Draft Submission

Submission to be copied into online form available on the EPA website.

Part A – name and contact details

Submission on:	Proposed amendments to the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1988.
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Part B - questions

Criteria for assessing proposals

The proposed criteria for assessing the proposals are: consistency with the purpose and principles of the HSNO Act; certainty and predictability: the Regulations must provide express exclusions; and international context: be consistent with New Zealand's international obligations.

Question 1 — Do you agree with the proposed criteria? If not, why not?

No – The three criteria that are listed are appropriate but the words used with regard to the international context are too narrow. The wording needs to reflect not just international obligations but also an awareness of international practice and regulations.

Question 2 — Would you propose any other criteria not covered?

No The criteria appear to be appropriate provided the suggested wording change in the answer to question 1 is included.

Consistency with the purpose and principles of the Act, including the precautionary approach

Question 3 — From your perspective, how do you think that the proposals meet the purpose and principles of the HSNO Act? Why? Why not?

The proposals as drafted do not directly impact on the purposes and principles of the HSNO Act, beyond the fact they do clarify what is regulated under the HSNO Act and what is not. This meets the purposes and principles of the Act in that procedures and processes, which have been used for decades and do have a demonstrable benefit for economic development, are being preserved and their status under the act clarified.

Question 4 — Do you think the proposals are consistent with the precautionary approach? Why? Why not?

The proposals are consistent with the precautionary approach in that they clarify the regulations about what is covered and what is not under the Act and they correct a drafting error which could lead to an unintended interpretation of the Act, as indicated in a High Court decision. This also recognises that mutagenesis is a technology that causes genetic re-arrangements within the limits of an organism's own genome and results in changes that could occur by random natural mutations. Mutagenesis has been used in conventional plant breeding over several decades (predating the Act). There are now multiple examples across crop types, and associated food or feed products, of successful commercial application in New Zealand with no evidence of linked health and/or environmental risks beyond normal boundaries.

The proposals are too limited in that they are dealing only with a correction in the wording of the regulations. The opportunity should be taken to consider mutagenic treatments (both chemical and radiation) developed and applied since 1998, as well as the more recent genome editing technologies.

New mutagenic treatments operate in the same manner as those developed prior to 1998, so do not pose any greater risk through their mode of action. They do offer improved efficiencies in the development of useful genetic variation over a wide range of crop species. If New Zealand adopts this cut-off date, we will significantly disadvantage our plant breeders in terms of the available breeding tools, relative to international breeding programmes.

Genome editing technologies offer even more efficient, controlled and targeted approaches, where equivalent genetic changes can be induced using more precise approaches than random (chemical) mutagenesis. Like mutagenesis, such technologies do not involve DNA foreign to the subject species. Again, these technologies are being developed and freely

applied internationally and New Zealand will be disadvantaged if such technology is excluded under the HSNO Act.

Certainty and predictability

Question 5 — Do you think our proposal will provide sufficient certainty and predictability for users? Why? Why not?

The proposals do provide certainty in correcting and clarifying the issue around mutagenesis that was identified by the High Court in the existing regulations.

However, they do not provide certainty around the use of the new technologies or the importation of material subject to such technologies that has been developed overseas. Genome editing technologies, where they operate without the introduction of foreign DNA, are equivalent to mutagenesis so no further risk is being introduced. The nature of any changes are such that they could occur through natural variation or the use of existing mutagenesis methods. This means it would not be possible to readily detect any such changes in the genome of an organism.

The new genome editing technologies are being used around the world. In a number of countries, including Australia, these technologies are not regulated, provided no foreign DNA is incorporated. This means that there is uncertainty about material that may be imported into New Zealand and any laws would be unenforceable as it would not be possible to verify claims around any particular technological origin. It also means that it is appropriate for New Zealand to address the use of genome editing technologies now.

International context

Question 6 — What are your views on the relative importance of international alignment?

International alignment is critical for New Zealand as a small advanced economy, but particularly so with regard to our primary sector industries because our major markets are international. The current proposals do meet this need for alignment with overseas markets in regard to long-standing mutagenesis techniques. However, they do not meet this need in regard to the new technologies. As mentioned above, a number of overseas countries have already accepted genome editing technologies as non-GMO and others (e.g. EU) are giving this consideration. A lack of alignment provides for confusion with regard to export or import of material, possible loss of trade, inability to enforce laws and a disadvantage to our industries where competitors are able to use particular technologies but New Zealand is not. This will impact on the diversity of crops available to growers and thus to the New Zealand economy as a whole.

Question 7 — Can you describe what impact implementing these proposals would have on your business or the market you operate in, particularly if you trade internationally?

As a professional organisation representing those involved in agricultural and horticultural science, the proposals as written clarify an interpretation of regulations that may have impacted on the status and use of existing technologies and organisms. This removes the possibility for unintended effects or outcomes around what are accepted practices.

The fact that the new mutagenic and genome editing technologies are not being considered at the same time, places a limit on what New Zealand scientists and science companies can undertake across a range of plant and animal based industries. This stifles innovation and makes us less efficient and effective in leveraging R&D for economic growth, placing New Zealand at a disadvantage with respect to what is happening in other countries. The proposals do clarify existing regulations but they do not recognise the essential equivalence in outcome and risk of these new technologies.

Proposal: Redraft clause 3(1)(b) to clarify the list of chemical treatments covered by the Regulations (see paragraph 46)

Question 8 — Do you agree with this proposal? Why? Why not?

Yes. It corrects mistakes in the current wording of the regulations.

Proposal: clarify that the Regulations cover all organisms created using chemical and radiation treatments in use for mutagenesis on or before 29 July 1998 (see paragraph 47)

Question 9 — Do you agree with this proposal? Why? Why not?

Yes, the proposal clarifies the existing regulations and removes the likelihood of unintended interpretations of the existing regulations.

However, the proposed changes do not address or include the development of new mutagenic treatments and genome editing technologies. These technologies are already in use around the world, as they provide more efficient, targeted and precise methods for developing genetic variation. Their status needs to be considered as part of this review.

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