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Regulation Review, Office of the Gene Technology Regulator
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Nuseed appreciates the opportunity to provide comment on the Discussion paper: Options for regulating new technologies, as well as provide input to the Technical Review of the Gene Technology Regulations 2001.

Gene technology methods have continued development since the drafting and implementation of the *Gene Technology Act 2000* and *Regulations 2001*. Even with regular reviews the pace of change will outstrips legislation. New techniques have developed and are further developing so that a continuum of techniques now exists. The wording of some exclusions in Schedule 1, particularly item 1 which remains unchanged from the original GT Regulations, raises uncertainty about whether or not some new technologies are subject to regulation as GMOs.

The uncertainty has an immediate impact on research and development opportunities for a commercial enterprise. Development opportunities with a clear path to market would be favoured over those with less clarity, regardless of potential risk/benefits.

Further, there is a practical need to be able to detect and enforce legislation regarding GMOs and when this cannot be achieved compared to conventional breeding and mutagenesis, clarity in the legislation should be provided, as stated in the European review of new plant breeding techniques by Lusser *et al*., 2011.

> "The registration costs will be low if a technique is classified as non-GMO or very high if classified as GMO. Therefore, the legal status of the new plant breeding techniques will influence the decision on whether to use these techniques only for the introduction or modification of traits in crops with very high value or more extensively for a broad field of applications, and therefore will be of specific importance for small and medium enterprises."
> "The main constraints for the adoption of the techniques are the regulatory uncertainty and the potentially high costs for risk assessment and registration (if the crops derived by these techniques are classified as GMOs). Crops resulting from most of the techniques cannot be distinguished from conventionally bred crops and detection is therefore not possible."
> Maria Lusser *et al.* in 2011: http://ftp.jrc.es/EURdoc/JRC63971.pdf

This uncertainty goes against the central consideration of the OGTR technical review where organisms should be regulated commensurate with risk. Most of the new technologies discussed in the OGTR discussion paper can be perceived as having less risk than original gene technology approaches. In addition, scientific advances, method development and increased computing power since the development of the *Act 2000* and *Regulations 2001* have enabled a better prediction of any unintended effects and has reduced the inherent risk of all genetic techniques.

- Genome sequencing can be completed in a matter of weeks, rather than years.
- Open Reading Frame analysis is becoming more robust with growing scientific knowledge of nucleotides, amino acid sequences and protein translation as well as method sensitivity.
- Allergen/toxins databases are continually growing so that a sequence analysis for homology will provide better predictive confidence of a possible reaction or no reaction to a peptide sequence or protein.

A history of safe use and commercialization of various genetic technology products to date also adds weight of evidence to the reduced risk of these techniques.

Nuseed supports Option 4 of the discussion paper for Schedule 1A to include ODM, SDN-1 SDN-2 as techniques as a process exclusion. The Regulations should also consider using Schedule 1 for the exclusion of certain products where detection cannot be achieved, and reduced risk can be proven (i.e. null segregants). A more overt approach should be taken to explicitly name certain options that can be considered excluded under Schedule 1. Regulation of new technologies, if needed, should be based on sound scientific principles and proportional to any new potential risks to human health and safety or the environment.

RNAi

A position on RNAi technology should be given in the Regulations to remove uncertainty. Where RNAi is involved with transgenes it fits within the scope of a GMO; where no transgenes are involved the regulatory framework should be clarified. RNAi techniques that include silencing or modulating the expression of endogenous genes would fit into the same category as ODM, SDN-1 and SDN-2, in that no new genetic material has been introduced, and as such should be treated similarly (as excluded under Option 4). RNAi-based methods involving topical application of double-stranded RNA (dsRNA) for the purpose of silencing or modulating the expression of specific endogenous genes in a target organism should not be included in the scope of gene technology regulation, as they are sufficiently regulated by existing schemes for biological products.

FSANZ acknowledge that RNAi techniques have a different risk compared to defined GMOs and require a special dataset for RNAi technology products as explained in the most recent FSANZ Application Handbook 01Mar2016. FSANZ have also included clarity around cisgenesis and intragenesis with a reduced safety package regarding the expressed protein. The OGTR

should take the opportunity to provide a similar level of clarity regarding RNAi and other techniques under this review.

IBC responsibilities

Paragraph 4 (a) of the *Gene Technology Act* provides that the regulatory framework will provide "an efficient and effective system for the application of gene technologies" and to this end the OGTR has devolved certain responsibilities to accredited Institutional Biosafety Committees. IBCs have the responsibility of screening application, overseeing PC facilities and issuing NLRDs for work within those facilities.

With regard to PC facilities, once a facility has been built and inspected the certification process is a simple paper exercise with the OGTR and has a turnaround timeframe of 90 working days. Suspension of a certification and re-opening of a suspended facility is also a paper exercise with the OGTR. There are very clear guidelines for the requirements of the PC facility (all types) and annual checklists. The 90 working days translates to 4.5 months real time, and although the OGTR are open to requests for timeliness of certification, it is not a practical situation for a built and ready-to-go facility to lay dormant for over a third of a calendar year. Similarly even though suspension of a certification is swift, the removal of the suspension and re-opening of a facility has inherent delays.

Nuseed proposes that owner-initiated suspension of a PC facility can be handled more efficiently within the IBC, and therefore OGTR resources can be directed to better use. IBC's already have the ability to inspect and report on the suitability of a facility, and managing a temporary suspension within a certification period would not be outside of its capabilities. The OGTR could be informed to meet the requirements of the Act, but the IBC is capable of doing the "leg-work" on an owner-initiated suspension or on lifting an owner-initiated suspension. This option could be clarified under the Technical Review of the Gene Technology Regulations 2001.

Finally, the Regulation review while welcome and beneficial does not future-proof the legislation and this should be considered under this Technical Review as well as in the anticipated review of the *Gene Technology Act* in 2017. The pace of technology change will always outstrip legislative change and future-proofing consideration should be employed whenever possible.

Yours sincerely

Nuseed Pty Ltd