



The Regulations Review
Office of the Gene Technology Regulator (MDP 54)
GPO Box 9848
CANBERRA ACT 2601

Dear Dr Bhula

Re: Association of Biosafety Australia and New Zealand (ABSANZ) Submission on the draft amendments to the Gene Technology Regulations

ABSANZ is pleased to have the opportunity to have input into the consultative draft of the Gene Technology Regulation Technical Review on behalf of our members. In order to do so, we have listed a number of areas where our members believe that there remains a need for consideration. These are listed below.

Use of Gene Splicer Technologies

ABSANZ supports the measured response to the use of gene splicer technologies and the decision not to require single nucleotide and undirected (lacking a template) nucleotide changes to be notified to the Regulator.

11A Time limit for deciding variation application

ABSANZ notes that under section 11A there has been no consideration of an amendment to the statutory 90 day period by which a decision on a variation to a licensed dealing must be made, even where the variation is minor and would not alter the risk of the dealing. This was a concern raised by members and attendees to the IBC forum in 2017 and such an amendment would substantially reduce delays in conducting licensed dealings.

Division 2 Notifiable Low Risk Dealings (NLRD)

ABSANZ previously raised a proposal to amend the Regulations to enable amendment or extension of an NLRD. It was proposed that this be facilitated where the change in dealing did not change the class of NLRD, or the scope of the dealing as assessed by the IBC. Concern does not seem to have been addressed in the draft as presented.

Additionally, ABSANZ members indicated that there could be a facility to extend the lifespan of an NLRD, provided that an IBC had undertaken an assessment within the 5-year period and assessed that the dealing was still current and had not changed.

These two amendments would allow accredited organisations to significantly reduce administration and record keeping by IBCs, without a concomitant increase in risk. For example, in instances where an IBC assesses that the amendment would not change the class or scope or class of the NLRD, it would be beneficial to be able to amend the NLRD, with records to be kept by the organisation and provided as per s13 of the Regulations. Another example of an instance in which it would be appropriate to allow an amendment, and where there would be no increase in risk would include a



variation to include a new facility at the same certification level as that originally approved and the IBC believes the work can be safely undertaken there.

13B Requirements for Institutional Biosafety Committees about records of assessments of notifiable low risk dealing proposals

It would be extremely helpful if the OGTR could provide the required proforma for completion of information about NLRDs at the beginning of the financial year rather than towards the end. This is because there is currently a duplication of effort to record information for a considerable number of dealings. Organisations should not have to incur such administrative burden where the proforma spreadsheet could be completed in real time, as all information required by OGTR is prescribed in these Regulations and should therefore not have to be amended from year to year.

13C Information to be kept or given to the Regulator by persons or accredited organisations

In clause (b) of this Section, it is not clear what information is required. It could be interpreted that an organisation is required to include in its annual report a list of all applications that it assessed in the financial year including those assessed as not being an NLRD either because they were licensable or that were exempt? If the “in any other case” refers to an organisation that is not an accredited organisation, or an individual that is not part of an accredited organisation, then the wording needs to be clearer. A suggestion is provided below.

(b) Where an organisation that is not accredited or an individual not part of an accredited organisation has an NLRD assessed—give to the Regulator collated records of all such dealings assessed in a single financial year.

These comments reflect those where ABSANZ believes there would be some benefit from consideration and implementation. ABSANZ would be happy to discuss these points further with members of the Regulation Technical Review if clarification is required.

Yours Sincerely

Gordon McGurk Ph.D., GAICD
Chair, Regulatory Liaison and Communication Sub-Committee
ABSANZ

21 February 2018