Updating Gene Technology Regulation in Australia

Feedback on the draft Regulations, from the Curtin University Institutional Biosafety Committee, Chaired by Dr Rob Steuart.

Consultation questions:

1. What is your preferred option? Please explain why.

We prefer Option 2 – amend the GT Regulations by introducing all elements of the draft amendments, as detailed in full in section 3 of the Consultation RIS. Although we have some questions about the proposed draft Regulations (outlined below), we have no major concerns about them. We feel that the redefinition of genetically modified organisms to not exclusively deal with inserted DNA is an important one and is very timely given the advent of CRISPR and other editing techniques. We also believe the OGTRs decision to not include SDN-1 type activities is fair as it gives researchers better control of random mutagenic processes.

2. Do the draft amendments clearly implement the measures described in Section 3 of the Consultation RIS? If not, which areas of the draft amendments do you think require additional clarification, and what clarification is needed?

Schedule 1A Item 11(a) – Introduction of RNA into an organism is not a GMO if it RNA cannot be translated into a polypeptide.
What are the mechanisms for regulation if the RNA is translated into a polypeptide? For example, the transient expression of GFP in cells that have been transfected with mature GFP mRNA?
In general, how will items not covered under Schedule 1A Item 11be regulated?

Schedule 1 Item 8.
We imagined a hypothetical situation where CRISPR was used to make a change to a particular trait causing gene in a random manner (SDN-1) and at the same time CRISPR was used to incorporate a GFP marker in another area in the genome. The GFP marker was used to select for positive CRISPR events and the resulting isolates are screened for those that contain the desired random SDN-1 mutation event. If these are then cross bred, are those isolates that are negative for GFP and positive for the SDN-1 change considered a GMO?

3. If your preferred option is Option 3, please indicate which amendments (or parts thereof) you support being progressed and why.

4. What are the costs and benefits to you or your organisation from the proposed amendments? To support further analysis of impacts, particularly changes to regulatory burden , OGTR encourages submitters to provide information on how the amendment proposals could directly impact them, including:

- the number of required NLRD, DNIR and DIR authorisations that would change (and in what way)
- how the need to maintain facility certifications would change, and
- how the amount of time needed to administer authorisations would change.

Please describe these compared to current arrangements, for each area of amendment:

4.1 Clarifying the GT Regulations to take technological developments into account (i.e. in relation to SDN-1, SDN-2, ODM and RNAi)

The costs would only be those expected from any update of the Regulations and have been budgeted into normal business operations. The benefit is a clarification of the Regulations that allows us to plan our research better.

4.2 Repeal of Schedule 1 item 1, specifically whether you currently work with organisms that are not GMOs solely because of this item

No effect.

4.3 Updating the categorisation of contained dealings with GMOs

The costs would only be those expected from any update of the Regulations and have been budgeted into normal business operations.

4.4 Clarifying the regulatory status of organisms derived from GMOs that are not themselves GMOs

The costs would only be those expected from any update of the Regulations and have been budgeted into normal business operations.

4.5 minor administrative changes.

The costs would only be those expected from any update of the Regulations and have been budgeted into normal business operations.

5. Are the proposals to change the classification of certain NLRDs and exempt dealings (identified in Appendix B of the Consultation RIS) commensurate with any risks to the health and safety of people and the environment posed by the dealings?

We would like to better understand the OGTRs reasoning for the changes to Schedule 2 Part 1 Item 5 that has changed the way that cDNA libraries expressed in non-bacterial vectors are to be regulated. Under the new proposed regulations any cDNA libraries expressed in *Saccharomyces cerevisiae* or *Picchia pastoris* would be considered an automatic NLRD. This would increase the administrative burden of the IBC and may impact on researchers' ability to do this work in Australia. We believe that the proposed changes confer too high a regulatory burden on a very low risk activity.

6. Are there any features in the options presented that you have concerns with? Or, are there any particular features that you believe should be included? Please explain why and give substantiating evidence where possible.

Given that non-replicative viral vectors are now considered a gene technology both within and without a host, what are the OGTRs thoughts on the impact of the sale of these within Australia, such as RediFect reagents from Perkin Elmer. Will the selling companies have to hold an NLRD? Will they have to ensure that all people they sell to provide an NLRD number before items can be shipped? Our concern is that the increased regulatory burden placed on vendors would cause them to remove these items from the Australian market, potentially impacting Australian researchers.

The regulations currently give emphasis to dealings that affect gene involved immune modulations or that are carcinogenic in nature. Although the OGTR has decided that RNAi technologies where mature interfering RNAs are delivered into a cell are not considered a

GMO, there is a potential risk posed by these types of technologies. An amendment to Schedule 1A Section 11 could include that the introduced RNA is not targeted against an immunomodulatory or tumour supressing protein.

Questions were raised about the use of the terminology GMO and the negative connotations that this has with some aspects of the community. Is there a different type of language that we can use that is less evocative with certain parts of the community?