

With the relatively recent development and adoption of new gene-editing technologies it is timely to consider whether these are appropriately governed by existing genetic technology regulations. To date, CSL's IBC has had to review very few applications relating to these but we anticipate that this will increase in the near future with the in-house implementation of technologies such as CRISPR/Cas9 as well as other considerations including the target organism, the vector and genes being modified. Overall we feel that the current regulations adequately cover the use of these technologies so do not see a benefit to adding additional governance above what is currently required. In more detail:

1. Which option do you support and why?

We support option 1 as we believe that this adequately covers the new technologies which in many ways pose less risk compared with older technologies such as random chemical mutagenesis. When applications are submitted to the CSL IBC they must cover the following:

- a. The organism being modified
- b. The vector being used
- c. The DNA/genes being introduced e.g. Cas9 and what genes they target

Any gene editing tools and their use are covered by the above and allows the IBC to assess the risk hence why our support for option 1.

2. Are there other risks and benefits of each option that are not identified in this document?

N/A

3. Is there any scientific evidence that any of options 2-4 would result in a level of regulation not commensurate with risks posed by the gene technology.

N/A

4. How might options 2-4 change the regulatory burden on you from the gene technology regulatory scheme?

N/A.

5. How do you use item 1 of Schedule 1, and would it impact you if this item was changed?

Item 1 of Schedule 1 refers to organisms that have naturally occurring mutations. Presently, at CSL we do not deliberately use selective pressures to intentionally generate mutants to confer an advantage over the wild type organism and it is difficult to envisage that this will change in the short and medium term.

6. Might contained laboratory research on GM gene drive organisms pose different risks to other contained research with GMOs, and how could these risks be managed?

We believe the risk posed by laboratory research on GM gene drive organisms is similar to other contained research with GMOs that confer a selective advantage and this is presently captured by GT Regulations. As long as the phenotypes of the GMOs that are being selected are clearly stated in applications, then the risks posed by the GMO can be identified and mitigated.

7. What RNA interference techniques are you using, and are there RNA interference techniques that you believe have unclear regulatory status?

We are not currently using RNA interference but if we were, this would be adequately captured in the current gene therapy regulations.

8. Do you have a proposal for amendments?

None