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Updating Gene Technology
Regulation in Australia
Regulation Impact Statement for consultation
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Consultation questions

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

The VMDA is not able to support the adoption of all of the draft amendments (option 2). These do little to address the issues raised in our submission; the over-regulation of certain low risk vaccine strains of pathogenic organisms and the potential for identical organisms to be either regulated or excluded from regulation depending on how they were created. The deletion of Item 1 of Schedule 1, while reducing uncertainty by making explicit the GT Regulators current interpretation, is a move in the wrong direction. The argument provided for exclusion of SDN-1 from regulation under the GT act, that:*" they pose directly equivalent risks to organisms with natural mutations so that regulating these organisms would not be commensurate with the risks they pose, and reliably detecting organisms that might be indistinguishable from naturally occurring mutants or the products of techniques that are not gene technology presents a great challenge for enforcing compliance with the scheme"*, applies equally to any deletion mutant. The guiding principle that template directed sequence change is a hallmark of Gene Technology, while random substitution or deletion at a pre-determined site is not, is a regulatory convenience that is not justifiable on the basis of scientific assessment of risk. It entrenches a worldview that sees randomness as risk free while human directed changes necessarily entail significant risk of harm.
Item 1 of Schedule 1 permits an alternative interpretation, in which it is the addition of new, functional DNA sequences to the genome of an organism, beyond those that are available through natural mutation processes such as substitution, duplication and deletion, which constitute genetic modification. The deletion of Item 1 consolidates a more restrictive interpretation and further entrenches the perception that the use of gene technology is a negative thing, involving significant risk of harm, even when the end result is within the range of natural genetic variation.
As a consequence, the development of live veterinary vaccines for control of disease causing organisms is likely to be inhibited, and traditional mutagenesis methods will remain preferred for their low regulatory burden, despite presenting a level of risk that is at least equal to, if not greater than the use of biotechnology to create attenuated strains.

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?**

Organisms derived from GMOs that are not themselves GMOS: The reference to 'null segregants' suggests that this clause is intended to refer to diploid organisms with distinct chromosomes. A haploid organism such as a bacteria or virus may lose a genetic modification through a natural process of mutagenesis (spontaneous deletion) following passage *in vitro*. Is it intended that, for instance, a virus that has lost a marker gene such as *gfp* following *in vitro* passage, also losing part of the gene in which the marker was inserted, may be considered to be *not a GMO* under Item 8 and Item 9 of Schedule 1?

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? 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 regulation of SDN-2 and ODM does not increase costs compared to the current arrangements, however it represents a lost opportunity to reduce the cost of developing new vaccine products through the adoption of low risk technologies. It is not possible to estimate the loss of revenue due to the inability to develop products that are not economically viable if developed using traditional random mutagenesis methods. The inability to develop these products also represents a loss to Australian agriculture, who will not receive access to vaccines tailored to local strains and conditions. It will put Australian scientists and companies in a handicapped position vis a vis most other developed and undeveloped countries in developing global vaccines for manufacture and exports.

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

Repeal of Schedule 1 item 1 is unlikely to incur any new costs as the Regulator has interpreted the current item 1 in a manner that negates its meaning. Repeal therefore does nothing to change the existing policy, but rather makes the policy more legally defensible.

We note that the deletion mutant Vaxsafe PMP has been explicitly excluded from regulation, and that previously the status of this organism was determined by agreement from the Regulator rather than on the basis of Item 1.

4.3 Updating the categorisation of contained dealings with GMOs

It is noted that the changes to the categorisation of NLRDs (deletion of *donor nucleic acid* in favour of *genetic modification*) is necessary for consistency with deletion of Item 1 of Schedule 1.

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

This would be of benefit if it were recognised that the same principle should apply to haploid organisms.

4.5 minor administrative changes.

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?

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.

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.

Summary:

Unfortunately, the OGTR in these changes, has missed the opportunity to make the necessary amendments to reduce the cost of developing new world class vaccine products through the adoption of low risk genetic technologies.

It puts Australia out of line and at a commercial disadvantage with, other advanced and even 3rd world countries in terms of vaccine development who have almost universally adopted changes that make it easier for low risk genetic technologies to be utilised without triggering the punitive costs associated with GMO regulation in Australia.

Further, the OGTR has even entrenched their present restrictive interpretation of Schedule 1 Item 1 (which exempted certain deletion organisms and other low risk organisms) by removing the ability to be exempted by repealing the item. This is a big step backwards and the VMDA wonders if this has been undertaken in attempt to make the regulator's present regressive and legally indefensible interpretation of exempt organisms, more legally defensible.

Sincerely,

Jim Adams
Executive Director