Testing of the Guidance on Risk Assessment of Living Modified Organisms

#10

COMPLETE

Collector: BCH website (Website Survey)
Started: Thursday, March 27, 2014 12:25:11 PM
Last Modified: Thursday, April 17, 2014 5:55:29 AM
Time Spent: Over a week

PAGE 1

Q1: **Type of submission:**	Organization

PAGE 2

Q2: Name of the Party:	*Respondent skipped this question*
Q3: Person submitting this questionnaire:	*Respondent skipped this question*
Q4: Institution(s) or organization(s) that participated in the testing:	*Respondent skipped this question*
Q5: Context in which the testing was conducted	*Respondent skipped this question*
Q6: Actual case(s) of risk assessment used in the testing: Note: Please enter the hyperlinks of BCH Risk Assessment Records (e.g. http://bch.cbd.int/database/record.shtml?documentid=104904 and http://bch.cbd.int/database/record.shtml?documentid=104905) or other publicly accessible web pages containing the technical and scientific data of the actual cases of risk assessment used in the testing.	*Respondent skipped this question*
Q7: In what language was the Guidance tested?	*Respondent skipped this question*

PAGE 3

Q8: Name of the other Government:	*Respondent skipped this question*
Q9: Person submitting this questionnaire:	*Respondent skipped this question*
Q10: Institution(s) or organization(s) that participated in the testing:	*Respondent skipped this question*
Q11: Context in which the testing was conducted	*Respondent skipped this question*
Q12: Actual case(s) of risk assessment used in the testing: Note: Please enter the hyperlinks of BCH Risk Assessment Records (e.g. http://bch.cbd.int/database/record.shtml?documentid=104904 and http://bch.cbd.int/database/record.shtml?documentid=104905) or other publicly accessible web pages containing the technical and scientific data of the actual cases of risk assessment used in the testing.	*Respondent skipped this question*
Q13: In what language was the Guidance tested?	*Respondent skipped this question*

PAGE 4

Q14: **Name of the organization:**	Global Industry Coalition (GIC)
Q15: **Person submitting this questionnaire:**	
Full Name:	Sarah Lukie
Email Address:	sarah.lukie@croplife.org
Q16: **Institution(s) or organization(s) that participated in the testing:**	Business organization(s)
Q17: **Context in which the testing was conducted**	Other (please specify) completed using a third party consultant and vetted/reviewed/approved by our GIC Risk Assessment Workgroup

Q18: **Actual case(s) of risk assessment used in the testing: Note: Please enter the hyperlinks of BCH Risk Assessment Records (e.g. http://bch.cbd.int/database/record.shtml?documentid=104904 and http://bch.cbd.int/database/record.shtml?documentid=104905) or other publicly accessible web pages containing the technical and scientific data of the actual cases of risk assessment used in the testing.**

Risk Assessment 1:	https://bch.cbd.int/database/record.shtml?documentid=102518
Risk Assessment 2:	https://bch.cbd.int/database/record.shtml?documentid=102523
Risk Assessment 3:	https://bch.cbd.int/database/record.shtml?documentid=100880
Risk Assessment 4:	https://bch.cbd.int/database/record.shtml?documentid=103211
Risk Assessment 5:	https://bch.cbd.int/database/record.shtml?documentid=101240

Q19: **In what language was the Guidance tested?**	English

PAGE 5

Q20: **Would you like to submit an evaluation of the following section of the Guidance: Part I: The Roadmap for Risk Assessment**	Yes

PAGE 6

Q21: **This section of the Guidance is practical.1**

(no label)	Disagree

Q22: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:

The current structure of the Guidance makes the testing difficult because it does not resemble the structure used in the BCH risk assessment reports posted and does not reflect the structure of most risk assessments that are conducted by developers to support regulatory applications. This makes the location of relevant information complex and time consuming. Further, there are elements in the Guidance that could not be found in any of the risk assessment reports.
In the Guidance, each of the steps to follow for a risk assessment listed comprise a consideration of various issues: gene flow (including vertical and horizontal gene transfer), effects on target and non-target organisms (including toxicity, allergenicity and multi-trophic effects), changes in management practices, etc. By structuring the Guidance in this way, it is unclear how a novice risk assessor will understand the principles underpinning establishing a link between the different steps within the area of assessment or issue under consideration to complete a risk assessment.
There is insufficient guidance on discerning "need to know" versus "nice to know" information necessary to conduct a risk assessment. For example in Step 1, the Guidance lists the points to consider, but when it moves to the other steps there is no clear link on how information from Step 1 (hazard identification) is used with information in Step 2 (exposure) and Step 3 (hazard) to complete Step 4 (risk characterisation). The Guidance resembles a list of potential hazards and exposure scenarios without context and with no clear guidance on how to integrate the various pieces of information in performing a risk assessment in practical terms.
The Guidance sometimes wanders into areas of policy and fails to present scientific consensus, this is not useful to experienced risk assessors in countries that have functioning regulatory systems that follow a scientific approach.

Q23: This section of the Guidance is useful or has utility.2

(no label) Disagree

Q24: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:

The Guidance does describe the main concepts within the methodology used in conducting a risk assessment, and makes clear some key distinctions that risk assessment considers, e.g., hazard and exposure as unique components of risk. However, development of a succinct section on problem formulation is recommended, as well as further explanation on how to determine what information is relevant to characterise exposure and hazard for a particular area of assessment and how to characterise risk. This section should outline and clearly define key elements of the risk assessment such as: protection goals, assessment endpoints and measurement endpoints.
The Guidance should provide more insights as to how risk assessments discern "need to know" versus "nice to know" information necessary to conduct a risk assessment. Listing potential hazards and exposure scenarios without context (real-world examples) and with no clear guidance on how to integrate the various pieces of information in performing a risk assessment in practical terms should be avoided.
The "prescriptive" tone and policy-based statements in the Guidance should be revised, as should the inappropriate notion that risk assessment occurs in discrete "steps".
Overall, the Guidance should be reduced in length to represent a true scientific consensus based on real-world experience for it to become useful.

Q25: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label) Disagree

Q26: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:

The Guidance goes beyond the recommendations in the Cartagena Protocol. The "prescriptive" tone and policy-based statements in the Guidance should be revised. The Guidance should be reduced in length and represent a true scientific consensus so it is in line with risk assessments procedures followed by most parties.

Q27: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label) Strongly Disagree

Q28: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:

The Guidance needs re-structuring and simplification. A problem formulation section should be included and clear explanation on how to link hazard, exposure and risk.

Q29: **Here you may provide further details to explain your answers in evaluating this section of the Guidance:**

The GIC sponsored an analysis to "test" the risk assessment Guidance following the concept note made available by the Secretariat. The goal was to develop a methodology for testing the Guidance and report on the results of using this method. The search engine on the BCH website was used to identify records for risk assessments completed related to commercial production. Based on the BCH information, for this project, risk assessments conducted in different countries for one particular product were used.
A detailed Excel spreadsheet was developed to present the results of the testing in a visual format. The "recommendations" and "points to consider" outlined in the Guidance were entered and compared with information extracted from each of the risk assessment reports selected. Examination of the spreadsheet reveals which of those elements were discussed in the reports and what elements described in the Guidance did not appear in the reports.
For more details see Q.67

PAGE 7

Q30: **Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LMOs with stacked genes or traits**	Yes

PAGE 8

Q31: **This section of the Guidance is practical.1**

(no label)	Disagree
Q32: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*

Q33: **This section of the Guidance is useful or has utility.2**

(no label)	Disagree
Q34: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*

Q35: **This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3**

(no label)	Disagree
Q36: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*

Q37: **This section of the Guidance takes into account past and present experiences with LMOs.4**

(no label)	Disagree
Q38: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q39: Here you may provide further details to explain your answers in evaluating this section of the Guidance:	*Respondent skipped this question*

PAGE 9

Q40: **Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LM crops with tolerance to abiotic stress**	No

PAGE 10

Q41: This section of the Guidance is practical.1	*Respondent skipped this question*
Q42: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q43: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
Q44: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q45: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
Q46: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q47: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*
Q48: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q49: Here you may provide further details to explain your answers in evaluating this section of the Guidance:	*Respondent skipped this question*

PAGE 11

Q50: **Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LM mosquitoes**	No

PAGE 12

Q51: This section of the Guidance is practical.1	*Respondent skipped this question*
Q52: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q53: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*

Q54: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q55: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
Q56: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q57: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*
Q58: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q59: Here you may provide further details to explain your answers in evaluating this section of the Guidance:	*Respondent skipped this question*

PAGE 13

Q60: **Would you like to submit an evaluation of the following section of the Guidance: Part II: Specific types of LMOs or Traits - Risk assessment of LM trees**	No

PAGE 14

Q61: This section of the Guidance is practical.1	*Respondent skipped this question*
Q62: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q63: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
Q64: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q65: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
Q66: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q67: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*

Q68: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q69: Here you may provide further details to explain your answers in evaluating this section of the Guidance:	*Respondent skipped this question*

PAGE 15

Q70: **Would you like to submit an evaluation of the following section of the Guidance: Part III: Monitoring of LMOs Released into the Environment**	No

PAGE 16

Q71: This section of the Guidance is practical.1	*Respondent skipped this question*
Q72: Would you like to suggest improvements to this section to increase its practicality? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q73: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
Q74: Would you like to suggest improvements to this section to increase its usefulness/utility? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q75: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
Q76: Would you like to suggest improvements to this section to increase its consistency with the Protocol? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q77: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*
Q78: Would you like to suggest improvements to this section in order to better take into account past and present experiences with LMOs? If so, please indicate the line numbers and explain which improvements could be made:	*Respondent skipped this question*
Q79: Here you may provide further details to explain your answers in evaluating this section of the Guidance:	*Respondent skipped this question*

PAGE 17

Q80: **Would you like to submit an evaluation of the following section of the Guidance: Background Documents**	No

PAGE 18

Q81: This section of the Guidance is practical.1	*Respondent skipped this question*
Q82: This section of the Guidance is useful or has utility.2	*Respondent skipped this question*
Q83: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3	*Respondent skipped this question*
Q84: This section of the Guidance takes into account past and present experiences with LMOs.4	*Respondent skipped this question*

PAGE 19

Q85: **Please use the space below if you wish to provide additional feedback regarding the testing of the Guidance on Risk Assessment of Living Modified Organisms:**

(see annex)

ANNEX – GENERAL COMMENTS

1. INTRODUCTION

The Guidance for the risk assessment of living modified organisms (LMOs) developed by the Parties to the Cartagena Protocol on Biosafety is currently under discussion. Following the decision at the sixth Meeting of the Parties (MOP-6), the Parties were encouraged to test the Guidance using actual cases of risk assessment and share their findings through the Biosafety Clearing-House (BCH) and the open-ended online forum. In the context of this testing, the MOP-6 requested to the Executive Secretariat to:

a) Develop appropriate tools to structure and focus the testing of the Guidance;

b) Gather and analyse, in a transparent manner, feedback provided as a result of testing on the practicality, usefulness and utility of the Guidance, (i) with respect to consistency with the Cartagena Protocol on Biosafety; and (ii) taking into account past and present experiences with living modified organisms; and

c) Provide a report on possible improvements to the Guidance for consideration by the Conference of the Parties serving as the meeting of the Parties to the Protocol at its seventh meeting.

The Secretariat developed a concept note and a questionnaire to structure and focus the testing of the Guidance. The concept note describes the testing process to follow:

a) The objective of the testing is to evaluate the practicality, usefulness and utility of the Guidance on Risk Assessment of Living Modified Organisms with respect to consistency with the Cartagena Protocol on Biosafety, in particular Article 15 and Annex III, and taking into account past and present experiences with LMOs;

b) The testing may be conducted by Parties, other Governments and relevant organizations through their risk assessors and other experts who are actively involved in risk assessment;

c) The testing may be conducted by individuals or as a group initiative (e.g. workshops);

d) The Guidance is to be tested using actual cases of risk assessment conducted in accordance with Annex III of the Cartagena Protocol, noting that the actual case of risk assessment itself is not the subject of the testing:

a. The technical and scientific data of actual cases of risk assessment used in the testing may originate from various sources. These sources may include application dossiers, and previous or on-going risk assessment processes. Alternatively, the summaries of notifications may also be used;

b. Irrespective of the source of the technical and scientific data described in subsection ”d” above, the actual cases of risk assessment used in the testing must be clearly identified either through references to Risk Assessment Records in the Biosafety Clearing House (BCH), or hyperlinks to their original source;

c. The BCH Risk Assessment Records referring to the actual cases of risk assessment used in the testing may be generated either through the regulatory process of a country or through an independent or non-regulatory process.

Reporting the results of the testing:

a) The results of the testing are to be submitted through the BCH using the questionnaire common format that is made available for this purpose;

b) The BCH Risk Assessment Records or hyperlinks to webpages containing information on the actual cases of risk assessment used in the testing are to be linked to the questionnaire;

c) The results of the testing conducted by Parties and other Governments are to be submitted by their respective BCH National Focal Points and those by relevant organizations through their head offices; each Party, other Government or relevant organization may test the Guidance with as many actual cases of risk assessment available but may only complete and submit one questionnaire reporting their results.

Taking these requests into consideration, Estel Consult Ltd. has developed an approach for testing the Guidance. This document describes the methods used and a summary of the initial findings.

2. DESCRIPTION OF THE TESTING METHODOLOGY USED

2.1. SELECTION OF RISK ASSESSMENT RECORDS FOR THE TESTING

Following the Secretariat recommendation in the concept note, the first step was to map the risk assessment information available in the BCH website. The objective of the search was to identify and compare risk assessment records from different countries on the same product with the same scope of application. Using the search engine on the BCH website, the following criteria were used: “any country”, risk assessments for “Regulatory processes” and “LMOs for introduction into the environment-commercial production”. This search returned 218 records, although close examination revealed that despite selecting “commercial production”, most of the records returned were confined field trial evaluations. However, the search was useful for determining which countries have posted records of risk assessment reports conducted with a scope that includes food, feed and cultivation. These countries are: Argentina, Brazil, Canada, EU, India and Japan. All of the risk assessments found were for genetically modified plants, no records for trees, mosquitoes, or abiotic stress traits were available.

Since one of the objectives was to compare risk assessment reports from different countries on the same product with the same scope, the next step was to map the risk assessments posted by each of the countries for specific products (“organism id”) and select those products for which records were available from more than one country. The search focussed on three crops: maize, cotton and soybean. This search showed that:

- The only maize product for which risk assessment records are available for most of the countries listed above is the genetically modified maize MIR162 from Syngenta. Risk assessments including cultivation in the scope for this maize have been posted by Argentina, Brazil, Canada and Japan.

- For cotton there are risk assessment records including cultivation in the scope from Argentina and Brazil for the Monsanto product MON531xMON1445.

- For soybean the only product for which more than one country have posted risk assessment records including cultivation in the scope is the Bayer soybean A2704-12 (from Brazil and Argentina).

2.2. TESTING METHOD

Risk assessment records including cultivation in the scope for MIR162 maize were downloaded from the BCH website. The records retrieved were: 102518 and 102523 from Argentina; 100880 from Brazil; 103211 from Canada and 101240 from Japan.

A number of issues were encountered when retrieving the risk assessments:

- The first issue was that the links for the records from Argentina do not work.

- Another issue is that the records from Argentina are written in Spanish. For MIR162 the risk assessment report can be found at: http://64.76.123.202/site/agregado_de_valor/biotecnologia/50-EVALUACIONES/___favorable/_archivos/DOC_DEC_MIR162.pdf

- Record 100880 from Brazil is in Portuguese, although links to the English and Portuguese documents are included, both links lead to the document written in Portuguese. The English document can be found at: http://www.ctnbio.gov.br/index.php/content/view/15160.html

As mentioned earlier, all risk assessment records available on the BCH website are for genetically modified plants only. Risk assessments have been posted for stacked events, but they have not yet been tested.

The initial approach in testing the Guidance was to align the information between the risk assessment reports and then align them with the Guidance. However, once the reports were examined, it became apparent that the format used, the information included and the level of information provided by each country were very different. Therefore, a decision was made to list in an Excel spreadsheet the steps described in the Guidance and information to be considered in each step. Each report was then reviewed and compared against the points outlined in the Guidance. The comparison focused on whether a country had addressed or considered a particular step and information. Following Secretariat's directions, the risk assessment itself was not the subject of the evaluation. Once all the risk assessments were compared against the Guidance, a further evaluation was made to establish:

- What elements in the Guidance appear in all the risk assessments?

- What elements in the Guidance do not appear in any of the risk assessments?

- What elements in the Guidance are considered in some risk assessments and not in others?

During the evaluation, the practicality, usefulness and utility of the Guidance were also examined.

Given the request from the Secretariat to use "actual cases of risk assessments" for which links to webpages can be provided, the testing focused only on risk assessments posted on the BCH. It is important to note that these risk assessments, written by regulatory authorities, often provide a summary of the risk assessment and may not contain all the information provided by the developer or all the information considered by the evaluator. However, the approach used in testing the Guidance allowed the identification of elements addressed in all risk the assessment reports contained within each BCH record. It also allowed the identification of elements not included in these risk assessments. These elements may be examined further to determine if they are an essential part of the risk assessment.

3. FINDINGS

3.1. GENERAL COMMENTS

Testing of the Guidance led to the following findings:

- The format and prescription of the Guidance is confusing. The structure of the Guidance does not reflect the structure followed in any of the risk assessments analysed. The presentation of the methodology is not sufficiently similar to published methodologies that are conducted to support regulatory applications, and made it difficult to conduct the test.

- The Guidance describes a strict step-wise approach, presumably due to interpreting Annex III.8 without taking into account the term "as appropriate". The step-wise process to follow in the risk assessment described in the Guidance is:

- Step 1: Hazard identification

- Step 2: Exposure assessment

- Step 3: Hazard characterization

- Step 4: Risk characterization

- Step 5: Report, summary and recommendations

This is in contrast to the records reviewed in the BCH.

- In the Guidance, each step comprises a consideration of various issues: gene flow (including vertical and horizontal gene transfer); effects on target and non-target organisms (including toxicity, allergenicity and multi-trophic effects); changes in management practices; etc. By structuring the Guidance in this way, it is unclear how a novice risk assessor would understand the principles

underpinning establishing a link between the area of assessment or issue under consideration. There is insufficient guidance on discerning "need to know" information necessary to conduct a risk assessment versus "nice to know". For example in Step 1, the Guidance lists the points to consider, but when it moves to the other steps, there is no clear link on how information from Step 1 (hazard identification) is used with information in Step 2 (exposure) and Step 3 (hazard) to complete Step 4 (risk characterisation). So the Guidance almost becomes a list of potential hazards and exposure scenarios without context and with no clear guidance on how to integrate the various pieces of information for performing a risk assessment in practical terms. This approach does not allow a necessary connection between each phase of the risk assessment, and may generate confusion and lack of harmonization between risk assessments. The main problem is the seemingly prescriptive approach taken in the Guidance that is inconsistent with the more flexible, evidence based approach that occurs in practice as witnessed in the risk assessment records examined.

- The risk assessment reports reviewed follow national guidelines. Each report is structured in a way that allows a separate risk assessment (where a hazard and exposure characterization are conducted) of each issue, such as weediness potential and effects on non-target organisms, considered by the country important to their environmental protection goals. This allows for risk assessments that are easier to understand, where the problem under assessment is clearly defined (problem formulation), information already available is considered and an analysis is conducted to determine what additional information may be needed to complete the risk assessment.

- In addition to a prescriptive step-wise approach, the Guidance also has two generic sections, "overarching issues" and "planning phase".

- The "overarching issues" section contains discussions on data quality and relevance, and on uncertainty. However, none of the risk assessment records reviewed contained such a section or discussed these elements. Sections like "criteria for the quality of scientific information", drift beyond guidance into policy statements that may run counter to national practices of risk assessment that are compliant with the Protocol.

- The "planning phase" section discusses how to establish the context, mentions the need to take into account protection goals, assessment endpoints and national regulations, and discusses the choice of comparators. While it is good that the Guidance brings attention to the need to take into account these elements, countries usually do this within their national system. Besides, problem formulation needs to be understood as a composite of protection goals, assessment endpoint and measurement endpoints; the latter are not even mentioned in the Guidance, yet they are necessary in enabling the translation of protection goals into concrete measureable indicators and parameters. The risk assessment reports reviewed quote the directives under which they were conducted and the scope of the application. No specific mention of protection goals, assessment endpoints or comparators was found in any of the reports.

These two sections of the Guidance are more likely to bring confusion than clarity — they contain speculation and opinion on complex topics, which could potentially lead to conflict with national policies.

One of the critical elements of a risk assessment is to facilitate the communication between the risk assessor and the risk manager, so the risk assessor can outline in a clear way what problems were addressed, what information was used to address them, what were the conclusions and what information supports these conclusions. The Guidance in its current form fails to provide this.

The Guidance is useful in that it describes the critical distinctions between hazard and exposure and the need to consider both to characterize risk. However the Guidance does not offer much practical support to risk assessors as it is not clear how to match relevant hazard data with relevant exposure data to assess the risk for a particular area of assessment. The Guidance is supposed to cover all LMOs and all scopes of application, including risk assessments for confined field trials. However, the points to consider outlined in each of the steps are very broad and it is not immediately obvious what points would be applicable to a specific product or to a certain scope.

One of the important elements that could be improved is the introduction of a problem formulation step (mentioned in the Guidance but not developed or explained in detail). This step would help risk assessors in focussing the risk assessment according to the product type, the receiving environment and the scope. This would also help in clarifying the key areas to assess, given national protection goals, what information is already available and relevant for the assessment and what information is missing to complete the assessment. Another potential improvement would be to re-structure the Guidance or provide examples to clarify how the Steps described fit together for the assessment of a particular risk or issue under consideration.

3.2. COMMENTS ON SECTIONS OF THE GUIDANCE

This section provides general comments and observations that were made in the course of conducting the test. They are provided in a manner relevant to each of the sections of the Guidance tested.

3.2.1. Overarching issues

The Guidance gives only brief mention to protection goals and assessment endpoints. These are key elements in the risk assessment, but they are not sufficiently explained in the Guidance to help risk assessors. For example, assessment endpoints are brought up in several sections, but the term “measurement endpoint” is never mentioned. Understanding the difference between the two terms is key to understanding risk assessment. As such, this is a gap that should be addressed.

Another topic raised in this section is the quality and relevance of data. The testing revealed that these two topics are not mentioned in any of the BCH risk assessment reports examined. Sections like “criteria for the quality of scientific information”, drift beyond guidance into policy statements that may run counter to national practices of risk assessment that are compliant with the Protocol. This is also

the case for the section on relevance of information. Here it could be made clear that developers and evaluators could easily establish the relevance of data by using the problem formulation approach.

This section on “criteria for the quality of scientific information” also contains a discussion about uncertainty and a recommendation to identify sources of uncertainty and establish their nature. Again, none of the risk assessments reviewed during this project had an explicit mention of uncertainty or types of uncertainty. Usually evaluators deal with uncertainty in a practical way. Often the perception of “uncertainty” stems not just from the data included in the risk assessment, but from lack of familiarity with risk assessment methodologies or a problem of communication between the developer and the evaluator. Since the environmental risk assessments (ERAs) are conducted on a case-by-case basis, different approaches may be taken for different risk assessments. Unless the approach is clearly outlined and explained, evaluators may have difficulties following or understanding the approach and may have different interpretations of the data or they may reach different conclusions. Establishing a good line of communication between developers and evaluators could be a good way to deal with uncertainty, rather than prescribe elaborated requirements to address uncertainty. Pre-consultation meetings are encouraged in some countries to allow discussions regarding the best approach to take in the ERA before the assessment starts. Discussions may also take place during the review to facilitate a common understanding. Failing this, evaluators often request clarification or ask for more data to complete the assessment. It is surprising that the Guidance does not strongly recommend this very helpful dialogue that occurs in most countries around the world.

Uncertainty also often arises from the lack of familiarity with risk assessment methodology, either from the developer or the evaluator. Risk assessments are conducted to aid decision making and do not provide definitive answers regarding safety, there is always some degree of uncertainty. The more knowledgeable and experienced the risk assessors and evaluators are the more at ease they are with these concepts and the more able they are to deal with uncertainty. It is likely that the less experienced risk assessor will be greatly confused by this discussion on uncertainty and struggle to translate the Guidance into practicable terms.

This section of the guidance also describes the importance of establishing the scope and context of the risk assessment, taking into consideration country policies and regulations and protection goals. The section also includes a reference to the comparative assessment and choice of comparator. In essence the section introduces some of the aspects of problem formulation, but does not explain properly how problem formulation can be used to make the risk assessment fit for purpose by guiding the compilation of information and the risk assessment approach.

All of the risk assessments reviewed use the comparative approach and take into consideration background information on the conventional crop and the history of safe use. None of the reports make specific mention of protection goals, assessment endpoints or risk thresholds. None use a formal approach to problem formulation, although some do provide an introduction on the purpose of the assessment.

3.2.2. Conducting the risk assessment- STEP 1: Hazard identification

"An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health."

In this section the guidance recommends to "identify changes in the LMO, resulting from the use of modern biotechnology, that could cause adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. The potential adverse effects may be direct or indirect, immediate or delayed".

Some of the examples given of potential adverse effects are:

i. affect non-target organisms,
ii. cause unintended effects on target organisms,
iii. become persistent or invasive or develop a fitness advantage in ecosystems with limited or no management,
iv. transfer genes to other organisms/populations, and
v. become genotypically or phenotypically unstable.

All these examples, with the possible exception of (i) and (iii) prejudge a possible outcome as potentially adverse without providing guidance on the nature of the "harm". Effects on non-target organisms and persistence and invasiveness are areas of assessment that were considered in all risk assessments reviewed. However, there was no specific mention of "unintended effects on target organisms" in any of the risk assessments. "Unintended effects on target organisms" is a vague term and not clear what it means (usually effects on non-target organisms are evaluated) or what would be the mechanism of harm to the environment or its predictability (magnitude, duration, nature, etc.). Similarly, gene flow is a natural biological phenomenon, but it is presented to the novice as a potential adverse effect without proper explanation that the objective of the assessment is the consequences of gene flow, not its possible occurrence. All the risk assessment reports reviewed did consider whether sexually compatible wild relatives are present in the countries, but none of the reports contained an assessment of gene flow to other organisms (horizontal gene transfer).

The terms presented as potential adverse effects in the section on Hazard Identification raise concerns about the objectivity of the Guidance and cast doubt on its broad usefulness for those not familiar with environmental risk assessment methods.

Following the review of the risk assessment reports analysed, the following observations were made:

- All of the risk assessment reports:
    - Use the comparative approach (history of safe use of the conventional crop) taking into account relevant characteristics of the conventional crop;
    - Consider the scope of the application;

- Consider the molecular characterization data (insertion site, copy number, stability, integrity, insert sequence, etc);
- Consider compositional and agronomic comparison data;
- Consider expression data;
- Assess potential for outcrossing and vertical gene transfer;
- Assess persistence and invasiveness or weediness potential;
- Assess effects on non-target organisms (NTOs).

- None of the reports make specific mention to:

  - Direct, indirect, immediate or delayed adverse effects;
  - Cumulative effects;
  - Unintended effects on target organisms;
  - Horizontal gene transfer (only one country refers to this, but the assessment made is based on gene transfer from the GM plant to sexually compatible wild relatives, which in most countries is referred to as "vertical gene transfer").

Insect resistance management is one of the points recommended for consideration in this step as a potential environmental hazard. However, of the risk assessment reports reviewed only one country discussed this topic.

This assessment shows the elements of the Guidance considered in all risk assessment reports and the elements outlined that that do not appear in any of the risk assessment reports (for example: "direct, indirect, immediate and delayed effects" and "cumulative effects").

As discussed above, the Guidance prejudges hazards, which may be confusing when trying to implement this Guidance by a person without previous experience in risk assessment.

3.2.3. Conducting the risk assessment- STEP 2: Exposure characterization

"An evaluation of the likelihood of adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism."

In this section the Guidance provides recommendations on the points to consider for assessing the likelihood of an adverse effect occurring and characterizing exposure. The Guidance acknowledges that the characterization of exposure can be quantitative or qualitative, but fails to explain how to do this. Qualitative expressions are suggested but with no clear criteria as to how to harmonise their use in the risk assessment.

Following the review of the risk assessment reports, the following observations were made:

- All of the risk assessment reports:

  - Use the comparative approach (history of safe use of the conventional crop) taking into account relevant characteristics of the conventional crop;

- Consider factors that may affect the spread of the LMO;
- Consider factors that may affect the persistence and establishment of the LMO;
- Consider the likelihood of outcrossing;
- Consider the expected type or level of exposure (level of expression is taken into account).

- None of the reports:

  - Specify “plausible pathways of a hazard”;
  - Contain a specific quantification of exposure other than expression data in different tissues.

This evaluation shows that all risk assessment reports consider exposure and use the comparative approach. In this case most of the points to consider recommended by the Guidance appear to be addressed. However, there is no useful information to characterise exposure in practical terms.

3.2.4. Conducting the risk assessment- STEP 3: Hazard characterization

“An evaluation of the consequences should these adverse effects be realized.”

In this section the Guidance provides recommendations on the points to consider when conducting a hazard characterization. Following the review of the risk assessment reports, the following observations were made:

- All of the risk assessment reports:

  - Use the comparative approach (history of safe use of the conventional crop) taking into account relevant characteristics of the conventional crop;
  - Consider results from field trials;
  - Consider if transgene introgression may occur.

- Some risk assessment reports consider:

  - Relevant knowledge and experience with the LMO in similar environments;
  - Results from laboratory tests (most do, but there was no specific mention of this in the reports from two of the countries).

- None of the risk assessment reports:

  - Discuss the duration of the potential adverse effect (short/long-term);
  - Discuss the mechanisms of the effect (direct/indirect);
  - Discuss cumulative effects;
  - Discuss the reversibility of the effect or ecological scale;
  - Specify a quantitative or qualitative measure.

Here the testing revealed a greater variability in the risk assessments regarding hazard characterization. This could be due to differences in the level of detail provided by the reports. However, there are some elements proposed by the Guidance that do not seem to appear in the risk assessments, for example cumulative effects, direct, indirect immediate and delayed effects, reversibility of effects. No quantitative measures of hazard appear in the reports.

3.2.5. Conducting the risk assessment- STEP 4: Risk characterization

"An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized."

This section recommends conducting a risk characterization taking into consideration both hazard and exposure. This could leave a novice thinking that risk assessment occurs in distinct, successive steps rather than a gathering of evidence based on a plan articulated in problem formulation. It also recommends considering "identification and consideration of uncertainty". As discussed above, some inexperienced risk assessors may interpret this as a need to formally address uncertainty. The points to consider also include reference to the need to consider "Individual risks and any interaction among them, such as synergism or antagonism". Presumably this last point refers to an assessment of stacks. Unless further explained, this point can lead to confusion as it is unclear when or why this is recommended. There is also a point referring to "Broader ecosystem and landscape considerations, including cumulative effects due to the presence of various LMOs in the receiving environment". No further explanation is given on how to address this. Importantly, this is an example of the Guidance extending beyond science and experience into policy.

The review of the risk assessment reports confirmed that all reports assess the risk considering exposure and hazard. However none of the reports makes specific mention of uncertainty, cumulative effects, broader landscape considerations or interaction between individual risks.

3.2.6. Conducting the risk assessment- STEP 5: Report, summary and recommendations

"A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks"

This step recommends that risk assessors prepare a report summarizing the risk assessment process, identified individual risks and the estimated overall risk, and provide recommendation(s) as to whether or not the risks are acceptable or manageable and, if needed, recommendation(s) for risk management options that could be implemented to manage the risks associated with the LMO.

This section discusses the use of "acceptability criteria" and thresholds stressing that these are set by each country. The section also recommends considering a "scientific benefit analysis". Benefit analyses are not usually an integral part of the risk assessment, although some countries may consider them during the decision-making process. However, this appears to be outside the scope of the risk assessment Guidance and more a matter of policy.

The review of the risk assessment reports shows that all the reports make overall risk conclusions, but there is no mention of acceptability criteria or thresholds. No formal benefit analysis was found in any of the reports. Some of the reports recommended the preparation of an Insect Resistance Management (IRM) plan.

4. SUMMARY

This document describes the approach followed to "testing" the risk assessment Guidance following the concept note provided by the Secretariat and the main findings from this test. For this project, risk assessments conducted in different countries for one particular product were used. The goal was to determine whether similar approaches were followed by all countries and how these approaches matched with the approach recommended by the Guidance.

The criteria used to select the risk assessments to test were that (1) they should be available on the BCH website; (2) there should be risk assessments from different countries for the same product. After mapping the information available on the BCH website the first product selected was MIR162 maize. Risk assessment reports from Argentina, Canada, Brazil and Japan were used for the testing and comparison.

For the testing, the "recommendations" and "points to consider" outlined in the Guidance were entered in an Excel spreadsheet. Each of the risk assessment reports was then examined to determine which of the elements described in the Guidance were considered and discussed in the reports and which were not. Once all the records were compared against the Guidance, a further evaluation of the Guidance took place.

This exercise showed that finding information in the BCH website is not easy as there are many links broken and the risk assessments that are retrieved can be in different languages. Comparing the reports was also challenging as the reports reviewed followed different formats, and contained different types of information and different levels of detail.

Trying to align each report with the Guidance was also challenging. The current structure of the Guidance is very different from the structure of these reports, making the location of relevant information very time consuming. Experience in risk assessment was essential to complete this task.

The test allowed the identification of elements described in the Guidance that were taken into consideration in all the risk assessments examined. There were elements in the Guidance that could not be found in any of the risk assessment reports. Given the request from the Secretariat to use "actual cases of risk assessments" for which links to webpages can be provided, the testing conducted focused only on risk assessments published in the BCH. It is important to note that these risk assessments, written by regulatory authorities, often provide a summary of the risk assessment and they may not contain all the information provided by the developer or all the information considered by the evaluator. Therefore the elements that do not appear in any of the reports may need further examination to determine if they are an essential part of the risk assessment or they could be removed from the considerations altogether.

5. MAIN CONCLUSIONS

Finding a practical methodology for testing the Guidance taking into account the concept note provided by the Secretariat is challenging, time consuming and requires a good knowledge of the risk assessment methods currently used to assess the environmental safety of LMOs. However, the method described in this document provided important insights into the practicality and usefulness of the Guidance, and allowed the identification of key issues that could be considered for improvement.

The current structure of the Guidance makes the testing difficult because it does not reflect the structure of most risk assessments that are conducted to support regulatory applications. Concluding the latter point requires that the tester have experience in conducting and submitting risk assessments. It would probably be easier to test the Guidance within the context of particular areas of assessment, for example testing the points to consider recommended in each of the five steps for the assessment of persistence and invasiveness or the assessment of effects on NTOs, etc. This would facilitate the grouping of points to consider for each area of assessment and check whether they are considered in the actual case of risk assessment tested.

The testing described in this document suggests that the Guidance is useful in that it describes the main concepts within the methodology used in conducting the risk assessment, and makes clear some key distinctions that risk assessment considers, e.g., hazard and exposure as unique components of risk. However, the Guidance would benefit from revision; in particular removing the prescriptive tone, the inappropriate notion that risk assessment occurs in discrete “steps” and deleting all statements that are policy based. Overall, to become useful, the Guidance should be reduced in length to represent a true scientific consensus based on real-world experience. The development of a succinct section on problem formulation is recommended as well as further explanation on how to determine what information is relevant to characterise exposure and hazard for a particular area of assessment and how to characterise risk.

Some of the “points to consider” outlined in each of the steps do not appear in actual cases of risk assessment and their mention in the Guidance may not be helpful to guide inexperienced assessors, but bring confusion instead. Therefore, some of these points should be re-considered and if necessary removed.