Environmental Risk Assessment Guidance Documents

The Global Industry Coalition's (GIC) overarching view on existing guidance materials on risk assessment and risk management is that significant and substantial guidance materials exist to ensure that robust and appropriately protective risk assessment. Such guidance materials are in line with the principles and methods of risk assessment and risk management in Annex III, and are appropriate for current and realistically foreseeable LMOs globally. Search of the BCH for any regulatory process conducted for release into the environment gives 977 records. In addition, a search of national laws and guidelines for risk assessment and risk management gives 419 records from 141 countries. However, the GIC continues to contend that a more appropriate path forward is for experienced Parties to share their best practices, existing guidance, and practical and real-life experience in undertaking risk assessments of various LMOs. As examples, links to readily available guidance available from national authorities and international/intergovernmental bodies with experience in real-world risk assessment of LMOs are provided below. (The following list is not exhaustive; it is merely exemplary.) Importantly, all the authorities listed have Competent National Authorities available for consultation.

A. National Guidelines and Regulations

Countries/regions with experience in risk assessment for commercial release of LMOs :

Argentina, Comisión Nacional Asesora de Biotecnología Agropecuaria, CONABIA, has been evaluating and assessing LMO's since 1991. Guidance can be found at: https://www.agroindustria.gob.ar/sitio/areas/biotecnologia/solicitudes/
CONABIA: https://www.agroindustria.gob.ar/sitio/areas/biotecnologia/solicitudes/ and https://www.agroindustria.gob.ar/sitio/areas/biotecnologia/marco_legal/
SENASA: http://www.senasa.gob.ar/cadena-vegetal/cereales/industria/biotecnologia

Australia, Department of Health and Aging, Office of the Gene Technology Regulator. Risk Analysis Framework. May 2013. 139 pages. Available through: www.ogtr.gov.au.
Guidelines for certification of containment conditions: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/guidelines-1
Risk analysis framework: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/risk-analysis-framework
Risk assessment reference documents: http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1

Canada, Canadian Food Inspection Agency (CFIA) has been evaluating Plants with Novel Traits since 1996, http://www.inspection.gc.ca/plants/plants-with-novel-traits/eng/1300137887237/1300137939635.
Guidelines for Assessment of Novel Feeds: Plant Sources, http://www.inspection.gc.ca/animals/feeds/regulatory-guidance/rg-1/chapter-2/eng/1329298059609/1329298179464?chap=6, and Directive 94-08 revised (2004). Assessment criteria for determining environmental safety of plants with novel traits at: http://www.inspection.gc.ca/plants/plants-with-novel-traits/applicants/directive-94-08/eng/1304475469806/1304475550733
The CFIA – Plant BioSafety Office just released this update to Directive 94-08 last week, and it won't be in effect until June of 2018: http://inspection.gc.ca/plants/plants-with-novel-traits/applicants/directive-94-08-revised-/eng/1512588596097/1512588596818
A link to the guidance document for Health Canada who also is part of the Canadian approval system can be found at: https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-

guidelines/guidance-documents/guidelines-safety-assessment-novel-foods-derived-plants-microorganisms/guidelines-safety-assessment-novel-foods-2006.html

European Union, Guidance document of the Scientific Panel on Genetically Modified Organisms for the risk assessment of genetically modified plants and derived food and feed, *the EFSA Journal* (2006) 99, 1-100; and, EFSA Guidance Document on the ERA of GM Plants: https://www.efsa.europa.eu/en/efsajournal/pub/1879 . Adopted 21-Oct-2010.

Note further that, based on the EU regulation for GMOs, each EU member state provides guidance materials available from each Competent National Authority.

Philippines, the departments of Science and Technology, Agriculture, Environment and Natural Resources, Health, and Interior and Local Government published a joint circular which provides guidance for the Philippines. Available at: http://biotech.da.gov.ph/upload/Final_DOST-DA-DENR-DOH-DILG_JoinDepartmentCircular.pdf

United States of America, US EPA and USDA regulate the environmental safety of biotechnology in the USA. The US EPA publishes Biopesticides Registration Action Documents on all plant incorporated protectants (PIPs) after they have been registered by the agency. These documents are extensive and provide useful information on the GM crops (typically Bt crops) and the risk assessments conducted by the US EPA. The documents are publicly available by searching at: https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/epas-regulation-biotechnology-use-pest-management

USDA guidance documents are available at: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/sa_guidance_documents. In addition all regulatory petitions and decision documents are available at: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status

Uruguay, Gabinete Nacional de Bioseguridad (GNBio): http://www.mgap.gub.uy/unidad-ejecutora/bioseguridad/bioseguridad/analisis-de-riesgo

Vietnam, http://antoansinhhoc.vn/thong-tu-so-082013tt-btnmt/ for the ERA guideline in local language http://antoansinhhoc.vn/thong-tu-so-022014tt-bnnptnt/ for food-feed safety assessment guideline in local language

Parties that have experience approving LMOs for import use:

Indonesia, http://indonesiabch.or.id/regulasi/?lang=en for the law in local language http://indonesiabch.or.id/panduan/?lang=en for the guideline in local language

Japan, Japan Biosafety Clearing House (J-BCH) publishes relevant laws, regulations, and guidelines related to ERA which are available in English: http://www.biodic.go.jp/bch/english/law.html

Malaysia, Biosafety Act 2007 and Biosafety (Approval and Notification) Regulations 2010 available at: http://www.biosafety.nre.gov.my/law_regulation.shtml

Singapore, Singapore release and research guidelines for GM are available at: https://www.gmac.sg/Index_Guidelines_Overview_on_GMAC_Guidelines.html

South Korea, The Korean Biosafety Clearing House (KBCH) contains guidelines and regulations for GMOs: KBCH available at: http://www.biosafety.or.kr/sub/info.do?m=020205&s=kbch

B. Guidelines available from International Expert Bodies:

UNEP, the UNEP International Technical Guidelines for Safety in Biotechnology were adopted in 1995 by the Global Consultation of Government-designated Experts, and were developed under with GEF funding: https://unep.ch/biosafety/old_site/development/devdocuments/Techguidelines.pdf

ICGEB, Search of the International Centre for Genetic Engineering and Biotechnology with terms "risk assessment guidelines" gives 400 results for actual risk assessments by regulatory authorities: http://rasm.icgeb.org.

ILSI, the Center for Environmental Risk Assessment of GM Crops of the International Life Sciences Institutes (ILSI-CERA GMC) offers e-learning courses on safety assessment for LM Crops: http://cera-gmc.org/Courses and ERA guidance available in Spanish and Portuguese (Guia para la evaluación de riesgo ambiental de organismos genéticamente midificados / [editores] Paulo Paes de Andrade, Wayne Parrott. -- 1. ed. -- Sâo Paulo : Internacional Life Sciences Institute do Brasil, 2012.

IPCS, WHO Integrated Program on Chemical Safety (2001), Integrated Risk Assessment, http://www.who.int/ipcs/publications/new_issues/ira/en/

IPPC, FAO International Plant Protection Convention (1951), Pest Risk Analysis for Quarantine Pest, ISPM 11 (2017): https://www.ippc.int/en/publications/639/ , and Pest Risk Analysis for Regulated non Quarantine Pests, ISPM 21 (2016): https://www.ippc.int/en/publications/601/

OECD, the Organization for Economic Cooperation and Development has been publishing expert documents and guidance on biotechnology since 1986. More recent guidance and consensus documents can be found at: http://www.oecd-ilibrary.org/. See also OECD. 1992. Safety considerations for biotechnology. OECD. Paris. pp. 45. (includes micro-organisms); and OECD. 1993. Safety considerations for biotechnology. Scale-up of Crop Plants. OECD. Paris. pp 43.

Select Expert Publications – Reviews

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Rissler, J. and M.G. Mellon. 2000. The ecological risks of engineered crops. Massachusetts Institute of Technology. The MIT press, Cambridge, Massachusetts.

Tiedje, J.M., R.K. Colwell, Y.L. Grossman, R.E. Hodson, R.E. Lenski, R.N. Mack, and P.J. Regal. 1989. The planned introduction of genetically engineered organisms: ecological considerations and recommendations. *Ecology* 70:298-315.

Selected literature demonstrating experience with

risk assessment (2012 - 2016) (from GIC submission on synbio)

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4. Zheng-jun G, Shun-bao L, Zheng-Ping G, Biao L, Wei W (2016) Do genetically modified plants affect adversely on soil microbial communities? *Agriculture, Ecosystems and Environment* 235:289-305. doi.org/10.1016/j.agee.2016.10.026.

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6. Casacuberta JM, Devos Y, du Jardin P, Ramon M, Vaucheret H, Nogué F (2015) Biotechnological uses of RNAi in plants: risk assessment considerations, *Trends in Biotechnology* 33: 145–47. doi:10.1016/j.tibtech.2014.12.003.

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genetically engineered plants: a conceptual framework, *Transgenic Research* doi:10.1007/s11248-014-9785-0.

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