Submission to the 'Technical Review of the Gene Technology Regulations' on the 'Regulation Impact Statement for Consultation' regarding the 'Draft Amendment Proposals to the Gene Technology Regulations'

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

Response

Option 2 is preferred, which proposes to amend the Gene Technology Regulations as per the draft amendments at Appendix C: of the Regulation Impact Statement for consultation

The proposed Options

Option 1 proposes there be no changes made to the GT Regulations.
Option 2 proposes to amend the GT Regulations as per the draft amendments at Appendix C: of the Regulation Impact Statement for consultation
Option 2 proposes to amend the GT Regulations with some but not all draft amendment proposals

Rational for preferring Option 2

Option 2 best meets the views of those who made submissions to earlier phases of the Review. The proposed draft amendment s will continue to ensure safety and provide greater clarity. For example, the proposal to require a licence for contained dealings with GM gene drive organisms will enable risks to be properly assessed and the proposal to clarify that organisms modified using SDN-2 and ODM are GMOs while organisms modified using SDN-1 are not GMOs will assist the administration of the Regulations without compromising safety.

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

Response

Yes, the draft amendments clearly implement the measures described in section 3

Rationale

The measures described in Section 3 aim to exclude from Regulation only those organisms:

- that do not pose a particular biosafety risk to the environment or human health and safety as a consequence of the techniques used

  The following proposals will contribute to achieving this:
  - the exclusion of organisms modified using SDN-1;
  - the listing of non-segregants, NoGall and VaxSafe PM as organisms that are not GMOs; the proposed exempt classification of cloned viral genomes that are unable to give rise to infectious agents;
  - the addition of *Zymomonas mobilis* and *Corynebacterium glutamicum* as exempt hosts;
  - Changing wording regarding pathogenic determinants to:
    'shift the focus of assessment towards the outcome of the modification (e.g. immunomodulatory effects, ability to cause harm) rather than the characteristics of

the introduced sequences.'[1]

- whose genomic DNA sequence would not be changed by techniques used
    - the proposed listing of RNA-delivered RNAi as a technique that is not gene technology will contribute to this aim

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

Response

Not applicable as Option 2 is preferred

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)

Response

No costs, only benefits due to increased clarity

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

Response

No costs, only benefits due to increased clarity

4.3 Updating the categorisation of contained dealings with GMOs

Response

No costs, only benefits due to increased clarity

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

Response

No costs, only benefits due to increased clarity

4.5 Minor administrative changes.

Response

No costs, only benefits due to increased clarity

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

Response

Yes

[1] Regulatory Impact Statement for consultation, paragraph 3, p.14

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.

Response

No. It is also understood that the current Review of the whole Gene Technology Scheme has there is potential for future proofing the Scheme in response to new developments.