**CARTAGENA PROTOCOL ON BIOSAFETY**

**NOTIFICATIONS 2015-002 and 2015-088**

**UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES**

**AUSTRALIAN COMMENTS, 1 SEPTEMBER 2015**

Australia is responding to the invitation[[1]](#footnote-1) to Parties to the Cartagena Protocol (the Protocol), and other Governments to submit to the Executive Secretary:

1. Information on actual cases of unintentional transboundary movement and case studies related to their existing mechanisms for emergency measures in case of unintentional transboundary movements of living modified organisms that are likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, including information on existing rapid alert mechanisms and monitoring systems; and
2. Views on what constitutes unintentional transboundary movements in contrast with illegal transboundary movements and what type of information should be exchanged through the Biosafety Clearing-House

Australia thanks the Secretariat for the opportunity to provide input on this issue.

**Background**

In Australia, genetically modified organisms (GMOs) (equivalent to living modified organisms (LMOs)) are regulated under the *Gene Technology Act 2000*, in order to protect human health and the environment from risks posed by GMOs. Australia’s GMO regulatory system is administered by the Gene Technology Regulator, supported by the Office of the Gene Technology Regulator (OGTR).

All dealings with GMOs in Australia, including import, must be authorized under the *Gene Technology Act 2000*. Authorization of dealings involving the intentional release of GMOs to the environment normally requires application for a licence from the Gene Technology Regulator. Import of organisms into Australia may also require authorization from the Department of Agriculture under the *Quarantine Act 1908* or the *Biosecurity Act 2015[[2]](#footnote-2)*. There are significant penalties for dealing with GMOs without a licence.

The licence authorisation process requires the Gene Technology Regulator to prepare of a risk assessment and risk management plan, consult with other Australian government agencies and technical experts and the Australian public. All Australian environmental release assessments and approvals are listed on the GMO Record <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/gmorec-index-1>

Australia recognizes the issues raised by the potential for unauthorized (unintentional or intentional) transboundary movement of LMOs, including the potential effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. Australia also recognizes that in relation to LMOs that this issue is variously referred to as low level presence (LLP) or unintended presence (UP) and that there has been significant and ongoing activity in various international fora, including in relation to environmental risk/safety assessment in LLP situations and in relation to assessment or management of LLP situations involving LMOs for food, feed or processing (LMO-FFP).

Australia has developed an Unintended Presence strategy to address the possibility of unauthorized environmental release of LMOs (see below). Australia’s approach to the potential for unauthorized transboundary movements of LMOs has been informed by Australia’s geography, agricultural production systems and commodity trading situation (eg level of imports). Australia is an island state and has no contiguous borders with other countries. As a result Australia’s focus is on the potential for transboundary movements through imports. It may also be noted that Australia imports very limited quantities of bulk (live and viable) grain commodities.

**Cases of unintentional transboundary movement**

Australia has not identified any cases of unauthorised transboundary movements and release to the environment of LMOs (intentional or unintentional) and consequently there have been no adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

In 2005, a case of unintentional importation of genetically modified (GM) tomato seeds was identified in Australia. The imported tomato seeds were supposed to be conventional (non-GM) and intended for contained research. However the supplier subsequently identified and advised the importer that GM tomato seeds had been mislabeled as non-GM. There was no release to the environment and following investigation it was “determined that there was full control of the GM tomato seeds at all times whilst they were in Australia and the risk to human health and safety and the environment was assessed as negligible.” Further details are available on the OGTR website: <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/qrtreports2004-2005-3/$FILE/mar2005qrpt.pdf>

This case illustrates that human error (eg mislabeling a LMO) has the potential to result in unintentional transboundary movement.

***Transboundary Movements – factors affecting practical occurrence***

Australia has noted the submissions already made by some Parties and observes that the ‘pathways’ for transboundary movement (whether unintentional or illegal) fall into two categories:

1. **Direct human agency** causing or leading to transboundary movement e.g. import/transport, human error (eg mislabeling); and
2. **Biological agency** causing or leading to transboundary movement e.g. pollen or seed movement by wind, water or animals (ie occurs naturally without human agency).

Depending on a given country’s geographical (eg contiguous borders) and agricultural production context, and of (any) neighboring countries or trading partners, consideration of these two pathways may be relevant to considering the potential for unintentional or illegal transboundary movements of unauthorized LMOs.

**Emergency measures in the case of unintentional transboundary movements likely to have significant adverse effects**

Australia has not had to implement emergency measures, as there have been no cases of unauthorized transboundary movement of LMOs to date,. However in the event of detection of unapproved LMOs, appropriate responses would be determined on a case-by-case risk management basis. In the event of an unauthorized transboundary movement of an LMO that posed risks to human health or the environment, Australian Government agencies would develop and implement a response to manage any risks to people or the environment. Any responses would be informed by science based risk assessment and consultation with states and territories and relevant industry organisations. Any response would also take account of any compliance actions necessary in relation to breaches of Australian law.

**Existing rapid alert mechanisms and monitoring systems**

Given that Australia is an island nation with no contiguous borders with other countries, the focus of the approach to potential unauthorized transboundary movements of LMOs is on imports. As noted above, Australia imports bulk grain commodities only infrequently and in small amounts.

***Australia’s National Unintended Presence Strategy***

Australia has developed a National Unintended Presence Strategy for Unapproved GMOs (UP Strategy). It is focused on imported seeds for sowing. The UP Strategy is led by the OGTR but involves coordination with other government agencies and voluntary engagement by industry, in particular a voluntary auditing and testing program of industry quality assurance measures.

Australia’s Unintended Presence Strategy has six main components: risk profiling, quality assurance and identity preservation, industry testing, advance risk assessments, post market detection and enforcement action. These are described in Table 1.

Further details are available on the OGTR website: <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/mon-unintended-1>

**Illegal transboundary movements**

Australia does not have any comments to offer on what constitutes illegal transboundary movements under Article 25 of the Protocol, noting that this would have implications for the operation of Article 34 (Compliance). Australia notes however that in the case of commercial trade (eg in bulk commodities), the ‘actors’ involved are often not countries but private business entities.

The term ‘intention’ has a specific legal meaning in Australian domestic law and is important in establishing culpability in relation to illegal actions and determined on the basis of knowledge and/or recklessness. Under Australia’s gene technology legislation, a person is guilty of an offence if the person deals with a GMO, knowing that it is a GMO (and the person knows or is reckless to the fact that the dealing is not authorised or otherwise exempt from authorisation requirements).

**Information relevant to unintentional (unauthorised) transboundary movements**

As noted above, a number of international fora have developed guidance documents to assist countries and regulators to respond to situations of LLP of unauthorised GMOs or GM products. Australia notes the work of the OECD and the Codex Alimentarius Commission, in particular documents providing guidance on risk/safety assessments in LLP situations:

**OECD** – ENV/JM/MONO(2013)19 – Low Level Presence of Transgenic Plants in Seed and Grain Commodities: Environmental Risk/Safety Assessment, and Availability and Use of Information - <http://www.oecd.org/science/biotrack/> and

<http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2013)19&doclanguage=en>

**CODEX** – Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA plants CAG/GL 45-2003, Annex 3: Food Safety Assessment in Situations of Low-Level Presence of Recombinant DNA Plant Material in Food <http://www.fao.org/fileadmin/user_upload/gmfp/docs/CAC.GL_45_2003.pdf>

Australia understands that this OECD document is already available through the BCH.

Australia also notes that there is other international work being undertaken relevant to unintentional transboundary movements as a result of LLP situations.

Australia has endorsed the ***International Statement on Low Level Presence****[[3]](#footnote-3)* and in doing so has decided *inter alia* to work collaboratively with importing and exporting countries on the issue of low level presence (the ‘Global Low Level Presence Initiative’, GLI) to facilitate international trade of agriculture commodities by developing practical approaches, designed to address low level presence globally.

It may be noted that asynchronous approvals between jurisdictions is one of the issues identified as contributing to the occurrence of LLP situations. Asynchronous approval of GM crops or commodities (eg LMO-FFP) refers to situations where a GMO may have been assessed and approved in an exporting country (and other countries) but an assessment and/or approval has not occurred in an importing country. Reducing asynchronous approvals may contribute to reducing the incidence of LLP situations and this may be aided by timely submission of applications by developers and timely assessment and decisions on applications by individual jurisdictions.

The **UN Food and Agriculture Organisation** has also undertaken work in relation to LLP, including a technical consultation in 2014 and published two reports which may be considered for inclusion in the BCH:

FAO (2014) Consultation on Low Levels of Genetically Modified (GM) Crops in International Food and Feed Trade. Rome, Italy, 20-21 March 2014. Technical Background Paper 1. Low Levels of GM crops in food and feed: Regulatory issues <http://www.fao.org/fileadmin/user_upload/agns/topics/LLP/AGD803_2_Final_En.pdf>

FAO (2014) FAO Commodity and Trade Policy Research Working Paper No. 44 – Low Levels of Genetically Modified Crops in International Food and Feed Trade: FAO International Survey and Economic Analysis. <http://www.fao.org/docrep/019/i3734e/i3734e.pdf>

Australia also notes that the **International Life Sciences Institute Research Foundation** has recently published a paper relevant to risk assessment of LLP situations:

Roberts, A.; Finardi-Filho, F.; Hegde, S.; Kiekebusch, J.; Klimpel, G.; Krieger, M.; Lema, M.A.; Macdonald, P.; Nari, C.; Rubinstein; C.; Slutsky, B.; Vicien, C. (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**. DOI 10.1007/s11248-015-9899-z. <http://link.springer.com/article/10.1007/s11248-015-9899-z?wt_mc=email.event.1.SEM.ArticleAuthorOnlineFirst>

**Information that should be exchanged through the Biosafety Clearing-House**

Australia considers the current inclusions for notifications via the Biosafety Clearing-House, as set out in Article 17 of the Protocol to be appropriate.

Australia supports the importance of information sharing between countries and industry in situations where unauthorised transboundary movements of GMOs occur, in particular to obtain information on which to base risk management decisions. Risk assessments available through the BCH, OECD BioTrack or from national regulators are an important source of information to inform considerations of whether a particular LMO might pose a risk to a country’s biodiversity.

**Table 1 – Six key components of Australia’s Unintended Presence Strategy**

| **Component** | **Description** |
| --- | --- |
| **Risk profiling**—identifying seed imports posing the highest likelihood of unintended presence | Data on imported seeds for sowing together with information on overseas approvals and commercial production of GMOs was used to identify 12 priority crops: canola, cotton, maize, potato, tomato, papaya, soybean, squash, alfalfa, grasses, rice and wheat |
| **Quality assurance and identity preservation** | Industry uses quality assurance and identity preservation systems for seed quality purposes. The OGTR has developed a program for auditing and testing industry quality assurance systems that industry has agreed and adopted. |
| **Industry testing** | The voluntary code of conduct refers to testing programs. Industry needs to be able to assure itself that it is managing the risk of importing unapproved seeds. |
| **Advance risk assessments** | The OGTR has prepared GMO incident response documents for 12 crops identified through risk profiling as having the highest likelihood of unintended presence in imports of seeds for sowing. These documents will provide a basis for rapid risk assessment and management actions should an unintended presence of an unapproved GMO be detected. |
| **Post-market detection** | The OGTR has worked cooperatively with industry to develop a voluntary code. The code aims to isolate risks as early as possible in the commercial seed supply chain. This is supported by the standard OGTR practice of investigating information about potential and possible incidents. |
| **Enforcement action** | In the event of detection of unapproved GMOs, appropriate responses would be determined on a case-by-case risk management basis. The OGTR continues engagement with Australian Government agencies, relevant industry organisations and states and territories on this issue. |

1. Refer to decision BS-VII/10 the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety [↑](#footnote-ref-1)
2. The *Biosecurity Act 2015* will commence on 16 June 2016 and will replace the *Quarantine Act 1908*. [↑](#footnote-ref-2)
3. Vancouver, Canada, March 22, 2012 see <http://www.agriculture.gov.au/ag-farm-food/biotechnology/international-statement-low-level-presence> [↑](#footnote-ref-3)