated effect is observed and further information is needed to identify the cause of this effect, COGEM considers it important that this study makes use of data that warrant statistical analysis and that these data are analysed by means of a thorough statistical procedure. Therefore, control data need to be collected during the investigation into the cause of an unanticipated adverse effect, including quantitative data, such as the number of organisms present.

Additional comments: process of public consultation

The EFSA GMO panel has been working for almost two years on this revised guidance document on the ERA of GM plants. During these two years, information and opinions were gathered and discussed, eventually resulting in the present guidance document which should guide applicants as well as risk assessors in future evaluations of GM plants. COGEM points out that the determined public consultation period of less than 2 months is too short for such an important and decisive document, hampering a thorough evaluation of the document.

Since time for public consultation is limited, at least the process of submitting comments should be easy accessible and accommodating in order to encourage stakeholders to submit their reaction. Eventually this will create a broad basis of support for this guidance document. However, comments submitted by e-mail or by post cannot be taken into account. Exclusively comments submitted by the electronic template on the EFSA website will be taken into consideration. COGEM understands that having the comments submitted one by one per chapter is easy to process for the EFSA. However, she is of the opinion that this limitation interferes with submitting a profound and thorough reaction to the ERA guidance document.