

Environmental Risk Assessment Guidance

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-](http://www.inspection.gc.ca/animals/feeds/regulatory-guidance/rg-1/chapter-2/eng/1329298059609/1329298179464?chap=6)

[2/eng/1329298059609/1329298179464?chap=6](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>

27 January 2018

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-btntmt/> 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

27 January 2018

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. -- São 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.

27 January 2018

Select Expert Publications – Reviews

Layton R, et al, (2015) Building better environmental risk assessments. *Frontiers in Bioengineering and Biotechnology* **3**:110. doi: 10.3389/fbioe.2015.00110

Garcia-Alonzo M, Jacobs E, Raybould A, Nickson TE, Sowig P, Willekens H, van der Kouwe P, Layton R, Amijee F, Fuentes AM, et al (2006) A tiered system for assessing the risk of genetically modified plants to non-target organisms. *Environ Biosafety Res.* **5**: 57–65

Raybould A (2006) Problem Formulation and Hypothesis Testing for Genetically Modified Crops. *Environ. Biosafety Res.* **5**: 119-125

Hill RA, Sendashonga C (2003) General principles for risk assessment of living modified organisms: Lessons from chemical risk assessment. *Environ. Biosafety Res.* **2**: 81–88

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)**

1. Brookes G, Barfoot P (2016) GM crops: global socio-economic and environmental impacts 1996-2014. PG Economics Ltd, UK.
2. National Academy of Sciences (2016) Publisher: National Academies of Sciences, Engineering, and Medicine. p. 606 DOI: <https://doi.org/10.17226/23395>.
3. Yaqoob H, Shahid AA, Samiullah TR, Rao AQ, Khan MA, Tahir S, Mirza SA, Husnain T (2016) Risk assessment of Bt crops on the non-target plant-associated insects and soil organisms, *Journal of the Science of Food and Agriculture* 96:2613-2619 doi: 10.1002/jsfa.7661.
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.
5. Aldemita RR, Reaño IM, Solis RO, Hautea RA (2015) Trends in global approvals of biotech crops (1992–2014), *GM Crops Food* 6:150-166. doi: 10.1080/21645698.2015.1056972.
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.
7. Koch MS, Ward JM, Levine SL, Baum JA, Vicini JL, Hammond BG (2015) The food and environmental safety of Bt crops, *Frontiers in Plant Science* 6:283. doi: 10.3389/fpls.2015.00283.
8. Roberts A, Finardi-Filho F, Hegde S, Kiekebusch J, Klimpel G, Krieger M, Lema MA, Macdonald P, Nari C, Rubinstein C, Slutsky B, Vicien CI (2015) Proposed criteria for identifying GE crop plants that pose a low or negligible risk to the environment under conditions of low-level presence in seed, *Transgenic Research* 24(5), Springer International Publishing: 783–90. doi:10.1007/s11248-015-9899-z.
9. Singh D and Mathew IL (2015) The effect of *Bacillus thuringiensis* and Bt transgenics on parasitoids during biological control, *International Journal of Pure and App. Bioscience* 3:123-131.
10. CERA (2014) Low-level presence in seed : a science based approach to expedited environmental risk assessment, http://www.cera-gmc.org/files/cera/uploads/era_llp_in_seed_workshop_proceedings_2014.pdf.
11. Dubelman S, Fischer J, Zapata F, Huizinga K, Jiang C, Uffman J, Levine S, Carson D (2014) Environmental fate of double-stranded RNA in agricultural soils, *PLoS ONE* 9:e93155 doi:10.1371/journal.pone.0093155.

12. Garcia-Alonso M, Hendley P, Bigler F, Mayeregger E, Parker R, Rubinstein C, Satorre E, Solari F, McLean M (2014) Transportability of confined field trial data for environmental risk assessment of genetically engineered plants: a conceptual framework, *Transgenic Research* doi:10.1007/s11248-014-9785-0.
13. Roberts A, Devos Y, Raybould A, Bigelow P, Gray A (2014) Environmental risk assessment of GE plants under low-exposure conditions, *Transgenic Research* 23:971–83. doi:10.1007/s11248-013-9762-z.
14. Carstens K, Cayabyab B, De Schrijver A, Gadaleta PG, Hellmich RL, Romeis J, Storer N, Valicente FH, Wach M (2013) Surrogate species selection for assessing potential adverse environmental impacts of genetically engineered insect-resistant plants on non-target organisms, *GM Crops and Food* 5(1) Taylor & Francis: 11–15. doi:10.4161/gmcr.26560.
15. Häggman H, Raybould A, Borem A, Fox T, Handley L, Hertzberg M, Lu MZ, Macdonald P, Oguchi T, Pasquali G, Pearson L, Peter G, Quemada H, Séguin A, Tattersall K, Ulian E, Walter C, McLean M (2013) Genetically engineered trees for plantation forests: key considerations for environmental risk assessment, *Plant Biotechnology Journal* 11:785–98. doi:10.1111/pbi.12100.
16. Herman RA, Price WD (2013) Unintended compositional changes in genetically modified (GM) crops: 20 years of research. *Journal of Agricultural and Food Chemistry* 61:11695-11701. doi: 10.1021/jf400135r.
17. Keese PK, Robold AV, Myers RC, Weisman S, Smith J (2013) Applying a weed risk assessment approach to GM crops, *Transgenic Research* September. doi:10.1007/s11248-013-9745-0.
18. Nicolai A, Manzo A, Veronesi F, Rosellini D (2013) An overview of the last 10 years of crop safety research, *Critical Reviews in Biotechnology* doi: 10.3109/07388551.2013.823595.
19. Petrick JS, Brower-Toland B, Jackson AL, Kier LD (2013) Safety assessment of food and feed from biotechnology-derived crops employing RNA-mediated gene regulation to achieve desired traits: a scientific review, *Regulatory Toxicology and Pharmacology* 66:167-176. doi: 10.1016/j.yrtph.2013.03.008.
20. Steiner H-Y, Halpin C, Jez, JM, Kough J, Parrott W, Underhill L, Weber N, Hannah C (2013) Evaluating the potential for adverse interactions within genetically engineered breeding stacks, *Plant Physiology* pp.112.209817. doi:10.1104/pp.112.209817.
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22. Sanvido O, Romeis J, Gathmann A, Gielkens M, Raybould A, Bigler F (2012) Evaluating environmental risks of genetically modified crops: ecological harm criteria for regulatory decision-making, *Environmental Science and Policy*, 15:82-91.

27 January 2018

23. Snell C, Bernheim A, Berge J-B, Kuntz M, Pascal G, Paris A, Ricroch AE (2012) Assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials: A literature review, *Food and Chemical Toxicology* 50:1134-1148.
<http://doi.org/10.1016/j.fct.2011.11.048>.