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AD HOC TECHNICAL EXPERT GROUP ON RISK ASSESSMENT AND RISK MANAGEMENT UNDER THE CARTAGENA PROTOCOL ON BIOSAFETY
First meeting
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# LIST OF GUIDANCE MATERIALS AVAILABLE IN THE BIOSAFETY INFORMATION RESOURCE CENTRE OF THE BIOSAFETY CLEARING HOUSE

*Note by the Executive Secretary*

## INTRODUCTION

1. At its fourth meeting, the Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP), in its decision BS-IV/11, established an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management and an Open-ended Online Expert Forum on Risk Assessment and Risk Management through the Biosafety Clearing-House (BCH). 1/

2. In the terms of reference for the AHTEG 2/, the Parties specified that the deliberations of the AHTEG shall be based, *inter alia*, on guidance materials available in the Biosafety Information Resource Centre (BIRC) of the BCH.

3. Annex I to this document contains a compilation of guidance materials on risk assessment and risk management available through the BIRC. In addition to the documents that had already been published in the BIRC, this list includes the documents that were listed in the submissions by Parties, other Governments and organizations on views and/or information relevant to the work of the AHTEG 3/, as well as materials recommended by participants of the Open-ended Online Expert Forum.

4. Furthermore, annex II to this document contains references to original research articles, not included in the BIRC, that were recommended by Parties, other Governments and organizations or by participants of the Open-ended Online Expert Forum as relevant to the work of the AHTEG.

1/ http://bch.cbd.int.
2/ Decision BS-IV/11, annex.
3/ UNEP/CBD/BS/AHTEG-RA&RM/1/INF/1.

*Annex I*

# GUIDANCE MATERIALS AVAILABLE IN THE BIOSAFETY INFORMATION RESOURCE CENTRE OF THE BIOSAFETY CLEARING HOUSE RELEVANT TO THE WORK OF THE AHTEG ON RISK ASSESSMENT AND RISK MANAGEMENT

## CONTENTS

## A. GENERIC GUIDANCE 4/

### General Issues

**1. Approaches of Risk: an Introduction**

*Source / Year:* Réseau Interdisciplinaire Biosécurité (RIBios) & Institut Universitaire d'Etudes du Développement (IUED) / 2004.

*Description:* 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).

**2. UNEP International Technical Guidelines for Safety in Biotechnology**

*Source / Year:* United Nations Environment Programme (UNEP) / 1995

*Description:* These Guidelines are intended as a contribution or the implementation of Agenda 21 commitments and aim to assist Governments, intergovernmental, private sector and other organization in the establishment and maintenance of national capacities to provide for safety in biotechnology, to assist in developing expert human resources and for international exchange of information. They were 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).

**3. Manual for Assessing Ecological and Human Health Effects of Genetically Engineered Organisms. Part One: Introductory Materials and Supporting Text for Flowcharts & Part Two: Flowcharts and Worksheets**

*Source / Year:* The Edmonds Institute / 1998.

*Description:* This biosafety handbook was created by a group of scientists from a broad range of disciplines to help consumers and policy-makers evaluate likely impacts of genetically engineered organisms in a variety of settings and applications. It contains 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:* 42199 (http://bch.cbd.int/database/record.shtml?id=42199).

**4. Recombinant DNA Safety Considerations – Safety considerations for industrial, agricultural and environmental applications of organisms derived by recombinant DNA techniques**

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1986.

*Description:* The focus of this report is on the industrial, agricultural and environmental applications of recombinant DNA engineered organisms. It includes a series of recommendations for the safe use of LMOs as well as a list of definitions of terms used in modern biotechnology.

*BIRC Record ID:* 48487 (http://bch.cbd.int/database/record.shtml?id=48487).

4/ The "Generic Guidance" section contains guidance materials that refer to different types of living modified organisms (LMOs). This section may be of particular relevance for the development of the roadmap for risk assessment and risk management. Nevertheless, the development of the roadmap being a cross-cutting issue, relevant guidance material may also be found in the other sections of this compilation.

**5. Safety Considerations for Biotechnology**

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1992.

*Description:* 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).

**6. Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles**

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1993.

*Description:* This report is intended for the use of those involved in carrying out safety evaluations of new foods or food components derived by means of modern biotechnology, including microorganisms, plants and animals. It elaborates scientific principles to be considered in making such evaluations, based on a comparison with traditional foods that have a safe history of use.

*BIRC Record ID:* 48488 (http://bch.cbd.int/database/record.shtml?id=48488).

**7. LMOs and the Environment Proceedings of an International Conference**

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2001.

*Description:* These proceedings reflect the breadth of topics presented in the Conference "LMOs and the Environment" and include a few additional contributed papers that subsequently were developed by participants. These proceedings contain descriptions of the risk assessment process made for specific crops as well as presentations for how the process should be undertaken for any engineered crop.

*BIRC Record ID:* 41986 (http://bch.cbd.int/database/record.shtml?id=41986).

**8. Food Safety Risk Analysis – A Guide for National Food Safety Authorities**

*Source / Year:* Food and Agriculture Organization of the United Nations (FAO) and World Health Organization / 2006.

*Description:* This guide was developed to improve food safety regulators' understanding and use of risk analysis in national food safety frameworks. The primary audience is food safety officials at the national government level. This guide provides essential background information, guidance and practical examples of ways to apply food safety risk analysis. It presents internationally agreed principles, a generic framework for application of the different components of risk analysis, and wide-ranging examples rather than prescriptive instructions on how to implement risk analysis.

*BIRC Record ID:* 48517 (http://bch.cbd.int/database/record.shtml?id=48517).

**9. Strategies for Assessing the Safety of Foods Produced by Biotechnology**

*Source / Year:* Food and Agriculture Organization of the United Nations (FAO) & World Health Organization (WHO) / 1991.

*Description:* This is the report of a joint FAO/WHO consultation on strategies for assessing the safety of foods produced by biotechnology, including bacteria, fungi, plants and animals. 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).

**10. Guidelines for Pest Risk Analysis, International Standard for Phytosanitary Measures (ISPM No. 2)**

*Source / Year:* Secretariat of the International Plant Protection Convention (IPPC), Food and Agriculture Organization of the United Nations (FAO) / 1996.

*Description:* 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).

**11. International Standards for Phytosanitary Measures: Pest Risk Analysis for Quarantine Pests, Including Analysis of Environmental Risks and Living Modified Organisms (ISPM No. 11)**

*Source / Year:* Secretariat of the International Plant Protection Convention (IPPC), Food and Agriculture Organization of the United Nations (FAO) / 2004.

*Description:* These guidelines include a 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:* 42137 (http://bch.cbd.int/database/record.shtml?id=42137).

**12. Principles for the Risk Analysis of Foods Derived from Modern Biotechnology**

*Source / Year:* Codex Alimentarius Commission, Food and Agriculture Organization (FAO) / 2003.

*Description:* The purpose of these principles is to provide a framework for undertaking risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology. This document does not address environmental, ethical, moral and socio-economic aspects of the research, development, production and marketing of these foods.

*BIRC Record ID:* 42048 (http://bch.cbd.int/database/record.shtml?id=42048).

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

*Source / Year:* World Trade Organization (WTO) / 1995.

*Description:* 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).

**14. Enabling the Safe Use of Biotechnology – Principles and Practice**

*Source / Year:* The World Bank / 1996.

*Description:* This report describes and suggests an enabling environment required by a country to acquire new tools of biotechnology and to assess their potential usefulness. It is designed to guide policymakers through the issues and scientific principles that underlie the assessment of risk associated with the use of the products and environmentally sustainable development processes of modern biotechnology.

*BIRC Record ID:* 41670 (http://bch.cbd.int/database/record.shtml?id=41670).

**15. Release of Genetically Modified Organisms in the Environment: is it a Health Hazard?**

*Source / Year:* World Health Organization (WHO) and European Centre for Environment and Health / 2000.

*Description:* This report of a seminar on "Release of Genetically Modified Organisms in the Environment: is it a Health Hazard?" (World Health Organization, Rome, 7-9 September 2000) discusses the health consequences of the release of GMOS in the environment, providing for the scientific community at large a basis for future thinking and planning in this area.

*BIRC Record ID:* 41940 (http://bch.cbd.int/database/record.shtml?id=41940).

**16. Voluntary Code of Conduct for the Release of Organisms into the Environment**

*Source / Year:* United Nations Industrial Development Organization (UNIDO) / 1991.

*Description:* 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).

**17. International Standards for Risk Assessment and Risk Management of Biotechnology**

*Source / Year:* International Centre for Trade and Sustainable Development (ICTSD) / 2001.

*Description:* 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).

**18. Strategic Environmental Assessment: Assessing the Environmental Impact of Biotechnology**

*Source / Year:* International Food Policy Research Institute (IFPRI) / 2005.

*Description:* 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).

**19. Genetically Modified Organisms and Biosafety - A Background Paper for Decision-makers and others to Assist in Consideration of GMO Issues**

*Source / Year:* World Conservation Union, IUCN Environmental Law Centre / 2004.

*Description:* This document aims to enable IUCN and its members to determine how they should advance research, analysis and dissemination of knowledge regarding the potential ecological impact of the release of genetically modified organisms into the environment, focusing especially on biodiversity, socio-economic impact and food security.

*BIRC Record ID:* 41537 (http://bch.cbd.int/database/record.shtml?id=41537).

**20. Domestic Import Regulations for Genetically Modified Organisms and their Compatibility with WTO Rule: Some Key Issues**

*Source / Year:* International Institute for Sustainable Development (IISD) / 2003.

*Description:* The first part of this paper outlines regulations affecting the import of GMOs and GM products in selected countries, including import restrictions, risk assessment provisions and labelling requirements. The second part looks at possible conflicts between national import regulations and WTO rules, in particular regarding the current and proposed EU regulations.

*BIRC Record ID:* 41540 (http://bch.cbd.int/database/record.shtml?id=41540).

**21. Biosafety & Risk Assessment in Agricultural Biotechnology: A Workbook for Technical Training**

*Source / Year:* Agricultural Biotechnology Support Project (ABSP), Michigan State University / 2003.

*Description:* Designed to complement technical biosafety-assessment training courses in developing countries, this workbook provides a background for the practical application of biosafety review procedures using a case study approach. The intended audience includes members of national biosafety committees, biotechnology regulatory officials, and scientists working in the public and private sectors.

*BIRC Record ID:* 41800 (http://bch.cbd.int/database/record.shtml?id=41800).

**22. Models of Risk Analysis in Relation to GMO ERA Project Methodologies**

*Source / Year:* GMO ERA Project / 2003.

*Description:* The purposes of this teaching material are to:(i) orient participants to curriculum; (ii) introduce key terms that will be used across all sections; (iii) provide a risk assessment model to unify methodologies.

*BIRC Record ID:* 41651 (http://bch.cbd.int/database/record.shtml?id=).

**23. Non-target Environmental Risk Assessment Methodologies for GMOs**

*Source / Year:* GMA ERA Project.

*Description:* This paper contains guidelines on assessing how to determine the potential adverse effects of a GMO on Biodiversity.

*BIRC Record ID:* 41659 (http://bch.cbd.int/database/record.shtml?id=41659).

**24. Problem Formulation and Options Assessment Handbook**

*Source / Year:* GMO Era Project / 2007.

*Description:* This handbook provides an overview of problem formulation and options assessment (PFOA), including the findings of several workshops, considerations on how to design and conduct PFOA and recommendations.

*BIRC Record ID:* 48404 (http://bch.cbd.int/database/record.shtml?id=48404).

**25. Biosafety First - Holistic Approaches to Risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms**

*Source / Year:* Third World Network (TWN) / 2007.

*Description:* Chapters of a publication focusing on issues related to substantial equivalence, vertical and horizontal gene flow, ecosystem services and health.

*BIRC Record ID:* 48125 (http://bch.cbd.int/database/record.shtml?id=48125).

**26. Conceptualizing Risk Assessment Methodology for Genetically Modified Organisms**

*Source / Year:* Environment Biosafety Research / 2005.

*Description:* This article focuses on the concept of risk-assessment methodology for genetically modified organisms. It attempts to dissolve some of the misunderstanding by illustrating some of the core elements that are common to many frameworks for risk-assessment methodology and by pointing out two common sources of confusion.

*BIRC Record ID:* 41660 (http://bch.cbd.int/database/record.shtml?id=41660).

**27. Genetically Engineered Organisms and the Environment: Current Status and Recommendations**

*Source / Year:* Ecological Society of America / 2005.

*Description:* 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).

**28. Environmental Risk and the Precautionary Principle: A Bayesian View Applied to Genetically Modified Organisms**

*Source / Year:* International Consortium on Agricultural Biotechnology Research (ICABR) / 2003.

*Description:* This paper discusses the consequences for the ecosystem due to field releases of genetically modified crops. Further, it discusses policy responses to risk and the Bayesian analysis as a means for improving the informational basis for decision making under uncertainty about potentially irreversible effects on the ecosystem.

*BIRC Record ID:* 41545 (http://bch.cbd.int/database/record.shtml?id=41545).

**29. Risk Assessment in Action: Reviewing the Practice of Toxicological Risk Assessment of GMO Products in the European Union**

*Source / Year:* International Consortium on Agricultural Biotechnology Research (ICABR) / 2003.

*Description:* This paper sheds light upon the practice of toxicological risk assessment of GMO products in the European Union. The investigation focuses on selected novel food risk assessment dossiers (toxicity and allergenicity assessment and substantial equivalence). Further, it investigates and compares the general approach, the line of reasoning, exposure assessment, actual testing performed and data presented.

*BIRC Record ID:* 41562 (http://bch.cbd.int/database/record.shtml?id=41562).

**30. Annotated Bibliographies for Environmental/Ecological Impacts of Transgenic Organisms**

*Source / Year:* Information Systems for Biotechnology (ISB).

*Description:* This website provides a compilation of annotated bibliography with abstracts on environmental/ecological impacts of transgenic animals, microorganisms and plants.

*BIRC Record ID:* 41594 (http://bch.cbd.int/database/record.shtml?id=41594).

**31. AROMA - Análise de Riesgo para la Liberación de Organismos Genéticamente Modificados en el Medio Ambiente**

*Source / Year:* Instituto Nacional de Ecología, Mexico.

*Description:* This website provides a risk assessment online tool in the context of Biosafety.

*BIRC Record ID:* 41615 (http://bch.cbd.int/database/record.shtml?id=41615).

**National and Regional Guidelines**

**32. Risk Analysis Framework**

*Source / Year:* Office of the Gene Technology Regulator (OGTR), Australia / 2005.

*Description:* 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).

**33. Biosafety Guidelines for Bangladesh**

*Source / Year:* Ministry of Science and Technology, Bangladesh / 1999.

*Description:* 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).

**34. International Comparisons – Regulation of GMO Releases (AUS/NZ)**

*Source:* Office of the Gene Technology Regulator (OGTR), Australia, and Environmental Risk Management Authority (ERMA), New Zealand

*Description:* This document contains a table that refers to the functions and processes of the primary regulatory agency(ies) in Australia and New Zealand responsible for approving the release of GMOs (rather than GM products) into the environment in each jurisdiction. The details provided in this table do not represent the official position of any regulatory listed but instead should be used as a portal to official sources of documents and information.

*BIRC Record ID:* 48521 (http://bch.cbd.int/database/record.shtml?id=48521).

**35. Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits**

*Source / Year:* Canadian Food Inspection Agency (CFIA), Canada / 1994.

*Description:* 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).

**36. Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada**

*Source / Year:* Health Canada; Canadian Food Inspection Agency (CFIA) and Environment Canada, Canada / 2001.

*Description:* This report is a response to a request to the Royal Society of Canada from Health Canada, the Canadian Food Inspection Agency and Environment Canada that an expert panel be assembled to provide advice on a series of questions related to the safety of new food products being developed through the use of new genetic engineering technologies.

*BIRC Record ID:* 41802 (http://bch.cbd.int/database/record.shtml?id=41802).

**37. Organismos Vivos Modificados – Guía para la evaluación y Gestión de Riesgos (Living Modified Organisms – Guide for risk assessment and management)**

*Source / Year:* Centro Nacional de Seguridad Biológica, Cuba / 2006.

*Description:* These guidelines refer to the necessary steps for conducting risk assessments for confined use and release into the environment of plants and animals obtained through modern biotechnology in Cuba. This document is in Spanish.

*BIRC Record ID:* 48165 (http://bch.cbd.int/database/record.shtml?id=48165).

**38. Biosafety Regulations of Agricultural Genetically Modified Organisms, 2002**

*Source / Year:* State Council, China (People's Republic of) / 2001.

*Description:* 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).

**39. Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms**

*Source / Year:* The European Parliament and the Council of the European Union, European Community / 2001.

*Description:* The European Community Directive 2001/18/EC follows the precautionary principle and has as objective to approximate the laws, regulations and administrative provisions of its Member States and to protect human health and the environment when (i) carrying out the deliberate release into the environment of genetically modified organisms for any other purposes than placing on the market within the Community, and (ii) placing on the market genetically modified organisms as or in products within the Community. Annex II sets out the "Principles for the Environmental Risk Assessment".

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

**40. Communication from the Commission on the Precautionary Principle**

*Source / Year:* Commission of the European Communities / 2000.

*Description:* This Communication analyses the factors that trigger use of the precautionary principle and the associated measures. Further, it proposes guidelines for applying the principle.

*BIRC Record ID:* 41655 (http://bch.cbd.int/database/record.shtml?id=41655).

**41. The GMO Risk Assessment Process at EFSA**

*Source:* European Food Safety Authority (EFSA), European Community.

*Description:* 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).

**42. The Indian Recombinant DNA Safety Guidelines and Regulations**

*Source / Year:* Ministry of Environment and Forests, India / 1998.

*Description:* 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).

**43. The Guidance of Implementation of Assessment of Adverse Effect on Biological Diversity of Type 1 Use of Living Modified Organisms**

*Source:* Ministry of the Environment, Japan.

*Description:* This guidance sets the necessary steps to ensure that the assessment of potential adverse effects on biodiversity is done in accordance with the Japanese Law concerning the Conservation and Sustainable Use of Biological Diversity. It is designed to enable an applicant who wishes to obtain approval for an LMO to perform a scientifically sound risk assessment and to properly prepare the Risk Assessment Report.

*BIRC Record ID:* 48486 (http://bch.cbd.int/database/record.shtml?id=48486).

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

*Source / Year:* National Biosafety Office, Kenya / 2004.

*Description:* 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).

**45. Guidelines for Inspection and Monitoring GMOs in Kenya**

*Source / Year:* National Biosafety Office, Kenya / 2004.

*Description:* 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).

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

*Source / Year:* National Biosafety Office, Kenya / 2004.

*Description:* Checklist for inspection of field trials of GMOs.

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

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

*Source / Year:* Environmental Risk Management Authority (ERMA), New Zealand / 1999.

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

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

**48. Preparing Information on Risks, Costs and Benefits for Applications under the Hazardous Substances and New Organisms Act 1996**

*Source / Year:* Environmental Risk Management Authority (ERMA), New Zealand / 2000.

*Description:* This document describes the components of risk and options for risk characterization (e.g., qualitative versus quantitative, etc.). It also discusses how to take into consideration risks in a decision-making context.

*BIRC Record ID:* 42092 (http://bch.cbd.int/database/record.shtml?id=42092).

**49. Approach to Risk: Position Paper on the Approach to Risk, Methodologies for Dealing with this and the Technical and Community Information Required for Implementation**

*Source / Year:* Environmental Risk Management Authority (ERMA), New Zealand / 2002.

*Description:* This paper provides a background to the concepts of attitude to risk and uncertainty, a summary of current thinking in developing approaches to risk, and an overview of existing data sources in New Zealand. It is intended to provide a basis for the review of the approach to risk within the decision-making framework, and a structure for obtaining the required further information to support its implementation.

*BIRC Record ID:* 41652 (http://bch.cbd.int/database/record.shtml?id=41652).

**50. Nigeria Biosafety Guidelines**

*Source / Year:* Federal Ministry of Environment, Nigeria / 2001.

*Description:* 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).

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

*Source:* Genetic Modification Advisory Committee Secretariat (GMAC), Singapore.

*Description:* 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).

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

*Source / Year:* Genetic Modification Advisory Committee Secretariat (GMAC), Singapore / 2006.

*Description:* 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, 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).

**53. Technical and Technological Aspects of Biosafety**

*Source/Year:* National Sub Committee on Technical and Technological Aspects, National Biosafety Framework, Sri Lanka / 2004.

*Description:* 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).

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

*Source / Year:* National Biosafety Committee (NBC) Secretariat, Thailand / 1996.

*Description:* 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).

**55. The Thai Draft Guidelines on Contained Uses of GMOs**

*Source:* National Biosafety Committee (NBC) Secretariat, Thailand.

*Description:* 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).

**56. Guidelines for Ecological Risk Assessment**

*Source / Year:* Environmental Protection Agency (EPA), United States of America / 1998.

*Description:* 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).

**57. The SACGM Compendium of Guidance - Guidance from the Scientific Advisory Committee on Genetic Modification**

*Source / Year:* Health and Safety Executive (HSE), United States of America / 2007.

*Description:* The guidance represents what is considered to be good practice by the members of the Committee. It has been agreed by the Commission. Following this guidance is not compulsory and you are free to take other action. But if you do follow this guidance you will normally be doing enough to comply with the law. Health and safety inspectors seek to secure compliance with the law and may refer to this guidance as illustrating good practice.

*BIRC Record ID:* 47374 (http://bch.cbd.int/database/record.shtml?id=47374).

**58. NIH Guidelines for Research Involving Recombinant DNA Molecules**

*Source / Year:* National Institutes of Health, United States of America / 2002.

*Description:* The purpose of the NIH Guidelines is to specify practices for constructing and handling: (i) recombinant deoxyribonucleic acid (DNA) molecules, and (ii) organisms and viruses containing recombinant DNA molecules.

*BIRC Record ID:* 41856 (http://bch.cbd.int/database/record.shtml?id=41856).

**59. Science and Decisions: Advancing Risk Assessment**

*Source / Year:* National Academy of Science, United States of America / 2008.

*Description:* This book is a complement to the widely used 1983 National Academies book, Risk Assessment in the Federal Government. The earlier book established a framework for the concepts and conduct of risk assessment that has been adopted by numerous expert committees, regulatory agencies, and public health institutions. This new book embeds these concepts within a broader framework for risk-based decision-making.

*BIRC Record ID:* 48516 (http://bch.cbd.int/database/record.shtml?id=48516).

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

*Source / Year:* Association of Southeast Asian Nations (ASEAN) Secretariat / 1999.

*Description:* 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).

**61. Resource Book for Biosafety & Biotechnology in East Africa**

*Source:* East African Regional Programme and Research Network for Biotechnology, Biosafety and Biotechnology Policy Development (BIO-EARN).

*Description:* 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).

**62. Robust Methodologies for Ecological Risk Assessment: Best Practice and Current Practice in Ecological Risk Assessment for Genetically Modified Organisms**

*Source / Year:* Division of Marine Research, Commonwealth Scientific and Industrial Research Organisation (CSIRO) / 2004.

*Description:* This report compares current practice in ecological risk assessment for genetically modified (GM) plants and microorganisms, as evidenced by eight transnational and national frameworks, with what might reasonably be considered best practice. Best practice is defined for the scientific principles, hazard identification, risk calculation, social appraisal and monitoring stages of an ideal ecological risk assessment. Centre for Research on Introduced Marine Pests.

*BIRC Record ID:* 41646 (http://bch.cbd.int/database/record.shtml?id=41646).

**Baseline Information**

**63. An Introduction to the Biosafety Consensus Documents of the OECD Working Group for Harmonisation in Biotechnology**

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2005.

*Description:* This document describes the origin of the OECD 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. The resulting "Consensus Documents" provide a "snapshot" of current information on selected topics that may be relevant in a regulatory risk assessment.

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

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2006.

*Description:* This document 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. The resulting "Consensus Documents" provide a "snapshot" of current information on selected topics that may be relevant in a regulatory risk assessment.

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

**65. OECD Consensus Documents for the Work on Harmonisation of Regulatory Oversight in Biotechnology**

*Source:* Organization for Economic Co-operation and Development (OECD).

*Description:* This website provides links to the consensus documents published by the OECD. The consensus documents comprise technical information for use during the regulatory assessment of products of biotechnology and are intended to be mutually recognised among OECD Member countries. They focus on the biology of organisms (such as plants, trees or micro-organisms) or introduced novel traits.

*BIRC Record ID:* 48496 (http://bch.cbd.int/database/record.shtml?id=48496).

**66. International Assessment of Agricultural Knowledge, Science - Summary for Decision Makers of the Global Report**

*Source / Year:* International Assessment of Agricultural Knowledge, Science and Technology for Development (IAASTD) / 2008.

*Description:* This report integrates the key findings from the global and sub-global assessments under IAASTD, and focuses on eight topics: bioenergy; biotechnology; climate change; human health; natural resource management; traditional knowledge and community based innovation; trade and markets; and women in agriculture. It integrates scientific information on a range of topics that are critically interlinked. It was written for a range of stakeholders, i.e., government policy makers, private sector, NGOs, producer and consumer groups, international organizations and the scientific community. It is not directly focused on risk assessment of LMOs but may be used as a source of baseline information for some agricultural systems.

*BIRC Record ID:* 48489 (http://bch.cbd.int/database/record.shtml?id=48489).

**Contained Use**

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

*Source / Year:* Information Systems for Biotechnology (ISB) / 2001.

*Description:* 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).

**68. Biosafety Guidelines in Genetic Engineering and Biotechnology for Laboratory Work**

*Source / Year:* National Biosafety Committee (NBC) Secretariat, Thailand / 1992.

*Description:* 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, including transgenic plants and animals, 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).

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

*Source / Year:* National Biosafety Office, Kenya / 2004.

*Description:* This document contains a checklist for inspection of laboratory facilities used for GMOs.

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

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

*Source / Year:* National Biosafety Office, Kenya / 2004.

*Description:* 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).

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

*Source / Year:* National Biosafety Office, Kenya / 2004.

*Description:* 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).

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

*Source / Year:* Environmental Risk Management Authority (ERMA), New Zealand / 2005.

*Description:* 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).

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

*Source / Year:* Environmental Risk Management Authority (ERMA), New Zealand / 2003.

*Description:* 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).

**74. Biosafety in the Laboratory**

*Source / Year:* Flanders Interuniversity Institute for Biotechnology / 2004.

*Description:* This booklet gives a brief overview of the basic principles that are important for the safe use of pathogenic and/or genetically modified organisms. Safety measures discussed those to protect humans and the environment.

*BIRC Record ID:* 41589 (http://bch.cbd.int/database/record.shtml?id=41589).

**75. Integrated Confinement System for Genetically Engineered Plants: A Comprehensive Approach to Biosafety for Confined Field Trials**

*Source / Year:* International Food Policy Research Institute (IFPRI) / 2007.

*Description:* This document provides model procedures and documents for the regulation and conduct of confined field trials (CFTs) with genetically engineered (GE) plants. These models may be used by regulators and scientists in their efforts to develop a comprehensive national system ensuring biosafety, accountability, and transparency in field evaluations of GE plants.

*BIRC Record ID:* 46584 (http://bch.cbd.int/database/record.shtml?id=46584).

**Risk Management and Post-release Monitoring**

**76. A Risk Management Standard**

*Source / Year:* The Institute of Risk Management (IRM) / 2002.

*Description:* 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).

**77. Biological Confinement of Genetically Engineered Organisms**

*Source / Year:* National Academy of Sciences, United States of America / 2004.

*Description:* 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).

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

*Source / Year:* International Organization for Standardization (ISO) / 2002.

*Description:* 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).

**79. Guide 73, Risk Management Vocabulary Guidelines for Use in Standards (2002)**

*Source / Year:* International Organization for Standardization (ISO) / 2002.

*Description:* 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).

**80. GMO Detection Methods and Validation**

*Source / Year:* National Veterinary Institute, Norway / 2001.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1994.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1992.

*Description:* 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).

**83. Monitoring Protocol in accordance with the Gene Technology Act 2000**

*Source / Year:* Australian Office of the Gene Technology Regulator (OGTR) / 2007

*Description:* This monitoring protocol focuses on routine monitoring visits designed to determine whether the law and regulations have been complied with. This protocol covers the following activities related to routine monitoring: (i) understanding the purpose of monitoring visits; identifying when routine monitoring will occur; (iii) identifying the number of premises to be monitored; (iv) Specifying the people to undertake the monitoring visits; (v) conducting the monitoring visits; (vi) reporting on visits and implementing any necessary action; (vii) conducting follow up visits when non-compliance is found; and (viii) referring non-compliance issues for investigation.

*BIRC Record ID:* 48513 (http://bch.cbd.int/database/record.shtml?id=48513).

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

*Source / Year:* The European Parliament and the Council of the European Union / 2001.

*Description:* 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).

**85. A Conceptual Framework for the Design of Environmental Post-market Monitoring of Genetically Modified Plants**

*Source / Year:* Environmental Biosafety Research / 2005.

*Description:* This article presents a conceptual framework for the design of environmental post-market monitoring for genetically modified plants cultivation based on current European Union legislation and common risk analysis procedures.

*BIRC Record ID:* 41636 (http://bch.cbd.int/database/record.shtml?id=41636).

**86. Output on the Questionnaire on National Approaches to Monitoring, Detection, Identification of Transgenic Products**

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2003.

*Description:* This document compiles the results of a questionnaire that arose from a proposal by the delegation of the European Commission together with the OECD for a project to be undertaken by the Working Group on Harmonisation of Regulatory Oversight in Biotechnology.

*BIRC Record ID:* 41901 (http://bch.cbd.int/database/record.shtml?id=41901).

**87. Technologies for Biological Containment of GM and Non-GM Crops**

*Source / Year:* Department for Environment, Food and Rural Affairs (DEFRA), UK / 2005.

*Description:* This is a desk study to critically review effective, current and practical, as well as timely and potentially viable technologies that are aimed at reducing the dispersal of transgenes into the environment from GM (and non-GM) crops. The aim is to provide a literature review and critical assessment of current knowledge of strategies for biological containment of genes in transgenic and non-transgenic crops.

*BIRC Record ID:* 41592 (http://bch.cbd.int/database/record.shtml?id=41592).

**Databases (Containing Risk Assessment Summaries)**

**88. Office of the Gene Technology Regulator – List of Intentional Release Licence Applications under Evaluation**

*Source:* Office of the Gene Technology Regulator (OGTR), Australia

*Description:* This database contains the status of licence applications received by the Office of the Gene Technology Regulator (OGTR), Australia and includes links to the relevant documents.

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

**89. Release Permits for Pharmaceuticals, Industrials, Value Added Proteins for Human Consumption, or for Phytoremediation Granted or Pending by APHIS**

*Source:* Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA), United States of America

*Description:* This database contains a list of release permits for organisms intended for use as pharmaceuticals, industrials, and value added proteins or for phytoremediation received by APHIS including those still pending and otherwise not approved. The list is automatically updated daily and organized by year. The decision summary for each permit is also available.

*BIRC Record ID:* 48494 (http://bch.cbd.int/database/record.shtml?id=48494).

**90. Petitions of Nonregulated Status Granted or Pending by APHIS**

*Source:* Animal and Plant Health Inspection Service (APHIS), United States Department of Agriculture (USDA)

*Description:* This database contains a list of petitions for "nonregulated status" of LMOs received by the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). The lists of approved and pending petitions are automatically updated daily. Preliminary and final environmental assessment documents are also available.

*BIRC Record ID:* 48509 (http://bch.cbd.int/database/record.shtml?id=48509).

**91. Permits with Environmental Assessments**

*Source:* Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA)

*Description:* This database contains a list of Field Release Permits by the United States Department of Agriculture's (USDA) Animal and Plant Health Inspection Service (APHIS). This list automatically updated daily and contains current and outstanding permits with environmental assessments only, and may not contain permits with environmental assessments that are more then three years old.

*BIRC Record ID:* 48510 (http://bch.cbd.int/database/record.shtml?id=48510).

**92. Deliberate release into the environment of GMOs for any other purposes than placing on the market**

*Source:* Joint Research Centre, European Commission

*Description:* The EU database of deliberate environmental releases of LMOs includes documents that provide a discussion of potential environmental impacts as well as any measures taken for the mitigation of risks. These documents provide insight and examples of the issues addressed during risk assessments for particular LMOs on a case-by-case basis.

*BIRC Record ID:* 48511 (http://bch.cbd.int/database/record.shtml?id=48511).

**93. Japan Biosafety Clearing House (J-BCH) – Approved LMOs**

*Source:* Ministry of the Environment, Japan.

*Description:* The Japanese BCH database contains a list of LMOs approved under the Type 1 Use Regulation. The database is organized by year of approval and risk assessment reports are available for the majority of LMOs.

*BIRC Record ID:* 48522 (http://bch.cbd.int/database/record.shtml?id=48522).

## B. CROP PLANTS

**General Issues**

**94. Biotechnology and Biosafety at CIP Internal Guidelines**

*Source / Year:* International Potato Center (CIP), Peru / 1993.

*Description:* 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).

**95. Code of Practice on the Introduction of Genetically Modified Crops**

*Source / Year:* Supply Chain Initiative on Modified Agricultural Crops (SCIMAC), United States of America / 1999.

*Description:* 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).

**96. Environmental Risk Assessment of Transgenic Plants - Potential Secondary and Non-target Effects**

*Source:* Direction Générale de l' Environnement et des Eaux et Forêts (ME/LCD), Niger.

*Description:* This document, in a presentation format, describes a methodology for assessing the impact of GM plants on non-target organisms. It includes considerations on non-target indicator species and impact on soil organisms.

*BIRC Record ID:* 48483 (http://bch.cbd.int/database/record.shtml?id=48483).

**97. Canada - United States of America Bilateral on Agricultural Biotechnology. Appendix II: Environmental Characterization Data for Transgenic Plants Intended for Unconfined Release**

*Source / Year:* Canadian Food Inspection Agency, Plant Biosafety Office (CFIA-PBO) and United States Department of Agriculture, Animal and Plant Health Inspection Service (USDA-APHIS) / 2001.

*Description:* Information contained in this document focuses on how to evaluate the differences between the way transgenic plants and their non-transgenic counterparts interact with the environment in managed and unmanaged ecosystems. Such information is useful in assessing the likelihood that the plant will be harmful to the environment, either directly or indirectly.

*BIRC Record ID:* 48485 (http://bch.cbd.int/database/record.shtml?id=48485).

**98. Assessment of Toxic and Ecotoxic Properties of Novel Proteins in GMOs. Part 1: Report & Part 2: Supplement**

*Source / Year:* Federal Ministry for Health, Family and Youth, Austria / 2008.

*Description:* The overall goal of this report is to review the currently applied approaches in toxicity and ecotoxicity assessment of novel proteins in the context of genetically modified plants and to identify and discuss possible weaknesses and limitations. Recommendations for possible improvements of toxicity and ecotoxicity assessment in the context of GM crops are discussed.

*BIRC Record ID:* 48490 (http://bch.cbd.int/database/record.shtml?id=48490).

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

*Source / Year:* Public Research and Regulation Initiative (PRRI) / 2005.

*Description:* The focus of this guide is the technical and scientific information required for notification, and in particular for risk assessment. This guide is built up in modules, whereby the first module focuses on genetically modified crop plants.

*BIRC Record ID:* 48124 (https://bch.cbd.int/database/record.shtml?id=48124).

**100. Guidance Document for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed**

*Source / Year:* Health & Consumer Protection Directorate-General, European Commission / 2003.

*Description:* 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).

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

*Source / Year:* European Food Safety Authority (EFSA) / 2006.

*Description:* 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).

**102. Guiding Principles for Development and Deployment of Genetically Engineered Organisms**

*Source / Year:* International Potato Center (CIP), Peru / 2008.

*Description:* 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).

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

*Source / Year:* International Plant Genetic Resources Institute (IPGRI) / 2006.

*Description:* 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).

**104. Introduction to GMO: Technique and Safety**

*Source / Year:* Réseau Interdisciplinaire Biosécurité (RIBios) & Institut Universitaire d'Etudes du Développement (IUED) / 2004.

*Description:* 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 an 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).

**105. 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**

*Source / Year:* North American Plant Protection Organization (NAPPO) / 2003.

*Description:* 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).

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

*Source / Year:* National Academies Press, United States of America / 2003.

*Description:* 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).

**107. Application for Approval of Type 1 Use Regulations with Regard to the Genetically Modified Plants**

*Source:* Ministry of the Environment, Japan

*Description:* This document describes the details of the procedures for Application for Approval of Type 1 Use Regulations in Japan, including the collection of information pertaining to genetically modified crops and how to fill out the risk assessment report.

*BIRC Record ID:* 48518 (http://bch.cbd.int/database/record.shtml?id=48518).

**108. Safety Considerations for Biotechnology: Scale-Up of Crop Plants**

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1993.

*Description:* 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).

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

*Source / Year:* Zentrum für Biosicherheit und Nachhaltigkeit (BATS), Switzerland / 1998.

*Description:* 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).

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

*Source / Year:* Resilience Alliance Publications, Canada / 2000.

*Description:* 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).

**111. Review Article – The Mutational Consequences of Plant Transformation**

*Source / Year:* Hindawi Publishing Corporation, Egypt / 2006.

*Description:* This journal article discussed the possible causes and consequences for insertion site- and genome-wide mutations following the genetic transformation of crop plants.

*BIRC Record ID:* 41601 (http://bch.cbd.int/database/record.shtml?id=41601).

**112. Transformation-induced mutations in transgenic plants: Analysis and biosafety implications**

*Source / Year:* Biotechnology and Genetic Engineering Reviews / 2006.

*Description:* This paper reviews what is known about the effect of the plant transformation process on the plant genome. It analyses the extent and frequency of transformation-induced mutations in transgenic plants created by Agrobacterium-mediated transformation and particle bombardment. It discusses the potential of such mutations to result in unintended harmful phenotypes and the biosafety and regulatory implications of these findings.

*BIRC Record ID:* 48401 (http://bch.cbd.int/database/record.shtml?id=48401).

**113. Science-based risk assessment for non-target effects of transgenic crops**

*Source / Year:* American Institute of Biological Sciences / 2004.

*Description:* This paper discusses that non-target risk assessment for transgenic crops should be case specific, depending on the plant, the transgene and the intended release environment. It proposes an ecological risk-assessment model as an alternative to other methods currently in use.

*BIRC Record ID:* 48402 (http://bch.cbd.int/database/record.shtml?id=48402).

**114. Commission Recommendation on Guidelines for the Development of National Strategies and Best Practices to Ensure the Co-existence of Genetically Modified Crops with Conventional and Organic Farming**

*Source / Year:* European Commission / 2003.

*Description:* These guidelines are intended to help member States to develop workable measures for co-existence in conformity with European Union legislation. They set out the general principles and the technical and procedural aspects to be taken into account, and provide a list of possible actions that could be tailored for implementation at national or regional or local level.

*BIRC Record ID:* 42013 (http://bch.cbd.int/database/record.shtml?id=42013).

**115. Rethinking the Risk Management Process for Genetically Engineered Crop Varieties in Small-scale, Traditionally Based Agriculture**

*Source / Year:* Resilience Alliance Publications / 2005.

*Description:* This article discusses on the analysis of the potential for negative effects of GE crops in the developing countries using the risk management framework.

*BIRC Record ID:* 41575 (http://bch.cbd.int/database/record.shtml?id=41575).

**Baseline Information**

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2005.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2004.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2003.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2004.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2002.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2002.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2004.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2001.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2002.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1996.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1999.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1999.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2001.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1997.

*Description:* This document addresses the biology of oilseed rape. It contains a general description as a crop plant, taxonomy, centre of origin/diversity, reproductive biology, crosses and weed characteristics.

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

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2001.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2000.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2005.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1999.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2005.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1997.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2006.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1999.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2003.

*Description:* 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).

**139. Consensus Document of Safety Information on Transgenic Plants Expressing *Bacillus thuringiensis*-derived Control Proteins**

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2007.

*Description:* This document summarizes the information available on the source of *Bacillus thuringiensis* δ-endotoxin genes, the structure and properties of the toxins they encode, unique mechanisms of action, use in plants, toxicity and exposure data, and assessment methods. Some information on *Bacillus thuringiensis*, the bacterial source of these traits, is included as background and where relevant to the risk assessment of the δ-endotoxins in plants, however this document does not attempt to address the vast amount of information available on the microorganism.

*BIRC Record ID:* 48495 (http://bch.cbd.int/database/record.shtml?id=48495).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2002.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2006.

*Description:* 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).

**142. Biology Document BIO1992-02: the Biology of *Brassica rapa* L.**

*Source / Year:* Canadian Food Inspection Agency (CFIA) / 1992.

*Description:* 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).

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

*Source / Year:* Canadian Food Inspection Agency (CFIA) / 1994.

*Description:* 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).

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

*Source / Year:* Canadian Food Inspection Agency (CFIA) / 1994.

*Description:* 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).

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

*Source / Year:* Canadian Food Inspection Agency (CFIA) / 1994.

*Description:* 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).

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

*Source / Year:* Canadian Food Inspection Agency (CFIA) / 1996.

*Description:* 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).

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

*Source / Year:* Canadian Food Inspection Agency (CFIA) / 1996.

*Description:* 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).

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

*Source / Year:* Canadian Food Inspection Agency (CFIA) / 1999.

*Description:* 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).

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

*Source / Year:* Canadian Food Inspection Agency (CFIA) / 2002.

*Description:* 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).

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

*Source / Year:* Canadian Food Inspection Agency (CFIA) / 2003.

*Description:* 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).

**151. Biology Document BIO2005-01: The Biology of *Helianthus annuus* L. (Sunflower)**

*Source / Year:* Canadian Food Inspection Agency (CFIA) / 2005.

*Description:* 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).

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

*Source / Year:* Canadian Food Inspection Agency (CFIA) / 2005.

*Description:* 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).

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

*Source / Year:* Canadian Food Inspection Agency (CFIA) / 2006.

*Description:* 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).

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

*Source / Year:* Canadian Food Inspection Agency (CFIA) / 2007.

*Description:* 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).

**Case Studies / Specific Modified Crops or Traits**

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

*Source / Year:* Food and Agriculture Organization of the United Nations (FAO) / 2001.

*Description:* 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).

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

*Source / Year:* CAB International / 2001.

*Description:* 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).

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

*Source / Year:* CAB International / 2006.

*Description:* 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).

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

*Source / Year:* CAB International / 2007.

*Description:* 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).

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

*Source / Year:* Secretariat of the Advisory Committee on Releases to the Environment (ACRE) / 2006.

*Description:* 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).

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

*Source / Year:* Secretariat of the Advisory Committee on Releases to the Environment (ACRE) / 2006.

*Description:* 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).

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

*Source / Year:* Farm Scale Evaluations Research Consortium and the Scientific Steering Committee / 2003.

*Description:* 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).

**162. MON 810 Environmental Risk Assessment Case Study**

*Source:* Agriculture & Biotechnology Strategies (AGBIOS).

*Description:* 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).

**163. MON 810 Food Safety Assessment Case Study**

*Source:* Agriculture & Biotechnology Strategies (AGBIOS).

*Description:* 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).

**164. GTS 40-3-2 Food Safety Assessment Case Study**

*Source:* Agriculture & Biotechnology Strategies (AGBIOS).

*Description:* 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).

**165. Genetically Modified Pest-Protected Plants: Science and Regulation**

*Source / Year:* National Academy of Sciences / 2000.

*Description:* 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).

**166. Genetically Modified Maize: Pollen Movement and Crop Coexistence**

*Source / Year:* PG Economics / 2004.

*Description:* This paper provides a discussion on co-existence issues based on specific reference to maize and the extent to which adventitious presence of GM maize may be detected in non-GM maize crops through maize pollen movement and gene flow.

*BIRC Record ID:* 41980 (http://bch.cbd.int/database/record.shtml?id=41980).

**167. On Science and Precaution in the Management of Technological Risk: a Synthesis Report of case studies**

*Source / Year:* European Science and Technology Observatory / 1999.

*Description:* The aim of this research project was to examine, in an open-minded and interdisciplinary fashion, some of the key conceptual issues arising in the application of "science" and "precaution" to the management of technological risk and to draw some practical conclusions for policy-making.

*BIRC Record ID:* 41656 (http://bch.cbd.int/database/record.shtml?id=41656).

**168. Proceedings of a Workshop on: Ecological Effects of Pest Resistance Genes in Managed Ecosystems**

*Source / Year:* Information Systems for Biotechnology / 2002.

*Description:* This workshop was organized to promote multidisciplinary discussions that would lead to synthesis of what is known and not known regarding the environmental impact of pest resistant crops.

*BIRC Record ID:* 41669 (http://bch.cbd.int/database/record.shtml?id=41669).

**169. Monitoring the Environmental Consequences of Gene Flow from Transgenic Sugar Beet**

*Source / Year:* Ohio State University / 2002.

*Description:* These proceedings of a workshop on gene flow (Ohio State University, 5-6 March 2002) focus on monitoring and environmental consequences of gene flow from transgenic sugar beet.

*BIRC Record ID:* 41806 (http://bch.cbd.int/database/record.shtml?id=41806).

**170. Novel aspects of the environmental risk assessment of drought-tolerant genetically modified maize andomega-3 fatty acid genetically modified soybean**

*Source / Year:* Schenkelaars Biotechnology Consultancy / 2007.

*Description:* This document is the report of a study on drought-tolerant GM maize and GM soybean with an increased content of omega-3-fatty acids with the aim to answer whether the environmental risk assessment (ERA) of these novel generation GM plants, as required by EU Directive 2001/18/EC, involves novel aspects, which cannot be addressed by current ERA methodologies, and; If so, how to consider these novel aspects adequately in the ERA.

*BIRC Record ID:* 45858 (http://bch.cbd.int/database/record.shtml?id=45858).

**171. Maize and Biodiversity: The Effects of Transgenic Maize in Mexico. Chapter 3 - Assessment of Effects on Genetic Diversity**

*Source / Year:* Secretariat of the Commission for Environmental Cooperation (CEC) of North America / 2004.

*Description:* This document was prepared as background for the work of the Maize Advisory Group as part of the CEC Article 13 study on transgenic maize and biodiversity.

*BIRC Record ID:* 47565 (http://bch.cbd.int/database/record.shtml?id=47565).

**172. Maize and Biodiversity: The Effects of Transgenic Maize in Mexico. Chapter 10 - Managing Potential Risks and Enhancing Potential Benefits: Identification and Analysis of Management Tools and Policy Options**

*Source / Year:* Secretariat of the Commission for Environmental Cooperation (CEC) of North America / 2004.

*Description:* This document was prepared as background for the work of the Maize Advisory Group as part of the CEC Article 13 study on transgenic maize and biodiversity.

*BIRC Record ID:* 41595 (http://bch.cbd.int/database/record.shtml?id=41595).

**173. Interferences in the Agrisystem and Environmental Risks of Herbicide Tolerant and Insect Protected Transgenic Crops**

*Source / Year:* Cadernos de Ciência & Tecnologia / 2005.

*Description:* This journal article provides a comparison of agricultural practices and environment risks between herbicide-tolerant crops and non-transgenic counterparts (in Portuguese).

*BIRC Record ID:* 41642 (http://bch.cbd.int/database/record.shtml?id=41642).

**174. Genetically Engineered Corn and the Monarch Butterfly Controversy**

*Source / Year:* The Pew Initiative on Food and Biotechnology / 2006.

*Description:* This paper reviews the chronology of the monarch butterfly controversy from the perspective of a number of key players. It also provides a brief review of the current state of scientific knowledge on the issue - what is now known, and what questions remain.

*BIRC Record ID:* 41682 (http://bch.cbd.int/database/record.shtml?id=41682).

**175. The Environmental Effects of Genetically Modified Crops Resistant to Insects**

*Source / Year:* Neotropical Entomology / 2002.

*Description:* This review article discusses the potential ecological consequences of the commercial use in agriculture of genetically modified insect resistant crops. Further, it also examines the impacts caused by the change in agricultural practices, and attempt to identify gaps and possible opportunities for research, considering this new technological tool.

*BIRC Record ID:* 41643 (http://bch.cbd.int/database/record.shtml?id=41643).

**176. Ecological Impacts of Insect-resistant Bt Maize on Various Insects and the European Corn Borer**

*Source / Year:* GMO Safety / 2002.

*Description:* This review evaluates scientific studies published in peer-review journals during the last 3-4 years that considered ecological effects of insect resistant (Bt) and herbicide tolerant maize.

*BIRC Record ID:* 41676 (http://bch.cbd.int/database/record.shtml?id=41676).

**Food and Feed Safety**

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2003.

*Description:* 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).

**178. Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants**

*Source / Year:* Codex Alimentarius Commission, Food and Agriculture Organization of the United Nations (FAO) / 2003.

*Description:* 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).

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

*Source / Year:* Ministry of Science and Technology, India / 1998.

*Description:* 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).

**180. Risk Assessment of GMO Products in the European Union: Toxicity Assessment, Allergenicity Assessment and Substantial Equivalence in Practice and Proposals for Improvement and Standardisation**

*Source / Year:* Austrian Federal Environment Agency, Austria / 2004.

*Description:* 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).

**181. Risk Assessment of Genetically Modified Organisms**

*Source / Year:* Associação Brasileira de Pós-Graduação em Saúde Coletiva (ABRASCO) / 2007.

*Description:* 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).

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

*Source:* Codex Alimentarius Commission, Food and Agriculture Organization of the United Nations (FAO).

*Description:* 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).

**183. GM Food Safety Assessment - Tools for Trainers (Pre-publication)**

*Source / Year:* Food and Agriculture Organization of the United Nations (FAO) / 2009

*Description:* This document contains a standardized training package to assist countries in implementing relevant Codex texts related to the safety assessment of foods derived from recombinant-DNA plants. This training package contains both theory and practical examples of risk assessments of foods derived from modern biotechnology and a guide for training regulators. This is a "pre-publication" and a final version of this document is expected in the coming months.

*BIRC Record ID:* 48514 (http://bch.cbd.int/database/record.shtml?id=48514).

**184. International Comparison of Regulatory Frameworks for Food Products of Biotechnology**

*Source / Year:* Canadian Biotechnology Advisory Committee (CBAC) / 2000.

*Description:* This document provides a comparison of the regulatory frameworks in Argentina, Australia, Japan, the United Kingdom and the United States. The objective is to situate Canada internationally with respect to the regulation of agricultural biotechnology products and highlight best practices in a manner that will help CBAC identify issues related to the governance and organization of Canada's regulatory system.

*BIRC Record ID:* 41805 (http://bch.cbd.int/database/record.shtml?id=41805).

**185. Evaluation of Allergenicity of Genetically Modified Foods**

*Source / Year:* World Health Organization (WHO) and Food and Agriculture Organization of the United Nations (FAO) / 2001.

*Description:* This is the report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology on the evaluation of allergenicity of genetically modified foods. It provides scientific advice in relation to the assessment of allergenicity in genetically modified foods.

*BIRC Record ID:* 41976 (http://bch.cbd.int/database/record.shtml?id=41976).

**186. Safety aspects of genetically modified foods of plant origin**

*Source / Year:* World Health Organization (WHO) / 2000.

*Description:* This report addresses food safety and nutritional questions regarding foods and food ingredients derived from plants that have been genetically modified using recombinant DNA techniques.

*BIRC Record ID:* 41625 (http://bch.cbd.int/database/record.shtml?id=41625).

**Risk Management and Monitoring**

**187. Compliance Management of Confined Field Trials of Genetically Engineered Plants**

*Source / Year:* CropLife International / 2005.

*Description:* 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).

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

*Source / Year:* Department for Environment, Food and Rural Affairs (DEFRA), UK / 2003.

*Description:* 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).

## C. TREES

### General Issues

**189. Genetically Engineered Trees & Risk Assessment – An overview of Risk Assessment and Risk Management Issues**

*Source / Year:* Federation of German Scientists / 2008.

*Description:* This document provides a literature review and provides an assertion of how trees differ in a number of important characteristics from field crops, and how these characteristics play a role in the risk assessment of genetically engineered (GE) trees.

*BIRC Record ID:* 48398 (http://bch.cbd.int/database/record.shtml?id=48398).

**190. Genetically Engineered Forest Trees – Identifying Priorities for Ecological Risk Assessment**

*Source / Year:* Institute of Forest Biotechnology (IFB) / 2008.

*Description:* This publication is a compilation of research presentations, identified knowledge gaps, and ideas for next steps in answering ecological risk questions about genetically engineered forest trees. This material was generated during the second meeting from the Institute of Forest Biotechnology (IFB) that focused on ecological issues.

*BIRC Record ID:* 48204 (http://bch.cbd.int/database/record.shtml?id=48204).

**191. Report of the Workshop on the Environmental Considerations of Genetically Modified Trees**

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2001.

*Description:* This document is a compilation of the presentations and plenary session reports made at the Workshop on the Environmental Considerations of Genetically Modified Trees, which was held in Norway, in September 1999. Some of these documents present a quite important data set on the organisms in question, but several member States felt some need to address the questions specific to the risk assessment of long-lived species like trees.

*BIRC Record ID:* 41902 (http://bch.cbd.int/database/record.shtml?id=41902).

**192. Gene flow from tree plantations and implications for transgenic risk assessment**

*Source / Year:* Research Signpost / 2004.

*Description:* This journal article discusses on gene flow a major determinant of impacts of forest tree plantations on surrounding populations and ecosystems. It emphasizes that the choice of methods for measuring gene flow will be dictated by the organism and environment under study, the availability of tools and resources, and the desired scope of inference. Methods include direct tracking of propagule movement, parentage analysis, and analysis of genetic diversity in seeds, seedlings, and pollen.

*BIRC Record ID:* 47286 (http://bch.cbd.int/database/record.shtml?id=47286).

**193. Measuring and Modeling Gene Flow From Hybrid Poplar Plantations: Implications for Transgenic Risk Assessment**

*Source / Year:* Dr. Stephen P. DiFazio, West Virginia University, United States of America / 2002.

*Description:* This PhD thesis describes a study where gene flow from poplar plantations was analyzed using a combination of large-scale field studies, genetic analyses and simulation modelling. The results are discussed in connection with risk assessment of transgenic poplars.

*BIRC Record ID:* 47373 (http://bch.cbd.int/database/record.shtml?id=47373).

**194. Genetically engineered trees: promise and concerns**

*Source / Year:* Resources for the Future, United States of America / 2004.

*Description:* This report describes the implementation and outcomes of procedures related to the authorized field tests for transgenic trees in the United States of America and a description of the types of tests and how they are evaluated. It also evaluates the potential environmental benefits and concerns of transgenic trees.

*BIRC Record ID:* 47289 (http://bch.cbd.int/database/record.shtml?id=47289).

**Baseline Information**

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2003.

*Description:* This document addresses the biology of European white birch. It contains a general description as a crop plant, taxonomy, centre of origin/diversity, reproductive biology, crosses and weed characteristics.

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

**196. Consensus Document on the Biology of *Picea abies* (L) Karst (Norway Spruce)**

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1999.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1999.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2002.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2002.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2001.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2002.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2006.

*Description:* 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).

**203. Consensus Document on the Biology of *Pinus banksiana* (Jack Pine)**

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2006.

*Description:* This document addresses the biology of Jack Pine. It contains a general description of its taxonomy, centre of origin/diversity, reproductive biology and crosses.

*BIRC Record ID:* 48525 (http://bch.cbd.int/database/record.shtml?id=48525).

**204. Consensus Document on the Biology of the Native North American Larches: Subalpine Larch (*Larix lyalli*), Western Larch (*Larix occidentalis*) and Tamarack (*Larix laricina*)**

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2007.

*Description:* This document addresses the biology of the native North American larches. It contains a general description of its taxonomy, centre of origin/diversity, reproductive biology and crosses.

*BIRC Record ID:* 48524 (http://bch.cbd.int/database/record.shtml?id=48524).

## D. LMOS WITH STACKED GENES OR TRAITS

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

*Source / Year:* European Food Safety Authority (EFSA) / 2006.

*Description:* 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).

**206. Guidance document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants Containing Stacked Transformation Events**

*Source / Year:* European Food Safety Authority (EFSA) / 2007.

*Description:* This document provides guidelines with respect to the risk assessment under Regulation (EC) No 1829/2003 and Directive 2001/18/EC of genetically modified plants containing stacked transformation events. For the purpose of this document "stacked" events are defined as those combined by conventional breeding.

*BIRC Record ID:* 48484 (http://bch.cbd.int/database/record.shtml?id=48484)

**207. Risk Assessment of "Stacked Events"**

*Source / Year:* Federal Ministry for Health, Family and Youth, Austria / 2007.

*Description:* This document provides a brief overview of the risk assessment requirements for "stacked events" proposed in guidance documents and in the scientific literature available at the time when this document was written. It provides a comparison of the proposals and approaches described in these documents was undertaken to identify potential areas of consent and dissent.

*BIRC Record ID:* 48492 (http://bch.cbd.int/database/record.shtml?id=48492).

## E. PHARMAPLANTS

**208. Assessment Criteria for the Evaluation of Environmental Safety of Plants with Novel Traits Intended for Commercial Plant Molecular Farming – DRAFT**

*Source / Year:* Canadian Food and Agriculture Agency (CFIA) / 2005.

*Description:* This draft directive is the Canadian Food and Agriculture Agency's starting point in developing an appropriate, science-based regulatory framework for the environmental release of LMOs intended for plant molecular farming in Canada.

*BIRC Record ID:* 47317 (http://bch.cbd.int/database/record.shtml?id=47317).

**209. Guidance for APHIS Permits for Field Testing or Movement of Organisms Intended for Pharmaceutical or Industrial Use**

*Source / Year:* Animal and Plant Protection Service (APHIS), United States Department of Agriculture (USDA) / 2008.

*Description:* This guidance document is intended to provide guidance for field testing and movement of organisms engineered to produce compounds intended for industrial or pharmaceutical use.

*BIRC Record ID:* 48493 (http://bch.cbd.int/database/record.shtml?id=48493).

**210. A Growing Concern. Protecting the Food Supply in an Era of Pharmaceutical and Industrial Crops**

*Source / Year:* Union of Concerned Scientists / 2004.

*Description:* This document addresses the challenge of protecting the U.S. food supply from contamination by crops genetically engineered to produce drugs and industrial substances ("pharma" crops).

*BIRC Record ID:* 41854 (http://bch.cbd.int/database/record.shtml?id=41854).

## F. ANIMALS

### General Guidance

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

*Source / Year:* World Organisation for Animal Health (OIE) / 2005.

*Description:* 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).

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

*Source / Year:* World Organisation for Animal Health (OIE) / 2004.

*Description:* 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).

**213. The Cartagena Protocol on Biosafety: Interaction between the Convention on Biological Diversity and the World Organisation for Animal Health**

*Source / Year:* World Organisation for Animal Health (OIE) / 2005.

*Description:* 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).

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

*Source / Year:* World Organisation for Animal Health (OIE) / 2005.

*Description:* 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).

**215. Animal Biotechnology: Science-Based Concerns**

*Source / Year:* National Research Council, United States of America / 2002.

*Description:* 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).

**216. Animal Health Risk Analysis Framework for Biotechnology-Derived Animals**

*Source / Year:* Canadian Food Inspection Agency (CFIA) / 2004.

*Description:* 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).

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

*Source / Year:* Food and Agricultural Organization of the United Nations (FAO) and the World Health Organization (WHO) / 2003.

*Description:* 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).

**218. Notification Guidelines for the Environmental Assessment of Biotechnology – Derived Livestock Animals**

*Source / Year:* Canadian Food Inspection Agency (CFIA), Canada / 2004.

*Description:* 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).

**219. Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Animals (CAC/GL 68-2008)**

*Source / Year:* Codex Alimentarius Commission, Food and Agriculture Organization (FAO) / 2008.

*Description:* The Guideline describes the recommended approach for the food safety assessment of foods derived from recombinant-DNA animals where a conventional counterpart exists, and identifies the data and information that are generally applicable to making such assessments. In assessing the safety of food from recombinant-DNA animals, this approach takes into account the following (a) the nature of the recombinant-DNA construct and its expression product(s), if any; (b) the health status of the recombinant-DNA animal; and (c) the composition of foods produced from recombinant-DNA animals, including key nutrients.

*BIRC Record ID:* 48526 (http://bch.cbd.int/database/record.shtml?id=48526).

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

*Source / Year:* Food and Agriculture Organization of the United Nations (FAO) and International Atomic Energy Agency (IAEA) / 2006.

*Description:* 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).

**221. Guidance for Industry – Regulation of Genetically Engineered Animals Containing Heritable rDNA Constructs**

*Source / Year:* Food and Drug Administration (FDA), United States of America / 2009.

*Description:* This guidance explains the process by which FDA is regulating genetically engineered (GE) animals and provides a set of recommendations to producers of genetically engineered animals to help them meet their obligations and responsibilities under the law. While the guidance is intended for industry, it may also help other stake holders gain a better understanding on genetically engineered animals.

*BIRC Record ID:* 48499 (http://bch.cbd.int/database/record.shtml?id=48499).

**222. The Use of Genetically Modified Animals**

*Source / Year:* The Royal Society, United Kingdom / 2001.

*Description:* This report is primarily about the scientific issues involved in the genetic modification of animals. This report examines genetic modification of vertebrates such as mammals, birds, fish and amphibians, as well as invertebrates such as insects. Only these groups of animals that have been genetically modified were considered in this report.

*BIRC Record ID:* 48501 (http://bch.cbd.int/database/record.shtml?id=48501).

**Fish and Other Aquatic Animals**

**223. Abstracts of the OECD Workshop on the Biology of Atlantic Salmon (*Salmo salar*)**

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 2006.

*Description:* This document summarizes the discussions of a workshop on the biology of Atlantic salmon organized by the OECD with the objective of identifying and reviewing the kinds of (and availability of) baseline information of (non-transgenic) from traditional fish farming or breeding, and to determine what information might be relevant to risk/ safety assessment; and what information might be needed for the development of a biology document. The overall approach used by the workshop was similar to that done to first identify and circumscribe the issues about crop species that would inform a risk/safety assessment of the same species after it had been transformed.

*BIRC Record ID:* 47263 (http://bch.cbd.int/database/record.shtml?id=47263).

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

*Source / Year:* CAB International / 2007.

*Description:* 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).

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

*Source / Year:* World Organisation for Animal Health (OIE) / 2005.

*Description:* 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).

**226. Environmental Impacts of Aquatic Biotechnology**

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1995.

*Description:* 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).

**227. Performance Standards for Safely Conducting Research with Genetically Modified Fish and Shellfish**

*Source / Year:* United States Department of Agriculture (USDA) / 1995.

*Description:* These performance standards were prepared by the USDA with the objective of guiding evaluations of the performance and environmental safety of aquatic GMOs in the United States and abroad. These standards addresses issues related to environmental safety with respect to genetic effects on natural populations of aquatic organisms and ecological effects on aquatic ecosystems.

*BIRC Record ID:* 48504 (http://bch.cbd.int/database/record.shtml?id=48504).

**228. Genetically Engineered Fish and Seafood**

*Source / Year:* United States Congressional Research Service / 2005.

*Description:* This report provides an overview of the US Domestic regulation, environmental concerns, international developments, possible benefits and disadvantages of genetically modified fish and seafood.

*BIRC Record ID:* 48507 (http://bch.cbd.int/database/record.shtml?id=48507).

**229. Genetically Modified Fish in Future Aquaculture: Technical, Environmental and Management Considerations**

*Source / Year:* International Service for National Agricultural Research (ISNAR) / 1996.

*Description:* The objectives of this paper are to discuss technical, environmental and management considerations regarding the use of GMOs in aquaculture.

*BIRC Record ID:* 41804 (http://bch.cbd.int/database/record.shtml?id=41804).

**230. Future Fish: Issues in Science and Regulation of Transgenic Fish**

*Source / Year:* Pew Initiative on Food and Biotechnology / 2003.

*Description:* This report provides an overview of the issues surrounding transgenic fish. The report reviews the development of aquaculture biotechnology, the status of current research, its potential economic, environmental, and other benefits, its possible food safety and environmental risks, and the application of current U.S. laws and regulations as it moves to commercial development. While the report does not contain specific policy recommendations, it highlights a number of key regulatory issues for policymakers.

*BIRC Record ID:* 41551 (http://bch.cbd.int/database/record.shtml?id=41551).

## G. MICROORGANISMS, FUNGI AND VIRUSES

**231. 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)**

*Source / Year:* European Food Safety Authority (EFSA) / 2006.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development / 2006.

*Description:* This document addresses information of environmental applications involving the genus *Acidithiobacillus*.

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

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

*Source / Year:* Organisation for Economic Co-operation and Development / 2002.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development / 1997.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development / 2005.

*Description:* This consensus document addresses the biology of Oyster Mushroom. Included are descriptions of general information; taxonomy and natural distribution; agronomic practices; lifecycle and growth; sexual reproduction and grosses; genetics of P. ostreatus; and pests and diseases.

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

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

*Source / Year:* Organisation for Economic Co-operation and Development / 2004.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development / 2004.

*Description:* 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).

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

*Source / Year:* Codex Alimentarius Commission, Food and Agriculture Organization (FAO) / 2003.

*Description:* This 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).

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

*Source / Year:* Scientific Institute of Public Health, Belgium / 2005.

*Description:* 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).

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

*Source / Year:* Organisation for Economic Co-operation and Development (OECD) / 1995.

*Description:* 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).

**241. The Laboratory Biosafety Guidelines**

*Source / Year:* Health Canada / 2004.

*Description:* 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).

**242. Application for Approval of Type 1 Use Regulations with regard to the genetically modified live vaccines**

*Source:* Japan Ministry of the Environment, Japan

*Description:* This guidance sets the necessary steps to ensure that the risk assessments of transgenic microorganisms used as live vaccines are done in accordance with the Japanese Law concerning the Conservation and Sustainable Use of Biological Diversity. It is designed to enable an applicant who wishes to obtain approval for a genetically modified vaccine to perform a scientifically sound risk assessment and to properly prepare the Risk Assessment Report.

*BIRC Record ID:* 48161 (http://bch.cbd.int/database/record.shtml?id=48161).

**243. Safety assessment of foods derived from genetically modified microorganisms**

*Source / Year:* World Health Organization (WHO) and Food and Agriculture Organization of the United Nations (FAO) / 2001.

*Description:* This is the report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology on Safety assessment of foods derived from genetically modified microorganisms. It provides scientific advice in relation to the safety assessment of GMOs in food.

*BIRC Record ID:* 41975 (http://bch.cbd.int/database/record.shtml?id=41975).

*Annex II*

## RESEARCH ARTICLES RELEVANT TO THE WORK OF THE AHTEG ON RISK ASSESSMENT AND RISK MANAGEMENT

### ROADMAP

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