Environmental Protection Authority
Te Mana Rauhī Taiao

Briefing

Release of 'null segregants' statutory determination

Date submitted:	29 January 2024	EPA tracking number	ENQ-47391-X0T5G3
Security classification:	IN-CONFIDENCE	EPA Priority	Urgent

To	Hon Penny Simmonds, Minister for the Environment		
CC			
Action sought:	**Note** the contents of this briefing	Response by	5 February 2024
Attachments:	N/A		

Environmental Protection Authority contacts

Position	Name	Contact number	1st contact
General Manager, Hazardous Substances and New Organisms	Dr Chris Hill	s 9(2)(a) OIA	✓

Key messages

1. This briefing is to advise of a statutory determination made under section 26(1) of the HSNO Act regarding the "new organism" status of null segregants.
2. In December 2020, 15 applicants from the agricultural, horticultural and research sectors applied to the EPA to request a determination to clarify the status of organisms known as 'null segregants'.
3. On 18 January 2024, a decision-making committee (DMC) made a statutory determination that a null segregant is not a genetically modified organism under the Hazardous Substances and New Organisms Act 1996 (HSNO Act).
4. The determination provides certainty for researchers in New Zealand's primary industries and brings New Zealand into line with other countries in the OECD, such as Australia and the United States.
5. The EPA will announce the determination on 7 February 2024.

Background

Null segregants

6. Null segregants are eukaryotic organisms such as plants and animals descended from genetically modified organisms, but do not contain genetic modifications themselves. Similar to the way brown-eyed parents may have blue-eyed children who did not inherit the gene for brown eyes, eukaryotic organisms that are descended from genetically modified organisms may not inherit their parents' specific genetic modifications, meaning they do not contain any genetic modifications themselves.
7. Possible uses for null segregants include what is known as accelerated breeding, where a genetic modification can be used to make plants like apples or kiwifruit flower earlier. Traditional, non-genetically modifying breeding work can be done with such plants in containment, and when a desirable new variety is achieved, null segregant offspring can be created from the rapid flowering plants and subsequently commercialised. This would vastly reduce the amount of time to bring a new variety to market.
8. Another potential area of research which could improve animal welfare is sex selection in chickens. Currently male chicks from egg-laying hen breeds are culled shortly after hatching. The use of a light-detectable fluorescent protein gene that only male embryos carry would enable separation of male embryos from female as early as the day they are laid. The hens would be null segregants, so neither they, nor the eggs they lay, would contain any genetic modifications.

Statutory determination

9. In December 2020, 15 applicants from the agricultural, horticultural and research sectors applied to the EPA to request a determination to clarify the status of organisms known as null segregants.
10. Historically, a null segregant organism has been treated as if it is a genetically modified organism, largely because there were no real-world uses for null segregants, and because the technology to verify organisms as null segregants was not practical to use.
11. On 11 January 2024, the EPA recommended to a DMC that null segregants cannot be genetically modified organisms for the purpose of the HSNO Act.
12. The DMC made its determination on 18 January 2024. The unusually long timeframe between lodgement and decision was due to the need for EPA staff to provide technical expertise and determinations for the Government's COVID-19 response.
13. The Ministry for Primary Industries, with input from the EPA, will be responsible for granting biosecurity clearance for null segregants at the border or in a containment facility. This determination brings us into line with regulations in Australia and the US.
14. The introduction of any specific null segregant into the environment will be verified on a case-by-case basis by MPI, who will be responsible for granting biosecurity clearance for null segregants at the border, or from a secure research facility.
15. This determination does not change the regulations for food that contains genetically modified organisms or ingredients derived from genetically modified organisms, which come under the Food Standards Code, which are overseen by Food Standards Australia New Zealand (FSANZ).

Sustainability Council letter

16. Although this application for a determination was not publicly notified by the EPA, we received one unsolicited letter, from the Sustainability Council, opposing the application.
17. In 2014, the Sustainability Council sought a judicial review resulting in the quashing of the decision of our DMC on a decision made in 2013. Our attempt to then amend the relevant regulations in 2016 was rejected by the government of the day.
18. In this case, there is no legal ambiguity with the statutory regime that underpins the determination. Rather, it is based on the establishment of a clear set of criteria defining a null segregant, followed by evaluating organisms that meet these criteria against the key definitions in the Act. As such, is the direct application of the law to the set of criteria defining a null segregant.
19. Regardless of these points, it is possible that the EPA could receive a request for a reconsideration based on new information, or a judicial review of this determination may be sought by the Sustainability Council or others.

Next steps

20. The EPA will announce the determination on 7 February 2024, which is within the 30-working day period from the decision date to gazette and notify the applicants.
21. As the Minister for Science, Innovation and Technology has an interest in genetic modification, we recommend providing a copy of this briefing to her prior to public announcement.
22. If Ministers wish to be involved in the announcement, we can liaise with your offices to accommodate that.
23. We also recommend providing a copy of the briefing to the Prime Minister's Chief Science Adviser prior to the announcement.

Recommendations

We recommend that you:

a.	**Note** the contents of this briefing	Yes/No
b.	**Forward** this briefing to the Minister for Science, Innovation and Technology and the Prime Minister's Chief Science Adviser	Yes/No

Dr Chris Hill
General Manager, Hazardous Substances and New Organisms
Date: 29 January 2024

Hon Penny Simmonds
Minister for the Environment
Date:

Environmental Protection Authority
Te Mana Rauhī Taiao

Ministerial
Internal use only

MINISTERIAL BRIEFING COVER SHEET

Document title:	Release of 'null segregants' statutory determination
Purpose:	To advise the Minister of a determination that null segregants will no longer be classified at GMOs under the HSNO Act
Audience:	Minister Simmonds
Author:	**Annie Williams**
Any other comments:	

Review

	Name	Signature/initials	Date
Expert peer review	Dr Tim Strabala		25 Jan 2024
Proof reading review	Kaia Kento	*Kaia Kento*	26/01/2024
Acting Manager GE & IM	Annie Williams		26 January 2024
General Manager	Dr Chris Hill		26 Jan 2024
Chief Executive	Dr Allan Freeth		

Environmental Protection Authority
Te Mana Rauhī Taiao

Ministerial
Internal use only

MINISTERIAL BRIEFING COVER SHEET

Document title:	Release of 'null segregants' statutory determination
Purpose:	To advise the Minister of a determination that null segregants will no longer be classified at GMOs under the HSNO Act
Audience:	Minister Simmonds
Author:	**Annie Williams**
Any other comments:	

Review

	Name	Signature/initials	Date
Expert peer review	Dr Tim Strabala		25 Jan 2024
Proof reading review	Kaia Kento	Kaia Kento	26/01/2024
Acting Manager GE & IM	Annie Williams		26 January 2024
General Manager	Dr Chris Hill		
Chief Executive	Dr Allan Freeth		26-1-24