14 November 2016

The Regulations Review
Office of the Gene Technology Regulator (MDP 54)
GPO Box 9848, Canberra ACT 2601
ogtr@health.gov.au

Dear OGTR,

RE: Technical Review of the Gene Technology Regulations 2001 - Options

GrainGrowers is a national grain farmer body with 17,500 members across Australia. It is also a grains industry representative organisation to which the Grains Research and Development Corporation consults and reports. Grain farmers should always have freedom of choice for the production systems and markets they use; be that genetically modified organisms, conventional, organic, or any combination of these.

The Gene Technology Regulator has initiated a technical review of the Gene Technology Regulations 2001 (*the Regulations*) to provide clarity about whether organisms developed using a range of new technologies are subject to regulation as genetically modified organisms (GMOs) and enable new technologies to be regulated in a manner commensurate with the risks they pose.

On behalf of our membership and the grains sector more broadly, we express our support for Option 4: Exclude certain new technologies from regulation on the basis of the outcomes they produce. This option would exclude organisms from regulation as GMOs if the genetic changes they carry are similar to or indistinguishable from the products of conventional breeding (e.g. chemical and radiation mutagenesis methods and natural mutations).

The reasons GrainGrowers supports Option 4 include:

- Genetic technologies which result in plant varieties developed through the latest breeding methods should not be differentially regulated based on the techniques employed during their development if they are similar to, or indistinguishable from, varieties that could have been produced through earlier breeding methods. This approach will promote innovation in plant variety development and provide enhanced choice for grain farmers.

- As noted in the discussion paper, gene technology regulation could exclude organisms indistinguishable from conventionally bred organisms as they do not pose different risks.

- GrainGrowers agrees with the Gene Technology Technical Advisory Committee that mutagenesis techniques based on cellular DNA repair, namely site directed nucleases (SDN-1, SDN-2) and oligo-directed mutagenesis (ODM) are unlikely to pose risks that are different to naturally mutated organisms. These techniques have been used in plants for the targeted mutagenesis of endogenous genes resulting in agronomically useful traits such as herbicide tolerance, enhanced nutrition, and resistance to biotic and abiotic stresses. An advantage of these techniques is that there will be much fewer off-target results (comparable to cross-breeding) than produced by

chemical and radiation mediated mutagenesis, theoretically making SDN-1, SDN-2 and ODM techniques safer than the currently unregulated chemical and radiation mutagenesis techniques. Chemical and radiation mutagenesis can result in random deletions and rearrangement of large (millions of base pairs) DNA sequences.

- We also acknowledge that drawing a line between SDN-2 and SDN-3 techniques will be difficult. However, as long as the principle that the same outcome could occur through conventional breeding or mutagenesis techniques, then a distinction can be made based on the organism. Single nucleotide mutations in plants would appear to occur at a rate of more than ten spontaneous mutations per generation. Larger rearrangements of sequences of nucleotides may occur via transposition of DNA, which often results in new genes, gene replication or deletion. For example, bread wheat is a hexaploid which evolved through hybridisation events followed by chromosome doubling to produce a plant with 3 pairs of chromosomes. These evolutionary mechanisms are considered to have a greater impact on genome sequence and function than gene insertion using genetic engineering. Plant breeders have hybridised wheat and rye followed by chromosome doubling using colchicine to produce triticale. So, determining if an organism produced by SDN-3 could occur via conventional breeding and/or mutagenesis is problematic from a process perspective. SDN-2 aims to make a site-specific modification to an organism's native DNA, whereas SDN-3 is used to insert a specific functional gene (either a transgene or cisgene). Therefore, because SDN-3 has the potential to produce both non-GM and GM organisms, it is appropriate to exclude organisms from regulation that are indistinguishable from conventionally bred organisms. As mentioned in the Discussion Paper it is more appropriate to consider Option 4 in the context of the upcoming review of the scheme for the Legislative and Governance Forum on Gene Technology.

- In terms of trade implications from Option 4, GrainGrowers supports Australia's continued involvement in international fora seeking to harmonise regulation of new technologies.

- With regard to other considerations in the review, GrainGrowers applies the same principles as expressed above in the decision to support Option 4:
  - Plants comprised of genetically modified (GM) parts grafted to non-GM parts are GMOs - ✓ but as FSANZ noted in the case of GM rootstock grafting, the majority of foods will not contain any novel genetic material or have altered characteristics and therefore should only require a simplified (food) safety assessment.
  - Null segregants are not GMOs - ✓
  - Organisms that are genetically modified in a transient manner (e.g. agroinfiltration) are GMOs while the genetic modification or trait is present, and are no longer GMOs once both the trait and genetic modification are no longer present - ✓
  - Schedule 1 Item 1 – the uncertainty surrounding Schedule 1 Item 1 of the Regulations should disappear using the principle that varieties developed through the latest breeding methods should not be differentially regulated based on the techniques employed during their development if they are similar to, or indistinguishable from, varieties that could have been produced through earlier breeding methods.
  - Gene drives – this is more complex as gene drives occur in nature but the outcomes (from either natural, mutagenic or GM processes) have the potential for serious deleterious (as well

as beneficial) consequences. This is one area where a case-by-case assessment by the Regulator is warranted.

- RNA interference – again using the principle that varieties/organisms developed through the latest breeding methods should not be differentially regulated based on the techniques employed during their development if they are similar to, or indistinguishable from, varieties/organisms that could have been produced through earlier breeding methods will determine if organisms that have undergone RNA interference techniques should be regulated.

GrainGrowers proposes that clarity around whether organisms developed using a range of new technologies are regulated in a manner commensurate with the risks they pose is best addressed by Option 4: exclude certain new technologies from regulation on the basis of the outcomes they produce.

This is based on the premise that genetic technologies which result in plant varieties developed through the latest breeding methods should not be differentially regulated based on the techniques employed during their development if they are similar to, or indistinguishable from, varieties that could have been produced through earlier breeding methods.

If you require more information, please contact me ( ).

Kind regards,

Michael Southan
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