Technical Review of the Gene Technology Regulations 2001

Summary of options

Option 1: No changes

Contradicts the *Gene Technology Act, 2000* as SDN-2 and SDN-3 involve insertion of foreign DNA.

Option 2: Regulate certain new technologies

Regulate SDN-1, SDN-2 and SDN-3. Contradicts the treatment that is currently acceptable for radiation and chemical mutagenesis.

Option 3: Regulate some new technologies based on the process used

Remains in line with current legislation. SDN-1 remains unregulated whilst SDN-2 and SDN-3 are regulated as they involve insertion of foreign DNA.

Option 4: Exclude certain new technologies from regulation on the basis of the outcomes they produce

Only SDN-3 is regulated. This will cause confusion as there is no set definition distinguishing SDN-2 and SDN-3. A loop hole is also created as SDN-3 type organisms can be created through repeated SDN-2 methods.

Consultation questions

1. Which option/s do you support, and why?

Option 3.

This option provides the greatest clarity for which new technologies/techniques are regulated and it is the only option that remains in line with the current legislation. SDN-2 and SDN-3 both use nucleic acid template to guide repair, thereby deliberately inserting foreign DNA. By definition of the *Gene Technology Act 2000*, these give rise to a GMO.

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

Option 1 contradicts the *Gene Technology Act, 2000* SDN-2 and SDN-3 introduce foreign DNA.
Option 2 contradicts the current exemption for organisms generated by chemical and radiation mutagenesis. SDN-1 should not be regulated as foreign DNA is not being inserted.
Option 4 contradicts the *Gene Technology Act, 2000* as SDN-2 techniques introduce foreign DNA. This creates a loop hole as SDN-3 type organisms can be created through repeated SDN-2 methods.

The biggest risk is with option 4 as there is no set definition distinguishing SDN2 and SDN3. There is also no way of differentiating between an organism derived from a single SDN3 or multiple rounds of SDN2 procedures. For this reason, they (SDN2 and SDN3) should be regulated together.

Risk that has not been considered is the specificity of SDN and the genes that could be targeted. If SDN1 is not going to be regulated, then a clause should be included that states as long as the intended change does not confer a breeding advantage or make an organism more toxic.

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 gene technology?

The scientific evidence would be based on the evidence supporting chemical and radiation mutagenesis.

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

Options 2-4 will create extra work for researchers who are required to keep track of GMO traits. Options 2 and 3 will create the biggest burden as records will need to reflect the gene targeted for mutagenesis as well as the new allele created by the technique. Option 4 has the least regulatory burden, however it creates a loop hole as SDN-2 will remain unregulated.

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

In-vitro-fertilisation of zebra fish embryos
Fish derived from chemical induced mutagenesis

From an IBC perspective this would lead to an increased number of applications to review.

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? Supporting information and science-based arguments should be provided where possible.

Yes they do pose different risk as gene drivers provide an advantage to the host and have been deigned to be favoured for inheritance, enabling them to spread through populations at a greater rate than genes with Mendelian inheritance. Gene drive systems should be treated as PC1 - PC2 NLRDs if they have been engineered to include a fail-safe mechanism to prevent spread, should accidental release occur. If no fail-safe mechanism is in place, and depending on the host and modification, GM gene drive organisms should be treated as PC2 NLRD – DNIR. The regulations require updating in schedule 3 to clearly differentiate between different containment requirements.

7. What RNA interference techniques are you using, and are there RNA interference techniques that you believe have unclear regulatory status? Please provide details of the techniques and science-based arguments for whether these techniques pose risks to human health or the environment.

No comment

8. Do you have proposals for amendments to any other technical or scientific aspects of the GT Regulations? All proposals should be supported by a rationale and a science-based argument.

1. Regulatory board will need to consider how synthetic organisms, which can have unpredicted phenotypes will be regulated. The Gene Technology Act, 2000 only classifies a GMO as something *"modified"* by gene technology. In the case of synthetic organisms, these are *"written"* using gene technology.

2. GRAS (generally regarded as safe) organisms should be considered as exempt dealings

http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/MicroorganismsMicrobialDerivedIngredients/default.htm