

Testing of the Guidance on Risk Assessment of Living Modified Organisms

#1



COMPLETE

Collector: BCH website (Website Survey)

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Time Spent: 00:25:28

PAGE 1

Q1: Type of submission:

Party

PAGE 2

Q2: Name of the Party:

Czech Republic

Q3: Person submitting this questionnaire:

Full Name:

Zuzana Doubkova

Email Address:

Zuzana.Doubkova@mzp.cz

Q4: Institution(s) or organization(s) that participated in the testing:

Government authority(ies), Academic institution(s)

Q5: Context in which the testing was conducted

Individual exercise(s)

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.

Risk Assessment 1:

<http://bch.cbd.int/database/record.shtml?documentid=104345>

Risk Assessment 2:

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO&questiontype=2>

Risk Assessment 3:

<http://bch.cbd.int/database/record.shtml?documentid=103227>

Q7: In what language was the Guidance tested?

English

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

Testing of the Guidance on Risk Assessment of Living Modified Organisms

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:

Respondent skipped this question

Q15: Person submitting this questionnaire:

Respondent skipped this question

Q16: Institution(s) or organization(s) that participated in the testing:

Respondent skipped this question

Q17: Context in which the testing was conducted

Respondent skipped this question

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.

Respondent skipped this question

Q19: In what language was the Guidance tested?

Respondent skipped this question

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)

Agree

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:

I propose to delete in line 407 the term “scientifically plausible scenarios”. The sentence should be: “In this step, risk assessors develop meaningful risk hypotheses...”

I propose to change the text in line 423: “considered in the context of any suitable comparator (e.g. the non-modified recipient or other reference line already adapted to receiving environment...”

This is important in case of LMO with tolerance to abiotic stress, where the recipient species can be seriously handicapped in comparison to other naturally occurring species in receiving environment.

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

(no label)

Agree

Testing of the Guidance on Risk Assessment of Living Modified Organisms

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:

In line 229: the statement concerning the data quality should be defined "Used data should be of acceptable scientific quality."
Lines 263 to 265: are of great importance. Usually, two to three evaluators are asked to prepare RA, but usually all of them experienced in the same field (e.g. plant biology). Some special problems concerning chemistry, biochemistry, or population genetics are not so exactly evaluated although they could be important for some assessment endpoints.

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

(no label)

Strongly Agree

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:

No special text modifications are needed. The evaluation of an LMO takes into account also the interactions with other species present in receiving environment.

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

(no label)

Strongly Agree

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:

All important questions which emerged in previous risk assessments were incorporated in Part I.

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

Lines 707 to 708: in most risk assessments the evaluators focus in particular on the possible threat given by an introduction of LMO. To make the correct decision the benefit analysis should be included as mentioned in this Protocol.

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)

Neutral

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:

The uncertainty (how many combinations of newly stacked genes could arise, see statement in line 909) is great and this section surely does not include all potential risks.

In our case (the field trials with *Phytophthora infestans* resistant potato plants) this section does not cover it precisely (see definition in lines 771, 780, 790). Nevertheless, LMO contains three transgenes two of them conferring the resistance to the pathogen and one the resistance to herbicide.

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

(no label)

Agree

Testing of the Guidance on Risk Assessment of Living Modified Organisms

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:

The section mentions the problems connected with the higher variability among LMOs with stacked genes (see line 800). The unrelated non-LMOs were used even in these field trials with transgenic potato to obtain some basis of resistance data. The variability increased also due to different pathovars which emerged each year and due to climatic changes favorable or less favorable to the spread of oomycete.

Two other lines refer correctly to the occurrence of LMOs with stacked genes in environment (line 909 and line 919).

The line 864: "...of interactions between the novel and endogenous genes..." (see also line 850) refers rather to common situation which concerns any single transgene to be introduced. Such information could be in this special section omitted.

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

(no label)

Agree

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:

The importance of this section will increase with increased number of different LMOs introduced in the recipient environment.

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

(no label)

Neutral

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:

The present experience is not very frequent. Some crops with stacked genes are already prepared (especially the combination of different cry genes and their expression together with herbicide resistance), but the transgenes are usually physically linked the cases not covered by this section.

Q39: Here you may provide further details to explain your answers in evaluating this section of the Guidance:

The risk assessment of genetically modified potatoes with improved resistance to *Phytophthora infestans* took into account the negligible possibility of out-crossing of the transgenes to other cultivated potato plants. Fortunately, such transfers are not dangerous as potatoes are propagated vegetatively. As for the herbicide resistance imidazolin herbicides are not allowed for application to this crop in the Czech Republic.

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

Yes

PAGE 10

Q41: This section of the Guidance is practical.1

(no label)

Agree

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:

Line 1007: "taking into account risks to human health." These seem to be connected especially with the products of the genes introduced. Such genes usually originate from non-crop plants which can withstand harsh environmental conditions. Nobody has experienced such species as food. The cold-shock protein from *B.subtilis* (expressed in MON87460) has been experienced as food and it is safe.

Q43: This section of the Guidance is useful or has utility.2

(no label)

Agree

Testing of the Guidance on Risk Assessment of Living Modified Organisms

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:

No improvements are needed. The Protocol mentions even aspects that are not frequently evaluated (e.g. the cross-talk between abiotic resistance and biotic resistance of plant LMO, see line 974).

Q45: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.³

(no label)

Agree

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:

This part also generates materials useful for the application of the article 19 - Handling of Biotechnology and Distribution of its Benefits of the Convention on Biological Diversity.

Q47: This section of the Guidance takes into account past and present experiences with LMOs.⁴

(no label)

Agree

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:

No improvements are suggested.

Q49: Here you may provide further details to explain your answers in evaluating this section of the Guidance:

The Introduction of this Guidance (lines 956-1007) refers to all specific ways leading to the LMOs resistant to abiotic stress. Some instructions have more general character. I have no experience with the risk assessment concerning LMO resistant to abiotic stress but I used the data concerning maize MON87460 where no adverse effects were observed during cultivation under either well-watered or water-limited conditions. As the additional source of RA the text "Novel aspects of the environmental risk assessment of drought-tolerant genetically modified maize and omega-3 fatty acid genetically modified soybean" prepared by NIPHEN in 2007 was used.

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

Testing of the Guidance on Risk Assessment of Living Modified Organisms

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

Yes

Q71: This section of the Guidance is practical.1

(no label)

Agree

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:

All steps involved in the procedure are mentioned in lines 1851 to 1855.

Line 1886: "The selection of monitoring methods should also take into account the level of sensitivity and specificity..." The estimation of both characters can be rather difficult. Methods with higher sensitivity can reveal the higher variability of parameter which in turn can pose a problem to find the base line.

Q73: This section of the Guidance is useful or has utility.2

(no label)

Agree

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:

In para "3. Choice of monitoring sites" the shift of the field trial is not mentioned. Such attitude is obligatory for long lasting trials with aim to find the next season some volunteers. It introduces some additional environmental variability.

Line 1980: "...to inform competent authorities about the results yearly." In para 4. should be mentioned that the management practices (see lines 1974 to 1975) and especially substantial changes (irrigation, application of different insecticides or fungicides etc.) should be reported.

Q75: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label)

Neutral

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:

The monitoring mentioned in CPB stresses the identification of stabilizing components in environment. The LMOs could have such function but the monitoring is aimed to detect their destabilizing function.

Q77: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label)

Strongly Agree

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:

I have no such knowledge.

Q79: Here you may provide further details to explain your answers in evaluating this section of the Guidance:

The monitoring is more problematic than RA. It is affected by forced changes in agrotechnique (the occurrence of climatic changes or the occurrence of pests etc.). The notifier usually performs only general monitoring as the field trials are placed in distance from any protected area. My personal experience concerns only such monitoring which is usually short-term. The greatest problem in monitoring of LMOs released into the environment represents the fact that a long-term monitoring is missing.

Q80: Would you like to submit an evaluation of the following section of the Guidance: Background Documents

Yes

Testing of the Guidance on Risk Assessment of Living Modified Organisms

Q81: This section of the Guidance is practical.1

(no label)

Neutral

Q82: This section of the Guidance is useful or has utility.2

(no label)

Neutral

Q83: This section of the Guidance is consistent with the Cartagena Protocol on Biosafety.3

(no label)

Neutral

Q84: This section of the Guidance takes into account past and present experiences with LMOs.4

(no label)

Neutral

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:

The testing of the Guidance on Risk Assessment of Living Modified Organisms was conducted by the risk assessor RNDr. Oldřich Navrátil, CSc., who is working for the Institute of Experimental Botany of the Academy of Sciences of the Czech Republic and is a member of The Czech Commission for the Use of Genetically Modified Organisms and Genetic Products.