



## The Government is weakening the regulation of GMOs

The Australian government is tearing up regulations that were put in place to protect us from potentially dangerous genetically modified organisms (GMOs). Changes to the Gene Technology Regulations currently tabled in Federal Parliament will allow anyone to genetically modify animals, plants and microbes - posing major risks to the environment and human health.<sup>1</sup> This would leave the majority of new CRISPR and other gene editing applications unregulated.

## New GM techniques pose unknown risks and need to be regulated

In July 2018, the European Union's top court ruled that new GM techniques such as CRISPR pose similar risks to older GM techniques and need to be assessed for safety in the same way.<sup>2</sup> This ruling is consistent with the findings of reviews commissioned by the Austrian<sup>3</sup> and Norwegian<sup>4</sup> Governments. These concluded there is insufficient knowledge regarding the risks posed by these techniques and products derived from them, so they require a comprehensive case-by-case risk assessment. Because of these risks, over 60 international scientists have signed a statement calling for these GM processes to be strictly regulated.<sup>5</sup>

Other countries have taken a more precautionary approach than Australia's. In 2016 our key agricultural competitor New Zealand announced it will regulate organisms derived from these techniques as GMOs.<sup>6</sup>

## Gene editing is not as precise as previously thought

More evidence<sup>7</sup> is coming to light about the potential environmental and human health risks posed by the new GM techniques, belying the biotechnology industry's claims that they are precise and predictable. For example, a recent study in *Nature Biotechnology* found that in around a fifth of cells, CRISPR causes unexpected deletions or rearrangements more than 100 DNA letters long.<sup>8</sup> Given these risks, a recent peer-reviewed study concluded that assuming these GM processes are safe "lacks a robust scientific basis".<sup>9</sup>

## Our regulators are failing us

Both the Office of the Gene Technology Regulator (OGTR) and FSANZ relied on advice from scientists with serious conflicts of interest when arriving at their recommendation to deregulate these techniques.<sup>10</sup>

The OGTR consulted its Gene Technology Technical Advisory Committee (GTTAC). The Gene Tech Regulations clearly state that members of GTTAC with possible conflicts of interest in a topic must not participate in any Committee decision on that matter. However, FOI documents reveal that scientists with serious conflicts of interest led the GTTAC discussion of these techniques and advised the OGTR that they posed risks no different to conventional breeding. This opinion is starkly at odds with those of government agencies overseas.<sup>11</sup>

In 2012 and 2013 FSANZ convened an expert panel – comprised almost entirely of genetic engineers with gene technology patents – to look at whether these new GM techniques should be considered genetic engineering. Not surprisingly, the panel concluded that the majority of these methods did not pose food safety concerns, and could either be deregulated or undergo a simplified form of food safety assessment. Furthermore, FSANZ appears to have deliberately misled the Senate when it claimed it was "not aware



that any members of the expert panel have potential conflicts of interest.” From subsequent statements it is clear that FSANZ was aware of these potential conflicts of interest and simply chose to ignore them.<sup>12</sup>

It's time our regulators stopped letting industry write the rules for them and put public health and our environment before private profit.

## What needs to happen?

Friends of the Earth is calling for:

- Parliament to disallow the Gene Technology Amendment (2019 Measures No. 1) Regulations 2019;<sup>13</sup>
- Products derived from all GM techniques to be subject to a comprehensive case-by-case risk assessment - including full molecular characterisation and independent safety testing - to ensure they are not harmful to human health or the environment;
- All products derived from GM techniques to be labelled to protect choice for farmers, producers and consumers.

## For more information contact:

Louise Sales, Friends of the Earth, Mob: 0435 589 579; Email: [louise.sales@foe.org.au](mailto:louise.sales@foe.org.au)

<sup>1</sup> *Gene Technology Act 2000—Gene Technology Amendment (2019 Measures No. 1) Regulations 2019* [F2019L00573], [https://www.aph.gov.au/Parliamentary\\_Business/Bills\\_Legislation/leginstruments/senate-dissallowable-instruments](https://www.aph.gov.au/Parliamentary_Business/Bills_Legislation/leginstruments/senate-dissallowable-instruments)

<sup>2</sup> Court of Justice of the European Union (2018) PRESS RELEASE No 111/18, available at: <https://cloud.foeeurope.org/index.php/s/okMF4jP4agmsZgW#pdfviewer>

<sup>3</sup> Austrian Agency for Health and Food Safety (AGES) (2012) *Cisgenesis. A report on the practical consequences of the application of novel techniques in plant breeding*. Report for the Austrian Federal Ministry of Health; Austrian Agency for Health and Food Safety (AGES) (2013) *New plant breeding techniques. RNA-dependent methylation, Reverse breeding, Grafting*. Report for the Austrian Federal Ministry of Health; Eckerstorfer, M., Miklau, M. & Gaugitsch, H. (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](http://www.ekah.admin.ch/fileadmin/ekah-dateien/New_Plant_Breeding_Techniques_UBA_Vienna_2014_2.pdf)

<sup>4</sup> 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, [http://genok.no/wp-content/uploads/2015/06/250615\\_Emerging\\_technologies\\_final.pdf](http://genok.no/wp-content/uploads/2015/06/250615_Emerging_technologies_final.pdf)

<sup>5</sup> ENSSER (2017) *ENSSER statement on new genetic modification techniques*, <https://ensser.org/news/ngmt-statement/>

<sup>6</sup> Smith, N. (2016) *GMO regulations clarified*, 5/4/16, <https://www.beehive.govt.nz/release/gmo-regulations-clarified-0>

<sup>7</sup> Eckerstorfer, M. F. *et al.* (2019) An EU Perspective on Biosafety Considerations for Plants Developed by Genome Editing and Other New Genetic Modification Techniques (nGMs), *Front. Bioeng. Biotechnol.*, 5/3/19, <https://www.frontiersin.org/articles/10.3389/fbioe.2019.00031/full>; Kwall, K. (2019) New Possibilities on the Horizon: Genome Editing Makes the Whole Genome Accessible for Changes, *Front. Plant Sci.*, 24/4/19, <https://www.frontiersin.org/articles/10.3389/fpls.2019.00525/full>

<sup>8</sup> Le Page, M. (2018) CRISPR gene editing is not quite as precise and as safe as thought, *New Scientist*, 16/7/18, <https://www.newscientist.com/article/2174149-crispr-gene-editing-is-not-quite-as-precise-and-as-safe-as-thought/>

<sup>9</sup> Eckerstorfer, M. F. *et al.* (2019)

<sup>10</sup> For more information see FoE (2018) Mutant Meat: will Australia deregulate genetically modified animals?, <http://emergingtech.foe.org.au/wp-content/uploads/2018/10/Mutant-Meat-Friends-of-the-Earth-Australia-2018.pdf>

<sup>11</sup> *Ibid.*

<sup>12</sup> *Ibid.*

<sup>13</sup> Gene Technology Amendment (2019 Measures No. 1) Regulations 2019. <https://www.legislation.gov.au/Details/F2019L00573>