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KENMERK CGM/131210-01

ONDERWERP Advies praktische bruikbaarheid van het richtsnoer voor de risicobeoordeling van 'living modified organisms' van het Cartagena Protocol inzake Bioveiligheid

Geachte mevrouw Mansveld,

Naar aanleiding van een adviesvraag over de praktische bruikbaarheid van het richtsnoer voor de risicobeoordeling van *'living modified organisms'* die in het kader van het Cartagena Protocol inzake Bioveiligheid is ontwikkeld, deelt de COGEM u het volgende mee.

Samenvatting
In het kader van het Cartagena Protocol is een richtsnoer voor de risicobeoordeling van 'living modified organisms' (LMOs) ontwikkeld. De COGEM is van mening dat de praktische bruikbaarheid van dit richtsnoer verbeterd zou kunnen worden door de specifieke richtsnoeren voor de risicobeoordeling van bepaalde groepen van LMOs uit te breiden tot op zichzelf staande documenten. De 'roadmap' kan dan beperkt worden tot een beschrijving van de verschillende stappen in de risicobeoordeling en een weergave van algemene achtergronden van de risicobeoordeling. De specifieke richtsnoeren voor de risicobeoordeling van specifieke LMOs zouden moeten aansluiten bij de stappen van de risicobeoordeling zoals die in de 'roadmap' zijn beschreven.
Daarnaast is de COGEM van mening dat het richtsnoer over monitoring aparte secties zou moeten bevatten waarin wordt beschreven hoe het monitoren van specifieke typen van LMOs vorm gegeven kan worden. Verder mist de COGEM in de richtsnoeren referenties naar eerder opgedane ervaringen met de risicobeoordeling van specifieke LMOs en gegevens verkregen door monitoring.
Concluderend is de COGEM van mening dat het richtsnoer een nuttig document is, maar dat de praktische bruikbaarheid verbeterd kan worden wanneer de opzet van het document wordt gewijzigd, de aspecten van de risicobeoordeling ook visueel worden weergegeven en wanneer referenties naar eerdere ervaringen met LMOs in het document worden vermeld.

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

Hoogachtend,

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Practicality and usefulness of the 'Guidance on risk assessment of living modified organisms'

COGEM advice CGM/131210-01

Introduction

The Ad Hoc Technical Expert Group (AHTEG) on risk assessment and risk management under the 'Cartagena Protocol on Biosafety'[1] developed a 'guidance on risk assessment of living modified organisms (LMOs)'.[1] The objective of the guidance is to provide a reference that assists governments and other parties involved to implement the risk assessment part of the Cartagena Protocol.

The guidance consists of three parts: a roadmap for risk assessment of all LMOs (Part I), guidance for the risk assessment of specific types of LMOs and traits (Part II) and guidance on monitoring of LMOs released into the environment (Part III). In June 2013, the parties of the Cartagena Protocol invited stakeholders to test the practicality, usefulness and utility of the guidance using actual cases of risk assessment. The information obtained by the testing process will be used to further improve the guidance.

The Dutch ministry of Infrastructure and Environment decided to contribute to the testing process and organised workshops with experienced risk assessors to test the guidance. In addition, COGEM was asked to advice on the practicality, usefulness and utility of the guidance. Due to time constraints COGEM did not test the specific guidance on living modified plants with tolerance to abiotic stress and did not study the background materials that are linked to the guidance.

Previous advices

COGEM previously advised on the draft 'guidance on risk assessment of living modified organisms (LMOs)', such as genetically modified (GM) crops, GM animals, and GM microorganisms. In its previous advice COGEM scientifically reviewed the guidance and the concepts therein and made some suggestions to improve the guidance document.[2]

General remarks

Practicality of the guidance

COGEM welcomes the initiative to develop a guidance on the risk assessment of all types of LMOs and greatly appreciates the huge effort that the AHTEG made to create it. COGEM is pleased to note that the document seems to contain all the background information that is needed to perform a

[1] The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is an international treaty governing the movements of living modified organisms (LMOs) resulting from modern biotechnology from one country to another. The Protocol seeks to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology. It was adopted on 29 January 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on 11 September 2003.

risk assessment. As an explanatory document the guidance will be of great value to novices in the risk assessment of LMOs.

The guidance describes risk assessment in general terms, but doesn't appear to provide sufficient focus on the questions which are most important when assessing the environmental risk of a specific LMO. Therefore, reservations can be made on the practicality of the guidance. Because no information is provided on the aspects which are more or less relevant in a certain case, one might wrongfully conclude that information on all aspects is necessary to assess the risk of a LMO. This limits the practicality of the guidance for risk assessment of a specific LMO.

Past experiences with risk assessment

Past experiences with risk assessment appear not to be included in the guidances. A substantial body of knowledge has been gathered in countries cultivating LM crops, e.g. monitoring data collected from previous environmental releases of LM crops in Spain. Information from past releases are a useful and important source of information for subsequent risk assessments. The practicality of the guidance could be improved by referring to these experiences in various parts of the guidance.

Applicability to risk assessment of experimental releases

According to the document, the roadmap and the specific guidances are applicable to all types of environmental releases of LMOs, including early stage experimental releases. Neither the roadmap nor the specific guidances, however, provide sufficient support in case of the risk assessment of experimental releases. In the general and specific guidances all aspects that could be important to assess the risks of a LMO are listed. It is very unlikely that information on all these aspects is available in case of an experimental release, because in many cases the aim of such a release is to generate additional information on the characteristics and/or environmental effects of a LMO. In addition, in case of an experimental release containment measures may be imposed which could reduce the amount of information needed for risk assessment. Although the guidance mentions that in certain cases, such as early stage releases and trials, less information may be required to assess the risks (line 262), information on the questions which need to be answered before an experimental release can be carried out, and the questions which do not necessarily have to be answered is not provided. COGEM is of the opinion that detailed information on the questions which are crucial to assess the risk of an experimental release should be provided in the guidance. Alternatively, the scope of the guidance could be limited to large-scale releases (cultivation and import).

Applicability to risk assessment of seed spillage

As mentioned previously, the guidance claims to be applicable to all types of environmental releases. COGEM notices that although import (or seed spillage) is mentioned in the guidance (line 332), the roadmap and the specific guidances do not provide real support to assess the risk of seed spillage. In case of seed spillage, the environmental exposure is much smaller than in case of cultivation and therefore certain points may not have to be considered. An example is the

assessment of the potential adverse effects on target organisms, because such effects are unlikely to occur due to the limited exposure of target organisms in case of seed spillage. The practicality of the guidance could be improved by listing the points that do not need to be answered when the risk of seed spillage is assessed, for instance when the seeds are unable to germinate in the area of interest.

Remarks on the roadmap (Part I)

The roadmap provides useful insight in the issues and aspects of the risk assessment process and is a helpful source of information when assessing the risks of LMOs. The roadmap aims to be applicable to all types of environmental releases of LMOs (line 187) although it was based on the risk assessment of LM crops. For this reason, the practical use of the guidance for other types of LMOs, such as LM micro-organisms and LM fish, is limited. Some points to consider that are mentioned in the roadmap are not relevant for a certain type of LMO, whereas other relevant points are not mentioned, such as potential adverse effects due to a change in behaviour (in case of LM animals).

Developing a roadmap which contains all aspects that are important to assess the risks of every possible LMO seems not feasible. Therefore, the roadmap should focus on the explanation of the different steps in risk assessment and should not discuss every point to consider for every possible LMO, because the points to consider vary significantly for different types of LMOs. The practicality of the guidance could be improved by transferring the detailed information on the points to consider from the roadmap to the guidances for specific types of LMOs.

The roadmap should provide general information on risk assessment and focus on the different steps of the risk assessment without going into detail on the different points to consider when assessing the risks of various types of LMOs. Consequently, the content of the roadmap could be reduced. The guidances on specific types of LMOs should be expanded to stand-alone guidances that can be used without consulting the roadmap.

Remarks on the guidances for specific types of LMOs (Part II)

COGEM welcomes the initiative of developing guidances for specific types of LMOs. These specific guidances allow the inclusion of more detailed information on the risk assessment of specific types of LMOs, which greatly improves the practicality of the guidance.

A) risk assessment of living modified plants with stacked genes or traits

In the guidance several ways in which stacked LM plants may be obtained are listed: cross-breeding of two LM plants, transformation of a plant with a multi-gene transformation cassette, retransformation of an LM plant or simultaneous transformation with different transformation cassettes or vector.

The guidance assumes that the individual transformation events making up the stacked event have been assessed previously, or are being assessed simultaneously (concomitantly). Often this will not be the case. If an applicant does not intend to market the individual parental lines, data on the parental lines will often not be available. Importantly, there is no need to assess the risks of the

individual parental lines since the environmental risk of a stacked LM plant can be assessed by itself. The assumption that the parental lines are being assessed simultaneously (or have been assessed previously) hampers the usefulness and practicality of this specific guidance. The guidance should assess the risk of the stacked LM plant by itself (e.g. by comparing it to a conventional comparator) and should not impose a comparison with the parental lines.

COGEM notes that the scope of this guidance is limited to stacked LM plants generated by cross breeding (line 798). Stacked LM plants that are generated in another way (e.g. by retransformation) are not covered by the guidance. The distinction between these types of stacked plants is arbitrary. Many of the relevant questions are identical for all types of stacked LM plants. Therefore, this guidance should not be limited to stacked LM plants generated by cross-breeding.

The guidance on specific types of LMOs (Part II) complements the guidance given in the roadmap (Part I) by emphasising on the issues that are particularly relevant for specific types of LMOs. The fact that the general points are listed in another document severely hampers the practicality of the document. In the specific guidance on stacked LM plants the risk assessment is focused on the interactions between the stacked genes. The points to consider that concern interactions are less relevant for the risk assessment of the LM plants than the general points mentioned in the roadmap. In addition, the scientific rationale for many of the points to consider is not provided and it is in some cases unclear why certain data (e.g. data on post-transcriptional regulation of genes, the expression level compared to the parental LM plants) are necessary to assess the risks.

C) risk assessment of living modified trees

COGEM notes that the guidance on the risk assessment of living modified trees only considers the aspects of the biology of living modified trees that might be relevant when assessing the risks. The specific guidance does not consider the aspects of the introduced trait. These aspects are dealt with in the roadmap. As both aspects are essential for risk assessment, mentioning them in different documents reduces the practicality of the guidance for the risk assessment of living modified trees. In its current state, the specific guidance would benefit from an explicit statement that it only focuses on the aspects of risk assessment that involve the biology of trees and that the aspects of the introduced trait are mentioned in the roadmap. If the suggestion of COGEM to develop stand-alone guidances for specific types of LMOs is followed, there is no longer a need to include such a statement.

D) risk assessment of living modified mosquitoes

The specific guidance document on LM mosquitoes concerns self-limiting as well as self-propagating strategies. Sterile insects generated by conventional techniques have been released frequently in the past decades. The inclusion of information gained by these previous releases would improve the practicality of the guidance as this information is relevant when assessing the environmental risk of LM mosquitoes, especially when assessing the risk of LM mosquitoes with self-limiting traits.

Remarks on the guidance on monitoring of living modified organisms released in the environment (Part III)

The guidance on monitoring contains an overview of points that should be considered when a monitoring plan is being developed. The guidance describes in general the differences between case-specific and general monitoring, but does not provide guidance in the development of monitoring plans suited for these different types of monitoring.

Furthermore, the usefulness of the guidance could be improved by elaborating on and explaining the relationship between the outcome of risk assessment and the (possible) need for case-specific monitoring.

The guidance is written based on the experience gained with monitoring of LM plants which are being cultivated. In COGEM's view the guidance is not well tailored to monitoring of experimental releases. A separate section focusing on monitoring of field trials would help to set up monitoring of experimental releases.

Additional remarks

In figure 1 (page 20) the arrows which go from the box on risk assessment to the box on risk management strategies and decision making are solid. To an unexperienced risk assessor, this could lead to the conclusion that decision making is a part of the risk assessment process. To prevent this the arrows should be changed into dotted arrows.

In the chapter on the use on terms, the term introgression is defined quite broadly. A correct definition of introgression is "the stable incorporation of genes or genetic elements from one species or population into another species or population".

Conclusion

COGEM is of the opinion that the roadmap and specific guidances contain useful background information on the aspects that are important when assessing the risks of an LMO. The usefulness and practicality of the documents could be further improved if the documents would provide more focus on the aspects that are most important to assess the risks of a specific LMO.

While assessing the risks of a LMO for which specific guidance is present in Part II the impression could arise that all relevant points to consider when assessing the risk of this LMO are listed in the specific guidance and that the roadmap doesn't need to be consulted. As a consequence, some important points that should be considered in the risk assessment might be overlooked. When the guidances for specific types of LMOs are adjusted to stand-alone documents, only one document needs to be consulted.

In addition, COGEM notes that the guidance documents do not refer to past experiences with risk assessments of LM plants, data obtained by monitoring LM plants or experiences gained with conventional organisms (e.g. sterile insects).

Recommendations

The practicality of the guidances on specific types of LMOs can be improved when these guidances are changed and expanded into stand-alone guidances that contain all points to consider for the

specific type of LMO. The roadmap could contain general background information on risk assessment. Consequently, the content of the roadmap could be reduced.

The roadmap should provide general information on risk assessment and focus on the different steps of the risk assessment without going into detail on the different points to consider when assessing the risks of various types of LMOs. In Part II of the document the expanded stand-alone guidances for specific types of LMOs could follow the structure of the different steps in risk assessment as laid down in the roadmap and elaborate on the relevant points to consider for the specific type of LMO which is the topic of the guidance. Such an approach would improve the consistency and practicality of the guidance documents as it allows a better focus on the aspects of risk assessment which are most relevant for a specific type of LMO in Part II, while also providing useful background information on the risk assessment process in the roadmap. In addition, this approach allows a more easy inclusion of experiences from previous risk assessments and LMO releases.

COGEM recommends that a specific section on the risk assessment of experimental releases is included in each specific guidance. Also, COGEM is of the opinion that the guidance on monitoring could be improved by including a section on the monitoring of each specific type of LMO. In this way, more detailed practical information on the set-up of monitoring is available to risk assessors.

In addition, COGEM is of the opinion that the practicality of the roadmap and the specific guidances would be improved if they would adhere to the same structure and if a scheme is provided in which the aspects of risk assessment are presented in a visual manner. In this scheme numbers could be given that correspond to the paragraph numbers, which allows one to easily find the necessary information.

References

1. Convention on Biological Diversity – Biosafety Clearing-House. Guidance on risk assessment of living modified organisms. http://bch.cbd.int/onlineconferences/guidance_ra.shtml (visited November 18th, 2013).
2. COGEM (2011). Comments on the draft ‘guidance on risk assessment of living modified organisms’ from the Convention on Biodiversity. CGM/110311-03