



Конвенция о биологическом разнообразии

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КОНФЕРЕНЦИЯ СТОРОН КОНВЕНЦИИ О БИОЛОГИЧЕСКОМ РАЗНООБРАЗИИ, ВЫСТУПАЮЩАЯ В КАЧЕСТВЕ СОВЕЩАНИЯ СТОРОН КАРТАХЕНСКОГО ПРОТОКОЛА ПО БИОБЕЗОПАСНОСТИ

Пятое совещание

Нагоя, Япония, 11-15 октября 2010 года

Пункт 13 предварительной повестки дня*

ОЦЕНКА РИСКОВ И РЕГУЛИРОВАНИЕ РИСКОВ (СТАТЬИ 15 И 16)

Записка Исполнительного секретаря

I. ВВЕДЕНИЕ

1. Картахенский протокол по биобезопасности определяет условия оценки рисков (статья 15 и приложение III) с целью выявления и оценки возможных неблагоприятных воздействий в отношении живых измененных организмов для сохранения и устойчивого использования биоразнообразия, с учетом также рисков для здоровья человека, и по регулированию рисков (статья 16) с тем, чтобы дать возможность Сторонам разработать и поддерживать соответствующие механизмы, меры и стратегии для регулирования, уменьшения и контроля рисков, которые определены в положениях настоящего Протокола.

2. На своем первом совещании Конференция Сторон, выступающая в качестве Совещания Сторон Протокола, постановила рассмотреть на своем пятом совещании условия, содействующие идентификации живых измененных организмов, которые вряд ли способны оказывать неблагоприятное воздействие на сохранение и устойчивое использование биологического разнообразия, с учетом также рисков для здоровья человека, в целях принятия решения в соответствии с пунктом 4 статьи 7¹.

3. На своем четвертом совещании при рассмотрении вопроса о необходимости разработки дальнейшего руководства по конкретным аспектам оценки рисков и регулирования рисков Стороны учредили онлайн-форум открытого состава по конкретным аспектам оценки рисков через Механизм посредничества по биобезопасности (МПБ) и Специальную группу технических экспертов по оценке рисков и регулированию рисков (СГТЭ) с кругом полномочий, содержащихся в приложении к этому решению. Кроме того, Стороны Протокола поручили Исполнительному секретарю создать: i) специальные дискуссионные группы и по меньшей мере

* UNEP/CBD/BS/COP-MOP/5/1.

¹ Пункт 7 а) i) приложения к решению BS-I/12.

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В целях сведения к минимуму воздействия процессов секретариата на окружающую среду и оказания содействия инициативе Генерального секретаря по превращению ООН в климатически нейтральную организацию, настоящий документ напечатан в ограниченном количестве экземпляров. Просьба к делегатам приносить свои копии документа на заседания и не запрашивать дополнительных копий.

одну онлайн-конференцию в режиме реального времени в каждом регионе перед каждым совещанием СГТЭ с целью выявления основных вопросов, связанных с конкретными аспектами оценки рисков и регулирования рисков, указанных в приложении к данному решению; а также ii) два совещания СГТЭ до пятого совещания Конференции Сторон, выступающей в качестве Совещания Сторон Протокола².

4. При рассмотрении вопроса о создании потенциала в области оценки рисков Стороны на своем четвертом совещании далее поручили Исполнительному секретарю: i) координировать наряду с другими соответствующими органами Организации Объединенных Наций и другими международными организациями разработку системы обучения оценке рисков и регулированию рисков в отношении живых измененных организмов и содействовать ей; ii) созвать до пятого совещания Сторон региональные или субрегиональные учебные курсы, которые позволят странам получить практический опыт составления и оценки докладов по оценке рисков в соответствии с Протоколом; и iii) созвать семинар по вопросам создания потенциала и обмена опытом в области оценки рисков и регулирования рисков в отношении живых измененных организмов в Тихоокеанском субрегионе³.

5. В дополнение к решению вопроса о необходимости разработки дальнейшего руководства по конкретным аспектам оценки рисков, как указано в пункте 3, и в соответствии со своим кругом полномочий, изложенным Сторонами, СГТЭ было также поручено рассмотреть возможные варианты сотрудничества в идентификации живых измененных организмов или конкретных признаков, которые могут оказывать неблагоприятное воздействие на сохранение и устойчивое использование биологического разнообразия, с учетом также рисков для здоровья человека. Для оказания помощи СГТЭ в ее работе, Конференция Сторон, выступающая в качестве Совещания Сторон Протокола, поручила Сторонам и предложила другим правительствам и соответствующим организациям представить имеющуюся научно обоснованную информацию об идентификации живых измененных организмов или конкретных признаков, способных оказывать неблагоприятное воздействие на сохранение и устойчивое использование биологического разнообразия, с учетом также рисков для здоровья человека. Стороны также поручили Исполнительному секретарю обобщить полученную информацию и подготовить сводный доклад для рассмотрения СГТЭ и Сторонами⁴.

6. Соответственно, настоящая записка подготовлена Исполнительным секретарем с целью содействия Сторонам Протокола в рассмотрении ими пункта повестки дня по оценке рисков и регулированию рисков. Раздел II содержит анализ основных итогов этого процесса для разработки дальнейшего руководства по конкретным аспектам оценки рисков. Раздел III содержит обзор мероприятий по созданию потенциала, проведенных в ответ на поручения совещания Сторон. Раздел IV содержит обзор материалов и рекомендаций, касающихся сотрудничества в идентификации живых измененных организмов, которые *могут оказывать неблагоприятное воздействие* на сохранение и устойчивое использование биологического разнообразия, с учетом также рисков для здоровья человека⁵. Раздел V содержит некоторые элементы, которые могут помочь Сторонам в рассмотрении условий идентификации живых измененных организмов, *которые вряд ли способны оказывать неблагоприятное воздействие* на сохранение и устойчивое использование биологического разнообразия, с учетом также рисков для здоровья человека⁶. В разделе VI приводится ряд выводов, и предлагаются некоторые элементы проекта решения для рассмотрения Сторонами.

² Пункты 3, 4 и 6 решения BS-IV/11.

³ Пункты 12 и 13 решения BS-IV/11.

⁴ Пункты 3, 4 и 6 решения BS-IV/11.

⁵ Согласно пункту 4 b) iii) приложения к решению BS-I/12.

⁶ Согласно пункту 7 a) i) приложения к решению BS-I/12.

II. ДАЛЬНЕЙШЕЕ РУКОВОДСТВО ПО КОНКРЕТНЫМ АСПЕКТАМ ОЦЕНКИ РИСКОВ

7. Для реализации различных элементов решения BS-IV/11 в связи с разработкой дальнейшего руководства по оценке рисков секретариат на основании консультаций с бюро Конференции Сторон, выступающей в качестве Совещания Сторон Протокола, учредил непрерывный процесс, включающий в себя три вида мероприятий: i) специальные онлайн-дискуссионные группы; iii) региональные онлайн-конференции в режиме реального времени; и iv) совещания с физическим участием членов СГТЭ.

8. Процесс начался с открытия онлайн-экспертного форума открытого состава по оценке рисков и регулированию рисков (Онлайн-форум) через Механизм посредничества по биобезопасности⁷.

9. В уведомлении Исполнительный секретарь предложил Сторонам, другим правительствам и соответствующим организациям назначить экспертов в области оценки рисков для участия в Онлайн-форуме, используя общий формат назначения экспертов по биобезопасности. Секретариат рассмотрел кандидатуры на предмет их соответствия критериям и минимальным требованиям для экспертов по биобезопасности, изложенным в решении BS-IV/4.

10. В общей сложности в Онлайн-форуме открытого состава было зарегистрировано 229 экспертов. Среди них 153 эксперта были выдвинуты в общей сложности 48 Сторонами, 11 экспертов были выдвинуты 5 субъектами, не являющимися Сторонами, и 65 экспертов были зарегистрированы в качестве наблюдателей⁸.

11. В рамках подготовки к работе СГТЭ было проведено восемь специальных онлайн-дискуссионных групп и четыре региональных онлайн-конференции в режиме реального времени (в Европе, Латинской Америке, Африке и Азии) в рамках Онлайн-форума в период с ноября 2008 года по февраль 2009 года⁹.

12. Участники СГТЭ были отобраны на основе их активного участия в мероприятиях Онлайн-форума в соответствии с обобщенным *modus operandi* Вспомогательного органа по научным, техническим и технологическим консультациям (ВОНТТК) Конвенции о биологическом разнообразии¹⁰, в соответствии с решением BS-IV/11 и на основании консультаций с бюро Конференции Сторон, выступающей в качестве Совещания Сторон Протокола. Список участников СГТЭ прилагается к настоящему документу в качестве приложения I.

13. Первое совещание СГТЭ по оценке рисков и регулированию рисков было проведено в Монреале с 20 по 24 апреля 2009 года. Восемнадцать участников из семнадцати Сторон, а также восемь наблюдателей от трех государств, не являющихся Сторонами, и пять организаций приняли участие в совещании в качестве членов СГТЭ.

14. Между двумя совещаниями, проведенными СГТЭ, состоялись следующие мероприятия с целью поддержки разработки проекта руководства по каждому из конкретных вопросов, обозначенных на первом совещании СГТЭ, и проверки стратегического плана в соответствии с решением Сторон:

⁷ Размещено по адресу: http://bch.cbd.int/onlineconferences/forum_RA.shtml.

⁸ Со списком участников можно ознакомиться по адресу: http://bch.cbd.int/onlineconferences/participants_ra.shtml.

⁹ Полные тексты дискуссионных групп размещены по адресу: http://bch.cbd.int/onlineconferences/archived_discussions_ra.shtml.

Документы и полные тексты онлайн-конференций в режиме реального времени размещены по адресу: http://bch.cbd.int/onlineconferences/realtime_ra.shtml.

¹⁰ Пункт 18 приложения III к решению VIII/10 Конференции Сторон.

а) *в рамках Онлайнного форума открытого состава*: десять специальных дискуссионных групп и четыре региональных онлайнных конференции в режиме реального времени (Африка, Азия и Тихоокеанский регион, ЗЕДГ, ЦВЕ, и GRULAC)¹¹; а также

б) *в рамках СГТЭ*: 5 раундов онлайнных дискуссионных групп, две телеконференции бюро СГТЭ, а также совещания с физическим участием членов Рабочей подгруппы по стратегическому плану и бюро СГТЭ¹².

15. Мероприятия, перечисленные выше в пункте 14, были распределены между Онлайнным экспертным форумом открытого состава и СГТЭ в целях создания обратной связи для каждой новой версии проекта руководящих документов, подготовленных рабочими подгруппами СГТЭ, и обеспечения участия широкого числа экспертов на протяжении всего процесса.

16. Второе совещание СГТЭ состоялась с 20 по 24 апреля 2010 года в Любляне (Словения). Во встрече приняли участие четырнадцать членов СГТЭ от Сторон, а также два члена от государств, не являющихся Сторонами, и четыре члена от организаций.

17. Полный перечень мероприятий, проводимых в рамках Онлайнного форума и СГТЭ, прилагается к настоящему документу в качестве приложения II.

А. Итоги Онлайнного экспертного форума открытого состава по оценке рисков и регулированию рисков

18. Рекомендации Онлайнного форума СГТЭ до ее первого совещания были даны по следующим вопросам:

а) разработка руководства по следующим конкретным аспектам оценки рисков и регулирования рисков: i) живые измененные рыбы, деревья, микроорганизмы и лекарственные растения; ii) живые измененные организмы с пакетированными генами или признаками; iii) конкретная принимающая среда; iv) мониторинг после выбросов и долгосрочное воздействие живых измененных организмов, высвобождаемых в окружающую среду; а также

б) план действий по разработке руководства по конкретным приоритетным аспектам, а также стратегического плана.

19. После первого совещания СГТЭ обсуждения в рамках Онлайнного экспертного форума открытого состава способствовали продвижению проекта и тестированию стратегического плана, а также содействовали разработке руководства по конкретным аспектам оценки рисков, которые были определены СГТЭ в качестве приоритетных (то есть живые измененные комары, живые измененные сельскохозяйственные культуры с устойчивостью к абиотическим стрессам и живые измененные организмы с пакетированными генами).

20. В течение нескольких раундов дискуссий эксперты Онлайнного форума внесли существенный вклад в работу СГТЭ по содержанию стратегического плана и конкретным аспектам оценки рисков. При тестировании стратегического плана в большинстве высказанных мнений была дана положительная оценка его полезности и актуальности, а также был внесен ряд рекомендаций о путях повышения удобства пользования стратегическим планом.

¹¹ Полные тексты дискуссионных групп размещены по адресу: http://bch.cbd.int/onlineconferences/archived_discussions_ra.shtml.
Документы и полные тексты онлайнных конференций в режиме реального времени размещены по адресу: http://bch.cbd.int/onlineconferences/realtime_ra.shtml.

¹² Совещания Рабочей подгруппы по стратегическому плану и бюро СГТЭ проводились в Гааге с 12 по 14 октября 2009 года.

21. В ходе последнего раунда работы специальных дискуссионных групп членам Онлайнного форума было предложено выработать рекомендации совещанию Сторон для рассмотрения на его пятом совещании о путях продвижения в области процессов оценки рисков и регулирования рисков. Участники форума выразили мнения о полезности стратегического плана и руководства по конкретным аспектам оценки рисков и отметили, что эти документы должны регулярно пересматриваться и обновляться с тем, чтобы обеспечить их актуальность и соответствие новым разработкам.

22. Участники Онлайнного форума также отметили необходимость разработки дополнительного руководства по другим конкретным аспектам оценки рисков. Вопросы оценки рисков, перечисленные в информационных документах UNEP/CBD/BS/COP-MOP/5/INF/12 и UNEP/CBD/BS/COP-MOP/5/INF/13, были отмечены Форумом в качестве отправной точки для разработки дальнейшего руководства¹³. Кроме того, участникам было также рекомендовано рассмотреть следующие вопросы: i) создание сценариев рисков; ii) стратегии регулирования рисков, в том числе мониторинг воздействия живых измененных организмов после высвобождения их в окружающую среду; iii) анализ неопределенности и изменчивости; iv) «перечень», содержащий важнейшие элементы процесса оценки рисков; и v) порядок оптимальной привязки процесса оценки рисков в рамках Протокола к положениям и решениям в рамках Конвенции о биологическом разнообразии.

23. Кроме того, было рекомендовано во время обсуждений на Онлайнном форуме, чтобы при разработке нового руководства были продолжены консультации между Сторонами и чтобы существующие руководящие указания, разработанные другими международными организациями (например, ОЭСР, МКЗР) были приняты во внимание.

24. Что касается механизма решения проблем разработки дальнейшего руководства, большое число экспертов рекомендовали СГТЭ, онлайнные дискуссии и обмен информацией через МПБ, либо их сочетание. Дополнительные примеры механизмов решения проблем разработки руководства включали проведение консультаций между экспертами и создание фонда экспертов по ресурсам для осуществления обучения после разработки руководства.

25. Мнения и рекомендации, представленные в рамках Онлайнного экспертного форума открытого состава, обобщены и представлены в качестве информационных документов для рассмотрения Сторонами (UNEP/CBD/BS/COP-MOP/5/INF/12 и 14)¹⁴.

В. Итоги работы Специальной группы технических экспертов по оценке рисков и регулированию рисков

26. Основными итогами первого совещания СГТЭ стали: i) проект стратегического плана; ii) выявление и определение приоритетности трех других конкретных вопросов оценки рисков (то есть живые измененные москитные насекомые, живые измененные сельскохозяйственные культуры с устойчивостью к абиотическим стрессам и живые измененные организмы с пакетированными генами) для разработки руководства; iii) создание четырех рабочих подгрупп, фокусирующихся на каждой из выявленных проблем; и iv) разработка плана действий, состоящего из резюме условий и процедур разработки руководства до второго совещания СГТЭ.

¹³ Размещены по адресу: <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=3018>.

¹⁴ Информационные документы UNEP/CBD/BS/COP-MOP/5/INF/12 и UNEP/CBD/BS/COP-MOP/5/INF/14 размещены по адресу: <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=3018>.

27. В межсессионный период на основании консультаций с Онлайн-экспертной группой открытого состава, рабочие подгруппы СГТЭ продолжили разработку проектов документов для руководства по четырем конкретным вопросам оценки рисков и провели тестирование проекта стратегического плана по оценке рисков живых измененных организмов.

28. На втором совещании СГТЭ основными итогами ее работы стали:

а) завершение разработки документа, озаглавленного «Руководство по оценке рисков живых измененных организмов» и состоящего из двух разделов под названием «Часть I. Стратегический план по оценке рисков живых измененных организмов» и «Часть II. Конкретные виды и признаки живых измененных организмов (то есть живые измененные комары, живые измененные сельскохозяйственные культуры с устойчивостью к биотическим стрессам и живые измененные организмы с пакетированными генами или признаками). Этот документ прилагается к настоящему документу в качестве приложения III, а также будет доступен через МПБ¹⁵;

б) рекомендации секретариата о порядке интегрирования и обновления руководящих документов, подготовленных СГТЭ, и инструментов для поиска справочных материалов, имеющихся в Центре информационных ресурсов по биобезопасности МПБ;

с) оценка плана действий, принятого на первом совещании.

29. СГТЭ также предложила Сторонам на их пятом совещании рекомендации по дальнейшей разработке руководства в отношении дополнительных вопросов оценки рисков, особенно тех конкретных вопросов оценки рисков, которые были определены и распределены в соответствии с их приоритетностью во время проведения Онлайн-форума открытого состава и первого совещания СГТЭ.

30. Доклад о работе первого совещания и окончательный доклад СГТЭ доступны в качестве информационных документов для рассмотрения Сторонами¹⁶.

31. Полный комплекс рекомендаций СГТЭ пятому совещанию Сторон прилагается к настоящему документу в качестве приложения IV.

III. СОЗДАНИЕ ПОТЕНЦИАЛА В ОБЛАСТИ ОЦЕНКИ РИСКОВ

32. В ответ на поручение Сторон по созданию потенциала в области оценки рисков секретариат выступил координатором процесса разработки системы обучения с участием нескольких субъектов деятельности в сотрудничестве с учреждениями Организации Объединенных Наций (Орхусская конвенция Европейской экономической комиссии Организации Объединенных Наций, Международная конвенция о защите растений Продовольственной и сельскохозяйственной организации Объединенных Наций (ФАО) и Организация Объединенных Наций по окружающей среде (ЮНЕП)), другими международными организациями (Глобальная промышленная коалиция и Третья мировая сеть) и академическим сектором (Университет Кентербери и Университет Миннесоты).

¹⁵ Размещено по адресу http://bch.cbd.int/onlineconferences/forum_RA.shtml.

¹⁶ Информационные документы UNEP/CBD/BS/COP-MOP/5/INF/13 и UNEP/CBD/BS/COP-MOP/5/INF/15 размещены по адресу: <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=3018>.

33. Разработка системы обучения была проведена на поэтапной основе. Сначала секретариат подготовил общий план обучения и предложил сотрудничающим организациям представить свои материалы и замечания. Затем на основе различных форм обратной связи секретариат подготовил проект учебного пособия и предложил сотрудничающим организациям провести экспертную оценку. Проект руководства был затем пересмотрен секретариатом на основе обратной связи и замечаний, представленных во время процесса экспертной оценки.

34. При использовании положений Картахенского протокола по биобезопасности, в частности его приложения III, в качестве основы для составления и рассмотрения разрабатываемого учебного пособия секретариат также попытался включить в него в полном объеме опыт и существующую практику ряда национальных нормативно-правовых структур и международных организаций.

35. Результатом этого процесса является проект учебного пособия под названием «Оценка рисков живых измененных организмов», который включает в себя четыре модуля: i) обзор биобезопасности и Картахенского протокола по биобезопасности; ii) подготовительная работа — понимание контекста, в котором проводится оценка рисков; iii) проведение оценки рисков; а также iv) подготовка доклада по оценке рисков.

36. Учебное пособие предлагается в качестве информационного документа, а также через МПБ для рассмотрения Сторон¹⁷.

37. Для дальнейшего рассмотрения поручения Сторон о проведении мероприятий по созданию потенциала с целью предоставления странам возможности обмена опытом и получения практических знаний по составлению и оценке докладов по оценке рисков в соответствии с Протоколом, вышеописанное учебное пособие было использовано при проведении следующих мероприятий:

а) Тихоокеанский субрегиональный семинар по созданию потенциала и обмену опытом в области оценки рисков в Нади, Фиджи, с 4 по 7 июля 2010 года; а также

б) Азиатские субрегиональные учебные курсы по оценке рисков в отношении живых измененных организмов в Сием Реап, Камбоджа, с 12 по 16 июля 2010 года.

38. На Тихоокеанском субрегиональном семинаре присутствовали двенадцать участников из шести Сторон Протокола (Кирибати, Ниуэ, Самоа, Соломоновы Острова, Тонга и Фиджи), двух государств, не являющихся сторонами (Вануату и Острова Кука), и одной организации (Университет Кентерберри, Новая Зеландия). Двадцать три участника из пятнадцати Сторон Протокола (Бутан, Вьетнам, Индия, Индонезия, Исламская Республика Иран, Йемен, Камбоджа, Лаосская Народно-Демократическая Республика, Малайзия, Монголия, Мьянма, Пакистан, Сирийская Арабская Республика, Таиланд, Туркменистан), неправительственных организаций (Третья мировая сеть) и Программы Организации Объединенных Наций по окружающей среде приняли участие в учебных курсах для Азии. В Азиатских учебных курсах также принял участие один эксперт из Нидерландов.

39. Участникам было предложено ответить на вопросы анкеты по оценке Тихоокеанского семинара и Азиатских учебных курсов. Результаты вышеуказанной анкеты свидетельствуют о наличии всеобщего согласия в том, что эти мероприятия i) обеспечили практическое обучение по

¹⁷ Учебное пособие представлено в виде информационного документа UNEP/CBD/BS/COP-MOP/5/INF/22 по адресу: <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=3018>, а также через Механизм посредничества по биобезопасности: http://bch.cbd.int/protocol/cpb_art15/training.

составлению и оценке докладов по оценке рисков в соответствии со статьями Протокола и приложением III к нему; ii) способствовали развитию навыков по использованию и толкованию существующей информации, а также выявлению и устранению информационных пробелов; а также iii) помогли понять порядок установления базовой информации, необходимой для оценки рисков.

40. Результаты анкеты также продемонстрировали согласие большинства участников в том, что учебное пособие, подготовленное секретариатом в сотрудничестве с другими органами Организации Объединенных Наций и соответствующими организациями i) является полезным инструментом обучения в области оценки рисков; ii) доступно для понимания благодаря поэтапной подаче материала; iii) включает в себя достаточный обзор процесса оценки рисков; а также iv) является полезным для широкого круга пользователей.

41. При установлении дальнейшей обратной связи участники высказали мнение о том, что учебное пособие является эффективным инструментом преподавания, обеспечивающим хорошо структурированное и комплексное введение в процесс оценки рисков, а также полезно для Сторон, равно как и для других стран и соответствующих организаций. Участники отметили, что для повышения полезности учебного пособия оно должно:

a) совершенствоваться далее, в частности путем добавления глоссария терминов, списка сокращений, блок-схем, диаграмм, примеров других живых измененных организмов, не являющихся сельскохозяйственными культурами, и т.д.;

b) включать в себя элементы из «Руководства по оценке рисков живых измененных организмов», разработанного СГТЭ, а именно из стратегического плана (например, блок-схемы), а также из руководства по конкретным видам и признакам живых измененных организмов (например, оценка рисков в отношении живых измененных москитных насекомых, живых измененных организмов с пакетированными генами или признаками и живых измененных сельскохозяйственных культур с устойчивостью к абиотическим стрессам); а также

c) быть представленным с помощью более удобного для пользователя инструмента обучения (например, такого, как интерактивное программное обеспечение); а также

d) быть опубликованным на всех языках Организации Объединенных Наций.

42. Участники Тихоокеанского семинара и Азиатских учебных курсов договорились, что Стороны могли бы рассмотреть на своем пятом совещании следующие элементы/мероприятия:

Создание потенциала в области оценки рисков:

a) дальнейшие учебные курсы по оценке рисков на национальном уровне, либо для небольших географических областей (например, около 5–7 стран) со сходной принимающей средой, допускающей участие основной группы экспертов по каждой стране;

b) последующие курсы повышения квалификации в области оценки рисков, сосредоточенные, например, на различных видах их предполагаемого использования (например, интродукция в окружающую среду и живые измененные организмы, предназначенные для непосредственного использования в качестве продовольствия, корма или для обработки) и на различных видах живых измененных организмов;

c) специализированные учебные курсы по следующим аспектам: i) подготовка докладов и рекомендаций по оценке рисков; ii) извлечение соответствующих данных из

уведомлений; iii) оценка качества данных, представленных для применения; и iv) сбор подробной исходной информации;

d) обучение инструкторов, которые далее могут осуществлять создание потенциала на национальном уровне;

Руководство по оценке рисков:

e) публикация и распространение «Руководства по оценке рисков в отношении живых измененных организмов» СГТЭ, включая онлайн-версию в Механизме посредничества по биобезопасности на всех языках Организации Объединенных Наций;

f) разработка дальнейших руководства по оценке рисков в соответствии с рекомендациями СГТЭ.

Создание общего потенциала в области биобезопасности:

g) дальнейшее обучение на региональном уровне идентификации живых измененных организмов;

h) обучение лиц, принимающих решения по вопросам толкования рекомендаций по оценке рисков и ходу осуществления стратегий регулирования рисков.

43. Доклады об осуществлении этих мероприятий по созданию потенциала доступны в качестве информационных документов для рассмотрения Сторонами (UNEP/CBD/BS/COP-MOP/5/INF/16 и 17)¹⁸.

IV. СОТРУДНИЧЕСТВО В ИДЕНТИФИКАЦИИ ЖИВЫХ ИЗМЕНЕННЫХ ОРГАНИЗМОВ ИЛИ КОНКРЕТНЫХ ПРИЗНАКОВ, КОТОРЫЕ МОГУТ ОКАЗЫВАТЬ НЕБЛАГОПРИЯТНОЕ ВОЗДЕЙСТВИЕ НА СОХРАНЕНИЕ И УСТОЙЧИВОЕ ИСПОЛЬЗОВАНИЕ БИОЛОГИЧЕСКОГО РАЗНООБРАЗИЯ, С УЧЕТОМ ТАКЖЕ РИСКОВ ДЛЯ ЗДОРОВЬЯ ЧЕЛОВЕКА

44. В уведомлении Исполнительный секретарь предложил Сторонам, другим правительствам и соответствующим организациям представить научно обоснованную информацию об идентификации живых измененных организмов или конкретных признаков, которые могут оказывать неблагоприятное воздействие на сохранение и устойчивое использование биологического разнообразия, с учетом также рисков для здоровья человека¹⁹.

45. В некоторых материалах, полученных секретариатом, были приведены ссылки на живые измененные организмы или конкретные признаки, которые могут оказывать неблагоприятное воздействие, такие как живой измененный хлопок, рыба, кукуруза, деревья, вирусы, а также живые измененные организмы для производства фармацевтических веществ с пакетированными генами или признаками, устойчивостью к насекомым, устойчивостью к абиотическим стрессам и пестицидам, измененным поглощением питательных веществ или генетическими маркерами устойчивости к антибиотикам. В некоторых из представленных материалов, с другой стороны,

¹⁸ Информационные документы UNEP/CBD/BS/COP-MOP/5/INF/16 и UNEP/CBD/BS/COP-MOP/5/INF/17 размещены по адресу: <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=3018>.

¹⁹ Уведомление SCBD/BS/MPDM/jh/67587 (2009-056) размещено по адресу: <http://bch.cbd.int/protocol/notifications/>.

отмечалось, что нет никаких научно обоснованных доказательств, указывающих на возможное неблагоприятное воздействие живых измененных организмов, подвергнутых коммерциализации к настоящему времени.

46. На основе представленных выше материалов секретариат подготовил «Сборник материалов по идентификации живых измененных организмов или конкретных признаков, которые могут оказывать неблагоприятное воздействие на сохранение и устойчивое использование биологического разнообразия, с учетом также рисков для здоровья человека» для рассмотрения СГТЭ и Сторонами²⁰.

47. После обсуждения этого вопроса СГТЭ определила следующие формы сотрудничества: i) обмен информацией через Механизм посредничества по биобезопасности; ii) семинары; iii) работа специальной группы технических экспертов и iv) сотрудничество в области тестирования живых измененных организмов.

48. Несколько членов СГТЭ также согласовали возможность выработки для этой цели поэтапного процесса, в котором за начальным этапом сбора информации последует второй этап анализа информации.

49. СГТЭ предложила дальнейшие конкретные рекомендации по этому вопросу, представленные ниже в пунктах f) и g) iv) приложения IV.

V. ИДЕНТИФИКАЦИЯ ЖИВЫХ ИЗМЕНЕННЫХ ОРГАНИЗМОВ, КОТОРЫЕ ВРЯД ЛИ СПОСОБНЫ ОКАЗЫВАТЬ НЕБЛАГОПРИЯТНОЕ ВОЗДЕЙСТВИЕ НА СОХРАНЕНИЕ И УСТОЙЧИВОЕ ИСПОЛЬЗОВАНИЕ БИОЛОГИЧЕСКОГО РАЗНООБРАЗИЯ, С УЧЕТОМ ТАКЖЕ РИСКОВ ДЛЯ ЗДОРОВЬЯ ЧЕЛОВЕКА

50. В пункте 4 статьи 7 Протокола говорится, что «процедура заблаговременного обоснованного согласия не применяется к преднамеренному трансграничному перемещению живых измененных организмов, которые в решении Конференции Сторон, выступающей в качестве Совещания Сторон настоящего Протокола, определены как вряд ли способные оказывать неблагоприятное воздействие на сохранение и устойчивое использование биологического разнообразия, с учетом также рисков для здоровья человека».

51. При обсуждении механизмов, которые способствовали бы идентификации живых измененных организмов, которые вряд ли способны оказывать неблагоприятное воздействие на сохранение и устойчивое использование биологического разнообразия, с учетом также рисков для здоровья человека, Стороны на своем пятом совещании могут принять во внимание, среди прочего, следующие материалы, представленные Сторонами через МПБ в упрощенном порядке (статья 13), в которых импорт живых измененных организмов был освобожден от процедуры заблаговременного обоснованного согласия²¹.

52. По состоянию на 10 июня 2010 года в МПБ были представлены по упрощенной процедуре следующие живые измененные организмы:

²⁰ Размещен в виде информационного документа UNEP/CBD/BS/COP-MOP/5/INF/11 по адресу: <http://bch.cbd.int/protocol/meetings/documents.shtml?eventid=3018>.

²¹ Пункт 1 b) статьи 13.

ЖИО, для которых была применена упрощенная процедура	Страна	Запись в МПБ
Хлопок Bollgard™	Колумбия	8151
Хлопок Roundup Ready™	Колумбия	8155
Хлопок Bollgard II™ (MON-15985-7)	Южная Африка	5666
Хлопок Bollgard™ (MON-00531-6)	Южная Африка	5679
Кукуруза YieldGard™ (MON-00810-6)	Южная Африка	5712
Кукуруза YieldGard™ (SYN-BT011-1)	Южная Африка	5715
Кукуруза Roundup Ready™ (MON-00603-6)	Южная Африка	8164
Соевые бобы Roundup Ready™ (MON-04032-6)	Южная Африка	8167
Хлопок Roundup Ready™ (MON-01445-2)	Южная Африка	8170
Кукуруза Roundup Ready™ YieldGard™ (MON-00603-6 x MON-00810-6)	Южная Африка	40513
Хлопок Roundup Ready™ Flex™ (MON-88913-8)	Южная Африка	40514
Кукуруза Roundup Ready™ Bollgard™ (MON-00531-6 x MON-01445-2)	Южная Африка	40516

VI. ВЫВОДЫ И ЭЛЕМЕНТЫ ПРОЕКТА РЕШЕНИЯ

A. Дальнейшие указания по конкретным аспектам оценки рисков

53. Задачи, включенные Сторонами в круг полномочий Онлайнного форума и СГТЭ для разработки дальнейших указаний по оценке рисков, были успешно выполнены в рамках процесса, включавшего как онлайнные обсуждения, так и обсуждения с физическим присутствием участников.

54. Большая группа экспертов провела онлайнное обсуждение через специальные дискуссионные группы и конференции в режиме реального времени и подготовила рекомендации для группы меньшего состава, СГТЭ, которая провела совещание с физическим присутствием участников. Этот процесс позволил большому числу экспертов в различных научных и технических областях, связанных с оценкой рисков, внести вклад в разработку руководящих материалов рентабельными методами в условиях ограниченных финансовых ресурсов.

55. Одним из результатов этого процесса является документ под названием «Руководство по оценке рисков в отношении живых измененных организмов». Согласно рекомендациям СГТЭ и Онлайнного форума этот руководящий документ должен i) публиковаться и распространяться, в том числе его онлайнная версия, в МПБ на всех языках Организации Объединенных Наций; ii) при необходимости пройти дальнейшее тестирование, например, в ходе региональных семинаров, включая сотрудничество с существующими инициативами по созданию потенциала и подготовке кадров; а также iii) быть пересмотрен в течение двух лет, а необходимость обновления списка справочных материалов должна быть определена в течение года.

56. Несмотря на значительный прогресс в решении вопроса о необходимости руководящих указаний по оценке рисков, достигнутый благодаря разработке вышеупомянутого документа, многие члены СГТЭ и Онлайнного форума высказали мнение о необходимости дальнейшей разработки руководящих указаний и поэтому рекомендовали продолжить совместную работу Онлайнного форума и СГТЭ.

57. На основе вышеприведенной информации и с учетом, среди прочего, рекомендаций Онлайнного форума и СГТЭ Конференция Сторон, выступающая в качестве Совещания Сторон Протокола, возможно, пожелает:

а) поддержать и одобрить продолжение работы как Онлайнного экспертного форума открытого состава, так и СГТЭ по оценке рисков и регулированию рисков с целью i) разработки дополнительных руководящих указаний по конкретным типам живых измененных организмов и признаков, принимая во внимание, среди прочего, вопросы, перечисленные ниже, в приложении V; и ii) пересмотра текста «Руководства по оценке рисков в отношении живых измененных организмов», например, на основе тестирования руководящих указаний в ходе мероприятий по созданию потенциала, и обновления своих перечней справочных материалов;

б) поручить Исполнительному секретарю: i) опубликовать и распространить на всех языках Организации Объединенных Наций документ «Руководство по оценке рисков в отношении живых измененных организмов», в том числе онлайнную версию в Механизме посредничества по биобезопасности (МПБ); ii) оттестировать в соответствующих случаях руководящий документ в ходе региональных семинаров, включая сотрудничество с существующими инициативами по созданию потенциала и подготовке кадров; iii) пересмотреть общий формат представления записей в Центр информационных ресурсов по биобезопасности (ЦИРБ) МПБ, чтобы связать записи ЦИРБ по оценке рисков с конкретными разделами руководящего документа;

в) продолжать обсуждение в рамках Онлайнного экспертного форума открытого состава по оценке рисков и регулированию рисков и поручить Исполнительному секретарю пригласить дополнительных экспертов;

г) создать Специальную группу технических экспертов по оценке рисков и регулированию рисков и поручить Исполнительному секретарю применять тот же *modus operandi* при отборе экспертов, что и в предыдущем процессе.

В. Создание потенциала в области оценки рисков

58. В помощь созданию потенциала было разработано учебное пособие совместно с некоторыми соответствующими учреждениями Организации Объединенных Наций и международными организациями. Руководство использовалось в качестве основы для мероприятий по созданию потенциала, проводившихся в Тихоокеанском и Азиатском субрегионах. Участники семинара и учебного курса предложили ряд рекомендаций по улучшению учебного пособия в плане его полезности и удобства пользования. Кроме того, участники рекомендовали, чтобы пособие было разработано в виде интерактивного учебного материала (например, компакт-диск), переведено на все языки Организации Объединенных Наций и распространено.

59. На основе вышеприведенной информации и с учетом, среди прочего, рекомендаций участников мероприятий по созданию потенциала Конференция Сторон, выступающая в качестве Совещания Сторон Протокола, возможно, пожелает:

а) поручить Исполнительному секретарю организовать в ближайший удобный срок и при условии наличия средств дальнейшие региональные или субрегиональные учебные курсы, чтобы позволить странам получить практический опыт составления и оценки докладов по оценке рисков в соответствии со статьями Протокола и приложением III к нему;

b) далее поручить Исполнительному секретарю в сотрудничестве с соответствующими учреждениями Организации Объединенных Наций и другими организациями повысить полезность учебного пособия «Оценка рисков в отношении живых измененных организмов» посредством: i) его регулярного пересмотра на основе рекомендаций, выработанных в ходе региональных и субрегиональных мероприятий по созданию потенциала; ii) его разработки в виде интерактивного инструмента обучения, такого как компакт-диск, и его распространения через МПБ; а также iii) опубликования и распространения пособия среди Сторон, других правительств и соответствующих организаций.

С. Идентификация живых измененных организмов или конкретных признаков, которые i) могут или ii) вряд ли способны оказывать неблагоприятное воздействие на сохранение и устойчивое использование биологического разнообразия, с учетом также рисков для здоровья человека

60. Сторонами, другими правительствами и соответствующими организациями были высказаны различные мнения об идентификации живых измененных организмов или конкретных признаков, которые могут оказывать неблагоприятное воздействие на сохранение и устойчивое использование биологического разнообразия, с учетом также рисков для здоровья человека. СГТЭ определила следующие способы решения этого вопроса: i) дальнейший обмен информацией через Механизм посредничества по биобезопасности; ii) проведение семинаров; iii) создание специальной группы технических экспертов; и iv) сотрудничество в оценке возможного неблагоприятного воздействия живых измененных организмов. Этот процесс может быть начат на поэтапной основе с первоначального сбора информации и последующего ее анализа.

61. В отношении идентификации живых измененных организмов, которые вряд ли способны оказывать неблагоприятное воздействие на сохранение и устойчивое использование биологического разнообразия, с учетом также рисков для здоровья человека Стороны могут принять к сведению, среди прочего, решения, принятые в рамках Упрощенной процедуры импорта живых измененных организмов, освобожденных от процедуры заблаговременного обоснованного согласия и представленных в МПБ.

62. На основе вышеизложенной информации и с учетом, среди прочего, мнений, высказанных Сторонами, другими правительствами и соответствующими организациями, и рекомендаций Онлайн-форума открытого состава и СГТЭ Конференция Сторон, выступающая в качестве Совещания Сторон Протокола, возможно, пожелает создать один или несколько механизмов, включая, например, обмен информацией, проведение семинаров и/или создание экспертной группы, с целью предоставления Сторонам возможности принимать решения об идентификации живых измененных организмов или конкретных признаков, которые i) *могут* или ii) *вряд ли способны* оказывать неблагоприятное воздействие на сохранение и устойчивое использование биологического разнообразия, с учетом также рисков для здоровья человека.

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Annex II

ACTIVITIES CARRIED OUT UNDER THE OPEN-ENDED ONLINE EXPERT GROUP ON RISK ASSESSMENT AND RISK MANAGEMENT AND BY THE AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT AND RISK MANAGEMENT

Activity	Date / Location
Opening of the Online Forum and announcement of the topics and calendar of the discussion groups	6 November 2008, online
Ad hoc discussion groups under the Open-ended Online Forum on risk assessment and risk management of: (i) living modified (LM) fish; (ii) LM trees; (iii) LM microorganisms and viruses; (iv) LM pharmaplants; (v) living modified organisms (LMOs) with stacked genes or traits; (vi) post-release monitoring and long-term effects of LMOs released into the environment; and (vi) specific receiving environments; as well as on a Flowchart ("Roadmap") for risk assessment: the necessary steps to conduct risk assessment according to Annex III of the Protocol	10 November – 19 December 2008, online
First Series of Regional Real-time Online Conferences (for Europe, Latin America, Africa and Asia)	28 January – 17 February 2009, online
First Meeting of the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management	20 – 24 April 2009, Montreal, Canada
Meeting of the AHTEG Bureau.	24 April 2009, Montreal, Canada
Ad hoc discussion groups within the AHTEG sub-working groups for further drafting of the guidance documents	May – June 2009, online
Ad hoc discussion groups under the Open-ended Online Forum for input to the work of the AHTEG Sub-working Groups	22 June – 12 July 2009, online
Teleconference of the AHTEG Bureau	24 July 2009
Ad hoc discussion groups within the AHTEG sub-working groups for further drafting of the guidance documents and testing of the Roadmap	August – October 2009, online
Progress reports on the work of the AHTEG sub-working groups	October 2009
Meetings of the AHTEG Sub-Working Group on the Roadmap and AHTEG Bureau	12 – 14 October 2009, The Hague, Netherlands
Ad hoc discussion groups within the AHTEG sub-working groups for further drafting of the guidance documents and testing of the Roadmap	November 2009, online
Ad hoc discussion groups under the Open-ended Online Forum for further input to the work of the AHTEG sub-working groups	23 November – 14 December 2009, online

Activity	Date / Location
Ad hoc discussion group under the Open-ended Online Forum on “The way forward for the development of further guidance on risk assessment and risk management of LMOs”	7 – 14 December 2009
Ad hoc discussion groups within the AHTEG sub-working groups for further drafting of the guidance documents	January 2010, online
Second series of Regional Real-time Online Conferences (for Africa, Asia and the Pacific, WEOG and CEE, and Latin America and the Caribbean)	2-11 February 2010, online
Ad hoc discussion group under the AHTEG for final drafting of the guidance documents in preparation for the second AHTEG meeting	March 2010, online
Teleconference of the AHTEG Bureau	7 April 2010
Preparatory meetings of the AHTEG sub-working groups	19 April 2010, Ljubljana
Second meeting of the Ad Hoc Technical Expert Group	20-23 April 2010, Ljubljana

*Annex III***GUIDANCE ON RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS**

1 This document was developed by the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment
2 and Risk Management under the Cartagena Protocol on Biosafety.²²

3 This is intended to be a “living document” that will be improved with time as new experience becomes
4 available and new developments in the field of applications of living modified organisms (LMOs) occur,
5 as and when mandated by the Parties to the Cartagena Protocol on Biosafety.

PART I:**ROADMAP FOR RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS**

8 This “Roadmap” provides an overview of the process of environmental risk assessment for a living
9 modified organism (LMO) in accordance with Annex III²³ to the Cartagena Protocol on Biosafety
10 (hereinafter “the Protocol”) and all other articles related to risk assessment. This Roadmap was
11 developed in response to decision BS-IV/11²⁴ of the Conference of the Parties serving as the meeting of
12 the Parties to the Protocol (COP-MOP). Annex III is the basis of the Roadmap. Accordingly, this
13 Roadmap is a guidance document and does not replace Annex III. The overall aim of the Roadmap is
14 facilitating and enhancing the effective use of Annex III by elaborating the technical and scientific
15 process of how to apply the steps and points to consider in the process of risk assessment.

16 The purpose of this Roadmap is to provide further guidance on using Annex III with additional
17 background material and links to useful references relevant to risk assessment. The Roadmap may be
18 useful as a reference for risk assessors when conducting or reviewing risk assessments and in
19 capacity-building activities.

20 The Roadmap applies to all types of LMOs²⁵ and their intended uses within the scope and objective of
21 the Protocol, and in accordance with Annex III. However, it has been developed based largely on living
22 modified crop plants because of the extensive experience to date with environmental risk assessments for
23 these organisms. It is intended to be a “living document” that will be modified and improved on over
24 time as and when mandated by COP-MOP, and in the light of new experience, information and
25 developments in the field of applications of LMOs, e.g. when other types of LMOs have been evaluated
26 more extensively in environmental risk assessments.

²² The AHTEG on Risk Assessment and Risk Management was established by the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) in its decision BS-IV/11. The terms of reference for the AHTEG as set out by the Parties may be found in the annex to decision BS-IV/11 (<http://bch.cbd.int/protocol/decisions/decision.shtml?decisionID=11690>).

²³ <http://www.cbd.int/biosafety/articles.shtml?a=cpb-43> .

²⁴ <http://www.cbd.int/biosafety/cop-mop/results/?id=11690> .

²⁵ Including products thereof, as described in paragraph 5 of Annex III to the Protocol.

27 INTRODUCTION

28 General introduction

29 *Background*

30 In accordance with the precautionary approach²⁶ the objective of the Protocol is “to contribute to
31 ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs
32 resulting from modern biotechnology that may have adverse effects on the conservation and sustainable
33 use of biological diversity, taking also into account risks to human health, specifically focusing on
34 transboundary movements”²⁷.

35 For this purpose, Parties shall ensure that risk assessments are carried out when making informed
36 decisions regarding LMOs.

37 An LMO and its use may have several effects, which may be intended or unintended, taking into account
38 that some unintended effects may be predictable. The objective of risk assessment is to *identify* and
39 *evaluate* the potential adverse effects of LMOs on the conservation and sustainable use of biological
40 diversity in the likely potential receiving environment, taking also into account risks to human health.²⁸
41 The risk assessment is performed on a case-by-case basis. What is considered an adverse effect depends
42 on protection goals and assessment end-points taken into consideration when scoping the risk assessment.
43 The choice of protection goals by the Party could be informed by Articles 7(a), 7(b) and 8(g) and
44 Annex 1 of the Convention on Biological Diversity.

45 According to the general principles of Annex III of the Protocol, risk assessments shall be based, at a
46 minimum, on information provided in accordance with Article 8 and other available scientific evidence
47 in order to identify and evaluate the possible adverse effects of LMOs on the conservation and
48 sustainable use of biological diversity, taking also into account risks to human health.²⁹

49 Annex III states that “risk assessment should be carried out in a scientifically sound and transparent
50 manner, and can take into account expert advice of, and guidelines developed by, relevant international
51 organizations. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted
52 as indicating a particular level of risk, an absence of risk, or an acceptable risk. (...) Risk assessment
53 should be carried out on a case-by-case basis. The required information may vary in nature and level of
54 detail from case to case, depending on the LMO concerned, its intended use and the likely potential
55 receiving environment”³⁰.

56 *The risk assessment process*

57 Risk assessment is a structured process. Paragraph 8 of Annex III provides a description of the key steps
58 of the risk assessment process to identify and evaluate the potential adverse effects and manage risks.

²⁶ “In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation” (Principle 15 of the Rio Declaration on Environment and Development) at:

(<http://www.unep.org/Documents/Multilingual/Default.asp?DocumentID=78&ArticleID=1163>), and in line with Articles 10.6 and 11.8 of the Protocol.

²⁷ <http://www.cbd.int/biosafety/articles.shtml?a=cpb-01> .

²⁸ Annex III, paragraph 1.

²⁹ Article 15, paragraph 1.

³⁰ Annex III, paragraphs 3, 4 and 6.

59 Paragraph 9 describes, depending on the case, points to consider in this process. The steps describe an
60 integrated process whereby the results of one step may be relevant to other steps. Also, risk assessment
61 may need to be conducted in an iterative manner, where certain steps may be repeated or re-examined to
62 increase or re-evaluate the confidence in the conclusions of the risk assessment. When new information
63 arises that could change its conclusions, the risk assessment may need to be re-examined accordingly.
64 Similarly, the issues mentioned in the ‘overarching issues’ section below can be taken into consideration
65 again at the end of the risk assessment process to determine whether the objectives and criteria that were
66 set out at the beginning of the risk assessment have been met.

67 Risk assessment is done in a comparative manner, meaning that risks associated with living modified
68 organisms should be considered in the context of the risks posed by the non-modified recipient organism
69 in the likely potential receiving environment.³¹ Additionally, experience with the same, or, as
70 appropriate, similar, genotypic or phenotypic characteristics may be taken into consideration along with
71 the non-modified recipient organism in the risk assessment of an LMO. For instance, the comparison
72 with the (near-)isogenic or closely related non-modified recipient is used in step 1 of the risk assessment
73 (see below) where the novel genotypic or phenotypic characteristics associated with the LMO are
74 identified. But when the potential consequences of adverse effects are evaluated, broader experience,
75 such as mentioned in step 3 (a), may be taken into account, when establishing a baseline. Results from
76 experimental field trials or other environmental information and experience with the same LMO may be
77 taken into account as information elements in a new risk assessment for that LMO. In all cases where
78 information, including baseline data, is derived from other sources, it is important to establish the validity
79 and relevance of the information for the risk assessment. For instance, it should be taken into account
80 that the behavior of a transgene,³² as that of any other gene, may vary because it depends on the genetic
81 and physiological background of the recipient as well as on the ecological characteristics of the
82 environment that the LMO is introduced into.

83 The concluding recommendations derived from the risk assessment in step 5 are required to be taken into
84 account in the decision-making process on an LMO. In the decision-making process, other Articles of the
85 Protocol or other relevant issues may also be taken into account and are addressed in the last paragraph
86 of this Roadmap: ‘Related Issues’.

87 A flowchart illustrating the risk assessment process according to this Roadmap is annexed hereto.

88 (*See references relevant to “[General Introduction](#)”*).

89 **Overarching issues in the risk assessment process**

90 There are some overarching issues to consider in the design/planning phase of the risk assessment
91 process to ensure the quality and relevance of the information used. These entail, among others:

- 92 • Setting criteria for relevancy in the context of a risk assessment – e.g. data may be considered
93 relevant if they can affect the outcome of the risk assessment.
- 94 • Establishment of scientifically robust criteria for the inclusion of scientific information.
 - 95 ○ Data should be of an acceptable scientific quality. Data quality should be consistent with
96 the accepted practices of scientific evidence-gathering and reporting and may include

³¹ Annex III, paragraph 5.

³² For the purpose of this document, a transgene is a nucleic acid sequence in an LMO that results from the application of modern biotechnology as described in Article 3 (i) (a) of the Protocol.

97 independent review of the methods and designs of studies. Data may be derived from a
 98 variety of sources, e.g. new experimental data as well as data from relevant peer
 99 reviewed scientific literature.

100 ○ Sound science is based on transparency, verifiability, and reproducibility (e.g. reporting
 101 of methods and data in sufficient detail, so that the resulting data and information could
 102 be confirmed independently), and on the accessibility of data (e.g. the availability of
 103 relevant, required data or information or, if requested and as appropriate, of sample
 104 material), taking into account the provisions of Article 21 of the Protocol on the
 105 confidentiality of information. The provisions of sound science serve to ensure and
 106 verify that the risk assessment is carried out in a scientifically sound and transparent
 107 manner.

108 ● Identification and consideration of uncertainty.

109 According to the Protocol, “where there is uncertainty regarding the level of risk, it may be
 110 addressed by requesting further information on the specific issues of concern or by implementing
 111 appropriate risk management strategies and/or monitoring the living modified organism in the
 112 receiving environment”.³³

113 Uncertainty is inherent in the concept of risk. To date, “there is no internationally agreed
 114 definition of ‘scientific uncertainty’, nor are there internationally agreed general rules or
 115 guidelines to determine its occurrence. Those matters are thus dealt with – sometimes differently
 116 – in each international instrument incorporating precautionary measures”.^{34, 35}

117 It should be kept in mind that uncertainty cannot always be reduced by providing additional
 118 information. For example, new uncertainties may arise as a result of the provision of additional
 119 information.

120 Considerations of uncertainty strengthen the confidence and scientific soundness of a risk
 121 assessment. In communicating the results of a risk assessment, it is important to consider and
 122 analyze in a systematic way the various forms of uncertainty that can arise at each step and in
 123 combination at step 4 of the Roadmap. An analysis of uncertainty includes considerations of its
 124 source and nature.

125 The *source(s)* of uncertainty may stem from the data/information itself and/or the choice of study
 126 design including the methods used, and the analysis of the information.

127 The *nature* of uncertainty may be described for each identified source of uncertainty arising
 128 from: (i) imperfect knowledge or lack of available information, which may be reduced with more
 129 research/information, and (ii) inherent variability.

³³ Annex III, paragraph 8 (f).

³⁴ *An Explanatory Guide to the Cartagena Protocol on Biosafety*, paragraph 57 (<http://data.iucn.org/dbtw-wpd/edocs/EPLP-046.pdf>).

³⁵ Article 10, paragraph 6, of the Protocol: “Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.”

130 (See references relevant to "[Identification and consideration of uncertainty](#)").

131 **Context and scoping of the risk assessment**

132 In setting the context and scope for a risk assessment, a number of aspects should be taken into
133 consideration, as appropriate, that are specific to the Party involved and to the specific case of risk
134 assessment. These aspects include:

- 135 • Existing policies and strategies based on, for instance, regulations and the international
136 obligations of the Party involved; (ii) Guidelines or regulatory frameworks that the Party has
137 adopted; and (iii) Protection goals, assessment end-points, risk thresholds and management
138 strategies. Setting the context and scope for a risk assessment that are consistent with these
139 policies, strategies and protection goals may involve a process that includes risk assessors,
140 decision-makers and various stakeholders prior to conducting the actual risk assessment;
- 141 • (i) Framing the risk assessment process; (ii) Taking into account the expected (potential)
142 conditions of handling and use of the LMO; (iii) Taking into account customary practices and
143 habits that could affect the protection goals or end-points; identification of relevant questions to
144 be asked for that purpose;
- 145 • Identification of methodological and analytical requirements, including any reviewing
146 mechanisms, that is required to achieve the objective of the risk assessment as laid down, for
147 instance, in guidelines published or adopted by the Party that is responsible for conducting the
148 risk assessment (i.e. typically the Party of import according to the Protocol);
- 149 • The nature and level of detail of the information required may depend on the intended use of the
150 LMO and the likely potential receiving environment. For small scale field releases, especially at
151 early experimental stages, less information may be available compared to the information
152 available for large scale environmental release, and for commercial scale planting;
- 153 • Experience and history of use of the non-modified recipient, taking into account its ecological
154 function;³⁶ and
- 155 • Establishing criteria for describing the level of the (potential) environmental adverse effects of
156 LMOs, as well as criteria for the terms that are used to describe the levels of likelihood (step 2),
157 the magnitude of consequences (step 3) and risks (step 4) and the manageability of risks (step 5;
158 see risk assessment steps below).

159 (See references relevant to "[Context and scoping of the risk assessment](#)").

160 **THE RISK ASSESSMENT**

161 To fulfill its objective under Annex III, as well as other relevant Articles of the Protocol, risk assessment
162 is performed in five steps, as appropriate. These five steps are indicated in Paragraph 8 (a)-(e) of
163 Annex III and also detailed below. Their titles have been taken directly from the paragraphs 8 (a)-(e) of
164 Annex III.

³⁶ The term "ecological function" (or: "ecological services") provided by an organism refers to the role of the organism in ecological processes. Which ecological functions or services are taken into account here will be dependent on the protection goals set for the risk assessment. For example, organisms may be part of the decomposer network playing an important role in nutrient cycling in soils or be important as a pollen source for pollinators and pollen feeders.

165 For each step a rationale and points to consider are provided. Some points to consider are taken from
 166 paragraph 9 of Annex III, whereas others have been added based on generally accepted methodology of
 167 LMO risk assessment and risk management. The relevance of each point to consider will depend on the
 168 case being analyzed.

169 (*See references relevant to “[Risk Assessment in general](#)”*).

170 **Step 1: “An identification of any novel genotypic and phenotypic characteristics associated with**
 171 **the living modified organism that may have adverse effects on biological diversity in the likely**
 172 **potential receiving environment, taking also into account risks to human health.”³⁷**

173 *Rationale:*

174 The purpose of this step is to identify biological changes resulting from the genetic modification(s),
 175 including any deletions, compared to the non-modified organism, and identify what, if any, changes
 176 could cause adverse effects on the conservation and sustainable use of biological diversity, taking also
 177 into account risks to human health. This step is similar to the ‘hazard identification step’ in other risk
 178 assessment guidance. The comparison of the LMO is performed with the non-modified recipient, or a
 179 (near-)isogenic line or, as appropriate, with a non-modified organism of the same species, taking into
 180 consideration the new trait(s) of the LMO.

181 In this step, scientifically plausible scenarios are identified in which novel characteristics of the LMO
 182 could give rise to adverse effects in an interaction with the likely potential receiving environment. The
 183 novel characteristics of the LMO to be considered can be genotypic or phenotypic, biological. They may
 184 be intended or unintended, predicted or unpredicted. The points to consider below provide information
 185 elements on which hazard identification can be built.

186 The type and level of detail of the information required in this step may vary from case to case depending
 187 on the nature of the modification of the LMO and on the scale of the intended use of the LMO. For small
 188 scale field releases, especially at early experimental stages, less information may be available and some
 189 of the resulting uncertainty may typically be addressed by risk management measures (see step 5).

190 *Points to consider regarding the characterization of the LMO:*

- 191 (a) Relevant characteristics of the non-modified recipient (e.g. (i) its biological characteristics, in
 192 particular those that, if changed, or interacting with the new gene products or traits of the LMO,
 193 could cause changes in the behavior of the non-modified recipient in the environment in a way
 194 that may cause adverse effects; (ii) its taxonomic relationships, (iii) its origin, centers of origin
 195 and centers of genetic diversity); (iv) ecological function, and (v) as a component of biological
 196 diversity that is important for the conservation and sustainable use of the biological diversity in
 197 the context of Article 7(a) and Annex I of the Convention;
- 198 (b) Relevant characteristics of the genes and of other functional sequences, such as promoters, that
 199 have been inserted into the LMO (e.g. functions of the gene and its gene product in the donor
 200 organism with particular attention to characteristics that could cause adverse effects in the
 201 recipient);
- 202 (c) Molecular characteristics of the LMO related to the modification (e.g. (a) characteristics of the
 203 insert(s) which may include (i) gene products (intended and unintended), (ii) levels of
 204 expression, (iii) functions, (iv) insertion site in the genome of the recipient and any effects of

³⁷ The bold printed headings of each step are direct quotes from Annex III of the Protocol.

205 insertion, (v) stability or integrity within the genome of the recipient; (b) (i) the transformation
 206 method, (ii) the characteristics of the vector if and, as far as it is present in the LMO, including
 207 its identity, source or origin and host range) with particular attention paid to any characteristics
 208 that are related to potential adverse effects. The availability and relevance of this information
 209 may vary according to the type of application. Characteristics related to adverse effects may
 210 also result from changed expression levels of endogenous genes due to effects of a transgene or
 211 from combinatorial effects;³⁸

212 (d) Consideration of genotypic (see point to consider (c) above) and phenotypic, biological changes
 213 in the LMO, either intended or unintended, in comparison with the non-modified recipient,
 214 considering those changes that could cause adverse effects. These may include changes at the
 215 transcriptional and translational level and may be due to the insert itself or to genomic changes
 216 due to the transformation or recombination processes.

217 *Point to consider regarding the receiving environment:*

218 (e) Characteristics of the likely potential receiving environment, in particular its attributes that are
 219 relevant to potential interactions of the LMO that could lead to adverse effects (see also
 220 paragraph (g) below),³⁹ taking into account the characteristics that are components of biological
 221 diversity;

222 (f) The intended scale and duration of the environmental release.

223 *Points to consider regarding the potential adverse effects resulting from the interaction between the*
 224 *LMO and the receiving environment:*

225 (g) Characteristics of the LMO in relation to the receiving environment (e.g. information on
 226 phenotypic traits that are relevant for its survival in, or its potential adverse effects on the likely
 227 receiving environment – see also paragraph (e) above);

228 (h) Considerations for unmanaged and managed ecosystems (such as agricultural, forest and
 229 aquaculture systems) that are relevant for the likely potential receiving environment. These
 230 include the potential for dispersal of the LMO through, for instance, seed dispersal or
 231 outcrossing within or between species, or through transfer into habitats where the LMO may
 232 persist or proliferate;

233 (i) Potential consequences of outcrossing and flow of transgenes from an LMO to other sexually
 234 compatible species, which could lead to introgression of the transgene(s) into the population of
 235 sexually compatible species;

236 (j) Effects on non-target organisms;

³⁸ For the purpose of this document, the term “combinatorial effects” refers to effects that may arise from the interactions between two (or more) genes. The effects may occur at the level of gene expression, or through interactions between RNA, or among gene products. The effects may be qualitative or quantitative; quantitative effects are often referred to as resulting in antagonistic, additive or synergistic effects.

³⁹ Examples of relevant attributes of the receiving environment include, among others: (i) ecosystem type (e.g., agroecosystem, horticultural or forest ecosystems, soil or aquatic ecosystems, urban or rural environments); (ii) extension of dimension (small, medium, large or mixed scale); (iii) previous use/history (intensive or extensive use for agronomic purposes, natural ecosystem, or no prior managed use in the ecosystem); (iv) the geographical zone(s) in which the release is intended, including climatic and geographic conditions and the properties of soil, water and/or sediment; (v) specific characteristics of the prevailing faunal, floral and microbial communities including information on sexually compatible wild or cultivated species; and (vi) biodiversity status, including the status as centre of origin and diversity of the recipient organism and the occurrence of rare, endangered, protected species and/or species of cultural value.

- 237 (k) Cumulative effects;⁴⁰
- 238 (l) Effects of the incidental exposure of humans to (parts of) the LMO (e.g. exposure to pollen),
239 and the toxic or allergenic effects that may ensue;
- 240 (m) Potential adverse effects as a consequence of horizontal gene transfer (HGT) of transgenic
241 sequences from the LMO to any other organism in the likely receiving environment. With
242 regard to HGT to micro-organisms (including viruses), particular attention may be given to
243 cases where the LMO is also a micro-organism; and
- 244 (n) A consideration of uncertainty arising in step 1 that may significantly impact the identification
245 of hazards in this step (see “Identification and consideration of uncertainty” under Context and
246 scoping of the risk assessment above).

247 (*See references relevant to “[Step 1](#)”*).

248 **Step 2: “An evaluation of the likelihood of adverse effects being realized, taking into account the**
249 **level and kind of exposure of the likely potential receiving environment to the living modified**
250 **organism.”**

251 *Rationale:*

252 The potential adverse effects identified in step 1 may result in risks, but this depends on the likelihood
253 and the consequence of the effects. In order to determine and characterize the overall risk (in step 4), the
254 likelihood of each adverse effect being realized has to be assessed and evaluated beforehand.

255 One aspect to be considered is whether the receiving environment will be exposed to the LMO in such a
256 way that the identified adverse effects may actually occur, e.g. taking into consideration the intended use
257 of the LMO, and the expression level, dose and environmental fate of transgene products as well as
258 plausible pathways leading to adverse effects.

259 Other aspects to be considered here are (i) the potential of the LMO (or its derivatives resulting from
260 outcrossing) to spread and establish beyond the receiving environment (in particular into protected
261 areas), and whether that could result in adverse effects; and (ii) the possibility of occurrence of adverse
262 (e.g. toxic) effects on organisms (or on organisms other than the ‘target organism’ for some types of
263 LMOs).

264 The levels of likelihood may be expressed, for example, by the terms ‘highly likely’, ‘likely’, ‘unlikely’,
265 ‘highly unlikely’. Parties may consider describing these terms and their uses in risk assessment
266 guidelines published and/or adopted by them.

267 *Points to consider:*

- 268 (a) Information relating to the type and intended use of the LMO, including the scale and duration
269 of the release, bearing in mind, as appropriate, user habits, patterns and agronomic practices;
- 270 (b) The relevant characteristics of the likely potential receiving environment that may experience or
271 may be a factor in the occurrence of the potential adverse effects (see also step 1 (e), (f) and
272 (g)), taking into account the variability of the environmental conditions and any long-term
273 adverse effects. Levels of expression in the LMO and persistence and accumulation in the

⁴⁰ For the purpose of this document, the term “cumulative effects” refers to effects that occur due to the presence of multiple LMOs in the receiving environment.

- 274 environment (e.g. in the food chain) of substances with potentially adverse effects newly
275 produced by the LMO, such as insecticidal proteins, toxins and allergens;
- 276 (c) Available information on the location of the release and the receiving environment (such as
277 geographic and biogeographic information, including, as appropriate, coordinates, information
278 on the sexually compatible species and whether they are co-localized with the LMO and
279 whether flowering occurs at the same time, or in general, interbreeding can occur);
- 280 (d) For the case of outcrossing and outbreeding from an LMO to sexually compatible species, the
281 considerations would include: (i) the biology of the sexually compatible species; (ii) the
282 potential environment where the sexually compatible species may be located; (iii) the chance of
283 introgression of the transgene into the sexually compatible species;
- 284 (e) Expected exposure to the environment where the LMO is released and means by which
285 incidental exposure could occur at that location or elsewhere (e.g. gene flow or incidental
286 exposure due to losses during transport and handling);
- 287 (f) A consideration of uncertainty arising in step 2 (see “Identification and consideration of
288 uncertainty” under “Context and scoping of the risk assessment” above).

289 (*See references relevant to “[Step 2](#)”*).

290 **Step 3: “An evaluation of the consequences should these adverse effects be realized.”**

291 *Rationale:*

292 This step describes an evaluation of the magnitude of the consequences in the likely potential receiving
293 environment, taking into account, among others, results of tests done under different conditions such as
294 laboratory experiments or experimental field releases. The evaluation is comparative and should be
295 considered in the context of the adverse effects caused by the non-modified recipient or, if more
296 appropriate, by a near-isogenic or other non-modified organism of the same species. The evaluation may
297 also be considered in the context of the adverse effects that occur in the environment and which are
298 associated with existing practices such as various agronomic practices, for example, for pest or weed
299 management if such information is available and relevant. The evaluation of the consequence of adverse
300 effects may be expressed as, for instance, ‘major’, ‘intermediate’, ‘minor’ or ‘marginal’. Parties may
301 consider describing these terms and their uses in risk assessment guidelines published and/or adopted by
302 them.

303 *Points to consider:*

- 304 (a) Relevant experience with the consequences of existing practices with the non-modified
305 recipient or, if more appropriate, with a non-modified organism of the same species in the likely
306 potential receiving environment, may be useful in order to establish baselines to evaluate, for
307 example, the consequences of (i) agricultural practices, such as the level of inter- and intra-
308 species gene flow, dissemination of the recipient, abundance of volunteer plants in crop
309 rotation; occurrence of pests and/or beneficial organisms such as pollinators and pest predators;
310 or (ii) pest management, including effects on non-target organisms in pesticide applications
311 while following accepted agronomic practices;
- 312 (b) Adverse effects which may be direct and indirect, immediate and delayed. Some of these
313 adverse effects may result from combinatorial and cumulative effects;
- 314 (c) Results from laboratory experiments examining, *inter alia*, dose-response relationships (e.g.,
315 EC 50s, LD 50s) and from field trials evaluating, for instance, potential invasiveness;

316 (d) For the case of outcrossing to sexually compatible species, the possible adverse effects that may
317 occur, after introgression, due to the expression of the transgenes in the sexually compatible
318 species; and

319 (e) A consideration of uncertainty arising in step 3 that may significantly impact the evaluation of
320 consequences should the adverse effects be realized (see “Identification and consideration of
321 uncertainty” under Context and scoping of the risk assessment above).

322 (*See references relevant to “[Step 3](#)”*).

323 **Step 4: “An estimation of the overall risk posed by the living modified organism based on the**
324 **evaluation of the likelihood and consequences of the identified adverse effects being realized.”**

325 *Rationale:*

326 The purpose of this step is to determine and characterize the level of the overall risk based on the
327 identified individual risks posed by the LMO on the conservation and sustainable use of biological
328 diversity, taking also into account human health. The individual risks are determined on the basis of an
329 analysis of the potential adverse effects identified in step 1, their likelihood (step 2) and consequences
330 (step 3), and also taking into consideration any relevant uncertainty that emerged in the preceding steps.

331 It should then be determined whether the assessed risks meet the criteria set out in the protection goals,
332 assessment endpoints and thresholds, as established in relevant legislation of the Party or in its practice.
333 Where there is uncertainty regarding the level of risk, it may be addressed by requesting further
334 information on the specific issues of concern or by implementing appropriate risk management strategies
335 and/or monitoring the LMO in the receiving environment (see also step 5). Description of the risk
336 characterization may be expressed as, for instance, ‘high’, ‘medium’, ‘low’, ‘negligible’ or
337 ‘indeterminate due to uncertainty or lack of knowledge’. Parties may consider describing these terms and
338 their uses in risk assessment guidelines published and/or adopted by them.

339 To date, there is no universally accepted method to estimate the overall risk but rather a number of
340 methods are available for this purpose. The outcome of this step may be, for example, a description
341 explaining how the estimation of the overall risk was performed.

342 *Points to consider:*

343 (a) The identified potential adverse effects (step 1);

344 (b) The assessments of likelihood (step 2);

345 (c) The evaluation of the consequences (step 3);

346 (d) Any interaction between the identified individual risks;

347 (e) Any cumulative effect due to the presence of multiple LMOs in the receiving environment; and

348 (f) A consideration of uncertainty arising in this and the previous steps (see “Identification and
349 consideration of uncertainty” under Context and scoping of the risk assessment above).

350 (*See references relevant to “[Step 4](#)”*).

351 **Step 5: “A recommendation as to whether or not the risks are acceptable or manageable,**
352 **including, where necessary, identification of strategies to manage these risks”**

353 *Rationale:*

354 In this way, step 5 provides an interface between the process of risk assessment and the process of
355 determining whether risk management measures are necessary and, if so, which measures could be
356 implemented to manage the risks associated with the LMO.

357 The evaluation of the overall risk on the basis of the identified individual risks conducted in the previous
358 step may lead to the conclusion that the identified risks are not acceptable in relation to the established
359 protection goals, assessment end-points and risk thresholds, also when taking into account risks posed by
360 the non-modified recipient and its use. Then the question arises whether risk management options can be
361 identified that have the potential to remove the identified risks or reduce their magnitude. In the process
362 of the formulation of risk management options, the effect of the proposed options on the identified risks
363 should be explained. The appropriate steps of the risk assessment should then be reiterated by taking into
364 account the implementation of the risk management options to estimate the new levels of likelihood,
365 consequence and risk and to assess if the risk management measures are appropriate and sufficient.

366 The issues mentioned in the ‘overarching issues’ section can be taken into consideration again at the end
367 of the risk assessment process to evaluate whether the objectives and criteria that were set out at the
368 beginning of the risk assessment have been met.

369 The recommendation of acceptability of risk(s) should acknowledge the previously identified
370 uncertainties. Some uncertainties may be reduced by monitoring (e.g. checking the validity of
371 assumptions about the ecological effects of the LMO), requests for more information, or implementing
372 the appropriate risk management options.

373 The recommendation(s) as to whether or not the risks are acceptable or manageable and
374 recommendations for risk management options are submitted for consideration in the decision-making
375 process.

376 *Points to consider related to the acceptability of risks:*

377 (a) The criteria for the establishment of acceptable/unacceptable levels of risk, including those set
378 out in national legislation or guidelines, as well as the protection goals of the Party, as
379 identified when setting the context and scope for a risk assessment;

380 (b) In establishing a baseline for the comparison of the LMO, any relevant experience with the use
381 of the non-modified recipient, and practices associated with its use in the potential receiving
382 environment; and

383 (c) The feasibility of the adoption of risk management or monitoring strategies.

384 *Points to consider related to the risk management strategies:*

385 (d) Existing management practices, if applicable, that are in use for the non-modified recipient
386 organism or for other organisms that require comparable risk management and that might be
387 appropriate for the LMO being assessed, e.g. isolation distances to reduce outcrossing potential
388 of the LMO, modifications in herbicide or pesticide management, crop rotation, soil tillage,
389 etc.;

390 (e) Methods to detect and identify the LMO and their specificity, sensitivity and reliability in the
391 context of environmental monitoring (e.g. monitoring for short- and long-term, immediate and
392 delayed effects; specific monitoring on the basis of scientific hypotheses and supposed
393 cause/effect relationship as well as general monitoring) including plans for appropriate
394 contingency measures to be applied in case the results from monitoring call for them;

395 (f) Management options in the context of the intended use (e.g. mitigating the effect of an LMO
396 producing insecticidal proteins by the use of refuge areas to minimize the development of
397 resistance against these proteins).

398 (*See references relevant to "[Step 5](#)"*).

399 **RELATED ISSUES**

400 Some members of the AHTEG considered some issues to be related to risk assessment and decision-
401 making process but outside the scope of this Roadmap. These issues were, *inter alia*:

- 402 • Risk management (Article 16);
- 403 • Capacity-building (Article 22);
- 404 • Public awareness and participation (Article 23);
- 405 • Socio-economic considerations (Article 26);
- 406 • Liability and redress (Article 27);
- 407 • Co-existence;
- 408 • Ethical issues.

Annex

FLOWCHART FOR RISK ASSESSMENT

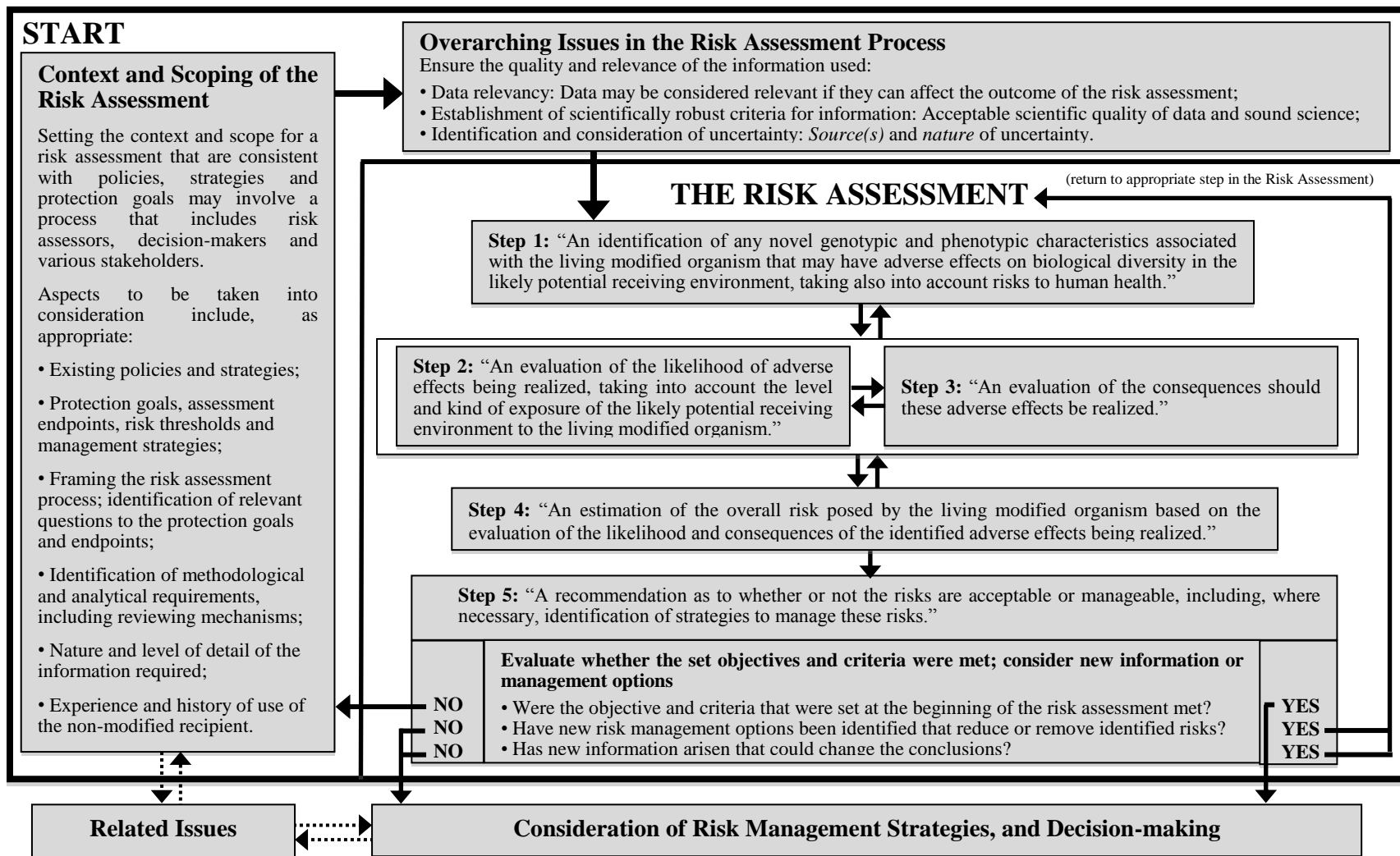


Figure 1. The Roadmap for Risk Assessment. The flowchart represents the steps to *identify* and *evaluate* the potential adverse effects of LMOs on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health. The box around steps 2 and 3 shows that these steps may sometimes be considered simultaneously or in reverse order.

PART II

SPECIFIC TYPES OF LMOs AND TRAITS

A. RISK ASSESSMENT OF LIVING MODIFIED ORGANISMS WITH STACKED GENES OR TRAITS

1 INTRODUCTION

2 Worldwide, a growing number of LMOs with stacked transgenic traits, particularly LM crops, are being
3 developed for commercial uses. As a result, the number of stacked genes in a single LMO and the
4 number of LMOs with two or more transgenic traits is growing.

5 Stacked transgenic traits can be produced through different approaches. In addition to the cross-
6 hybridising of two LMOs, multiple trait characters can be achieved by transformation with a multigene
7 cassette, retransformation of an LMO or simultaneous transformation with different transgene cassettes
8 (i.e., cotransformation).

9 This guidance document focuses on stacked transgenic traits that have been produced through cross-
10 breeding of two or more LMOs.

11 LMOs with multiple transgenic traits resulting from re-transformation, co-transformation or
12 transformation with a multigene cassette should be assessed according to the Roadmap.

13 This guidance document complements the Roadmap for Risk Assessment developed by the AHTEG on
14 Risk Assessment and Risk Management, and focuses on issues that are of particular relevance to the risk
15 assessment of LMOs with stacked events generated through cross breeding of single or multiple event
16 LMO.

17 This is intended to be a “living document” that will be shaped and improved with time as new
18 information and/or experience becomes available and new developments in the field of applications of
19 LMOs occur, as and when mandated by the Parties to the Protocol.

20 OBJECTIVE

21 The objective of this document is to give additional guidance on the risk assessment (RA) of LMOs with
22 stacked events generated through conventional crossing of single or multiple event LMOs. Accordingly,
23 it is meant to complement the Roadmap for Risk Assessment⁴¹ and address special aspects of LMOs with
24 stacked transgenes/traits resulting from the conventional crossing. For the time being it will be restricted
25 to plant LMOs.⁴²

⁴¹ In accordance with a mandate from the Parties to the Cartagena Protocol on Biosafety (the Protocol), the AHTEG has developed ‘a “roadmap”, such as a flowchart, on the necessary steps to conduct a risk assessment in accordance with Annex III to the Protocol and, for each of these steps,’ has provided ‘examples of relevant guidance documents’. The Roadmap is presented, together with the present document, to the Parties of the Protocol on the occasion of the fifth meeting of the Conference of the Parties serving as the meeting of the Parties.

⁴² It is also restricted to those LMO generated through the methods of Modern Biotechnology as defined in Art. 3 (i) (a) of the Protocol. LMOs derived from fusion of cells are not covered in this document.

26 USE OF TERMS

27 Transformation event (TraEv)

28 For the purpose of this document, a transformation event (TraEv) is an LM plant which results from the
29 use of modern biotechnology applying *in vitro* nucleic acid techniques⁴³ that may involve, but is not
30 limited to, single or multiple gene transformation cassettes. In either case, the result will be one
31 transformation event.

32 Stacked event (StaEv)

33 For the purpose of this document, a stacked event (StaEv) is an LM plant generated through conventional
34 cross breeding of two or more single parental transformation events (TraEvs) or two already stacked
35 events. Accordingly the transgene⁴⁴ cassettes may be physically unlinked (i.e. located separately in the
36 genome) and may segregate independently.

37 Unintentional stacked event

38 Unintentional stacked events are the result of outcrossing of stacked events into other LMOs or
39 compatible relatives in the receiving environment. Depending on the segregation pattern of the stacked
40 genes this may result in new and/or different combinations of TraEvs.

41 SCOPE

42 This guidance document focuses on stacked events (StaEv) resulting from conventional crossings
43 between two or more single transformation events (TraEv) as parental lines so that the resulting LMO
44 contains two or more transgenic traits. It is understood that the individual TraEvs making up the StaEv
45 have been assessed previously in accordance with Annex III of the Cartagena Protocol on Biosafety and
46 as described in the Roadmap.

47 ISSUES TO BE CONSIDERED IN THE RISK ASSESSMENT

48 **Assessment of sequence characteristics at the insertion sites and genotypic stability** (*see step 1,*
49 *Point to consider (c) of the Roadmap for Risk Assessment*)

50 *Rationale:*

51 Although recombination, mutation and rearrangements are not limited to LMOs, the combination of
52 transgenic traits via cross breeding may further change the molecular characteristics of the inserted
53 genes/gene fragments at the insertion site and/or influence the regulation of the expression of the
54 transgenes. In addition, changes to the molecular characteristics may influence the ability to detect the
55 LMO, which may be needed in the context of risk management measures (see step 5 of the Roadmap.
56 The reappraisal of the molecular sequence at the insertion sites, and the intactness of the transgenes may
57 be confirmative to the molecular characteristics of the parental LMOs, but may also be a basis for
58 assessing any intended or unintended possibly adverse effects on the conservation and sustainable use of
59 biological diversity in the likely potential receiving environment and of potential adverse effects on
60 human health. The extent of the reexamination may vary case by case and take into account the results of
61 the parental LMO risk assessment.

⁴³ See Article 3 (i) (a) of the Protocol.

⁴⁴ For the purpose of this document, a transgene is a nucleic acid sequence that results from the application of modern biotechnology as described in Article 3 (i) (a) of the Protocol.

62 **Assessment of potential interactions between combined events and the resulting phenotypic effects**
63 *(see step 1, point to consider (d) of the Roadmap for Risk Assessment)*

64 *Rationale:*

65 The combination of two or more TraEvs resulting in a StaEv may influence the expression level of each
66 of the transgenes and there may be interaction between the genes and the expressed products of the
67 different transgenes. In addition, the stacked transgenes may alter the expression of endogenous genes.

68 Therefore, in addition to information about the characteristics of the parental single-TraEv LMOs,
69 specific information on potential for interactions between the altered or inserted genes, stacked proteins
70 or modified traits and endogenous genes and their products in the StaEv LMO should be considered and
71 assessed. For example, it should be assessed whether the different transgenes affect the same biochemical
72 pathways or physiological processes, or are expected to or may have any combinatorial effects that may
73 result in potential for new or increased adverse effects relative to the parent LMOs.

74 **Assessment of combinatorial and cumulative effects of stacked event LMOs on the conservation**
75 **and sustainable use of biological diversity in the likely potential receiving environment, taking also**
76 **into account potential adverse effects to human health** *(see step 1, point to consider (c), step 2, point*
77 *to consider (c) and step 3, point to consider (b) of the Roadmap for Risk Assessment)*

78 *Rationale:*

79 Assessment of combinatorial and cumulative effects⁴⁵ is based on the environmental risk assessment data
80 for the StaEv LMO in comparison to the closely related non-modified recipient species and the parent
81 LMOs in the likely receiving environment, taking into consideration the results of the genotypic and
82 phenotypic assessments outlined above.

83 If potential new or increased adverse effects on the conservation and sustainable use of biological
84 diversity or on human health are identified in relation to the StaEv through the above analysis of possible
85 interactions, additional supporting data on StaEv may be required, such as:

- 86 (a) Phenotypic characteristics, including the levels of expression of any introduced gene
87 products or modified traits, compared to the parent LMOs and to relevant non-modified
88 recipient organisms (plants);
- 89 (b) Compositional analysis (e.g. levels of expression in the LMO and persistence and
90 accumulation in the environment, such as in the food chain) of substances with
91 potentially harmful effects newly produced by the StaEv, (e.g. insecticidal proteins,
92 allergens, anti-nutritional factors, etc.) in amounts that differ from those produced by the
93 parental LMOs or non-modified recipient organisms;
- 94 (c) Additional information depending on the nature of the combined traits. For example,
95 further toxicological analysis of the StaEv may be required to address any combinatorial
96 effects arising from the stacking of two or more insecticidal traits that result in a
97 broadened target range or increased toxicity.

98 Also, indirect effects due to changed agricultural management procedures, combined with the use of the
99 transgenic stacked event LMO, should be taken into consideration.

⁴⁵ See definition of combinatorial and cumulative effects in the Roadmap (footnotes 38 and 40, respectively).

100 Intentional and unintentional StaEvs may have altered environmental impacts as a result of cumulative
101 and combinatorial effects of the stacked traits prevalent in different LMOs of the same species in the
102 receiving environment. Unintentional StaEvs may arise from outcrossing with other LMOs of the same
103 species or cross-compatible relatives (see “Use of terms”). If a number of different StaEvs are cultivated
104 in the same environment a number of varying unintentional StaEvs may occur. Changed impacts on non-
105 target organisms or a change in the range of non-target organisms in the likely receiving environment
106 should be taken into account.

107 **Development of specific methods for distinguishing the combined transgenes in a stacked event**
108 **from the parental LMOs** (*see step 5, point to consider (d) of the Roadmap for Risk Assessment*)

109 *Rationale:*

110 Some of the risk management strategies for StaEvs may involve methods for the detection and
111 identification of these LMOs in the context of environmental monitoring. Currently, many detection
112 methods for LMOs rely on DNA-based techniques, such as polymerase chain reaction (PCR) or protein
113 based ELISA tests targeted to single transformation events. The methods used to detect the transgene in
114 the parental lines may not be sensitive or specific enough to differentiate between single parental
115 transformation events and the same event being part of a stacked event. A special problem may arise
116 particularly in the cases where the StaEv contains multiple transgenes with similar DNA sequences.
117 Therefore, the detection of each and all individual transgenes in a StaEv may become a challenge and
118 need special consideration.

119 **BIBLIOGRAPHIC REFERENCES**

120 See references relevant to the “[Guidance Document on Risk Assessment of LMOs with Stacked Genes or](#)
121 [Traits](#)”.

B. RISK ASSESSMENT OF LIVING MODIFIED CROPS WITH TOLERANCE TO ABIOTIC STRESS

1 INTRODUCTION

2 The aim of this document is to provide further guidance for the risk assessment of living modified (LM)
3 crops with improved tolerance to abiotic stress.

4 This guidance document should be considered in the context of the Cartagena Protocol on Biosafety. The
5 elements of Articles 15 Annex III of the Protocol also apply to LM crops with tolerance to abiotic stress.
6 Accordingly, the methodology and points to consider⁴⁶ contained in Annex III are also applicable to this
7 type of LMO.

8 The potential environmental adverse effects of an LM crop with abiotic stress tolerance depends on (i)
9 the receiving environment; (ii) the modified crop, (iii) phenotypic changes resulting from the genotypic
10 changes made to the plant and (iv) its intended use. A risk assessment would be performed on a case-by-
11 case basis in accordance with Annex III of the Protocol.

12 This guidance document complements the Roadmap for Risk Assessment developed by the AHTEG on
13 Risk Assessment and Risk Management, and focuses on issues that are of particular relevance to the risk
14 assessment of LM crops tolerant to abiotic stress.

15 USE OF TERMS

16 “Abiotic stresses” are environmental conditions caused by non-living factors that are detrimental or
17 suboptimal to the growth, development and/or reproduction of a living organism. Types of abiotic
18 stresses include, for example, drought, salinity, cold, heat, soil pollution and air pollution (e.g., nitrous
19 oxides, ozone).

20 RISK ASSESSMENT

21 While the same general principles used in the risk assessments of other types of LMOs also apply to LM
22 crops with increased tolerance to abiotic stress, there are a number of specific issues that may be of
23 particular importance when assessing the risks of LM crops tolerant to abiotic stresses.

24 Questions that may be relevant to the risk assessment of LM crops with tolerance to abiotic stress in
25 connection with the intended use and receiving environment include:

- 26 • Would the tolerance trait have the potential to increase the invasiveness, persistence or
27 weediness of the LM crop that causes adverse effects to other organisms?
- 28 • Would a LM plant expressing tolerance to a particular abiotic stress have other advantages in
29 the targeted receiving environment that cause adverse effects?
- 30 • Would any LMO arising from outcrossing with the abiotic stress tolerant LM crop, have the
31 potential to colonize an ecosystem beyond the targeted receiving environment?
- 32 • Would the abiotic stress tolerance trait, for example, via pleiotropic effects, have the potential to
33 affect, *inter alia*, pest and disease resistance mechanisms of the LM crop?

⁴⁶ Paragraphs 8 and 9 of Annex III, respectively.

34 Some of the potential adverse effects to be evaluated in the risk assessment, from the introduction of
35 crops tolerant to abiotic stress into the environment include, for example: a) increased selective
36 advantage(s) other than the intended tolerance trait; b) increased persistence in agricultural areas and
37 increased invasiveness in natural habitats; c) adverse effects on organisms exposed to the crop; and d)
38 consequences of potential gene flow to wild or conventional relatives. While these adverse effects may
39 exist regardless of whether the tolerant crop is a product of modern biotechnology or conventional
40 breeding, some specific issues may be more relevant in the case of abiotic stress tolerant LM crops.

41 **Characterization of the LM crop with tolerance to abiotic stress in comparison with its non-**
42 **modified crop** (*see step 1 of the Roadmap for Risk Assessment*)

43 *Rationale:*

44 The first step in the risk assessment process involves the characterization of genotypic or phenotypic,
45 biological, intended and unintended changes associated with the abiotic stress tolerant LM crop that may
46 have adverse effects on biodiversity in the likely receiving environment, taking into account risks to
47 human health. This step is the ‘hazard identification step’ in other risk assessment guidance.

48 The identification of genotypic and phenotypic changes in the abiotic stress tolerant LM crop, either
49 intended or unintended, is typically done in comparison with the non-modified recipient organism (see
50 step 1 of the Roadmap). The non-modified comparator provides the baseline information for comparison
51 of trials when it is grown at the same time and location as the LM crop. Comparisons with the observed
52 range of changes in the non-modified crop in different environments, also provides baseline information.

53 *Challenges with respect to experimental design:* Abiotic stress crops may present unique challenges in
54 experimental design for risk assessment. In some cases, for instance, an approach uses different
55 reference plant lines, which typically include a range of genotypes representative of the natural variation
56 in the crop species. In such conditions, choosing appropriate comparators could be a challenge and there
57 are several proposals on whether and how the comparative approach can be used to characterize LM
58 crops tolerant to abiotic stress in these likely receiving environments. Another important consideration is
59 whether the experimental design properly controlled for the effect of the abiotic stress trait. In the
60 extreme case, when the non-modified crop has never been grown in the range of conditions of the
61 receiving environment because the abiotic stress conditions prevent or severely affect the growth of the
62 non-modified crop, a comparative approach between the LM crop and the non-modified crop will need to
63 be adjusted.

64 The use of non-isogenic reference lines can make it more difficult to identify statistically meaningful
65 differences. In some situations when a comparator may not be available to carry out a meaningful
66 comparison, a characterization of the abiotic stress tolerant LM crop as a novel genotype in the receiving
67 environment may be conducted. In the future, information available from “omics” technologies, for
68 example, “transcriptomics” and “metabolomics”, if available, may help to detect phenotypes (e.g., the
69 production of a novel allergen or anti-nutrient) that cannot be detected using a comparison between field
70 grown plants at a suboptimal condition.

71

72 *Points to consider:*

- 73 (a) Characteristics of the LM crop under the abiotic stress and non-stress conditions and under
74 different stresses, if applicable;
- 75 (b) Likelihood of gene flow to wild or domestic relatives; and
- 76 (c) Whether one or more suitable comparators are available and the possibility of their use in the
77 appropriate experimental design.

78 **Unintended characteristics** (*see step 1 of the Roadmap for Risk Assessment*)

79 *Rationale:*

80 Both intended and unintended changes to the LM crop which are directly or indirectly associated with the
81 abiotic stress tolerance that may have adverse effects should be identified. These include changes to the
82 biology of the crop plant (e.g. if the genes alter multiple characteristics of the plant) or to its distribution
83 range in relation to the potential receiving environment (e.g. if the plant can grow where it has not grown
84 before), that may cause adverse effects.

85 The abiotic-stress-tolerant LM crop may have unintended characteristics such as tolerances to other types
86 of biotic and abiotic stresses, which could lead to a selective advantage of these crop plants under
87 conditions other than that related to the modified trait. For instance, crops modified to become tolerant to
88 drought or salinity may be able to compete better than their counterparts at lower and higher growing
89 temperatures.

90 It is also possible the LM crops with enhanced tolerance to an abiotic stress could have changes in seed
91 dormancy, viability, and/or germination rates under other types of stresses. Particularly if genes involved
92 in abiotic stress are also involved in crucial steps in physiology, modifications involving these genes
93 may, therefore, have pleiotropic effects. Such LM crops may also transfer genes for stress tolerance at
94 higher frequencies than observed in non-modified crops.

95 A potential mechanism for interactions between abiotic and biotic stresses may exist in plants. For
96 example, drought or salinity-tolerant LM crops may acquire a changed tolerance to biotic stresses, which
97 could result in changed interactions with their predators, parasitoids and pathogens, and, therefore, have
98 both direct and indirect effects on organisms that interact with them.

99 *Points to consider:*

- 100 (a) Any intended or unintended change that may lead to selective advantage or disadvantage
101 acquired by the LM crop under other abiotic or biotic stress conditions that could cause
102 adverse effects;
- 103 (b) Any change in the resistance to biotic stresses and how these could affect the population of
104 organisms interacting with the LM crop; and
- 105 (c) A change in the substances (e.g., toxin, allergen, or nutrient profile) of the LM crop that could
106 cause adverse effects.

107 **Increased persistency in agricultural areas and invasiveness of natural habitats** (*see steps 1, 3 and 5*
108 *of the Roadmap for Risk Assessment*)

109 *Rationale:*

110 Climate change, water depletion or elevated salt content are examples of factors that limit the growth,
111 productivity, spread or persistence of a crop. Expression of the genes for abiotic stress tolerance could
112 result in increased persistence of the modified crop in agricultural areas. Expression of these genes may
113 also alter the capacity of LM crops to spread to and establish in climatic and geographic zones beyond
114 those initially considered as the likely or potential receiving environments.

115 The gene(s) inserted for tolerance to, for instance, drought and salinity might also affect molecular
116 response mechanisms to other forms of abiotic stress, such as cold temperatures. For example, when the
117 genetic modification affects genes that also regulate key processes in seeds, such as abscisic acid (ABA)
118 metabolism, physiological characteristics such as dormancy and accumulation of storage lipids may also
119 be changed. In such cases, the seeds of a tolerant crop, modified for drought or salinity tolerance, may
120 acquire in addition tolerance to cold resulting in an increased winter survivability of the seeds. Therefore,
121 an abiotic stress-tolerant crop may acquire the potential to persist better than its conventional counterpart
122 under different abiotic-stress conditions.

123 *Points to consider:*

- 124 (a) Consequences of the increased potential for persistency of the modified crop in agricultural
125 habitats and consequences of increased potential for invasiveness in natural habitats;
- 126 (b) Need for control measures if the abiotic stress-tolerant crop shows a higher potential for
127 persistency in agricultural or natural habitats, that could cause adverse effects;
- 128 (c) Characteristics that are generally associated with weediness such as prolonged seed dormancy,
129 long persistence of seeds in the soil, germination under a broad range of environmental
130 conditions, rapid vegetative growth, short lifecycle, very high seed output, high seed dispersal
131 and long-distance seed dispersal; and
- 132 (d) Effects of climate change on agriculture and biodiversity and how this could change the habitat
133 range of the LM crop in comparison to the non modified crop.
- 134 (e) If the LM crop expressing tolerance, would have a change in its agriculture practices.

135 **BIBLIOGRAPHIC REFERENCES**

136 *See references relevant to the “[Guidance Document on Risk Assessment of LM Crops with Tolerance to](#)*
137 *[Abiotic Stress](#)”.*

C. RISK ASSESSMENT OF LIVING MODIFIED MOSQUITOES

1 INTRODUCTION

2 Living modified (LM) mosquitoes are being developed through modern biotechnology to reduce
3 transmission of vector borne human pathogens, particularly those that cause malaria, dengue and
4 chikungunya. Control, including eradication of such diseases, is a recognized public health goal. Some of
5 the strategies being developed are to control mosquito vectors by suppressing their population or
6 reducing their competence. These strategies can be subcategorized according to the technology involved
7 and the method used. Some are intended to develop LM mosquitoes that are genetically modified to be
8 sterile or self-limiting (i.e., unable to pass the modified trait on indefinitely through subsequent
9 generations). Modern biotechnology techniques for developing sterile LM mosquitoes are different from
10 those based on the use of irradiation to induce male sterility.

11 Other modern biotechnology strategies are also being used for developing LM mosquito populations that
12 are self-sustaining or self-propagating (i.e., heritable modifications intended to spread through the target
13 population). The strategy used is an important factor to be considered in the risk assessment and risk
14 management process since there might be different points to be considered, depending on the specific
15 strategy used.

16 The biology and ecology of mosquitoes on the one hand, and their impact on public health as vectors of
17 human and animal diseases on the other hand, pose new considerations and challenges during the risk
18 assessment process, which have mainly dealt with LM crop plants thus far.

19 This guidance document provides information for the risk assessment of environmental releases of LM
20 mosquitoes and aims at helping to conduct risk assessments for environmental releases of LM
21 mosquitoes. Although the focus of this guidance is on LM mosquitoes, in principle, it may also be useful
22 for the risk assessment of similar non-LM mosquito strategies.

23 The main emphasis of this guidance document is the assessment of potential risks to biodiversity.
24 Nevertheless, the potential adverse effects to human health arising from environmental releases of LM
25 mosquitoes should also be considered.

26 This guidance document complements the Roadmap for Risk Assessment developed by the AHTEG on
27 Risk Assessment and Risk Management and focuses on specific issues that may need special
28 consideration on the risk assessment for environmental releases of LM mosquitoes.

29 OBJECTIVE

30 The objective of this document is to give additional guidance on the risk assessment (RA) of LM
31 mosquitoes in accordance with Annex III to the Cartagena Protocol on Biosafety.⁴⁷ Accordingly, it aims
32 at complementing the Roadmap for Risk Assessment on specific issues that may need special
33 consideration for the environmental release of LM mosquitoes.

⁴⁷ The Parties to the Cartagena Protocol on Biosafety have mandated the AHTEG to ‘develop a “roadmap”, such as a flowchart, on the necessary steps to conduct a risk assessment in accordance with Annex III to the Protocol and, for each of these steps, provide examples of relevant guidance documents’. The Roadmap is meant to provide reasoned guidance on how, in practice, to apply the necessary steps for environmental risk assessment as set out in Annex III of the Protocol. The Roadmap also demonstrates how these steps are interlinked.

34 SCOPE

35 This document focuses on the specific aspects of risk assessment of LM mosquitoes developed to be
36 used in the control of human and zoonotic diseases such as malaria, dengue, chikungunya, yellow fever
37 and West Nile.

38 ISSUES TO BE CONSIDERED IN THE RISK ASSESSMENT

39 *(See step 1 of the Roadmap for Risk Assessment of LMOs)*

40 Specific and comprehensive considerations should be undertaken with respect to the potential adverse
41 effects of a particular LM mosquito, taking into account the species of the mosquito, the LM trait, the
42 intended receiving environment, and the objective and scale of the intended release. These considerations
43 should focus on, for instance: (a) description of the genetic modification; (b) the kinds of possible
44 adverse effects for which there are scientifically plausible scenarios; (c) the species and ecological
45 processes that could be affected by the introduction of the LM mosquitoes; (d) the protection goals of the
46 country where the LM mosquitoes will be introduced; and (e) a conceptual link between the identified
47 protection goals and the introduction of the LM mosquito into the environment.

48 The biology and, to some extent, the ecology of the mosquito species that transmit malaria and dengue
49 are well known in many regions of the world. However, in certain regions and in the environment where
50 the LM mosquito is likely to be released, more information may be needed depending on the nature and
51 scale of the LM strategy to be deployed. In many of these environments few studies have been conducted
52 to examine gene flow among vectors, their mating behaviour, the interactions between vectors sharing
53 one habitat, how pathogens respond to the introduction of new vectors, etc. Such information may be
54 needed to establish a baseline in order to successfully assess the risks of LM mosquitoes. Additionally,
55 methods for the identification of specific ecological or environmental hazards are also needed.

56 **Effects on biological diversity (species, habitats, ecosystems, and ecosystem services)**

57 *(See step 2 of the Roadmap for Risk Assessment of LMOs)*

58 *Rationale:*

59 The release of LM mosquitoes may have a negative impact on the target vector and pathogen⁴⁸ and other
60 species, such as:

61 *New or more vigorous pests, especially those that have adverse effects on human health:* (i) the released
62 LM mosquitoes may not function as expected, for example gene silencing or production failures could
63 result in the release of non-sterile or competent mosquitoes and thus increase the vector population or
64 disease transmission; (ii) the released LM mosquitoes could transmit another disease more efficiently
65 than indigenous non-LM mosquitoes, such diseases might include yellow fever, chikungunya, etc.; (iii)
66 suppression of the target mosquito might result in the population of another vector species to increase
67 and result in higher levels of the target disease or the development of a new disease in humans and/or
68 animals. These other vector species may include other mosquito vectors of other diseases; (iv) the
69 released LM mosquitoes might become pests; (v) the released LM mosquitoes might cause other pests to
70 become more serious, including agricultural pests and other pests that affect human activities.

⁴⁸ For the purpose of this guidance, the term “target vector” refers to the mosquito that transmits the disease and “target pathogen” is the disease causing agent transmitted by the target mosquito.

71 *Harm to or loss of other species:* The released LM mosquitoes might cause other species (for instance
72 fish that rely seasonally on mosquitoes for food) to become less abundant. These include species of
73 ecological, economic, cultural and/or social importance such as wild food, endangered, keystone, iconic
74 and other relevant wildlife species. Ecological effects might result from competitive release if the target
75 mosquito population is reduced or from trophic consequences of species that rely on mosquitoes for food
76 at specific times of the year. Effects may also occur if (i) the target mosquitoes transmit a disease to
77 animal species, (ii) the released LM mosquitoes transmit a disease to animal species more efficiently,
78 (iii) another vector of an animal disease was released from control when the target mosquito population
79 was reduced, or (iv) the population of a target pathogen is reduced or lost and this may affect other
80 organisms that interact with it.

81 Although mosquitoes, like other insects, typically have strong reproductive isolating mechanisms that
82 will not allow interspecific gene flow, if sterile interspecific mating between released LM mosquitoes
83 and other mosquito species should occur, it could disrupt the population dynamics of these other species,
84 leading to harm or loss of valued ecological species. Moreover, cessation of transmission of pathogens to
85 other animals (e.g., West Nile virus to birds, Rift Valley fever virus to African mammals) might alter the
86 population dynamics of those species, favouring increases in their numbers.

87 *Disruption of ecological communities and ecosystem processes:* The ecological communities in the
88 ephemeral, small aquatic habitats occupied by the non-LM mosquitoes are unlikely to be disrupted
89 beyond the possibilities already addressed above under “harm to or loss of other species.” However, if
90 the released LM mosquitoes were to inhabit natural habitats (e.g. tree-holes), disruption of the associated
91 community is a possibility. The released LM mosquitoes might degrade some valued ecosystem process.
92 This might include processes such as pollination or support of normal ecosystem functioning. These
93 processes are often referred to as “ecosystem services”. However, the valued ecosystem processes may
94 also be culturally or socially specific. Under some circumstances, mosquito species are significant
95 pollinators. In those cases, mosquito control of any kind might reduce the rate of pollination of some
96 plant species or cause a shift to different kinds of pollinators. Habitats in which mosquitoes are the
97 dominant insect fauna (e.g., high Arctic tundra, tree holes) would be changed if mosquitoes were
98 eliminated; however, the common target vector species are usually associated with human activity and
99 therefore not as closely tied to ecosystem services.

100 *Points to consider:*

- 101 (a) Impacts on the target mosquitoes and pathogens resulting from the use of the strategy under
102 consideration;
- 103 (b) Whether the LM mosquitoes have the potential of causing adverse effects on other species
104 which will result in the other species becoming agricultural, aquacultural, public health or
105 environmental pests, or nuisance or health hazards;
- 106 (c) Whether the target mosquito species is native or invasive to a given area;
- 107 (d) The habitat range of the target mosquito species and whether the habitat range is likely to be
108 affected by climate change;
- 109 (e) Any other species (e.g. animal hosts, larval pathogens or predators of mosquitoes) in addition to
110 the pathogen, that typically interact with the LM mosquito in the likely receiving environment;
- 111 (f) Whether the release of LM mosquitoes is likely to affect other mosquito species that are
112 pollinators or otherwise known to be beneficial to ecosystem processes;
- 113 (g) Whether the LM mosquitoes are likely to have an adverse effect on other interacting organisms,
114 e.g. predators of mosquitoes;

- 115 (h) Whether species replacement by other disease vector species may occur, and if so, whether it
116 can result in an increased incidence of the target disease or new diseases in humans or animals.

117 **Gene Flow**

118 *(See steps 2 and 3 of the Roadmap for Risk Assessment of LMOs)*

119 *Rationale:*

120 With regard to the biosafety of LM mosquitoes, gene flow refers to the transfer of transgenes⁴⁹ or genetic
121 elements from the LM mosquitoes to non-LM mosquitoes. It can occur via cross-fertilisation or other
122 movement of the transgenes or genetic elements. Various factors may influence gene flow and any
123 associated adverse effects, such as, the strategy, the transgenes, the gene drive system⁵⁰ and the stability
124 of the trait(s) carried by the mosquito over generations, as well as the receiving environment, etc.

125 *Gene flow through cross-fertilization:* Some LM mosquitoes are being developed to spread the
126 introduced trait rapidly through the target mosquito population. For instance, when introduced into
127 *Anopheles gambiae*, the trait may be expected to spread throughout the *A. gambiae* species complex.
128 Other LM mosquito technologies are designed to be self-limiting and, in such cases, spread of the
129 transgenes or genetic elements in the target mosquito population is not intended or expected. For the self-
130 limiting technologies, the potential for an unexpected spread of the introduced trait should be considered
131 by focusing on the assumption that any management strategy to limit the spread could fail. Gene flow
132 between different species should be considered for all of the LM mosquito technologies in spite of the
133 fact that mosquitoes, like other insects, typically have strong reproductive isolating mechanisms that will
134 not allow interspecific gene flow. Identifying the key reproductive isolating mechanisms and possible
135 conditions that could lead to the breakdown of such mechanisms is of particular importance in the risk
136 assessment of LM mosquitoes with this trait. In addition, the fitness conferred by the introduced trait and
137 the population size and frequency of the introduction of the LM mosquito into the environment will also
138 determine the likelihood and rate of spread of the transgenes or genetic elements.

139 *Horizontal gene flow:* For the purpose of this document, “horizontal gene flow”, is the movement of
140 genetic information from one organism to another through means other than sexual transmission. Gene
141 drive systems for moving genes into wild populations may be the initial focus of the risk assessment. The
142 risk of horizontal gene flow in LM mosquitoes that do not contain a gene drive system is likely to be
143 smaller but should nevertheless be assessed on a case-by-case basis.

144 *Persistence of the transgene in the environment.* Some of the transgenes in LM mosquitoes are designed
145 not to persist whereas others are expected to spread rapidly and/or persist through wild populations. In
146 cases where the LM mosquitoes have been found through the risk assessment process to have the
147 potential to cause adverse effects to the biological diversity, taking also into account human health,
148 methods to reduce the persistence of the transgene in the environment needs to be considered

⁴⁹ For the purpose of this document, a transgene is a nucleic acid sequence in an LMO that results from the application of modern biotechnology as described in Article 3 (i) a of the Protocol.

⁵⁰ Gene drive systems are methods of effectively introducing the desired gene into a mosquito population (Selfish DNA versus Vector-Borne Disease, Environmental Health Perspectives (2008) 116 - <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2235231/pdf/ehp0116-a00066.pdf>).

149 *Points to consider:*

- 150 (a) Whether LM mosquitoes have the potential to transfer the modified traits to wild mosquito
151 populations (when it is not an intended strategy) and/or to non-related organisms, and if so, the
152 occurrence of any potential undesirable consequences;
- 153 (b) Whether the LM mosquitoes have the potential to induce undesirable characteristics, functions,
154 or behaviour within the target mosquito species, other wild related species or non-related
155 organisms;
- 156 (c) Any undesirable consequence should the transgene persist in the environment.

157 **Evolutionary responses (especially in target mosquito vectors or pathogens of humans and**
158 **animals)**

159 *(See step 1 of the Roadmap for Risk Assessment of LMOs)*

160 *Rationale:*

161 Any strong ecological effect also exerts an evolutionary selection pressure on the human and animal
162 pathogens and the mosquito vectors. The main evolutionary effects are those that could result in a
163 breakdown in the effectiveness of the technology and the resumption of previous disease levels. Some
164 LM mosquito strategies aim at modifying the mosquito vector's ability to transmit diseases through
165 changes in its physiological mechanisms. An evolutionary effect resulting in the development of
166 resistance to physiological mechanisms in the targeted pathogen might occur when modifying mosquito
167 vector competence. This might harm the effectiveness of the strategy used and result in a population of
168 pathogens that may be transmitted more easily by all types of vectors.

169 Other evolutionary effects could be hypothesized, including effects resulting from climate change, but
170 they would first require the occurrence of some adverse effect on a species, community or ecosystem
171 effect. Therefore, consideration of secondary evolutionary effects can be postponed until such effects are
172 identified and found to be significant.

173 *Points to consider:*

- 174 (a) Whether the target mosquito vector has the potential to evolve and avoid population
175 suppression, regain vector competence or acquire new or enhanced competence to another
176 disease agent, and if so, the occurrence of any possible undesirable consequences;
- 177 (b) Whether the trait has the potential to evolve and thus lose its effectiveness, or the pathogen to
178 evolve and overcome the limitation posed by the genetic modification, and if so, the occurrence
179 of any possible undesirable consequences.

180 **RISK-MANAGEMENT STRATEGIES**

181 *(See step 5 of the Roadmap for Risk Assessment of LMOs)*

182 Risk assessors may want to consider risk-management strategies such as the quality control of the
183 released LM mosquitoes and monitoring them and the environment for potential unintended adverse
184 effects. There should also be strategies in place for halting the release and application of mitigation
185 methods if an unanticipated effect occurs. Careful implementation of the technology including the
186 availability of mitigations measures (such as an alternative set of control measures should a problem
187 occur) and the integration of other population control methods should be considered. In some

188 circumstances methods to reduce the persistence of the transgene in the environment or to mitigate
189 adverse effects resulting from the expression of the transgene might be needed. Monitoring during and
190 after the environmental release of the LM mosquitoes so as to address prompt detection of unexpected
191 adverse effects may also be considered.

192 *Points to consider:*

193 (a) Availability of monitoring methods to:

194 (i) Measure the efficacy and effectiveness of LM mosquito technology;

195 (ii) Assess the potential evolutionary breakdown of the LM mosquito technology (monitoring
196 for transgene stability and proper function over time);

197 (iii) Determine the level to which the identified adverse effects may be realized, including
198 detection of unexpected and undesirable spread of the transgenic trait (monitor for
199 undesirable functions or behaviours within target species and other wild related species).

200 (b) Availability of mechanisms to recall the LM mosquitoes and transgenes in case they spread
201 unexpectedly (e.g. mass release of wild-type mosquitoes above a certain threshold, alternative
202 control methods including genetic control).

203 (c) Availability of methods for managing the dispersal of the LM mosquitoes and ensuring that they
204 do not establish themselves beyond the intended receiving environment (eg. vegetation-free
205 zones, traps, high threshold gene drive systems).

206 (d) Availability of methods to manage potential development of resistance, e.g. in the target vector
207 or pathogen.

208 **OTHER ISSUES**

209 There are other factors that may be taken into consideration in the decision for environmental releases of
210 LM mosquitoes which are not covered by Annex III of the Protocol. They encompass, *inter alia*, social,
211 economic, cultural and health issues associated with the application and acceptance of the technology.

212 **BIBLIOGRAPHIC REFERENCES**

213 See references relevant to the "[*Guidance Document on Risk Assessment of LM Mosquitoes*](#)".

Annex IV

RECOMMENDATIONS TO THE CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY AT ITS FIFTH MEETING

1. The Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management took note of the deliberations under the Open-ended Online Expert Forum on Risk Assessment and Risk Management in particular about the need for further guidance on specific aspects of risk assessment and considered the existing guidance materials on risk assessment of living modified organisms.
2. The AHTEG recognized the importance of involving experts in the various scientific and technical fields relevant to risk assessment in any future activity taking into account the limited financial and human resources.
3. The following recommendations were made by the AHTEG:
 - (a) The document “Guidance on Risk Assessment of Living Modified Organisms” should be published and distributed, including an online version under the Biosafety Clearing-House (BCH), in all UN languages;
 - (b) The “Guidance on Risk Assessment of Living Modified Organisms” should be further tested for example during regional workshops including cooperation with existing initiatives for capacity-building and training, as appropriate;
 - (c) The “Guidance on Risk Assessment of Living Modified Organisms” should be revisited within two years and the need for an update of the list of background materials should be assessed within a year;
 - (d) Further development of guidance on risk assessment of living modified organisms should be considered. The topics identified and prioritized during the first meeting of the AHTEG as well as those mentioned at the second meeting could be the starting point for the further development of guidance on risk assessment (see list annexed hereto as annex V);
 - (e) A process should be established for the incorporation of background materials, available in the Biosafety Information Resources Centre of the Biosafety Clearing-House, that are relevant in the different sections of the “Guidance on Risk Assessment of Living Modified Organisms”. In order to assist this process, the Secretariat should be requested to revise the common format for submission of records to the Biosafety Information Resources Centre (BIRC) of the BCH with the view to identifying and including a mechanism to link BIRC records on risk assessment to specific sections of the guidance document;
 - (f) Recognizing that the exchange of information is a central element for identifying living modified organisms or specific traits that have been assessed as having the potential to cause adverse effects on the conservation and sustainable use of biological diversity taking also into account risks to human health, a process should be established by:
 - (i) Urging Parties and inviting non-Parties to submit relevant information to the BCH on experiences in conducting risk assessment with regard to this topic;

- (ii) Requesting the Secretariat to undertake a regular analysis of the information contained in the BCH within the context of this process and reporting to the COP-MOP for that purpose;
- (iii) Organizing workshops where the information submitted would be analyzed through a guided-process.

(g) The goals of the above recommendations (a) to (f) could be achieved by a combination of an extended Open-ended Online Expert Forum on Risk Assessment and Risk Management and an AHTEG on Risk Assessment and Risk Management, as well as a combination of online conferences, ad hoc discussion groups and face-to-face meetings with a view to:

- (i) Developing additional guidance documents on the basis of the “Guidance on Risk Assessment of Living Modified Organisms” on specific types of living modified organisms and traits;
- (ii) Reviewing the text of the “Guidance on Risk Assessment of Living Modified Organisms” and updating the lists of background materials;
- (iii) Incorporating background materials, available in the Biosafety Information Resources Centre of the Biosafety Clearing-House, that are relevant to the different sections of the “Guidance on Risk Assessment of Living Modified Organisms”;
- (iv) Analysing the results of the workshops on living modified organisms or specific traits that have been assessed as having the potential to cause adverse effects.

(h) Human and financial resource implications should be considered for the process set up to achieve the above goals.

Annex V

TOPICS FOR THE DEVELOPMENT OF GUIDANCE MATERIALS ON RISK ASSESSMENT

*Further topics indentified in the first meeting of the AHTEG as priorities for the development of guidance:*⁵¹

- Post-release monitoring and long-term effects of LMOs released into the environment;
- Risk assessment and risk management in specific receiving environments;
- Risk assessment of living modified microorganisms and viruses;
- Risk assessment of living modified pharmaplants;
- Risk assessment of living modified crops;
- Risk assessment of living modified trees;
- Risk assessment of living modified fish;
- Risk assessment living modified organisms for production of pharmaceutical and industrial products;
- “Co-existence” between LMOs and non-LMOs in the context of small scale farming;
- Risk assessment of living modified plants for biofuels;
- Risk assessment of living modified organisms produced through synthetic biology.

Further topics identified in the second meeting of the AHTEG as possible priorities for the development of guidance:

- Uncertainty analysis;
- Establishment of criteria for transparency and reproducibility of information;
- Interface between risk assessment and risk management;
- Environmental risk assessment and monitoring taking into account human health;
- Unintentional transboundary movements;
- Risk assessment and management of LMOs intended for introduction into unmanaged environments

⁵¹ From annex II of the report of the first meeting of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management (UNEP/CBD/BS/COP-MOP/5/INF/13).