Report on Submissions

Submissions received on the consultation document – Proposed amendments to the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998

January 2016

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Consultation period

The consultation document “Proposed amendments to the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998” was released for public consultation for a period of six weeks on 30 October 2015, with submissions closing at 5:00pm Friday 11 December 2015. The consultation document was made available on the Environmental Protection Authority’s (the EPA) website and was also notified in the New Zealand Gazette and major newspapers in Auckland, Wellington, Christchurch, and Dunedin.

Submissions received

Thirty-three submissions were received by the EPA (in response to the consultation). The list of submitters is provided in Appendix 1 to this report. All submissions will be made available on the EPA website at www.epa.govt.nz.

Introduction

1. In October 2015, the Minister for the Environment requested that the EPA undertake public consultation on two proposed amendments to the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998 (the Regulations). The proposed amendments are intended to:

    a. correct drafting errors in clause 3(1)(b) of the Regulations, identified by the High Court in a judgment in 2014[1]; and

    b. clarify that any organisms developed using chemical and radiation treatments, where those treatments were in use in 1998, are captured by the Regulations and therefore do not require approval as genetically modified organisms (GMOs) under the Hazardous Substances and New Organisms Act 1996 (the HSNO Act).

Scope of this report

2. This report is mainly focussed on the proposed amendments that the EPA was asked to consult upon. However, submitters also commented on issues that are not related to the two proposed amendments outlined above. These other comments are dealt with in the section "Issues raised out of scope of the consultation" (paragraphs 51 to 57).

Background

3. In 2014, a High Court judgment identified drafting errors in the Regulations. It also held that the listed treatments must be read as an exhaustive list (i.e., only the listed treatments and no others may be considered excluded from regulation as GMOs). It was considered that the High Court's judgment may have implications for crops grown in New Zealand, because there are crops produced through treatments that were previously thought to be covered by the Regulations that could now require HSNO approval from the EPA. To restore clarity to the regulatory regime, two amendments to the Regulations were proposed.

4. The EPA consulted on these proposed amendments as under section 141(1) of the HSNO Act. Section 141(1) requires that before recommending a change to any regulations, the Minister shall:

    a. "request the [Environmental Protection] Authority to —

[1] The High Court judgment can be viewed online at: http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/APP201381_The%20Sustainability%20Council%20of%20New%20Zealand%20Trust%20v%20The%20Environmental%20Prot.pdf:

i. do everything reasonably practicable on its part to advise all persons, who or which in its opinion may be affected by any Order in Council made in accordance with the recommendation, of the proposed terms of the Order in Council; and

ii. give such persons a reasonable opportunity to make submissions on them to the Authority; and

iii. advise the Minister of any submissions received, and any comments the Authority wishes to make on the submissions or the proposed Order in Council; and

b. request the [Environmental Protection] Authority to advise on the best international practices and standards for the safe management of hazardous substances and new organisms."

5. The EPA will advise the Minister on international practices and standards separately to this submissions report.

Matters raised in submissions on the consultation document

6. A total of 33 submissions were received by the EPA during the consultation period representing a wide range of views from individuals, industry groups, non-governmental organisations, and businesses.

7. Submitters' responses are summarised below by the area that they commented upon.

Overall summary

8. Two proposals were presented. In summary, a majority of submitters were in agreement with proposal one. Similarly, the majority of submitters also agreed that proposal two was an improvement. However, in relation to both proposals a significant portion of submitters considered that further long-term action would be required and referenced the Ministry for the Environment's Regulatory Impact Statement (RIS). Submitters mostly agreed with the criteria to assess the proposed amendments but many suggested further criteria should be added. Submitters differed on whether the proposals were consistent with the purpose of the HSNO Act and the precautionary approach, and some considered the second proposal to be too conservative. Lastly, international alignment was seen to be important by submitters. Concerns were expressed that New Zealand's legislative framework was too restrictive and impacted upon business competitiveness.

Criteria for assessing the proposals

9. The majority of submitters agreed with the proposed criteria outlined in the consultation document. However, those who disagreed with the proposed criteria noted issues with the international context criterion being too narrow and inconsistencies with the HSNO Act.

10. Over two-thirds of submitters suggested additional criteria not covered in the consultation document. Submitters believed the international context criterion should be expanded to acknowledge international practices. Additionally, submitters suggested that the proposed criteria should reflect the difficulty in enforcing the proposed Regulations, expressly weigh up the costs and benefits of new techniques, and include criteria recommended in the Treasury's Best Practice Guidelines.

11. Submitters on the whole noted that the proposed Regulations would not provide sufficient certainty and predictability to users, particularly in the long-term. Submitters cited issues with the arbitrary 1998 cut-off date and noted that the Regulations would stifle innovation and be difficult to enforce.

Consistency with the purpose of the HSNO Act and the precautionary approach

12. A number of submitters agreed that the proposals meet the purpose and principles of the HSNO Act, however over half of submitters either disagreed or expressed concern with this approach.

Submitters noted that the second proposal is an overly risk averse approach and will not incentivise innovation in the sector, which is inconsistent with the original intentions of the HSNO Act.

13. The majority of submitters disagreed that the second proposal is consistent with an appropriate interpretation of the precautionary approach, noting that this it is overly cautious and not risk-based.

Feedback on international alignment and international impacts on business

14. Submitters considered that international alignment (question 6) was important and New Zealand should align its regulations with international standards. The EPA is not aware of relevant international standards in this area. Eleven submitters noted that New Zealand is not currently in line with other countries in relation to regulation of GMOs. Fourteen submitters noted that New Zealand's restrictive genetic modification (GM) laws makes it difficult for New Zealand to compete internationally, as many GM techniques available overseas are not available in New Zealand. Submitters would like more technologies included under the Regulations.

Responses to the proposed amendments to the Regulations

15. The majority of submitters agreed with proposal one to redraft clause 3(1)(b) to clarify the list of chemical treatments covered by the Regulations. However, a portion of submitters either agreed or disagreed with this proposal, but both considered that the proposal was not a long-term solution.

16. The majority of submitters also agreed that proposal two, which clarifies that organisms created using chemical and radiation treatments in use for mutagenesis on or before 1998 are captured by the Regulations, was an improvement on the current legislation. However, many submitters suggested that further action was necessary. Many submitters noted it was insufficient to only address the concerns from the High Court decision, and that organisms created using mutagenesis after 1998 should be included in the Regulations.

17. A number of submitters raised issues outside the scope of the consultation document with numerous references to the "RIS: Options for reviewing the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998". Thirteen submitters noted that the proposed Regulations were insufficient and recommended amending the Regulations, updating the list of techniques or commencing a full review of the new organisms provisions in the HSNO Act. Submitters also noted that the Regulations should be based on sound scientific principles and proportional to the degree of potential risks, and that compliance with the proposed Regulations would be burdensome and costly.

Issues raised out of scope of the consultation

18. Submitters also raised issues outside of the scope of the consultation. These issues include matters relating to costs, risk, detection, and the RIS. Please see paragraphs [49] to [53] for more.

Questions — Criteria for assessing proposals

19. The consultation document noted that three criteria were identified for assessing the proposed amendments and submitters were asked for feedback on the criteria. These criteria were:

    - 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?

Submitters

Overall, 23 (out of 33) submitters responded, including the following:

Category	Submitter numbers	Total submitters
Individual (I)	1, 5, 6, 9, 10, 17, 21, 32	8
Private business (PB)	2, 4, 7, 20, 28	5
Industry group (IG)	3, 12, 13, 14, 30	5
University (U)	11, 33	2
Crown research institute (CRI)	18, 19	2
Non-governmental organisation (NGO)	26	1

Submitters in agreement

20. Thirteen submitters agreed with the proposed criteria. This included five individuals (1, 9, 10, 17, 21), three private businesses (2, 20, 28), two universities (11, 33), one industry group (12), one CRI (18), and one NGO (26). There was one theme:

    - Two individual submitters (17, 21) noted that the cut-off date is arbitrary and appears inconsistent with the precautionary principle.

Submitters not in agreement

21. Ten submitters disagreed with the proposed criteria and recommended additional criteria. This included three individuals (5, 6, 32), two private businesses (4, 7), four industry groups (3, 13, 14, 30) and one CRI (19). Common themes included:

- Seven submitters noted that the international context criterion was too narrow. This included three industry groups (3, 13, 14), two private businesses (4, 7), one individual (5) and one CRI (19);
- Two submitters, one private business (4) and one individual (5), noted that the proposed criteria were not consistent with the purpose and principles of the HSNO Act and the certainty and predictability are not synonymous with providing express exclusions;
- Three submitters made reference to the 1998 cut-off date not being consistent with the precautionary principle and not a good method of determining which techniques are safe for use. This included two individuals (17, 21) and one industry group (14).

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

Submitters

Overall, 21 (out of 33) submitters responded, including the following:

Category	Submitter numbers	Total submitters
Individual	5, 6, 9, 10, 17, 21, 32	7
Private business	2, 4, 7, 20, 28	5
Industry group	3, 13, 14, 30	4
University	11, 33	2
Crown research institute	18, 19	2
Non-governmental organisation	27	1

Submitters proposing other criteria not covered

22. Twenty submitters proposed criteria not covered in the consultation document. This included five individuals (5, 6, 9, 10, 32), three private businesses (4, 7, 28), four industry groups (3, 13, 14, 30), two universities (11, 33), two CRIs (18, 19) and one NGOs (27). Common themes included:

- Five submitters suggested enforceability should be added to the criteria list. Submitters refer to the impossibility of distinguishing between naturally occurring mutations from those induced by chemical or radiation treatments. This included one individual (10), one industry group (14), one CRI (19), one private business (28) and one university (33). One industry group submitter (14) noted that if the organism has been subjected to induced mutagenesis then no enforcement of the HSNO Act is possible;

- Six submitters felt that the wording of the international context criterion needed to reflect an awareness of international practices and regulations to prevent New Zealand industry from being trade exposed and being at a competitive disadvantage. This included two industry groups (3, 13), one university (11), one individual (17), one CRI (19) and one private business (28);
- Three submitters suggested the need for assessment of equivalence - the economic-related benefits and costs of using a particular hazardous substance or new organism should be given equal weight as new technologies can offer enhancement and benefits over the existing exclusions. Therefore, this criterion should be taken into consideration. This included one private business (4), one individual (5) and one university (11);
- Two submitters referred to the inclusion of criteria outlined in the Treasury's Best Practice Regulation Guidelines namely: growth supporting, proportional, flexible and durable. This included one individual (6) and one industry group (30);
- One industry group submitter (30) suggested that "enduring and sustainable for future application of the HSNO Act" as a criterion to ensure consistency with the HSNO Act.

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

23. The consultation document noted that the purpose and principles of the HSNO Act are outlined in sections 4-8 of the HSNO Act. When amendments to the Regulations are proposed, consideration is required of the effects of the proposals on the environment, human health and safety, society and community, Māori, economy, and international obligations. Any amendments must be legally workable and sensible in the context of the HSNO Act.

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

Submitters

Overall, 23 (out of 33) submitters responded, including the following:

Category	Submitter numbers	Total submitters
Individual	1, 5, 6, 9, 10, 17, 21, 32	8
Private business	4, 7, 20	3
Industry group	3, 13, 14, 23, 24, 30	6
University	11, 33	2
Crown research institute	18, 19	2
Non-governmental organisation	26, 27	2

Submitters in agreement

24. Nine submitters agreed that the proposals meet the purpose and principles of the HSNO Act. This included submissions from two individuals (1, 21), two private businesses (7, 20), three industry groups (3, 13, 24), one CRI (18) and one NGO (26). Themes raised included:

    - Three submitters observed that the proposals provide consistency with the original intentions of the HSNO Act and the knowledge that these techniques are considered to be low risk. This included one individual (1), one industry group (13), and one CRI (18);
    - One industry group submitter noted agreement (24), however noted that this is not a long-term solution as stated in the RIS and would require further amendments in future.

Submitters not in agreement

25. Thirteen submitters either disagreed, or disagreed in part, that the proposals meet the purpose and principles of the HSNO Act. Of these thirteen submitters, nine disagreed that the proposals meet the purpose and principles of the HSNO Act, including four individual submitters (5, 9, 10, 17), one private business (4), two industry groups (14, 30), one CRI (19), and one university (11).

26. Four submitters either disagreed in part or noted issues disagreeing with the interpretation of the HSNO Act taken. These submitters comprised two individuals (6, 32), one university (33) and one NGO (27). Key themes and issues raised included:

- Six submitters noted that the proposals do not address the wider issues with the HSNO Act, and the proposals are not consistent with the original intentions of the Act – as they will not incentivise innovation and technological developments as new techniques are developed. These submitters comprised one private business (4), two individuals (5, 10), one university (11), one CRI (19) and one industry group (30);
- Two submitters from universities (11, 33) noted that regulations based on a specific date (1998) for when techniques were in use is not consistent with the purpose and principles of the HSNO Act because this approach is not risk-based and some techniques in use before or after this time will produce similar results;
- Three submitters disagreed with the interpretation of the HSNO Act, including one private business (4), and two individuals (5, 6). These submitters noted that the proposed approach is too risk averse with regard to new developments in the sector.

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

27. The HSNO Act requires a precautionary approach to managing adverse effects where there is scientific and technical uncertainty about those effects. The precautionary approach is not defined, but it is important to note that a precautionary approach does not necessarily mean a "no-risk" regime.

28. In the consultation document the EPA noted that when the currently-listed treatments were selected, a history of safe use was one of two criteria for selecting treatments – the other being sufficient scientific knowledge about the effects of a treatment.

Submitters

Overall, 23 (out of 33) submitters responded, including the following:

Category	Submitter numbers	Total submitters
Individual	1, 5, 6, 9, 10, 17, 21, 32	8
Private business	2, 4, 7, 20	4
Industry group	3, 8, 3, 14, 30	5
University	11,33	2
Crown research institute	18, 19	2
Non-governmental organisation	26, 27	2

Submitters in agreement

29. Seven submitters agreed that the proposals are consistent with a precautionary approach. These submitters comprised three private businesses (2, 7, 20), two NGOs (26, 27), one industry group (3) and one individual (21). One key theme was raised:

    - Three submitters noted that the proposals are consistent with the precautionary approach given the techniques covered have a long history of safe use and are supported by sound scientific knowledge. Submitters included one private business (20), one individual (21) and one NGO (27).

Submitters not in agreement

30. Fourteen submitters disagreed, including seven individuals (1, 5, 6, 9, 10, 17, 32), three industry groups (8, 14, 30), two CRIs (18, 19), one private business (4), and one university (33). Two submitters disagreed that proposal two is consistent with a precautionary approach, including one university (11) and one industry group (13). Key themes and issues raised included:

    - Seven submitters, including three industry groups (8, 13, 30), two individuals (1, 17), one university (11), and one CRI (18), noted that the use of a date (1998) to determine which techniques are exempt from regulation as producing GMOs is not consistent with the precautionary approach and is not based on scientific principles regarding risk;
    - Five submitters stated that the proposals are not consistent with the precautionary approach, as the risks associated with these mutagenesis techniques are not significantly different to new genome editing techniques. These submitters comprised two individuals (5, 9), one industry group (13), one private business (4), and one CRI (19);
    - Six submitters believe that an overly conservative interpretation of the precautionary approach has been taken with regard to these proposals, including three individuals (6, 10, 32), one industry group (30), one university (33) and one CRI (19);
    - Two submitters agreed that the correcting of drafting errors is consistent with the precautionary approach (Proposal One) but disagreed that Proposal Two is consistent (one university (11), and one industry group (13)).

Question 5 — Do you think the proposals would provide sufficient certainty and predictability for users? Why? Why not?

Submitters

Overall, 30 (out of 33) submitters responded, including the following:

Category	Submitter numbers	Total submitters
Individual	1, 5, 6, 9, 10, 17, 21, 25, 32	9
Private business	2, 4, 7, 20, 28	5
Industry group	3, 8, 12, 13, 14, 16, 23, 24, 30	9
University	11, 33	2
Crown research institute	18, 19, 31	3
Non-governmental organisation	26, 27	2

Submitters in agreement

31. Nine submissions agreed that the proposals would provide sufficient certainty and predictability for users. This included two private businesses (2, 20), four individuals (1, 6 17, 21), one CRI (18) one NGO and one university (33). The only theme from submitters was:

    - Six submitters noted that the proposals would remove uncertainty in previous drafts of the Regulation and provide greater clarity. This included three individuals (1, 6, 17), one CRI (18) one private business (20) and one NGO (27).

Submitters not in agreement

32. Eighteen submissions found that the proposals would not provide sufficient certainty and predictability for users. This included four individuals (5, 9, 10, 32), three private business (4, 7, 28), seven industry groups (3, 8, 13, 14, 16, 24, 30), one university (11), two CRIs (19, 31) and one NGO (26). Common themes were:

    - Twelve submitters noted that the proposals would put New Zealand industry at a competitive disadvantage and leave the industry trade exposed as international competitors such as the United States of America, China and Brazil are able to utilise techniques developed post-1998. This included one individual (10), two private businesses (7, 28), eight industry groups (8, 12, 13, 14, 16, 23, 24, 30), and one CRI (31);
    - Twelve submitters considered that the proposals would restrict innovation in New Zealand and provide a barrier to technology development, investment, field testing, and release. Such

restrictions would reduce New Zealand's competiveness and its ability to compete in product markets globally. This included two individuals (9, 25), eight industry groups (3, 8, 12, 14, 16, 23, 24, 30), and two private businesses (4, 7);

- Seven submitters noted that it would be difficult to enforce the proposed amendments as distinguishing between a gene edit and a natural mutation is nearly impossible and it would be difficult to determine whether a gene edit was the result of a technique approved prior to or after the 1998 cut-off date. This included one private business (28), three industry groups (13, 16, 23) one university (11) and two CRIs (18, 31). Furthermore, horticultural and pastoral industries will be unable to import germplasm created using ZFN, Talen and CRISPR/CAS based methods. This included one private business (7), and one CRI (19);
- Five submitters considered that the proposals would not provide sufficient certainty and predictability as they found the 1998 cut-off date arbitrary and illogical – given that international competitors were not restricted by this cut-off date. This included two individuals (9, 32), one private business (7), one university (11), and one CRI (31);
- Three submitters noted that the proposals would ensure more certainty and predictability if mutations other than chromosome rearrangements and changes in chromosome number are covered by the Regulations. This included one individual (5), one private business (4), and one industry group (5);
- Two submitters wanted greater clarity regarding the regulatory status of organisms bred using mutagenesis techniques developed after 1998 or gene editing technologies. This included one university (11), and one private business (28);
- Two submitters commented that the Regulations give regulatory certainty for the moment but options proposed in the document would need to be rewritten in one to three years and will be unpredictable in the short-to-medium term. This included one individual (10), and one industry group (30);
- One NGO submitter (26) suggested that there be some clarification regarding unapproved techniques in such a way that everyone knows they need EPA oversight under the HSNO Act.

Questions — International context

33. Section 6 of the HSNO Act requires that the EPA consider New Zealand's international obligations. In the consultation document, New Zealand's international obligations were outlined as well as how some of our major trading partners regulate GMOs, and chemical and radiation treatments. There were questions on the importance of international alignment and the potential impacts for businesses and markets.

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

Submitters

Overall, 31 (out of 33) submitters responded, including the following:

Category	Submitter numbers	Total submitters
Individual	1, 5, 6, 9, 10, 17, 21, 25, 32	9
Private business	2, 4, 7, 20, 28	5
Industry group	3, 8, 13, 14, 16, 23, 24, 29, 30	9
University	11, 33	2
Crown research institute	18, 19, 31	3
Non-governmental organisation	26, 27	2
Member of Parliament	22	1

34. Eighteen submitters noted that it was important for New Zealand to align its regulations with international standards. This included two individuals (1, 5), four private businesses (2, 7, 20, 28), four industry groups (13, 14, 16, 30), two universities (11, 33), two crown research institutes (18, 19), one NGO (26), and one Member of Parliament (22). Of these eighteen submitters, two industry groups (16, 24) noted that New Zealand must align with Australia in particular.

35. Eleven submitters noted that New Zealand is not currently in line with other countries with regard to regulation of GMOs. This included two private businesses (4, 28), five individuals (5, 6, 9, 17, 25), two industry groups (8, 30), one university (11), and one CRI (31). One NGO (27) noted that the proposals align New Zealand with international agreements and standards.

36. Three submitters, including two industry groups (8, 29) and a CRI (31), stated that the definition of a GMO under the HSNO Act should be revised to reflect current knowledge and international best practice as it offers the best long-term solution and it should be considered an urgent priority.

37. Fourteen submitters noted that New Zealand's restrictive GM laws will make it more difficult for New Zealand to compete internationally, as many GM techniques are available overseas, but not in New Zealand. This included three private businesses (4, 7, 28), three CRIs (18, 19, 31), four industry groups (3, 8, 14, 30), and four individuals (5, 9, 10, 25).

38. Six submitters noted that it is important that the same products are considered genetically modified (GM) in New Zealand as with our trading partners, as differences between countries complicate exports and imports (1, 4, 5, 7, 13, 18). This included two individuals (1, 5), two private businesses (4, 7), one industry group (13), and one CRI (18). Three submitters, including one private business (4), one individual (5), and one industry group (13), were concerned that if a product produced overseas is not considered to be GM in the country it is produced in, but is considered to be GM in New Zealand, importing this product into New Zealand would be illegal.

39. Other common themes included:

- Three submitters including two individuals (25, 32) and one industry group (14) noted that the law should focus on traits that pose a risk, not on the technology used to produce the organism;
- Two submitters including one individual (10), and one industry group (18) raised concerns that it is difficult to determine if a product is GM, and an industry group (18) raised concerns that it is difficult to determine if a product was produced using post-1998 technology;

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

Submitters

Overall, 27 (out of 33) submitters responded, including the following:

Category	Submitter numbers	Total submitters
Individual	1, 5, 9, 10, 25, 32	6
Private business	2, 4, 7, 20, 28	5
Industry group	3, 8, 12, 13, 14, 16, 24, 29, 30	9
University	11, 33	2
Crown research institute	18, 19, 31	3
Non-governmental organisation	26, 27	2

40. Fourteen submitters noted that the legislation reduces New Zealand's ability to compete internationally, as GM technologies are available overseas, but not in New Zealand (1, 4, 5, 8, 9, 12, 13, 18, 25, 28, 29, 30, 31, 33). This included four individuals (1, 5, 9, 25), two private businesses (4, 28), five industry groups (8, 12, 13, 29, 30), one university (33), and two crown research institutes (18, 31).

    - Certain technologies that are regarded as GM in New Zealand are regarded as not-GM elsewhere. This included two individuals (1, 5), one private business (4), and two crown research institutes (18, 31);
    - In addition, two submitters, an individual (10) and an industry group (16), noted that conventional mutagenesis technologies are unregulated by other trading partners.

41. Five submitters, including two individuals (1, 5), two private businesses (4, 7), and one industry group (16), were concerned that they could not commercialise certain technologies, as they were defined as GM under the Regulations. This discourages researchers from developing new products, and in particular developing safer and more precise ways of inducing mutations to make new varieties of crops.

42. Two submitters, including one individual (1) and one industry group (13), noted that the strength of New Zealand's economy is dependent on agricultural trade with other nations.

43. Three submitters, including one private business (4), one individual (5), and one industry group (3), noted that it was insufficient to just amend the definition of GM, and that more technologies should be included under the Regulations.

    - Four submitters, including one private business (7), one industry group (13), and two crown research institutes (18, 31), noted that post-1998 technology should be included in the Regulations;
    - In addition, three submitters, including one private business (7), one industry group (16) and a crown research unit (19), noted that more technologies than just chemical and radiation should be allowed.

44. Two individuals (9, 10) noted that in order to receive research grants through the Ministry for Business, Innovation, and Employment, they must show a credible path for their products to market.

    - One individual (9) stated that under the current HSNO Act there was in their view, no viable path to market for any GM product in New Zealand;
    - One individual (10) noted that the only credible path for their products to market is for randomly mutagenized plant varieties using reagents in use before 1998.

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

Proposal One: Redraft clause 3(1)(b) to clarify the list of chemical treatments covered by the Regulations.

Submitters

Overall 33 (out of 33) submitters responded, including the following:

Category	Submitter numbers	Total submitters
Individual	1, 5, 6, 9, 10, 17, 21, 25, 32	9
Private business	2, 4, 7, 20, 28	5
Industry group	3, 8, 12, 13, 14, 16, 23, 24, 29, 30	10
University	11, 15, 33	3
Crown research institute	18, 19, 31	3
Non-governmental organisation	26, 27	2
Member of Parliament	22	1

Submissions in agreement

45. Twenty-one submitters agreed with the proposal to redraft clause 3(1)(b) to clarify the list of chemical treatments covered by the Regulations. Submitters included three individuals (1, 17, 32), four private businesses (2, 7, 20, 28), seven industry groups (3, 12, 13, 16, 23, 24, 29), three universities (11, 15, 33), one CRI (18), one Member of Parliament (22), and two NGOs (26, 27). Common themes included:

    - Eleven submitters considered that the proposal would address the drafting errors identified in the High Court judgment. Submitters comprised one individual (17), one private business (20), six industry groups (3, 13, 16, 23, 24, 29), one university (11), one CRI (18), and one NGO (27);
    - Four submitters supported the proposal, however, they considered that it was not an adequate solution. Reasons for this included it not being seen as a long-term solution, that is was conservative, and a review of the HSNO Act was more relevant. Submitters comprised one individual (32), one private business (28), and two industry groups (24, 30).

Submitters not in agreement

46. Twelve submitters were not in agreement with the proposal to redraft clause 3(1)(b) to clarify the list of chemical treatments covered by the Regulations. These submitters comprised five individuals (5, 9, 10, 21, 25), two private businesses (4, 6), three industry groups (8, 14, 30), and two CRIs (19, 31). There was one theme from these submissions:

- Five submitters noted that the proposal had only addressed the drafting errors and commented that either it did not deal with larger issues, or go far enough. Submitters included two individuals (5, 6), one private business (4), one industry group (8), and one CRI (19).

Questions on the proposals

47. Lastly, the consultation document requested feedback on the two proposed amendments.

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

Proposal Two: clarify that the Regulations cover all organisms created using chemical and radiation treatments in use for mutagenesis on or before 29 July 1998.

Submitters

Overall, 33 (out of 33) submitters responded, including the following:

Category	Submitter numbers	Total submitters
Individual	1, 5, 6, 9, 10, 17, 21, 25, 32	9
Private business	2, 4, 7, 20, 28	5
Industry group	3, 8, 12, 13, 14, 16, 23, 24, 29, 30	10
University	11, 15, 33	3
Crown research institute	18, 19, 31	3
Non-governmental organisation	26, 27	2
Member of Parliament	22	1

Submitters in agreement with the proposal

48. Ten submitters were in agreement with the proposal to clarify that the Regulations cover all organisms created using chemical and radiation treatments in use for mutagenesis on or before

29 July 1998. This included three private businesses (2, 20, 28), four industry groups (3, 12, 16, 23), one university (15), one crown research institute (18), and one NGO (27). Comments from these submitters included:

- One industry group (12) noted that the proposal addresses the drafting errors from the 1998 Regulations that were highlighted in the High Court decision, and another industry group (3) agreed that it was necessary to clarify the scope of the Regulations to be limited to 'conventional or traditional mutagenesis' techniques;
- One CRI (18) noted that the proposal provides certainty to the regulatory status of crops currently cultivated in New Zealand;
- One university (15) noted that the amendments are necessary to correct the situation of some crops which are bred using traditional techniques being regulated as GMOs. In addition, categories of similar organisms should be included under the definition of not-GM;
- One private business (20) noted that technologies in existence before 1998 are already in use within the New Zealand primary sector and are widely used globally, and the change allows for continued use of these methods.

49. Twelve submitters agreed that the proposal to clarify the Regulations would improve the legislative framework, but suggested that further action was necessary. This included four individuals (1, 6, 17, 21), a private business (17), four industry groups (13, 23, 24, 29), one CRI (18), one NGO (27), and a Member of Parliament (22). Common themes included:

- Five submitters, including one individual (17), three industry groups (13, 23, 24), and one CRI (18), agreed that organisms created using chemical and radiation treatments for mutagenesis should be exempt from regulation as GM.
    - One industry group (13) noted that the proposal removes the likelihood of unintended interpretations of the existing Regulations;
    - One individual (17) and one CRI (18) noted that the proposal gives certainty to the regulatory status of crops.
- Two submitters, including one individual (17) and one CRI (18), noted that any method of creating mutations should be acceptable under legislation, as long as no foreign or introduced DNA is inheritable as a result;
- Two submitters, an individual (1) and an industry group (29), agreed with the proposal to classify mutagenesis as not GM, but disagreed with the 1998 date which determines whether a treatment is to be considered GM.

Submitters not in agreement

50. Twelve submitters disagreed with the proposal to clarify the Regulations. This included two private businesses (4, 7), three individuals (5, 9, 32), three industry groups (8, 14, 30), two universities (11, 33), and two CRIs (19, 31). Common themes are set out below.

- Three submitters, including one individual (5), one industry group (8), and one private business (4), noted that it is insufficient to only address the concerns in the High Court decision. One industry group (8) noted that the proposed changes do not address new technologies;
- Three submitters, including one individual (5), a private business (4), and one industry group (30), noted that the proposal is not in line with the principles of the HSNO Act. The HSNO Act requires caution to be taken into account, and the risks and benefits to be balanced. The amendment is based on caution, instead of balancing potential risks and benefits (4, 5);
- Seven submitters (7, 8, 9, 10, 11, 19, 31) disagreed with the Regulations only covering organisms developed using chemical and radiation treatments if they were in use in 1998. This included two individuals (9, 10), one industry group (8), one private business (7), one university (11), and two crown research institutes (19, 31). Of these submitters:
    - one individual noted that this creates a situation where organisms that are otherwise indistinguishable are treated differently based on whether they were produced before or after 1998 (9); and
    - one university (11) noted that whether an organism should be included under the not GM Regulations should not be based on whether it was produced before 1998, but should be determined by an EPA assessment which balances the risks of the organism with potential benefits.
- Three submitters, including one individual (10), one industry group (8), and one CRI (31), noted that the proposed amendment fails to take into account scientific progress since 1998, and forces organisations to use older technology. Four submitters, including two individuals (9, 10), one industry group (14), and one university (33), commented that techniques used in 1998 are not safer than current day techniques;
- Two submitters, including one private business (7), and one industry group (13) noted that the proposed changes do not address or include the development of new mutagenic treatments and genome editing technologies;
- Four submitters, including one individual (9), two industry groups (8, 30), and one CRI (31), noted that the proposal hinders progress in research and innovation, as technologies produced since 1998 are not included. Five submitters, including one industry group (8), two universities (11, 33), one CRI (31), and one individual (9), stated that this makes it more difficult for New Zealand to compete internationally, and places us behind trading partners as they adopt new technology.

Issues raised out of scope of the consultation

51. Submitters also raised issues outside of the scope of the consultation. These issues are outlined below.

Regulatory Impact Statement

52. Eleven submitters, including two individuals (25, 32), one private business (28), seven industry groups (8, 12, 16, 23, 24, 29, 30) and one CRI (31) commented on aspects of the RIS: Options for reviewing the Hazardous Substances and New Organisms (Organisms Not Genetically Modified) Regulations 1998:

- Six submitters, including one individual (32), four industry groups (8, 16, 23, 24), and one CRI (31) agreed with comments in the RIS that the proposed amendments are the "bare minimum" required to address only some of the challenges of HSNO and associated regulations and cannot be considered a long-term solution;
- Four submitters, including one private business (28), and three industry groups (16, 23, 30) expressed disappointment that the consultation focused solely on RIS Option 2: "Amend Regulations, but only address High Court drafting concerns" and not Option 3: "Amend Regulations and propose updating the list of techniques" and/or Option 4: "Undertake a full review of the new organisms provisions in the Act";
- Seven submitters supported the adoption of Option 3 as outlined in the RIS, including two individuals (25, 32), four industry groups (8, 12, 16, and 29), and one CRI (31).
    - Four of these submitters, including one individual (25), and three private businesses (8, 16, 29) noted that the Regulations were outdated as they had not been reviewed in over 20 years and Option 3 presented an opportunity to correct long-standing issues;
    - Two submitters, including two industry groups (12, 16) suggested that risks associated with Option 3 were overstated and there is an opportunity to broaden the exemptions without jeopardising trade.
- Six submitters, including one private business (28), four industry groups (8, 12, 16, 23), and one CRI (31) supported the adoption of Option 4 outlined in the RIS.
    - One industry group (8) disagreed with a statement in the RIS that Option 4 should be discarded due to the length of time and resources required to undertake a review of the HSNO Act.

Risk

53. Six submitters, including one individual (32), four industry groups (8, 16, 23, 24), and one CRI (31) noted that the Regulations should be based on sound scientific principles and proportional to the degree to which the organism is creating new potential risks to human health and safety or the environment, and not on the process by which the organism was created.

54. Two submitters, including one individual (17) and one CRI (18), observed that with regard to the precautionary approach in the HSNO Act the proposals are in some ways not precautionary enough when considering the use of chemicals for mutagenesis purposes and the risks they pose to handlers of such chemicals.

Costs

55. Seven submitters noted issues with compliance and/or opportunity costs:
    - Six submitters, including two individuals (25, 32), and four industry groups (8, 12, 16, 23) suggested that compliance with the Regulations is burdensome and/or costly and/or a barrier to further development;
    - One NGO (27) noted potential arguments against the Regulations on the basis of loss of innovation and international competitiveness but argued that such costs should be weighed against the costs to food exports and the New Zealand brand from early deregulation and use of GM products in the supply chain.

Detection/differentiation

56. One CRI (31) noted that it would be impossible to evaluate if seeds created using certain gene editing techniques are GM under New Zealand law and that New Zealand seed importers and horticulturalists would be placed in a difficult situation as they would need to assess each new seed. They noted that this could result in requests for new organism determinations for any new seed or plant variety imported since 1998; these parties will stop importing new seeds and plant varieties altogether or large scale non-compliance and widespread use of unapproved and uncontrolled GMOs in commercial and domestic use.

Other matters

57. Other matters raised by submitters included:
    - Three submitters suggested that legislation should define when and if gene edited animals are defined as GMOs and what barriers to entry (if any) should be put in place for germplasm from gene edited animals. This included one individual (6) and two industry groups (23, 24);
    - One NGO submitter (26) suggested that a list of new plant breeding technologies be expressly considered as genetic modification technologies;
    - A Member of Parliament (22) suggested that the EPA develop and maintain a register of new products developed using chemical and radiation mutagenesis that are "…shown as fit for purpose, e.g. for food or forage plants, following appropriate testing that shows that they do not cause harm."

Appendix 1: List of Submitters

Categories

Individual (I), Private business (PB), Industry group (IG), University (U), Crown research institute (CRI), Member of Parliament (MP), Non-governmental organisation (NGO)

Submitter #	Name	Organisation	Category
1	Darrell Lizamore	Individual	I
2	Kasey Kime	Life Technologies Australia Pty Ltd	PB
3	Thomas Chin	New Zealand Plant Breeding and Research Association	IG
4	Murray Willocks	New Zealand Agriseeds Ltd	PB
5	Colin Eady	Individual	I
6	Dr Michael Dunbier	Individual	I
7	Dr John Caradus	Grasslanz Technology Ltd	PB
8	Glen Mackie	NZ Forest Owners Association Inc	IG
9	Bart Jan Janssen	Individual	I
10	Revel Drummond	Individual	I
11	Michelle McConnell	IBSC, University of Otago	U
12	Will Barker, CEO	NZBIO	IG
13	David Lewis	New Zealand Institute of Agricultural and Horticultural Science	IG
14	Dr Geoff Ridley	Beef + Lamb New Zealand	IG
15	Prof. Jack	Centre for Integrated Biosafety University of	U

Submitter #	Name	Organisation	Category
	Heinemann	Canterbury	
16	Dr Lisa Harper & Dr William Rolleston	Federated Farmers of New Zealand	IG
17	Dr Kieran Elborough	Individual	I
18	Dr Richard Newcomb	The New Zealand Institute for Plant and Food Research Limited	CRI
19	Tony Conner	AgResearch	CRI
20	Jenny McGregor	Fonterra Cooperative Group Limited	PB
21	Dr Cliff Mason	Individual	I
22	Steffan Browning	Green Party Aotearoa New Zealand	MP
23	Mark Ross, CEO (Agcarm)	On behalf of Agcarm & Crop Life Australia (Joint submission)	IG
24	Bill Fuller, CEO (extension Wednesday)	Australian Seed Federation	IG
25		Individual	I
26	Claire Bleakley	GE Free	NGO
27	Stephanie Howard	Sustainability Council	NGO
28	Richard Spelman	Livestock Improvement Corporation Ltd	PB
29	Paul Gladstone	Meat Industry Association	IG
30	Katherine Rich,	New Zealand Food & Grocery Council	IG

Submitter #	Name	Organisation	Category
	CEO		
31	Warren Parker, CEO	Scion	CRI
32	Grant Jacobs	Individual	I
33	Associate Professor Andrew Allan & Dr. Robert Schaffer	Joint Graduate School for Plant and Food Science, University of Auckland	U

Categories

Category	**Submitter numbers**	**Total submitters**
Individual	1, 5, 6, 9, 10, 17, 21, 25, 32	9
Private business	2, 4, 7, 20, 28	5
Industry group	3, 8, 12, 13, 14, 16, 23, 24, 29, 30	10
University	11, 15, 33	3
Crown research institute	18, 19, 31	3
Non-governmental organisation	26, 27	2
Member of Parliament	22	1