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CONFERENCE OF THE PARTIES TO THE CONVENTION
ON BIOLOGICAL DIVERSITY SERVING AS THE
MEETING OF THE PARTIES TO THE CARTAGENA
PROTOCOL ON BIOSAFETY

Fourth meeting

Bonn, 12-16 May 2008

Item 11 of the provisional agenda*

**COMPILATION OF GUIDANCE DOCUMENTS ON RISK ASSESSMENT AND RISK
MANAGEMENT AVAILABLE THROUGH THE BIOSAFETY INFORMATION RESOURCE
CENTRE OF THE BIOSAFETY CLEARING-HOUSE**

Note by the Executive Secretary

I. INTRODUCTION

1. At its third meeting, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) took note of the report of the Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment held in Rome in November 2005. The report made reference to potential gaps in the guidance materials available for risk assessment and risk management with respect to emerging applications of modern biotechnology, namely in trees, fish, veterinary applications and specific plant varieties.

2. In paragraph 2 of decision BS-III/11, the COP-MOP requested the Executive Secretary to:

(a) Expand the compilation of available guidance documents on risk assessment and risk management contained in the Biosafety Information Resource Centre (BIRC) of the Biosafety Clearing-House (BCH), taking into account, *inter alia*, the numerous references to existing guidance materials in the report of the AHTEG;

(b) Provide an overview, through the BCH, illustrating the scope and applicability of each guidance material.

3. The number of guidance documents on risk assessment and risk management currently available through the BIRC has been expanded to 155 entries.

4. Section II of this document presents a complete list of these documents and a brief description of their scope. The classification of documents is in accordance with the types of organisms discussed in the AHTEG report. Note that, in comparison to the documents available for modified trees, microorganisms and animals, most of these guidance materials are focused on modified crop plants. Furthermore, there are no guidance documents on pharmaplants (i.e., plants that produce pharmaceutical compounds) currently available in the BIRC.

* UNEP/CBD/BS/COP-MOP/4/1.

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II. LIST OF GUIDANCE DOCUMENTS ON RISK ASSESSMENT AND RISK MANAGEMENT AVAILABLE THROUGH THE BIOSAFETY INFORMATION RESOURCE CENTRE

5. The guidance materials on risk assessment and risk management available through the Biosafety Information Resource Centre are categorized according to the type of LMO in the following categories: all types of LMO, crop plants, trees, animals, microorganisms and viruses and other organisms. Direct links to the guidance materials are set out next to the BIRC record number.

All types of LMOs

1. A Practical Guide to Containment: Greenhouse Research with Transgenic Plants and Microbes

Scope: Reference on appropriate biosafety and containment levels for GMO research conducted in greenhouses. It helps clarify what level of containment is needed and what measures are sufficient to achieve the various biosafety levels by providing information on the purpose of containment, the variety of methods used to achieve it, and the facilities and practices that satisfy the requirements of established guidelines and regulations.

BIRC Record ID: 41671 (<http://bch.cbd.int/database/record.shtml?id=41671>).

2. A Risk Management Standard

Scope: This guide aims at developing a practical standard, which is not certifiable and not prescriptive with regard to specific actions and processes but instead sets out the principles to be followed in the undertaking of a risk-management approach. Although not focused on biotechnology, the principles covered here can be applied for risk assessment and risk management of GMOs.

BIRC Record ID: 44305 (<http://bch.cbd.int/database/record.shtml?id=44305>).

3. Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

Scope: The WTO SPS agreement applies to all sanitary and phytosanitary measures, which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this agreement.

BIRC Record ID: 44011 (<http://bch.cbd.int/database/record.shtml?id=44011>).

4. An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology

Scope: This document describes the origin of OECD's Working Group for Harmonisation in Biotechnology and explains why biosafety consensus documents were included as part of its core work. It also addresses the purpose of these documents and their intended use as a practical contribution to the risk/ safety assessment of transgenic organisms.

BIRC Record ID: 41865 (<http://bch.cbd.int/database/record.shtml?id=41865>).

5. An Introduction to the Food/Feed Safety Consensus Documents of the Task Force

Scope: This text provides an introduction and describes the purpose of OECD's consensus documents and their use as a practical contribution to the risk/safety assessment of foods and feeds derived from transgenic organisms.

BIRC Record ID: 41887 (<http://bch.cbd.int/database/record.shtml?id=41887>).

6. ANNEX II to Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms: Principles for the Environmental Risk Assessment

Scope: Describes the characteristics of GMOs and releases that should be considered for an environmental risk assessment, the steps for the assessment and how to draw conclusions on the potential environmental impact from the release or the placing on the market of GMOs.

BIRC Record ID: 42115 (<http://bch.cbd.int/database/record.shtml?id=42115>).

7. ANNEX VII to Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms: Monitoring Plan

Scope: Describes the general principals and design of a monitoring plan, which should be detailed on a case-by-case basis taking into account the environmental risk assessment.

BIRC Record ID: 42116 (<http://bch.cbd.int/database/record.shtml?id=42116>).

8. Approaches of Risk: an Introduction

Scope: This document approaches risk management and risk management issues and outlines the precautionary approach principle.

BIRC Record ID: 41999 (<http://bch.cbd.int/database/record.shtml?id=41999>).

9. Asean Guidelines on Risk Assessment of Agriculture Related Genetically Modified Organisms (GMOs)

Scope: These guidelines focus on a science-based risk assessment of agriculture-related GMOs and provide a common framework for ASEAN (Association of Southeast Asian Nations) Member Countries to undertake risk assessment of agriculture-related GMOs.

BIRC Record ID: 42215 (<http://bch.cbd.int/database/record.shtml?id=42215>).

10. Biological Confinement of Genetically Engineered Organisms

Scope: This report examines bioconfinement of genetically engineered plants, animals, microbes, and fungi. Particular attention is given to transgenic fish and shellfish, trees and grasses, and microbes because many of these organisms have been successfully engineered and are currently under regulatory evaluation. The discussion is limited to scientific and societal components that are brought to bear on the process of choosing and applying bioconfinement of LMOs.

BIRC Record ID: 44040 (<http://bch.cbd.int/database/record.shtml?id=44040>).

11. Biosafety Guidelines for Bangladesh

Scope: Framework for field testing for GM plants and microorganisms. Potential risk management measures listed by type of LMO (plants, animals and microorganisms), discussion of options for physical or biological containment as well as a classification of microorganisms according to their risk potential are also included.

BIRC Record ID: 42117 (<http://bch.cbd.int/database/record.shtml?id=42117>).

12. Biosafety Guidelines in Genetic Engineering and Biotechnology For Field Work and Planned Release

Scope: These Guidelines cover research work involved in the field test/trial of genetically manipulated plants and microorganisms, including intentional releases of transgenic materials and products into the environment.

BIRC Record ID: 42010 (<http://bch.cbd.int/database/record.shtml?id=42010>).

13. Biosafety Guidelines in Genetic Engineering and Biotechnology for Laboratory Work

Scope: These Guidelines are applicable for research work involved in the construction and/or propagation of viroids, viruses, cells or other organisms carrying novel genetic material which are either improbable to arise naturally or are potentially detrimental towards public safety and environmental health.

BIRC Record ID: 42011 (<http://bch.cbd.int/database/record.shtml?id=42011>).

14. Checklist for Contained Use (Laboratory Activities) of Genetically Modified Organisms (GMOs) in Kenya. Guideline for Inspections

Scope: Checklist for inspection of laboratory facilities used for GMOs.

BIRC Record ID: 41697 (<http://bch.cbd.int/database/record.shtml?id=41697>).

15. Checklist For Contained Use (Animal Units) of Genetically Modified Organisms (GMOs) in Kenya. Biosafety Level 1 - 3. Guideline for Inspections

Scope: Checklist for inspection of animal facilities used for contained use of GMOs.

BIRC Record ID: 41698 (<http://bch.cbd.int/database/record.shtml?id=41698>).

16. Checklist for Contained Use (Glasshouses and Growth-rooms) of Genetically Modified Organisms (GMOs) in Kenya. Biosafety Level 1 - 3. Guidelines for Inspections

Scope: Checklist for inspection of greenhouses and growth-rooms used for contained use of GMOs.

BIRC Record ID: 41699 (<http://bch.cbd.int/database/record.shtml?id=41699>).

17. Checklist for Field trials of Genetically Modified Organisms (GMOs) in Kenya. Guideline for Inspections

Scope: Checklist for inspection of field trials of GMOs.

BIRC Record ID: 41700 (<http://bch.cbd.int/database/record.shtml?id=41700>).

18. China - Biosafety Regulations of Agricultural Genetically Modified Organisms, 2002

Scope: Describes a classification system for safety of agricultural GMOs, including a list with detailed information requirements for GM plants, animals and microorganisms.

BIRC Record ID: 42118 (<http://bch.cbd.int/database/record.shtml?id=42118>).

19. Draft: Guide for Notifications and Risk Assessments for Releases into the Environment of Genetically Modified Organisms. Module 1: Genetically Modified Crop Plants

Scope: The focus of this guide is the technical and scientific information required for notification, and in particular for risk assessment. Over recent years, there has been a tendency for not only regulators to request, but also for applicants to include, unrequested, as much technical information in the notifications as is available, regardless of whether such information is relevant to the risk assessment. This is neither in the interest of safety - as it distracts the risk assessment from focusing on relevant information - nor in the interest of public research. One of the main aims of this guide is to assist in keeping a focus on information that is relevant to risk assessment. This guide is built up in modules, whereby the first module focuses on genetically modified crop plants.

BIRC Record ID: 42149 (<http://bch.cbd.int/database/record.shtml?id=42149>).

20. Draft: Guide for Notifications and Risk Assessments for Releases into the Environment of Genetically Modified Organisms. Module 1: Genetically Modified Crop Plants

Scope: The focus of this guide is the technical and scientific information required for notification, and in particular for risk assessment. One of the main aims is to assist in keeping a focus on information that is relevant to risk assessment. This guide is built up in modules, whereby the first module focuses on genetically modified crop plants.

BIRC Record ID: 42149 (<http://bch.cbd.int/database/record.shtml?id=42149>).

21. Environment Management - The ISO 14000 Family of International Standards (2002)

Scope: Leaflet showing various ISO standards related to environmental management, including a brief description of the scope of each standard.

BIRC Record ID: 42119 (<http://bch.cbd.int/database/record.shtml?id=42119>).

22. Genetically Engineered Organisms and the Environment: Current Status and Recommendations

Scope: This paper proposes how scientifically-based assessment of the benefits and risks of genetically engineered organisms (GEOs) as well as monitoring and management for environmental effects that may occur over large spatial scales and long timeframes, should be performed.

BIRC Record ID: 41549 (<http://bch.cbd.int/database/record.shtml?id=41549>).

23. GMO Detection Methods and Validation

Scope: In this review, the current methodological status of detection of GMO-derivatives in the food chain is presented. The major focus is on DNA-based methods, in particular those involving PCR (polymerase chain reaction). An introduction to the DNA molecule is linked as an annex, to help those readers unfamiliar with molecular biology understand the technology of detection.

BIRC Record ID: 41960 (<http://bch.cbd.int/database/record.shtml?id=41960>).

24. Guide 73, Risk Management Vocabulary Guidelines for Use in standards (2002)

Scope: This document provides a set of basic definitions and terms relating to risk management for use in standardization at international, regional and national levels.

BIRC Record ID: 42121 (<http://bch.cbd.int/database/record.shtml?id=42121>).

25. Guidelines for Ecological Risk Assessment

Scope: The guidelines are drawn from a wide range of source documents including peer-reviewed issue papers and case studies previously developed by the US Environmental Protection Agency's Risk Assessment Forum. A major theme of the guidelines is the interaction among risk assessors, risk managers, and interested parties at the beginning and end of the risk-assessment process.

BIRC Record ID: 41647 (<http://bch.cbd.int/database/record.shtml?id=41647>).

26. Guidelines for Inspection and Monitoring GMOs in Kenya

Scope: These guidelines include detailed inspection and monitoring schemes for risk assessment and management of LMOs following the general principles of the Cartagena Protocol on Biosafety.

BIRC Record ID: 41696 (<http://bch.cbd.int/database/record.shtml?id=41696>).

27. Guidelines for Pest Risk Analysis, International Standard for Phytosanitary Measures #2, 1996

Scope: This document is not specific to LMOs, but applicable to any species, strain or biotype of plant, animal or microorganism that is injurious to plants or plant products. It describes risk-assessment methodology in some detail, in particular the methodological steps analogous to paragraphs 8(a) to 8(d) of Annex III of the Protocol, with a focus on risks associated with potential spread and establishment.

BIRC Record ID: 42123 (<http://bch.cbd.int/database/record.shtml?id=42123>).

28. Identifying Risks for Applications under the Hazardous Substances and New Organisms Act 1996

Scope: Detailed guidance on the process of identifying potential risks (expanding on paragraph 8(a) of Annex III). It is particularly helpful for those people who are reviewing applications.

BIRC Record ID: 42104 (<http://bch.cbd.int/database/record.shtml?id=42104>).

29. International Standards for Phytosanitary Measures: Pest Risk Analysis for Quarantine Pests, Including Analysis of Environmental Risks and Living Modified Organisms (2004)

Scope: These guidelines help countries assess the risks of LMOs and determine whether some should be considered as weeds or other organisms that damage plants in order to reduce the risks of releasing LMOs that are weedy and likely to harm crops and plant ecosystems. The guidelines will also help to harmonize and standardize the way countries analyze risks that LMOs may pose to plant health.

BIRC Record ID: 42137 (<http://bch.cbd.int/database/record.shtml?id=42137>).

30. International Standards for Risk Assessment and Risk Management of Biotechnology

Scope: This paper assesses the need, feasibility and fora for establishing internationally-agreed standards for risk assessment and risk management of GMOs/LMOs, including the role of the precautionary principle and labelling guidelines for GMOs and GM food products.

BIRC Record ID: 43696 (<http://bch.cbd.int/database/record.shtml?id=43696>).

31. Manual for Assessing Ecological and Human Health Effects of Genetically Engineered Organisms. Part One: Introductory Materials and Supporting Text for Flowcharts

Scope: This manual offers a framework for the systematic evaluation of the safety of a planned release of a genetically engineered organisms or introduction of a genetically engineered food. It offers a detailed flowchart-based approach for hazard identification and for consideration of specific risk pathways. Risk-management options are also discussed and some case studies are included.

BIRC Record ID: 41577 (<http://bch.cbd.int/database/record.shtml?id=41577>).

32. National Guidelines for the Release of Genetically Modified Organisms (GMOs) into the Environment

Scope: This document provides the Kenya National Guidelines for the release of genetically modified organisms (GMOs) into the environment.

BIRC Record ID: 41701 (<http://bch.cbd.int/database/record.shtml?id=41701>).

33. Nigeria Biosafety Guidelines

Scope: These guidelines include detailed inspection and monitoring schemes adopted by Nigeria for risk assessment and management of LMOs following the general principles of the Cartagena Protocol on Biosafety.

BIRC Record ID: 42105 (<http://bch.cbd.int/database/record.shtml?id=42105>).

34. Office of the Gene Technology Regulator, 2005

Scope: Scheme for the regulation of genetically modified organisms in Australia, in order to protect the health and safety of Australians and the Australian environment by identifying risks posed by or as a result of gene technology, and to manage those risks by regulating certain dealings with genetically modified organisms.

BIRC Record ID: 42109 (<http://bch.cbd.int/database/record.shtml?id=42109>).

35. Ottawa '92: The OECD Workshop on Methods for Monitoring Organisms in the Environment

Scope: This document is the report of the OECD Workshop on Methods for Monitoring Organisms in the Environment, which was hosted by the Canadian authorities in Ottawa, 14-17 September 1992.

BIRC Record ID: 41906 (<http://bch.cbd.int/database/record.shtml?id=41906>).

36. Pest risk analysis for quarantine pests including analysis of environmental risks and living modified organisms, International Standard for Phytosanitary Measures #11, 2004

Scope: These guidelines include detailed discussion on risk assessment and risk management applicable to any LMO that is a potential plant pest, which is of economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled. It also includes detailed discussion of elements of methodology in particular estimating the probability and potential economic consequences (including environmental impacts) of introduction and spread.

BIRC Record ID: 42125 (<http://bch.cbd.int/database/record.shtml?id=42125>).

37. Report of the OECD Workshop on Monitoring of Organisms Introduced into the Environment

Scope: This document provides a preliminary outline of considerations in approaches and methods for monitoring the fate and impact of organisms introduced into the environment. The utilization of appropriate approaches and methods may contribute to the safe development of the technology and to its beneficial applications. The focus for the discussion of monitoring in this workshop report is small-scale field introduction.

BIRC Record ID: 41907 (<http://bch.cbd.int/database/record.shtml?id=41907>).

38. Resource Book for Biosafety & Biotechnology in East Africa

Scope: This book explains the logic behind the principles of risk assessment, risk management and biosafety communication as well as effective GMO inspections and enforcement, and it provides resources for biosafety regulators, reviewers, applicants and trainers. It is an important step towards regional biosafety harmonization in eastern Africa.

BIRC Record ID: 42205 (<http://bch.cbd.int/database/record.shtml?id=42205>).

39. Risk Analysis Framework

Scope: This Risk Analysis Framework (RAF) is a key explanatory document that provides guidance on how the Australian Gene Technology Regulator approaches risk analysis of genetically modified organisms (GMOs). The purpose of this document is to: i) provide a guide to the rationale and approach to risk analysis used by the regulator; ii) enable the application of a consistent risk-analysis approach to evaluating license applications; iii) provide a clear guide to the provisions of the legislation that relate to risk assessment and risk management; and iv) ensure that the risk-analysis and decision-making processes are transparent to both applicants and the broader community.

BIRC Record ID: 41956 (<http://bch.cbd.int/database/record.shtml?id=41956>).

40. Safety Considerations for Biotechnology, 1992

Scope: This paper considers specific risk pathways for field trials of GM plants and microorganisms, including elaboration of criteria and principles for good practices in terms of industrial large-scale and small-scale field research of modified plants and microorganisms.

BIRC Record ID: 42208 (<http://bch.cbd.int/database/record.shtml?id=42208>).

41. Singapore Guidelines on the Release of Agriculture-Related Genetically Modified Organisms (GMOs)

Scope: These guidelines are established to ensure the safe movement and use in Singapore of agriculture-related GMOs and provide a common framework for: (i) assessment of risks of agriculture-related GMOs to human health and the environment; and (ii) approval mechanisms for their release in Singapore.

BIRC Record ID: 41954 (<http://bch.cbd.int/database/record.shtml?id=41954>).

42. Strategic Environmental Assessment: Assessing the Environmental Impact of Biotechnology

Scope: This brief paper outlines a Strategic Environmental Assessment (SEA) paradigm for biotechnology plans or programs based on quantitative and qualitative analyses.

BIRC Record ID: 41554 (<http://bch.cbd.int/database/record.shtml?id=41554>).

43. Strategies for Assessing the Safety of Foods Produced by Biotechnology

Scope: This is the report of a joint FAO/WHO consultation on strategies for assessing the safety of foods produced by biotechnology. The aim was to outline appropriate strategies and procedures to assist those responsible for assessing the safety of specific applications of biotechnology in food production and processing.

BIRC Record ID: 41977 (<http://bch.cbd.int/database/record.shtml?id=41977>).

44. Technical and Technological Aspects of Biosafety

Scope: This report provides information on the techniques used for the detection of genetically modified organisms, particularly plants and microorganisms, and their products and identifies the centres or institutions in Sri Lanka which have the infrastructure facilities to perform tests for detection of genetically modified organisms as well as for risk assessment and risk management.

BIRC Record ID: 44569 (<http://bch.cbd.int/database/record.shtml?id=44569>).

45. The Indian Recombinant DNA Safety Guidelines and Regulations

Scope: The booklet serves as a guide towards observance of the guidelines in research and also to meet the regulatory requirements by those in production, testing and use of genetically modified organisms and products in India.

BIRC Record ID: 41966 (<http://bch.cbd.int/database/record.shtml?id=41966>).

46. The Singapore Biosafety Guidelines for Research on Genetically Modified Organisms (GMOs)

Scope: These guidelines are established to ensure the safe containment, handling and transport of genetically modified organisms used in research and to provide a common framework for assessment and notification of research on GMOs. They were drawn up after a review of relevant guidelines, regulations and publications including those from Australia, United States of America (USA), Europe, World Health Organization (WHO) and the United Nations Environment Programme (UNEP).

BIRC Record ID: 41955 (<http://bch.cbd.int/database/record.shtml?id=41955>).

47. The Thai Draft Guidelines on Contained Uses of GMOs

Scope: These guidelines apply to any experiment carried out in laboratories of government, state enterprises, private organizations, or companies and involving the construction and/or propagation of viroids, viruses, cells or organisms of novel genotypes produced by genetic manipulation which are either unlikely to occur in nature or likely to pose a hazard to public health or to the environment.

BIRC Record ID: 42009 (<http://bch.cbd.int/database/record.shtml?id=42009>).

48. UNEP International Technical Guidelines for Safety in Biotechnology

Scope: These Guidelines have been developed on the basis of common elements and principles derived from relevant existing regional and international instruments and national regulations and guidelines, and drawing upon experience already gained through their preparation and implementation.

BIRC Record ID: 41493 (<http://bch.cbd.int/database/record.shtml?id=41493>).

49. User Guide to Making An Application for Rapid Assessment to Develop in Containment a Project of Low-Risk GMOs

Scope: This guide is particularly helpful for those who are reviewing applications, but it may also be useful for applicants and those people interested in HSNO (Hazardous Substances and New Organisms) related risks more generally.

BIRC Record ID: 42026 (<http://bch.cbd.int/database/record.shtml?id=42026>).

50. User Guide to Making An Application for Rapid Assessment to Import into Containment Low-Risk GMOs

Scope: This guide is particularly helpful for those who are reviewing applications, but it may also be useful for applicants and those people interested in HSNO (Hazardous Substances and New Organisms) related risks more generally.

BIRC Record ID: 42027 (<http://bch.cbd.int/database/record.shtml?id=42027>).

51. Voluntary Code of Conduct for the Release of Organisms into the Environment

Scope: The scope of this document covers GMOs at all stages of research, development, use and disposal, while focusing on release to the environment. It covers, but is not limited to, genetically modified plants, animals (including for example, insects, molluscs and fish), and microorganisms and their products and by-products. It contains the elements of a code of conduct for the release of genetically modified organisms (GMOs) into the environment and aims to set forth the minimum acceptable components necessary for international cooperation.

BIRC Record ID: 41915 (<http://bch.cbd.int/database/record.shtml?id=41915>).

Crop plants

52. Advice on a Notification for Marketing of Herbicide Tolerant and Insect Resistant GM Hybrid Maize

Scope: Advice of the Advisory Committee for Release into the Environment on the import and processing of grain derived from hybrid maize containing events NK603 and MON810. This document contains molecular characteristics, animal feed safety, environmental risk assessment and post-marketing monitoring.

BIRC Record ID: 42035 (<http://bch.cbd.int/database/record.shtml?id=42035>).

53. Biotechnology and Biosafety at CIP Internal Guidelines

Scope: This paper outlines future plans for biosafety activities at the International Potato Center (CIP). It was developed in close cooperation with experts in the field and with representatives from the Ministry of Agriculture of Peru.

BIRC Record ID: 42043 (<http://bch.cbd.int/database/record.shtml?id=42043>).

54. Code of Practice on the Introduction of Genetically Modified Crops

Scope: This Code of Practice was developed to establish a consistent, industry-wide approach to the supply of information relating to genetically modified (GM) crops from seed to primary end-product, and to promote practical guidelines for the management of specific aspects of GM crops.

BIRC Record ID: 41982 (<http://bch.cbd.int/database/record.shtml?id=41982>).

55. Compliance Management of Confined Field Trials of Genetically Engineered Plants

Scope: This document provides information that may be used for the development of quality assurance programs designed to ensure compliance with the terms and conditions of authorisation for confined field trials.

BIRC Record ID: 41544 (<http://bch.cbd.int/database/record.shtml?id=41544>).

56. Consensus Document on Compositional Considerations for New Varieties of Alfalfa and Other Temperate Forage Legumes: Key Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses compositional considerations for new varieties of alfalfa and other temperate forage legumes. A general description of feed nutrients, anti-nutrients and secondary plant metabolites is provided.

BIRC Record ID: 41888 (<http://bch.cbd.int/database/record.shtml?id=41888>).

57. Consensus Document on Compositional Considerations for New Varieties of Barley (*Hordeum vulgare* L.): Key Food and Feed Nutrients and Anti-Nutrients

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses compositional considerations for new varieties of barley by identifying the key food and feed nutrients and anti-nutrients. A general description of these components is provided.

BIRC Record ID: 41889 (<http://bch.cbd.int/database/record.shtml?id=41889>).

58. Consensus Document on Compositional Considerations for New Varieties of Bread Wheat (*Triticum aestivum*): Key Food and Feed Nutrients, Anti-Nutrients and Toxicants

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses compositional considerations for new varieties of wheat by identifying the key food and feed nutrients, anti-nutrients and toxicants. A general description of these components is provided.

BIRC Record ID: 41893 (<http://bch.cbd.int/database/record.shtml?id=41893>).

59. Consensus Document on Compositional Considerations for New Varieties of Cotton (*Gossypium hirsutum* and *Gossypium barbadense*): Key Food and Feed Nutrients and Anti-Nutrients

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses compositional considerations for new varieties of cotton by identifying the key food and feed nutrients, anti-nutrients and toxicants. A general description of these components is provided.

BIRC Record ID: 41890 (<http://bch.cbd.int/database/record.shtml?id=41890>).

60. Consensus Document on Compositional Considerations for New Varieties of Maize (*Zea Mays*): Key Food and Feed Nutrients, Anti-Nutrients and Secondary Plant Metabolites

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses compositional considerations for new

varieties of maize by identifying the key food and feed nutrients, anti-nutrients and toxicants. A general description of these components is provided.

BIRC Record ID: 41894 (<http://bch.cbd.int/database/record.shtml?id=41894>).

61. Consensus Document on Compositional Considerations for New Varieties of Potatoes: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses compositional considerations for new varieties of potatoes by identifying the key food and feed nutrients, anti-nutrients and toxicants. A general description of these components is provided.

BIRC Record ID: 41895 (<http://bch.cbd.int/database/record.shtml?id=41895>).

62. Consensus Document on Compositional Considerations for New Varieties of Rice (*Oryza sativa*): Key Food and Feed Nutrients and Anti-Nutrients

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses compositional considerations for new varieties of rice by identifying the key food and feed nutrients, anti-nutrients and toxicants. A general description of these components is provided.

BIRC Record ID: 41891 (<http://bch.cbd.int/database/record.shtml?id=41891>).

63. Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-Nutrients

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses compositional considerations for new varieties of soybeans by identifying the key food and feed nutrients and anti-nutrients. A general description of these components and the main toxicants are provided.

BIRC Record ID: 41897 (<http://bch.cbd.int/database/record.shtml?id=41897>).

64. Consensus Document on Compositional Considerations for New Varieties of Sugar Beet: Key Food and Feed Nutrients and Anti-Nutrients

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses compositional considerations for new varieties of sugar beet by identifying the key food and feed nutrients and anti-nutrients. A general description of these components and the main toxicants are provided.

BIRC Record ID: 41896 (<http://bch.cbd.int/database/record.shtml?id=41896>).

65. Consensus Document on General Information concerning the Biosafety of Crop Plants Made Virus Resistant through Coat Protein Gene-Mediated Protection

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document is intended to provide information concerning virus resistant plants. The focus of this report is limited to issues that can be discussed in a general fashion without reference to the specific environment in which the transgenic plant is to be introduced.

BIRC Record ID: 41886 (<http://bch.cbd.int/database/record.shtml?id=41886>).

66. Consensus Document on General Information Concerning the Genes and Their Enzymes that Confer Tolerance to Glyphosate Herbicide

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses general information concerning the genes and their enzymes that confer tolerance to the herbicide glyphosate.

BIRC Record ID: 41881 (<http://bch.cbd.int/database/record.shtml?id=41881>).

67. Consensus Document on General Information Concerning the Genes and Their Enzymes that Confer Tolerance to Phosphinothricin Herbicide

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses general information concerning the genes and their enzymes that confer tolerance to the herbicide Phosphinothricin.

BIRC Record ID: 41880 (<http://bch.cbd.int/database/record.shtml?id=41880>).

68. Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed (Canola)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses compositional considerations for new varieties of canola by identifying the key food and feed nutrients, anti-nutrients and toxicants. A general description of these components is provided.

BIRC Record ID: 41898 (<http://bch.cbd.int/database/record.shtml?id=41898>).

69. Consensus Document on the Biology of *Brassica napus* L. (Oilseed rape)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment.

BIRC Record ID: 41884 (<http://bch.cbd.int/database/record.shtml?id=41884>).

70. Consensus Document on the Biology of *Beta vulgaris* L. (Sugar Beet)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of sugar beet. It contains a general description as a crop plant, taxonomy, centre of origin/diversity, reproductive biology, crosses and weed characteristics.

BIRC Record ID: 41874 (<http://bch.cbd.int/database/record.shtml?id=41874>).

71. Consensus Document on the Biology of *Glycine max* (L.) Merr. (Soybean)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This consensus document addresses the biology of soybean. It contains a general description as a crop plant, taxonomy, centre of origin/diversity, identification methods, reproductive biology, crosses and ecology.

BIRC Record ID: 41876 (<http://bch.cbd.int/database/record.shtml?id=41876>).

72. Consensus Document on the Biology of *Helianthus annuus* L. (Sunflower)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of sunflower. It contains a general description as a crop plant, taxonomy, centre of origin/diversity, reproductive biology, crosses and weed characteristics.

BIRC Record ID: 41866 (<http://bch.cbd.int/database/record.shtml?id=41866>).

73. Consensus Document on the Biology of *Oryza Sativa* (Rice)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of rice. It contains a general description as a crop plant, taxonomy, centre of origin/diversity, reproductive biology, crosses and weed characteristics.

BIRC Record ID: 41877 (<http://bch.cbd.int/database/record.shtml?id=41877>).

74. Consensus Document on the Biology of Papaya (*Carica Papaya*)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of papaya. It contains a general description as a crop plant, taxonomy, centre of origin/diversity, reproductive biology, crosses and weed characteristics.

BIRC Record ID: 41864 (<http://bch.cbd.int/database/record.shtml?id=41864>).

75. Consensus Document on the Biology of *Solanum tuberosum* subsp. *tuberosum* (Potato)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of potato. It contains a general description as a crop plant, taxonomy, centre of origin/diversity, reproductive biology, crosses and weed characteristics.

BIRC Record ID: 41883 (<http://bch.cbd.int/database/record.shtml?id=41883>).

76. Consensus Document on the Biology of the *Capsicum annuum* Complex (Chili peppers, Hot peppers and Sweet peppers)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of chili peppers. It contains a general description as a crop plant, taxonomy, centre of origin/diversity, reproductive biology, crosses and weed characteristics.

BIRC Record ID: 41861 (<http://bch.cbd.int/database/record.shtml?id=41861>).

77. Consensus Document on the Biology of *Triticum Aestivum* (Bread Wheat)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of bread wheat. It contains a general description as a crop plant, taxonomy, centre of origin/diversity, reproductive biology, crosses and weed characteristics.

BIRC Record ID: 41882 (<http://bch.cbd.int/database/record.shtml?id=41882>).

78. Consensus Document on the Biology of *Zea mays* (Maize)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of maize. It contains a general description as a crop plant, taxonomy, centre of origin/diversity, reproductive biology, crosses and weed characteristics.

BIRC Record ID: 41868 (<http://bch.cbd.int/database/record.shtml?id=41868>).

79. Considerations for the Safety Assessment of Animal Feedstuffs derived from Genetically Modified Plants

Scope: This document addresses considerations in the safety assessment of GM foodstuffs, including the fate of DNA and protein in animal feeding, animal feeding studies, and future GM feedstuffs. As well, there is background material on the various organisms and traits constituting GM plants used as animal feeds.

BIRC Record ID: 41892 (<http://bch.cbd.int/database/record.shtml?id=41892>).

80. Draft Guidelines for Assessment of Ecological Hazards of Herbicide and Insect Resistant Crops

Scope: These draft guidelines describe the process of analysis and assessment of ecological hazards associated with the introduction of herbicide resistant crops (HRC) or genetically modified insect resistant crops (IRC). The main aim of the guidelines is to provide a framework, especially

for countries that have not developed their own regulations, on assessing the ecological risks of HRC/IRCs.

BIRC Record ID: 41974 (<http://bch.cbd.int/database/record.shtml?id=41974>).

81. Environmental Risk Assessment of Genetically Modified Organisms. Volume 2: Methodologies for Assessing Bt Cotton in Brazil

Scope: The book focuses on transgenic cotton in Brazil and addresses both environmental and agricultural impacts. It draws out some general risk assessment guidelines and demonstrates the need for case-by-case analysis.

BIRC Record ID: 41477 (<http://bch.cbd.int/database/record.shtml?id=41477>).

82. Environmental Risk Assessment of Genetically Modified Organisms. Volume 1: A Case Study of Bt Maize in Kenya

Scope: This book uses Bt maize in Kenya as a case study to detail generic approaches to the evaluation of environmental impact of GM technologies. It explores both the environmental and agricultural impacts of transgenic plants, draws general risk assessment guidelines and demonstrates the need for a case-by-case analysis.

BIRC Record ID: 41478 (<http://bch.cbd.int/database/record.shtml?id=41478>).

83. Farm Scale Evaluations of GM crops: Monitoring Gene Flow from GM Crops to Non-GM Equivalent Crops in the Vicinity

Scope: This report tests assumptions made in risk assessments concerning gene flow by pollen from the farm-scale evaluations to stipulate an effective separation distance for each of the crop types.

BIRC Record ID: 41981 (<http://bch.cbd.int/database/record.shtml?id=41981>).

84. General Advice on Notifications for Import and Marketing of GM Maize Grain

Scope: This document shows the advice from the Advisory Committee on Releases to the Environment for the import and processing of grain derived from GM maize. The scope of this document excludes cultivation and use as food or feed.

BIRC Record ID: 42036 (<http://bch.cbd.int/database/record.shtml?id=42036>).

85. Guidance Document for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed (6-7 March 2003)

Scope: This guidance material is for the use of risk assessors and notifiers who intend to apply for the commercial release of genetically modified plants and derived cultivars. The environmental assessment of GM plants used to produce medicinal products or other non-food products (e.g. cotton fibres, flowers) is covered in this document but additional guidance may be required, for example for long lived species such as trees.

BIRC Record ID: 42204 (<http://bch.cbd.int/database/record.shtml?id=42204>).

86. Risk Assessment of Genetically Modified Plants and Derived Food and Feed (Guidance Document of the Scientific Panel on Genetically Modified Organisms)

Scope: This document covers risk assessment of GM plants and derived food and feed. Issues related to risk management of GMOs (traceability, labelling, co-existence) are outside the scope of this guidance document.

BIRC Record ID: 41695 (<http://bch.cbd.int/database/record.shtml?id=41695>).

87. Environmental Risk Assessment of Genetically Modified Organisms. Volume 4: Challenges and Opportunities with Bt Cotton in Vietnam

Scope: This book is the first scientific effort to synthesize information relevant to GM crops in Viet Nam, taking Bt cotton as an example. It can be used as a technical manual to enable Vietnamese scientists to evaluate the potential environmental impacts of Bt cotton varieties prior to commercialization, and provides guidance for environmental risk assessment of any transgenic crop.

BIRC Record ID: 44303 (<http://bch.cbd.int/database/record.shtml?id=44303>).

88. Farm Scale Evaluations. Managing GM Crops with Herbicides: Effects on Farmland Wildlife

Scope: This brochure reports on the results from an independent consortium of researchers commissioned by the government to investigate how growing one kind of genetically modified (GM) crop might affect the abundance and diversity of farmland wildlife compared with growing conventional varieties of the same crops.

BIRC Record ID: 44304 (<http://bch.cbd.int/database/record.shtml?id=44304>).

89. Guide for Notifications and Risk Assessments for Releases into the Environment of Genetically Modified Organisms (Module 1: Genetically Modified Crop Plants)

Scope: This module on genetically modified crop plants contains guidance on the notification process and on general, administrative and technical information requirements as well as annexes with summaries of relevant characteristics of crop plants and genes that are frequently used for genetic modification.

BIRC Record ID: 41566 (<http://bch.cbd.int/database/record.shtml?id=41566>).

90. Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants (CAC/GL 45-2003)

Scope: The document addresses safety and nutritional aspects of foods consisting of, or derived from, plants that have been modified by modern biotechnology to exhibit new or altered expression of traits. It does not address environmental risks.

BIRC Record ID: 42122 (<http://bch.cbd.int/database/record.shtml?id=42122>).

91. Guiding Principles for Development and Deployment of Genetically Engineered Organisms

Scope: Leaflet showing the guiding principles for the development and deployment of GMOs, particularly genetically engineered crops.

BIRC Record ID: 41590 (<http://bch.cbd.int/database/record.shtml?id=41590>).

92. Guiding Principles for the Development of Future Harvest Centres's Policies to Address the Possibility of Unintentional Presence of Transgenes in *Ex Situ* Collections

Scope: List of actions that should be taken to prevent the unintentional introduction of transgenes into *ex-situ* germplasm collections including steps for risk assessment, inspection and data collection and knowledge management.

BIRC Record ID: 41547 (<http://bch.cbd.int/database/record.shtml?id=41547>).

93. Introduction to GMO: Technique and Safety

Scope: This document provides a compilation of current and future uses of genetic modification in plants, including agronomic and environmental traits and the genetic use restriction technology (GURTs). It also offers a useful overview of the basic techniques and molecular biology principles in genetic transformation and the potential risks of GMO crops.

BIRC Record ID: 41998 (<http://bch.cbd.int/database/record.shtml?id=41998>).

94. Module II: Herbicide Biochemistry, Herbicide Metabolism and the Residues in Glufosinate-Ammonium (Phosphinothricin) -Tolerant Transgenic Plants

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses glufosinateammonium (phosphinothricin) metabolites and residues in genetically modified, glufosinate-tolerant plants.

BIRC Record ID: 41869 (<http://bch.cbd.int/database/record.shtml?id=41869>).

95. MON 810 Environmental Risk Assessment Case Study

Scope: This document is a case study using genetically engineered maize (*Zea mays*) event MON 810 and its progeny. It has been developed as a teaching module to serve as a tool for providing regulators with practical training in the safety assessment of transgenic plants.

BIRC Record ID: 42184 (<http://bch.cbd.int/database/record.shtml?id=42184>).

96. MON 810 Food Safety Assessment Case Study

Scope: This document is a case study using genetically engineered maize (*Zea mays*) event MON 810 and its progeny. It has been developed as a teaching module to serve as a tool for providing regulators with practical training in the safety assessment of transgenic plants.

BIRC Record ID: 42183 (<http://bch.cbd.int/database/record.shtml?id=42183>).

97. North American Plant Protection Organization (NAPPO) Regional Standards for Phytosanitary Measures (RSPM) #14: Importation and Release into the environment of Transgenic Plants in NAPPO Member Countries

Scope: These guidelines include three modules: Importation Into Contained Facilities, Confined Release into the Environment and Unconfined Release into the Environment which are designed to provide guidance on the criteria for evaluating potential direct or indirect risks to plants and plant health posed by importation and release into the environment of transgenic plants associated with the transgenic plant itself.

BIRC Record ID: 42201 (<http://bch.cbd.int/database/record.shtml?id=42201>).

98. Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation

Scope: This book provides information about transgenic processes, previous experience with the introduction of novel crops, principles of risk assessment and management, the science behind current regulatory schemes, and issues in monitoring transgenic products already on the market. It also discusses public involvement and public confidence in biotechnology regulation and explores the potential of genetic engineering and the prospect for environmental effects.

BIRC Record ID: 44042 (<http://bch.cbd.int/database/record.shtml?id=44042>).

99. Genetically Modified Pest-Protected Plants: Science and Regulation

Scope: This book explores the risks and benefits of crops that are genetically modified for pest resistance, the urgency of establishing an appropriate regulatory framework for these products, and the importance of public understanding of the issues.

BIRC Record ID: 44043 (<http://bch.cbd.int/database/record.shtml?id=44043>).

100. Revised Guidelines for Research in Transgenic Plants. Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts

Scope: These guidelines cover areas of recombinant DNA research on plants including the development of transgenic plants and their growth in soil for molecular and field evaluation. The guidelines also deal with import and shipment of genetically modified plants for research use only.

BIRC Record ID: 41965 (<http://bch.cbd.int/database/record.shtml?id=41965>).

101. Risk Assessment of Genetically Modified Organisms

Scope: This work presents approaches for the risk assessment of GM food and reviews the various types of potential risks to the environment and human health. It also covers some of the problems related with the genetic construction or with the expression of the inserted gene.

BIRC Record ID: 43917 (<http://bch.cbd.int/database/record.shtml?id=43917>).

102. Risk Assessment of GMO Products in the European Union: toxicity assessment, allergenicity assessment and substantial equivalence in practice and proposals for improvement and standardisation

Scope: This study focuses on toxicity and allergenicity assessment, on how the concept of substantial equivalence was being put into practice but it also included some general aspects of risk assessments regarding genetically modified organisms.

BIRC Record ID: 41675 (<http://bch.cbd.int/database/record.shtml?id=41675>).

103. Risk Assessment of Plants Containing Genetic Modification Events Combined by Crossing

Scope: This document considers the risk assessment for the commercialization of crop plants containing genetic modification events combined by crossing. The cases likely to be presented for risk assessment will vary according to the type of crop or plant species on a case-by-case basis.

BIRC Record ID: 41973 (<http://bch.cbd.int/database/record.shtml?id=41973>).

104. Safety Considerations for Biotechnology: Scale-Up of Crop Plants, 1993

Scope: This publication expands OECD's earlier works "Recombinant DNA Safety Considerations" and "Good Developmental Principles (GDP) for Small-Scale Field research", and discusses scientific concepts and principles pertaining to the environmental safety of the scale-up of crop plants developed by biotechnology. It describes how the concept of "familiarity" - with the plant, the introduced trait, the environment and their interactions - may be applied to facilitate safety/risk analysis and to manage possible risks in the context of scaling up modified crop plants towards commercial release.

BIRC Record ID: 42126 (<http://bch.cbd.int/database/record.shtml?id=42126>).

105. The Deliberate Release of Transgenic Plants - Biology, Hazards and Safety

Scope: This report is a collection of articles published by the Agency BATS in scientific journals, on the safety issues pertaining to the deliberate release of transgenic plants.

BIRC Record ID: 42031 (<http://bch.cbd.int/database/record.shtml?id=42031>).

106. The GMO Risk Assessment Process at EFSA

Scope: This document shows the process through which the European Food Safety Authority (EFSA) is required to either provide the initial risk assessment or give scientific advice on each application for approval of a GM plant in the EU territory.

BIRC Record ID: 43698 (<http://bch.cbd.int/database/record.shtml?id=43698>).

107. The Risks and Benefits of Genetically Modified Crops: A Multidisciplinary Perspective

Scope: This document outlines that evolutionary and ecological factors must be considered when assessing genetically modified crops. Accordingly, it proposes that assessment of GM crops should be broadened to include alternative agricultural practices, ecosystem management and agricultural policy.

BIRC Record ID: 41938 (<http://bch.cbd.int/database/record.shtml?id=41938>).

108. Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius

Scope: Includes general principles and key elements of risk assessment and risk management in the context of food safety and human health, covering many aspects of Annex III of the Protocol.

BIRC Record ID: 42127 (<http://bch.cbd.int/database/record.shtml?id=42127>).

109. Points to Consider for Consensus Documents on the Biology of Cultivated Plants

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This "Points to Consider" document is meant as a structured explanatory checklist, regarding both order and contents, of relevant points to consider in preparing or evaluating a consensus document on the biology of a cultivated vascular plant species.

BIRC Record ID: 41862 (<http://bch.cbd.int/database/record.shtml?id=41862>).

110. GTS 40-3-2 Food Safety Assessment Case Study

Scope: This document is a case study using genetically engineered soybean (*Glycine max*) event GTS 40-3-2 and its progeny. It has been developed as a teaching module to serve as a tool for providing regulators with practical training in the safety assessment of transgenic plants.

BIRC Record ID: 42182 (<http://bch.cbd.int/database/record.shtml?id=42182>).

111. Biology Document BIO1992-02: The Biology of *Brassica rapa* L.

Scope: This document provides background information on the biology of *Brassica rapa*, its centres of origin and related species. Emphasis is placed on detailing potential hybridization events between *B. rapa* and its close relatives. Such species-specific information serves as a guide for addressing if the introduction of a GMO of this species would have the potential to become a weed of agriculture, invasive of natural habitats or be otherwise harmful to the environment.

BIRC Record ID: 43905 (<http://bch.cbd.int/database/record.shtml?id=43905>).

112. Directive 94-08 (Dir94-08): Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits

Scope: This Directive provides guidance regarding the submission of an application for the authorization of the unconfined release of a plant with a novel trait (PNT) in Canada. Its scope covers all plants (excluding aquatic plants) containing a novel trait that has been intentionally selected, created, or introduced into a distinct, stable population of the cultivated plant species through a specific genetic change, including agricultural and horticultural crop plants and forest trees.

BIRC Record ID: 42112 (<http://bch.cbd.int/database/record.shtml?id=42112>).

113. Biology Document BIO1994-09: The Biology of *Brassica napus* L. (Canola/Rapeseed)

Scope: This document provides background information on the biology of *Brassica napus*, its centres of origin and related species. Emphasis is placed on detailing potential hybridization events between *B. napus* and its close relatives. Such species-specific information serves as a guide for addressing if the introduction of a GMO of this species would have the potential to become a weed of agriculture, invasive of natural habitats or be otherwise harmful to the environment.

BIRC Record ID: 43904 (<http://bch.cbd.int/database/record.shtml?id=43904>).

114. Biology Document BIO1994-10: The Biology of *Linum usitatissimum* L. (Flax)

Scope: This document provides background information on the biology of *Linum usitatissimum*, its centres of origin, its related species, and the potential for gene introgression from *L. usitatissimum* into relatives, and details of the life forms with which it interacts. Such species-specific information serves as a guide for addressing if the introduction of a GMO of this species would have the potential to become a weed of agriculture, invasive of natural habitats or be otherwise harmful to the environment.

BIRC Record ID: 43909 (<http://bch.cbd.int/database/record.shtml?id=43909>).

115. Biology Document BIO1994-11: The Biology of *Zea mays* (L.) (Maize)

Scope: This document provides background information on the biology of *Zea mays*, its centres of origin, its related species, and the potential for gene introgression from *Z. mays* into relatives, and details of the life forms with which it interacts. Such species-specific information serves as a guide for addressing if the introduction of a GMO of this species would have the potential to become a weed of agriculture, invasive of natural habitats or be otherwise harmful to the environment.

BIRC Record ID: 43915 (<http://bch.cbd.int/database/record.shtml?id=43915>).

116. Biology Document BIO1996-09: The Biology of *Solanum tuberosum* (L.) (Potatoes)

Scope: This document provides background information on the biology of *Solanum tuberosum*, its centres of origin, its related species, and the potential for gene introgression from *S. tuberosum* into relatives, and details of the life forms with which it interacts. Such species-specific information serves as a guide for addressing if the introduction of a GMO of this species would have the potential to become a weed of agriculture, invasive of natural habitats or be otherwise harmful to the environment.

BIRC Record ID: 43912 (<http://bch.cbd.int/database/record.shtml?id=43912>).

117. Biology Document BIO1996-10: The Biology of *Glycine max* (L.) Merr. (Soybean)

Scope: This document provides background information on the biology of *Glycine max*, its centres of origin, its related species, and the potential for gene introgression from *G. max* into relatives, and details of the life forms with which it interacts. Such species-specific information serves as a guide for addressing if the introduction of a GMO of this species would have the potential to become a weed of agriculture, invasive of natural habitats or be otherwise harmful to the environment.

BIRC Record ID: 43906 (<http://bch.cbd.int/database/record.shtml?id=43906>).

118. Biology Document BIO1999-01: The Biology of *Triticum aestivum* L. (Wheat)

Scope: This document provides background information on the biology of *Triticum aestivum*, its centres of origin, its related species, and the potential for gene introgression from *T. aestivum* into relatives, and details of the life forms with which it interacts. Such species-specific information serves as a guide for addressing if the introduction of a GMO of this species would have the potential to become a weed of agriculture, invasive of natural habitats or be otherwise harmful to the environment.

BIRC Record ID: 43913 (<http://bch.cbd.int/database/record.shtml?id=43913>).

119. Biology Document BIO2002-01: The Biology of *Beta vulgaris* L. (Sugar Beet)

Scope: This document provides background information on the biology of *Beta vulgaris*, its centres of origin, its related species, and the potential for gene introgression from *B. vulgaris* into relatives, and details of the life forms with which it interacts. Such species-specific information serves as a guide for addressing if the introduction of a GMO of this species would have the potential to become a weed of agriculture, invasive of natural habitats or be otherwise harmful to the environment.

BIRC Record ID: 43898 (<http://bch.cbd.int/database/record.shtml?id=43898>).

120. Biology Document BIO2003-12: The Biology of *Lens culinaris* Medikus (Lentil)

Scope: This document provides background information on the biology of *Lens culinaris*, its centres of origin, its related species, and the potential for gene introgression from *L. culinaris* into relatives, and details of the life forms with which it interacts. Such species-specific information serves as a guide for addressing if the introduction of a GMO of this species would have the

potential to become a weed of agriculture, invasive of natural habitats or be otherwise harmful to the environment.

BIRC Record ID: 43908 (<http://bch.cbd.int/database/record.shtml?id=43908>).

121. Biology Document BIO2005-01: The Biology of *Helianthus annuus* L. (sunflower)

Scope: This document provides background information on the biology of *Helianthus annuus*, its centres of origin, its related species, and the potential for gene introgression from *H. annuus* into relatives, and details of the life forms with which it interacts. Such species-specific information serves as a guide for addressing if the introduction of a GMO of this species would have the potential to become a weed of agriculture, invasive of natural habitats or be otherwise harmful to the environment.

BIRC Record ID: 43907 (<http://bch.cbd.int/database/record.shtml?id=43907>).

122. Biology Document Bio2005-02: The Biology of *Medicago sativa* L. (Alfalfa)

Scope: This document provides background information on the biology of *Medicago sativa*, its centres of origin, its related species, and the potential for gene introgression from *M. sativa* into relatives, and details of the life forms with which it interacts. Such species-specific information serves as a guide for addressing if the introduction of a GMO of this species would have the potential to become a weed of agriculture, invasive of natural habitats or be otherwise harmful to the environment.

BIRC Record ID: 43911 (<http://bch.cbd.int/database/record.shtml?id=43911>).

123. Biology Document BIO2006-07: The Biology of *Triticum turgidum* ssp. *durum* (Durum Wheat)

Scope: This document provides background information on the biology of *Triticum turgidum*, its centres of origin, its related species, and the potential for gene introgression from *T. turgidum* into relatives, and details of the life forms with which it interacts. Such species-specific information serves as a guide for addressing if the introduction of a GMO of this species would have the potential to become a weed of agriculture, invasive of natural habitats or be otherwise harmful to the environment.

BIRC Record ID: 43914 (<http://bch.cbd.int/database/record.shtml?id=43914>).

124. Biology Document BIO2007-01: The Biology of *Brassica juncea* (Canola/Mustard)

Scope: This document provides background information on the biology of *Brassica juncea*, its centres of origin, its related species, and the potential for gene introgression from *B. juncea* into relatives, and details of the life forms with which it interacts. Such species-specific information serves as a guide for addressing if the introduction of a GMO of this species would have the potential to become a weed of agriculture, invasive of natural habitats or be otherwise harmful to the environment.

BIRC Record ID: 43903 (<http://bch.cbd.int/database/record.shtml?id=43903>).

Trees

125. Consensus Document on the Biology of European White Birch (*Betula pendula* Roth)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment.

BIRC Record ID: 41867 (<http://bch.cbd.int/database/record.shtml?id=41867>).

126. Consensus Document on the Biology of *Picea abies* (L) Karst (Noway Spruce)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of Norway spruce. It contains a general description of its taxonomy, centre of origin/diversity, reproductive biology and crosses.

BIRC Record ID: 41879 (<http://bch.cbd.int/database/record.shtml?id=41879>).

127. Consensus Document on the Biology of *Picea glauca* (Moench) Voss (White Spruce)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of white spruce. It contains a general description of its taxonomy, centre of origin/diversity, reproductive biology and crosses.

BIRC Record ID: 41878 (<http://bch.cbd.int/database/record.shtml?id=41878>).

128. Consensus Document on the Biology of *Picea Sitchensis* (Bong.) Carr. (Sitka Spruce)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of Sitka spruce. It contains a general description of its taxonomy, centre of origin/diversity, reproductive biology and crosses.

BIRC Record ID: 41872 (<http://bch.cbd.int/database/record.shtml?id=41872>).

129. Consensus Document on the Biology of *Pinus Strobus* L. (Eastern White Pine)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of the Eastern White pine. It contains a general description of its taxonomy, centre of origin/diversity, reproductive biology and crosses.

BIRC Record ID: 41871 (<http://bch.cbd.int/database/record.shtml?id=41871>).

130. Consensus Document on the Biology of *Populus* L. (Poplars)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of poplar trees. It contains a general description of its taxonomy, centre of origin/diversity, reproductive biology and crosses.

BIRC Record ID: 41875 (<http://bch.cbd.int/database/record.shtml?id=41875>).

131. Consensus Document on the Biology of *Prunus* Sp. (Stone Fruits)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of stone fruits. It contains a general description of its taxonomy, centre of origin/diversity, reproductive biology and crosses.

BIRC Record ID: 41870 (<http://bch.cbd.int/database/record.shtml?id=41870>).

132. Consensus Document on the Biology of Western White Pine (*Pinus Monticola* Dougl. ex D. Don)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of white pine. It contains a general description of its taxonomy, centre of origin/diversity, reproductive biology and crosses.

BIRC Record ID: 41859 (<http://bch.cbd.int/database/record.shtml?id=41859>).

Animals

133. A Framework for the Animal Health Risk Analysis of Biotechnology-Derived Animals a Canadian Perspective

Scope: This paper describes the framework used by the Canadian Food Inspection Agency to assess the risks to animal health associated with biotechnology-derived animals and their products. In Canada the risks to animal health associated with biotechnology-derived animals are one consideration among several other regulatory concerns (e.g. human health, the environment). The risk analysis process begins with hazard identification, includes a risk assessment for each hazard, and concludes with risk management and risk communication.

BIRC Record ID: 44036 (<http://bch.cbd.int/database/record.shtml?id=44036>).

134. Animal Biotechnology: Science-Based Concerns

Scope: This report identifies potential risks associated with advances in animal biotechnology, including the possibility that genetically engineered fish, shellfish or insects might escape and introduce engineered genes into wild populations.

BIRC Record ID: 44041 (<http://bch.cbd.int/database/record.shtml?id=44041>).

135. Animal Health Risk Analysis Framework for Biotechnology-Derived Animals

Scope: This framework is intended for the assessment of biotechnology-derived animal from the animal health perspective. It is anticipated that the regulated animals will principally include terrestrial mammalian and avian livestock species intended for release outside of research and development facilities.

BIRC Record ID: 43887 (<http://bch.cbd.int/database/record.shtml?id=43887>).

136. Current Scientific Understanding of the Environmental Biosafety of Transgenic Fish and Shellfish

Scope: This paper shows how assessing the environmental biosafety of an aquatic GEO requires integrating methods and knowledge from multiple fields, such as genetics, physiology, evolutionary biology, population biology and ecology, community ecology, ecosystem ecology, and system safety science.

BIRC Record ID: 44035 (<http://bch.cbd.int/database/record.shtml?id=44035>).

137. Environmental Impacts of Aquatic Biotechnology

Scope: This publication presents scientific papers and includes two expert group reports on modern aquatic biotechnology and its potential environmental impacts. This publication is of interest for persons involved in policy-making aimed at the sustainable management of aquatic resources and preserving natural biological diversity.

BIRC Record ID: 44007 (<http://bch.cbd.int/database/record.shtml?id=44007>).

138. Environmental Risk Assessment of Genetically Modified Organisms. Volume 3: Methodologies for Transgenic Fish

Scope: With a focus on developing countries, this book is the third in the series and provides detailed information on environmental biosafety policy and regulation and presents methodologies for assessing ecological risks associated with transgenic fish.

BIRC Record ID: 44302 (<http://bch.cbd.int/database/record.shtml?id=44302>).

139. FAO/WHO Expert Consultation on the Safety Assessment of Foods Derived from GM Animals, including Fish (FAO Food and Nutrition Paper 79)

Scope: Describes general principles and considerations relevant to risk/safety assessment of GM animals and derived foods, including fish.

BIRC Record ID: 42120 (<http://bch.cbd.int/database/record.shtml?id=42120>).

140. Handbook on Import Risk Analysis for Animals and Animal Products. Volume 1: Introduction and Qualitative Risk Analysis; Volume 2: Quantitative Risk Assessment

Scope: This handbook provides practical guidance to Veterinary Services confronted with the need to analyse the risks posed by animal imports to ensure that stakeholders, risk analysts and decision-makers can be confident that the disease risks posed have been identified and can be managed effectively. It is also a good resource for capacity building in this .

BIRC Record ID: 44010 (<http://bch.cbd.int/database/record.shtml?id=44010>).

141. Notification Guidelines for the Environmental Assessment of Biotechnology - Derived Livestock Animals

Scope: This document outlines the general information requirements for the notification of biotechnology-derived animals including those that have been genetically engineered.

BIRC Record ID: 43886 (<http://bch.cbd.int/database/record.shtml?id=43886>).

142. Status and Risk Assessment of the Use of Transgenic Arthropods in Plant Protection

Scope: This publication is the result of proceedings of a technical meeting organized by the Joint FAO/IAEA Programme of Nuclear Techniques in Food and Agriculture and the Secretariat of the International Plant Protection Convention. It compiles the results of working groups on (a) the current status of transgenesis in pest arthropods; (b) identification of risks associated with a transgenic release and (c) development of risk assessment protocols.

BIRC Record ID: 41909 (<http://bch.cbd.int/database/record.shtml?id=41909>).

143. The Cartagena Protocol on Biosafety: interaction between the Convention on Biological Diversity and the World Organisation for Animal Health

Scope: This paper reviews the key provisions of the Cartagena Protocol on Biosafety and attempts to highlight areas of the agreement which are also of interest to various international bodies, particularly the World Organization for Animal Health (OIE).

BIRC Record ID: 41693 (<http://bch.cbd.int/database/record.shtml?id=41693>).

144. The Safety Assessment of Foods from Transgenic and Cloned Animals Using the Comparative Approach

Scope: This article outlines the basic principles behind the comparative approach, discusses some of the potential food safety concerns associated with transgenic and cloned animals and describes important elements of the comparative approach and how these might be applied to assessing the safety of food from animals.

BIRC Record ID: 44037 (<http://bch.cbd.int/database/record.shtml?id=44037>).

Microorganisms, fungi and viruses

145. Assessment of Genetically Modified Microorganisms and their Derived Products Intended for Food and Feed Use (Guidance Document of the Scientific Panel on Genetically Modified Organisms)

Scope: This document provides guidance for the scientific risk assessment of genetically modified microorganisms (GMMs) and their derived products intended for food and feed use. In particular, it provides detailed guidance to assist in the preparation and presentation of applications to market GMMs and their products for food and/or feed use.

BIRC Record ID: 41972 (<http://bch.cbd.int/database/record.shtml?id=41972>).

146. Consensus Document on Information Used in the Assessment of Environmental Applications Involving Acidithiobacillus

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses information of environmental applications involving the genus *Acidithiobacillus*.

BIRC Record ID: 41860 (<http://bch.cbd.int/database/record.shtml?id=41860>).

147. Consensus Document on Information Used in the Assessment of Environmental Applications Involving Baculoviruses

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document contains general information on baculoviruses such as organism characteristics, behaviour in the environment, their history of use and interactions as well as environmental safety considerations.

BIRC Record ID: 41873 (<http://bch.cbd.int/database/record.shtml?id=41873>).

148. Consensus Document on information Used in the Assessment of Environmental Applications Involving Pseudomonas

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document contains general information on *Pseudomonas* such as organism characteristics, behaviour in the environment, their history of use and interactions as well as environmental safety considerations.

BIRC Record ID: 41885 (<http://bch.cbd.int/database/record.shtml?id=41885>).

149. Consensus Document on the Biology of *Pleurotus* spp. (Oyster Mushroom)

Scope: The Consensus Documents are a “snapshot” of current information that may be relevant in a regulatory risk assessment. This document addresses the biology of oyster mushroom.

BIRC Record ID: 41863 (<http://bch.cbd.int/database/record.shtml?id=41863>).

150. Guidance Document on Methods for Detection of Micro-organisms Introduced into the Environment: Bacteria

Scope: This guidance document addresses the use of methods for the detection of micro-organisms (focusing on bacteria) introduced into the environment. It is primarily intended for use by risk assessors, but it may also be useful for applicants and other stakeholders in the regulatory process.

BIRC Record ID: 41899 (<http://bch.cbd.int/database/record.shtml?id=41899>).

151. Guidance Document on the Use of Taxonomy in Risk Assessment of Micro-organisms: Bacteria

Scope: This guidance document addresses the use of microbial taxonomy in assigning or confirming the identity of a subject micro-organism. It is primarily intended for use by risk assessors, but it may also be useful for applicants and other stakeholders in the regulatory process.

BIRC Record ID: 41900 (<http://bch.cbd.int/database/record.shtml?id=41900>).

152. Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms

Scope: The Guideline describes approaches recommended for making safety assessments of foods produced using recombinant-DNA microorganisms, using comparison to a conventional counterpart. The safety assessments described here focus on the safety of the recombinant-DNA microorganisms used in food production, and, where appropriate, on metabolites produced by the action of recombinant-DNA microorganisms on food. The guideline identifies the data and information that are generally applicable to making such assessments.

BIRC Record ID: 42040 (<http://bch.cbd.int/database/record.shtml?id=42040>).

153. International Classification Schemes for Micro-Organisms Based on their Biological Risks

Scope: This document shows a list of international classification systems for pathogenic microorganisms including bacteria, viruses, fungi, protozoa and multi-cellular parasites.

BIRC Record ID: 44039 (<http://bch.cbd.int/database/record.shtml?id=44039>).

154. Safety Considerations for Biotechnology: Scale & Up of Microorganisms as Biofertilizers

Scope: This publication addresses the question of the environmental safety of the scale-up of micro-organisms developed by biotechnology, specifically for use as biofertilizers. It describes how the concept of "familiarity", with micro-organisms as biofertilizers, the introduced trait, the environment, and with their interactions, will help facilitate risk/safety analysis and manage possible risks in the context of scaling up modified micro-organisms towards commercial release.

BIRC Record ID: 41908 (<http://bch.cbd.int/database/record.shtml?id=41908>).

155. The Laboratory Biosafety Guidelines

Scope: The Laboratory Biosafety Guidelines were developed to guide government, industry, university, hospital, and other public health and microbiological laboratories in their development of biosafety policies and programs. The Guidelines also serve as a technical document providing information and recommendations on the design, construction and commissioning of containment facilities.

BIRC Record ID: 42045 (<http://bch.cbd.int/database/record.shtml?id=42045>).

Index of terms¹

Animal	10, 11, 15, 18, 27, 51, 52, 79, 133-135, 139-141, 143, 144
Baculovirus	See Virus
Bioconfinement	See Containment
Confinement	See Containment
Contained (use/facilities)	See Containment
Containment	1, 10, 11, 14-16, 46, 47, 49, 50, 97, 155
Crop	19, 20, 29, 54, 65, 70-78, 80, 83, 87-89, 91, 93, 98, 99, 103, 104, 107, 112
Detection	23, 44, 150
Field (introduction/evaluation/testing/trial)	11, 12, 17, 37, 40, 55, 100, 104
Fish	10, 51, 134, 136, 138, 139
Food	5, 23, 30, 31, 43, 57-64, 68, 79, 84-86, 90, 96, 101, 106, 108, 110, 133, 139, 142, 144, 145, 152
Fungi	10, 149, 153
Greenhouse	1, 16
Health	13, 29, 31, 34, 41, 46, 47, 97, 101, 108, 133, 135, 143, 155
Inspection	14-17, 26, 33, 38, 92, 133
Labelling	30, 86
Laboratory	13, 14, 155
Market	See Marketing
Marketing	6, 52, 84, 98, 145
Microbe	See Microorganism
Microorganism	1, 10, 11, 12, 18, 27, 40, 44, 50, 145, 152-154
Monitoring	7, 22, 26, 33, 35, 37, 52, 83, 98
Mushroom	See Fungi
Notification	19, 20, 46, 52, 84, 89, 141
PCR	See Polymerase chain reaction
Phytosanitary	3, 27, 29, 36, 97
Polymerase chain reaction	23
Precautionary approach	8, 30
Precautionary principle	See Precautionary approach
Release	6, 7, 12, 19, 20, 31, 32, 41, 51, 52, 84, 85, 89, 97, 104, 105, 112, 135, 142, 154
Shellfish	10, 134, 136
Standard	2, 21, 24, 27, 29, 30, 36, 97, 102
Standardization	See Standard
Tree	10, 85, 112, 130
Virus	13, 47, 65, 147, 153

¹ The numbers shown in the index of terms refer to the numbered list above.