

# Testing of the Guidance on Risk Assessment of Living Modified Organisms

#46



**COMPLETE**

**Collector:** BCH website (Website Survey)

**Started:** Wednesday, March 05, 2014 2:41:01 AM

**Last Modified:** Tuesday, April 01, 2014 8:22:30 AM

**Time Spent:** Over a week

## PAGE 1

**Q1: Type of submission:**

Party

## PAGE 2

**Q2: Name of the Party:**

Belarus

**Q3: Person submitting this questionnaire:**

Full Name:

Elena Makeyeva

Email Address:

E.Makeyeva@igc.bas-net.by, biosafety.by@gmail.com

**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**

Group event(s) (e.g., workshop, training course, meeting)

**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=104904>

Risk Assessment 2:

<http://bch.cbd.int/database/record.shtml?documentid=104905>

**Q7: In what language was the Guidance tested?**

Other (please specify): English and Russian

## 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*

# Testing of the Guidance on Risk Assessment of Living Modified Organisms

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

# Testing of the Guidance on Risk Assessment of Living Modified Organisms

**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:**

178-179 - The Guidance is worked out in such a way that it is not prescriptive in character and is devoid of particular recipes and prescriptive examples for assessing risks. The Guidance is rather difficult to be used as a training tool for unexperienced experts therefore. It most likely is a good tool for already trained experts. Also we propose to arrange terms in glossary in alphabetic order. Each term should be described as full as possible in clear manner. So, we would like to suggest the following text for lines 178-179: "...reviewing risk assessment and as basic tool for developing training modules on risk assessment process (procedure)".

193 - We propose to make the following correction: "...acceptable and/or manageable..."

199 - We would like that for simplicity of perception such concepts as "protection goals" and other ones were not only interpreted in the section "Use of Terms" but also particular examples or references to the examples illustrating well the concepts were given just after the definition in the text.

453-456 - We think it is necessary to include information whether target gene is expressed in a certain part of a plant (e.g. in tubers) or in all the plant parts with indication of the expression level. It is desirable to include figures illustrating instrument readings, for example, the gene expression level, insertion sites, copy number, PCR results, verifying stability and integrity of insertion. It is desirable also to give references to analogous scientific research and tests, if any, or to indicate them as "know-how".

519-522 - It would be fruitful to give an example of quantitative determination of uncertainty. The same thing could be made in the text of lines 580-582.

2030-2031 - In our opinion, it is unfortunate wording of the term "antagonism". We suggest to use the term which expresses an ecological sense of this term relevant to LMO and biodiversity, namely: "Antagonism - relationship of two (or more) species of alive organisms when individuals of one species negatively influence on individuals of other species as competition for use of the same ecological niche resulting in displacement (partly or in full) of competitors by one species".

2064-2065 - It is desirable to clarify the definition "cumulative effect". For example, the cumulative effect is the effect (impact), enhanced as a result of a joint or repeated influence of LMOs or their products on the receiving environment. Effect of accumulated exposure.

209-211 - Данное руководство не носит обязательного характера и лишено конкретных указаний и предписывающих примеров осуществления оценки риска. В силу этого руководство достаточно трудно использовать в качестве средства обучения на начальных этапах подготовки экспертов. Скорее всего это хороший инструмент для уже подготовленных экспертов. Для обучения, на наш взгляд, опираясь на данное руководство, следует подготовить специальное пособие (учебный модуль) с детальным разъяснением используемых терминов. Поэтому предлагаем изложить строки 21--211 в следующей реакции: "...оценок рисков или их анализе, а также использовать как основу для разработки обучающих модулей в рамках проведения мероприятий по созданию потенциала".

213-217 - Для более ясного понимания текста русскоязычными специалистами предлагаем сделать в нем следующие правки: "...к оценке рисков в отношении всех видов ЖИО и предполагаемого использования их в рамках сферы действия и цели Протокола. Данный документ разработан преимущественно на основе полученного и накопленного к настоящему времени опыта в области оценок экологических рисков ЖИО, относящихся к сельскохозяйственным растениям.

229 - Внести следующую редакционную правку: "...оцениваемый риск приемлемым и/или регулируемым..."

230 - Внести следующую редакционную правку: "...аспекты неопределенности. Оценки рисков служат основанием для принятия решений в отношении ЖИО".

237 - Для простоты восприятия хотелось бы, чтобы такие понятия, как "цели защиты" и др., были не только подробнее объяснены в разделе "Использование терминов", но и даны конкретные примеры либо ссылки на примеры, хорошо иллюстрирующие данные понятия, сразу после их использования в тексте.

262 - Внести следующую редакционную правку: "...рассматриваемой информации, а также способов выявления и описания степеней неопределенности..." (выражение "описание вопросов неопределенности" здесь некорректно. Неопределенность имеет вероятностный характер, который может быть выражен степенью этой неопределенности).

521-523 - Дать примеры к используемым понятиям.

627-628 - Привести ссылку на пример построения концептуальных моделей при оценке риска.

643 - Привести ссылку на пример количественного выражения вероятности. То же для 716, 770.

549 - 553 - Включить информацию о том, экспрессируется ли целевой ген в определенной части растения (например, в клубнях) или во всех частях растения с указанием уровня экспрессии. Желательно включить рисунки, иллюстрирующие показания приборов, например, уровень экспрессии, сайты встраивания, число копий, результаты ПЦР, подтверждающие стабильность и целостность вставки. Желательно дать ссылки на аналогичные научные исследования и испытания, если таковые есть, или указать, что это "ноу-хау".

1100, 1101, 1102, 1103 - В данных предложениях идет повторение. Для русскоязычных специалистов не понятно, что такое "антипитательные факторы". Предлагаем использовать термин "антиметаболиты", используемый в русскоязычной литературе.

2524, 2525 - По нашему мнению дана неудачная формулировка понятия "антагонизм". Предлагаем следующий вариант разъяснения термина, как имеющего отношение к ЖИО и биоразнообразию: "Антагонизм - взаимодействие двух (и более) видов живых организмов, при котором особи одного вида негативно влияют на особей другого вида при конкуренции за занятие одной и той же экологической ниши, частично или полностью вытесняя из нее конкурентов".

2564-2565 - Желательно уточнить формулировку термина "кумулятивный эффект". Например, кумулятивный эффект - это эффект (действие), усиленный в результате совместного или многократного действия ЖИО или их продуктов в принимающей среде; накопление и суммирование этого действия.

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

(no label)

Strongly 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:** *Respondent skipped this question*

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

(no label)

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:**

Moreover it should be noted that Article 15 of the Cartagena Protocol on Biosafety provides that risk assessment is conducted for determining and evaluating potential adverse effects of LMOs not only on conservation and sustainable use of biological diversity but in view of risk to human health. We would like to emphasize the importance of LMO risk assessment to human health and the necessity for the maximum coverage of the issues which should be taken into consideration by experts when conducting such risk assessment. We propose to develop a separate Guidance on the issues of LMO risk assessment to human health.

Руководство согласуется с Картахенским протоколом по биобезопасности. Вместе с тем следует отметить, что в Статье 15 Картахенского протокола определено, что оценка риска проводится с целью определения и оценки возможного неблагоприятного воздействия ЖИО не только на сохранение и устойчивое использование биологического разнообразия, но и с учетом риска для здоровья человека. Мы хотели бы отметить важность оценки риска ЖИО на здоровье человека и необходимость максимального освещения вопросов, которые должны быть учтены экспертами при проведении указанной оценки рисков. Предлагаем разработать отдельное "Руководство по оценке рисков ЖИО для здоровья человека". Стоит учесть тот факт, что людей (общественность) очень беспокоит проблема влияния ГМО именно на их здоровье.

**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:** *Respondent skipped this question*

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

The general conclusion of the guidance testing: Road map is an integral and comprehensive guidance and a reference material to concentrate experts' attention on main important issues which should be taken into consideration when conducting risk assessment and which may be missed. For example, it is absolutely right that in lines 453-456 emphasis is put on both intentional and unintentional genetic products, emergence and effect of which are frequently not taken into consideration.

Общий вывод по тестированию Дорожной карты руководства следующий: Дорожная карта является целостным и всеобъемлющим руководством и справочным материалом для того, чтобы акцентировать внимание экспертов на основных и важных вопросах, которые надо учесть при проведении оценок рисков и которые могут быть упущены. Так, например, в строках 552-553 очень правильно сделан акцент на уровне экспрессии генов, а также на преднамеренные и непреднамеренные генные продукты, появление и влияние которых часто не принимается во внимание.

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** No

PAGE 8

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

*Respondent skipped this question*

**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*

# Testing of the Guidance on Risk Assessment of Living Modified Organisms

**Q33: This section of the Guidance is useful or has utility.**<sup>2</sup> *Respondent skipped this question*

**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.**<sup>3</sup> *Respondent skipped this question*

**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.**<sup>4</sup> *Respondent skipped this question*

**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.**<sup>1</sup> *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.**<sup>2</sup> *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.**<sup>3</sup> *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.**<sup>4</sup> *Respondent skipped this question*

# Testing of the Guidance on Risk Assessment of Living Modified Organisms

**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

# Testing of the Guidance on Risk Assessment of Living Modified Organisms

<b>Q61:</b> This section of the Guidance is practical. <sup>1</sup>	<i>Respondent skipped this question</i>
<b>Q62:</b> 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>Respondent skipped this question</i>
<b>Q63:</b> This section of the Guidance is useful or has utility. <sup>2</sup>	<i>Respondent skipped this question</i>
<b>Q64:</b> 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:	<i>Respondent skipped this question</i>
<b>Q65:</b> This section of the Guidance is consistent with the Cartagena Protocol on Biosafety. <sup>3</sup>	<i>Respondent skipped this question</i>
<b>Q66:</b> 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:	<i>Respondent skipped this question</i>
<b>Q67:</b> This section of the Guidance takes into account past and present experiences with LMOs. <sup>4</sup>	<i>Respondent skipped this question</i>
<b>Q68:</b> 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>Respondent skipped this question</i>
<b>Q69:</b> Here you may provide further details to explain your answers in evaluating this section of the Guidance:	<i>Respondent skipped this question</i>

PAGE 15

<b>Q70:</b> 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

<b>Q71:</b> This section of the Guidance is practical. <sup>1</sup>	<i>Respondent skipped this question</i>
<b>Q72:</b> 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>Respondent skipped this question</i>
<b>Q73:</b> This section of the Guidance is useful or has utility. <sup>2</sup>	<i>Respondent skipped this question</i>
<b>Q74:</b> 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:	<i>Respondent skipped this question</i>
<b>Q75:</b> This section of the Guidance is consistent with the Cartagena Protocol on Biosafety. <sup>3</sup>	<i>Respondent skipped this question</i>

# Testing of the Guidance on Risk Assessment of Living Modified Organisms

**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:**

We would like to emphasize that testing was prepared and conducted very thoroughly with experts' involvement of the Parties from all regions of the planet. Taking into account the fact that at present many countries have no sufficient experience in assessing LMO risks, we propose to conduct repeated testing of the Guidance when a rather large number of comments and suggestions will be accumulated after practical application of the given Guidance.