Briefing: GMO deregulation through the back door

Proposed changes to the Food Standards Australia New Zealand Act 1991 would delete the definitions of GMO (genetically modified organism) and GM product from Section 4 of the Act.[1] Once they are gone the only definitions remaining are those in the Food Standards Code (Standard 1.5.2) which are not as broad and could be amended without Parliamentary debate. The Bill also removes FSANZ's requirement to notify the Gene Technology Regulator of any of its food regulatory measures that relate to food that is or contains a GMO or a GM product. There is no coherent justification for either change in the Explanatory Memorandum for the Bill.[2] It also appears that the Government has not discussed these proposed changes with either the state governments or the New Zealand Government.[3]

We are concerned that these changes pave the way for the deregulation of a range of un-assessed new GM techniques and are calling for:

- All members of the Legislative and Governance Forum on Food Regulation to be consulted on the changes.
- The matter to be referred to Committee to examine the full implications of the changes.
- A moratorium on the commercialisation of these techniques until our regulatory system for GMOs is adapted to deal with the potential risks posed by them.

Why is FSANZ doing this?

The definition of GMO in the Food Standards Australia New Zealand Act 1991 is currently the same as that in the Gene Technology Act 2000 refers to an organism (or progeny of an organism) that has been modified by gene technology. The Act defines gene technology as "any technique for the modification of genes or other genetic material". [4] This definition would clearly include new GM techniques unless they were specifically exempted. We are concerned that by deleting this definition from the Act FSANZ is attempting to deregulate these techniques by stealth. The definition of gene technology in Food Standards Code is not as broad and is defined as "recombinant DNA techniques that alter the heritable genetic material of living cells or organisms". Certain new GM techniques such as RNA interference may not be covered under this definition. The full implications of these changes in the context of new GM technologies need full examination before these amendments are considered.

What techniques does FSANZ want to deregulate?

In 2012[5] and 2013[6] FSANZ convened an expert panel – comprised almost entirely of genetic engineers with a vested interest in the technology – to look at whether a range of new techniques would be considered genetic engineering. These techniques included:

Oligo-directed mutagenesis (ODM)
This involves introducing short DNA fragments (oligonucleotides) into cells which trigger the cell to modify its own DNA to match the introduced DNA fragments - allowing targeted mutations to be introduced.[7] This technique can change, insert or delete one or a few base pairs of DNA.[8]

Site-directed nucleases (SDNs)
These techniques - also referred to as site-specific nucleases (SSN)[9] - use enzymes to cut DNA at specific sites so that genes can be deleted or new genes inserted. The cut DNA is repaired by the natural DNA repair systems of the plant. There are currently four major classes of SDNs: meganucleases, zinc finger nucleases (ZFNs), transcription activator-like effector nucleases (TALENs), and clustered regularly interspersed short palindromic repeats (CRISPR)/Cas9 reagents.

Not surprisingly, given their background, the scientists concluded that "when used to introduce small changes only, such techniques do not present a significantly greater food safety concern than other forms of mutagenesis. Providing any transgenes have been segregated away from the final food producing lines, derived foods would be similar to food produced using traditional mutagenic techniques. Such foods should therefore not be regarded as GM."[10] This conclusion is in marked contrast to recent research papers on the topic, which have found numerous unintended mutations in organisms modified using these techniques.[11] It is also a conclusion that contradicts the current definitions of GMO in the Food Standards Act.

What are the risks associated with these techniques?

The concerns associated with the use of these new GM techniques are the same as those raised by traditional genetic engineering. These include food safety concerns,[12] environmental impacts - including those on biodiversity[13]- and GM contamination of neighbouring non-GM crops or wild relatives.[14]

Unexpected effects

The main concern regarding these new GM techniques, as with traditional genetic engineering, is that they can unintentionally interfere with the functioning the plant's genome. Unintended changes to plant chemistry may result from:

- unforeseen interactions between the new or altered gene(s) and the plant's genes;
- gene irregularities arising from the genetic engineering process itself; and
- unintended alterations to plant biochemical pathways arising from the changed or new function(s) of the altered or new gene(s).

Although new GM techniques such as ODM, CRISPR, ZFN and TALENs have been touted as much more precise than genetic engineering (which was also touted as precise when it was introduced), off-target mutations have been found to occur with all of these techniques.[15]

Scientists have raised concerns that off-target mutations could result in the production of immunogenic or potentially even allergenic proteins. This is illustrated by the case of a GM pea developed by CSIRO that was found to cause significant immune responses and inflammation in the lungs of mice. [16] Notably, had this pea, which contained a closely related legume gene, gone through the normal assessment process for GM crops and food in Australia it would have been approved for human consumption - since our regulators do not require these types of feeding trials.[17]

There is also a danger that changes to plant genetic material, both intended and unintended, could unexpectedly alter the chemical composition of plants[18]. This could affect the nutritional quality or even the toxicity of the GM food/feed product.

These techniques pose unknown risks and need to be regulated

A review of these techniques commissioned by the Norwegian Government concluded that "these techniques are too new to make strong claims that all outcomes are predictable and

known".[19] Many of these GM techniques are new so it is not yet possible to fully evaluate the potential for unintended changes. However, it is evident that unintended changes to genetic material cannot be excluded, and indeed, might even be expected. Although more targeted than the random insertion of genes into plant genomes seen with traditional genetic engineering, the potential for unforeseen genomic interactions, genomic irregularities and unintended biochemical alterations still remains with new GM techniques.

A recent review commissioned by the Norwegian Government stresses the limitations in our understanding regarding the potential adverse effects of these new GM techniques. The authors argue that:

> *"according to the requirements of a scientifically based risk assessment and the application of the precautionary principle, further biosafety needs to be performed* a *priori to commercial release."* [20]

Friends of the Earth is calling for a moratorium on the commercialisation of these techniques until our regulatory system for GMOs is adapted to deal with the potential risks posed by them.

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[1] The Food Standards Australia New Zealand Amendment (Forum on Food Regulation and Other Measures) Bill 2015, http://parlinfo.aph.gov.au/parlInfo/download/legislation/ems/r5542_ems_0c02f9d0-bbf2-4b81-8f05-21b496ccc90e/upload_pdf/503834.pdf;fileType=application%2Fpdf

[2] http://parlinfo.aph.gov.au/parlInfo/download/legislation/ems/r5542_ems_0c02f9d0-bbf2-4b81-8f05-21b496ccc90e/upload_pdf/503834.pdf;fileType=application%2Fpdf

[3] Legislative and Governance Forum on Food Regulation communiqués, http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-communiques.htm; Food Standards Australia New Zealand Amendment (Forum on Food Regulation and Other Measures) Bill 2015 Second Reading Speech, 17th September 2015, http://parlinfo.aph.gov.au/parlInfo/genpdf/chamber/hansardr/108deaf7-f29c-4e1f-96aa-3f9b4ff9bf1a/0029/hansard_frag.pdf;fileType=application%2Fpdf

[4] Gene Technology Act 2000, https://www.comlaw.gov.au/Details/C2011C00539

[5] FSANZ (2012) New Planting Breeding Techniques: Report of a Workshop Hosted by Food Standards Australia New Zealand, http://www.foodstandards.gov.au/publications/Documents/New%20Plant%20Breeding%20Techniques%20Workshop%20Report.pdf

[6] FSANZ (2013) New Planting Breeding Techniques: Report of a Workshop Hosted by Food Standards Australia New Zealand, August 2013, http://www.foodstandards.gov.au/publications/Documents/New%20Plant%20Breeding%20Techniques%20-2013%20Workshop%20Report.pdf

[7] For a fuller explanation see Eckerstorfer, M. *et al.* (2014) *New plant breeding techniques: risks associated with their application*, Austrian Environment Agency, http://www.ekah.admin.ch/fileadmin/ekah-dateien/New_Plant_Breeding_Techniques_UBA_Vienna_2014_2.pdf p. 16-17.

[8] Agapito-Tenfen, S.G. & Wikmark, O-G (2015) *Current status of emerging technologies for plant breeding: Biosafety and knowledge gaps of site directed nucleases and oligonucleotide-directed mutagenesis*, p. 4, http://genok.no/wp-content/uploads/2015/06/250615_Emerging_technologies_final.pdf

[9] Eckerstorfer, M. *et al.* (2014) p. 22.

[10] FSANZ (2013) p. 10.

[11] For an overview see Eckerstorfer, M. *et al* (2014) and Agapito-Tenfen, S.G. & Wikmark, O-G (2015)

[12] Hilbeck, A. *et al.* (2015) No scientific consensus on GMO safety. *Environmental Sciences Europe* **27**: 4 doi 10.1186/s12302-014-0034-1

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[14] Price, B., & Cotter, J. (2014) The GM Contamination Register: a review of recorded contamination incidents associated with genetically modified organisms (GMOs), 1997-2013. *International Journal of Food Contamination*, **1**: 5.

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[19] Agapito-Tenfen, S.G. & Wikmark, O-G (2015), p. 33.

[20] Agapito-Tenfen, S.G. & Wikmark, O-G (2015), p. 35.