

Questionnaire on environmental risk/safety assessment of plants developed with New Plant Breeding Techniques (NPBT).

COUNTRY:

Contact details:

Preamble

Science is continuously developing new techniques for advancing plant breeding. It is important to begin to understand whether and how countries are contemplating regulation and environmental risk/safety assessment (ER/SA) of the ever-evolving continuum of emerging plant products and the biotechnologies used to develop them. Certain these new techniques have been identified by some as New Plant Breeding Techniques (NPBT, Lusser *et al*, 2012)¹. Examples include:

- Agro-infiltration
- Cisgenesis/intragenesis
- Grafting on GM rootstock
- Oligonucleotide directed mutagenesis (ODM)
- Reverse breeding
- Site-directed nucleases (e.g. zinc finger nucleases)
- RNA-dependent DNA methylation

However, we want to understand what types of plants and techniques are currently being discussed in countries **whether or not they are included in these examples.**

Workshop

At the 27th meeting of the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology it was agreed to have a workshop on NPBT, 10th February, 2014, in association with the upcoming 28th meeting of the Working Group. To prepare for the Workshop it was agreed to circulate a questionnaire to the delegates in order to provide input for discussions. This questionnaire was developed to obtain an understanding of the types of plants under development, the phenotypic changes being introduced and the new technologies deployed to develop them.

The upcoming workshop will likely be composed of several aspects including: 1) an overview of the science behind the application of some techniques, 2) presentations by specific countries and 3) discussion. In addition, the workshop may set the stage for future project proposal(s) to be developed. **The goal of this questionnaire is to characterise the perspective from which countries identify, address and assess new plants and NPBTs being used to develop them, particularly from an ER/SA perspective.** Ultimately, the responses can serve to guide the scope of work for future OECD discussions and projects in this area.

¹ Lusser *et al*. (2012), "Deployment of New Biotechnologies in Plant Breeding", *Nature Biotechnology*, 30, pp. 231-239.

We would like to receive responses to the questionnaire **by 30th November 2013** in order that we might use the information relayed to best advantage in preparations for the workshop and during the workshop itself, as well as in the subsequent meeting of the Working Group. We realize that this does not allow a lot of time for preparation of a response, so be assured that if a project is developed subsequently in which it would be advantageous to include country responses, it will be possible to add additional information later.

Question I

Does your country consider NPBT? Which techniques does your country consider as NPBT?

Australia (Office of the Gene Technology Regulator; OGTR) regulates environmental release of GMOs on a case-by-case basis. We have no specific category for plants developed using NPBT.

Food Standards Australia New Zealand held a workshop in 2012 on NPBTs and food safety assessments. The workshop report is available at <http://www.foodstandards.gov.au/consumer/gmfood/Pages/New-plant-breeding-techniques-in-the-spotlight.aspx>. Australia (OGTR) also participated in a European Commission JRC workshop on NPBT in 2011, and with industry and other Australian Government agencies in a 2013 ILSI workshop on NPBTs. These workshops discussed the techniques defined as NPBT by Lusser et al (2013).

Question II

Is your country seeing any plants developed with NPBT in the private or public sector (industry and/or academia)?

We are not aware of any proposals for imminent commercialisation of plants developed using NPBT in Australia. Due to the role of the OGTR in administering the *Gene Technology Act 2000* we have received queries from a range of correspondents about the regulation of plants developed using NPBT for environmental release. These are addressed on a case-by-case basis directly with the correspondent.

If yes,

(a) please describe this plant and the phenotypic change(s) introduced.

(b) please describe the NPBT involved in the development of the plant.

(c) when do you anticipate that a developer will apply for commercial release for this plant?

Question III

Does your country have any practical experience in performing an environmental risk/safety assessment on plants developed with NPBT?

The OGTR has assessed an application for limited and controlled release (contained field trial) for ryegrass and tall fescue genetically modified for improved forage qualities (DIR 082/2007) which contained some plants which would fit the general categorisation as 'intragenesis' (although the trialled plants also had a selectable marker which would/could be bred out at later date)

If yes,

(a) which technique(s) were involved?

Some of the GM grass plants contained constructs, introduced by biolistics, consisting of endogenous genes, promoters and terminators. The constructs also contained a selectable

marker gene which could be bred out at a later date. These plants could be described as intragenics.

(b) did you encounter any new environmental risk/safety assessment issues?

No, the risk assessment followed the case-by-case assessment process followed by the OGTR to assess any release of a GMO. This is detailed in the Risk Assessment Framework available on the OGTR website at [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/42D3AAD51452D5ECCA2574550015E69F/\\$File/raffinal5_2.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/42D3AAD51452D5ECCA2574550015E69F/$File/raffinal5_2.pdf). Please note that this document has been updated since the DIR 082/2007 assessment, to include the modified post-border weed risk assessment methodology used by the OGTR as part of the environmental risk assessment (Keese et al 2013). [This weed risk assessment methodology considers the modified phenotype, irrespective of the mechanism used to make the modification.]

(c) did your country issue any specific guidance or recommendations on environmental risk/safety assessment?

No

(d) have any environmental risk/safety assessments for plants developed with NPBT been made available to the public?

Yes, the full risk assessment for DIR082/ is available on the OGTR website at <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/DIR082-2007>

(e) please provide all relevant reports, guidance documents and links, if possible.

If no,

(a) do you expect plants developed using NPBT will give rise to new issues in environmental risk/safety assessment and, if so, what are those issues?

Question IV

Have the public or private sector (academia and/or industry) provided their perspective regarding environmental risk/safety assessment of plants developed with NPBT?

(a) If yes, please describe them.

The Australian system is application based. Applications to the OGTR for environmental release of a GM plant are publically notified. The OGTR also undertakes extensive consultation on risk assessments with the public, regulated community and other prescribed stakeholders, including gene technology advisory committees.

Biotechnology is a fast moving field with continuing advances in gene technology. It can prove challenging for legislation to keep up with recent developments. The ability of the Australian *Gene Technology Act 2000* to keep up with developments in biotechnology was raised in the recent review of the Act, which was also open for public comment. The review and the Governments' response to the review recommendations is available on the Department of Health website: <http://www.health.gov.au/internet/main/publishing.nsf/Content/gene-techact-review>. The Governments' response has indicated that appropriate regulation of new technologies is an area which requires follow-up work and this will also include consultation.

Question V

Are there other questions on NPBTs do you consider to be of importance in your country?

Australia's regulatory system is designed to manage risks to human health and safety and the environment in a manner commensurate with the potential risk. As in a number of other jurisdictions, the scope of regulation is determined by the definitions in the legislation. Australia is interested in how other jurisdictions envisage these new techniques fitting in with their current regulatory system and what steps they are taking to ensure that they are appropriately regulated and to inform an ongoing review of regulation and ERA. However, we consider that these discussions of definitional coverage fall outside the scope of this OECD NPBT workshop and involve policy and legal questions which are matters for individual jurisdictions..

Question VI

What do you consider to be important objectives and outcomes for the OECD workshop (10th February 2014)? Are there NPBT that are of particular interest to your country?

Focus on environmental risk assessment should be maintained

Biotechnology is a rapidly developing field, and is generating new techniques that may be of interest to the working group in the future. One of these techniques is exogenous application of RNAi to transiently elicit desired traits.

Delegates are invited to **submit relevant background information and suggestions** for the content of the workshop on NPBT and environmental risk/safety assessment **by 30th November 2013**. Inputs will be made available to all delegates on the Working Group protected website.

References

Keese, PK; Robold, AV; Myers, RC; Weisman, S; Smith, J (2013) Applying a weed risk assessment approach to GM crops. Transgenic Research DOI 10.1007/s11248-013-9745-0
<http://link.springer.com/article/10.1007/s11248-013-9745-0>