

Communications options: null segregants determination

15 January 2024

Summary

- In May 2021, 14 applicants from the agricultural, horticultural and research sectors, applied to the Environmental Protection Authority (EPA) to request a determination on the status of what are known as “null segregants”.
- A null segregant organism is the offspring of a genetically modified plant or animal - but the offspring is not genetically modified, nor contains any characteristics of being genetically modified, because it did not inherit the modifications from either parent. Currently a null segregant organism is treated as if it is a genetically modified organism. Examples of possible research areas where null segregants could be used are in speed breeding for horticulture or in selecting for a specific sex e.g. male chicken embryos could be identified and destroyed before hatching, rather than after.
- On 11 January 2023, the EPA recommended to a decision-making committee (DMC) that null segregants should not be classed as new or genetically modified organisms for the purposes of the Hazardous Substances and New Organisms Act 1996.
- If the DMC accepts the recommendation, MPI (with advice from the EPA) will be responsible for granting biosecurity clearance for null segregants at the border or in a containment facility.
- There may possibly be additional Food Safety requirements put on null segregant food products. However, Food Standards Australia New Zealand allows for null segregants.
- This determination brings us into line with regulations in Australia and US.
- We have 30 working days to notify/Gazette this determination.
- Although this application for a determination was not required to be publicly notified, we did receive one letter, from the Sustainability Council (an anti-GE group), opposing the application. In 2014, the Sustainability Council sought a judicial review and successfully overturned the decision of our DMC on a similar decision made in 2013. Our attempt to then amend the relevant Regulations in 2016 was rejected by the Government of the day.

Options for communications

We see three main options for communications. These will need to take into account the need to notify key stakeholders such as:

- The Minister's Office
- The applicant (either via AgResearch or individually)
- Sustainability Council

The Board and Ngā Kaihautū Tikanga Taiao will also need to be notified in advance of public release.

Option	Benefit	Risk	Notes
Reactive comms <ul style="list-style-type: none"> • Determination is Gazetted and docs loaded to website • Reactive lines for media 	<ul style="list-style-type: none"> • Media might not pick up on change so possibly no media attention (note this will depend on what approach the applicant and Sustainability Council/other anti-GE groups might take). 	<ul style="list-style-type: none"> • Opens us up to being accused of attempting to bury the information. • Media learn about the issue from another source and run a story focussing on others' key messages and potentially use inaccurate information. • Lost opportunity to show how we are making decisions that benefit NZ research and business, using our current legislation. 	<ul style="list-style-type: none"> • We are required to Gazette the determination and publish the application and decision documents to our website within 30 working days. • Ensure Ministers' office/s are kept informed as appropriate
Low-key proactive communication	<ul style="list-style-type: none"> • Media might not pick up on change so possibly no media attention (note this will depend on what approach 	<ul style="list-style-type: none"> • Media learn about the issue from another source and run a story focussing on others' key messages 	<ul style="list-style-type: none"> • Prepare a spokesperson in case we are asked for an interview.

<ul style="list-style-type: none"> • Determination is Gazetted and docs loaded to website. • The determination is promoted via a news story on our website. • Prepare reactive lines for media. • Item in HS Update 	<p>the applicant and Sustainability Council/other anti-GE groups might take).</p> <ul style="list-style-type: none"> • We still demonstrate a degree of transparency through our published information. 	<p>and potentially use inaccurate information.</p> <ul style="list-style-type: none"> • Lost opportunity to show how we are making decisions that benefit NZ research and business, using our current legislation. 	<ul style="list-style-type: none"> • Engage with MPI comms. • Involve Engagement team as many key industry bodies involved. • Ensure Ministers' office/s are kept informed as appropriate.
<p>Moderate proactive communications</p> <ul style="list-style-type: none"> • Distribute media release, publish this on our website. • Include as an item in our newsletters. • Publicise via social media (LinkedIn only). 	<ul style="list-style-type: none"> • We demonstrate maximum transparency. • We may get to lead the story and influence the angle by being the first out with the news. • We could be perceived positively as creating certainty for researchers and opening up avenues for horticultural and agricultural businesses. • Possibly show that current legislation is fit for purpose and does not need replacing. 	<ul style="list-style-type: none"> • Media report inaccurate information. • We could be perceived as opening up an avenue for GMOs to enter NZ food products. What does this mean for brands that are marketing themselves as non-GM? Some businesses may worry null segregants could breed/interfere with their products? • Possible questions about why there was no public consultation. 	<ul style="list-style-type: none"> • Need to consider timings – when must the applicants be informed of the decision? Can this timing be aligned with when we have public comms prepared? • Consider engaging with the Sustainability Council just ahead of releasing the PR. • Ensure Ministers' office/s are kept informed as appropriate. • Engage with MPI comms.
<p>High-profile proactive communications</p> <p>Proactively pitch story to journalists – this could include working with other</p>	<ul style="list-style-type: none"> • We may get to lead the story and influence the angle by being the first out with the news. • We get the best chance of ensuring our perspective makes the final 	<ul style="list-style-type: none"> • Very slight possibility embargo is not adhered to and information is released – suggest any embargo is only a day or two ahead of general release to mitigate this. 	<ul style="list-style-type: none"> • Consider providing Science Media Centre with the media release under embargo, so that they have time to seek expert reaction.

experts on the story as well as EPA expert/spokesperson.	story as our spokesperson and quotes are more likely to be central.		<ul style="list-style-type: none"> Consider sharing in advance with PM's Chief Scientist Professor Dame Juliet Gerrard.
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Communications considerations

- GE is poorly understood and highly emotive and there are many groups with a view on this issue.
- There is likely to be high public and media interest in this determination.
- The issue of GMO regulation has been raised by both National (when in opposition) [National party opens door to change on genetic engineering | BusinessDesk](#) and Act [Act wants completely new GMO legislation | BusinessDesk](#)
- Risks of taking a reactive or passive approach include the Sustainability Council/other anti GE group or the applicants going to media and framing the initial messages. If it's an anti-GE group, it is quite possible their information may be inaccurate, and they may seek to criticise EPA processes, communication or other aspects of our work.
- Risks of taking a more high-profile proactive approach include negative media for the EPA.
- It is possible that a judicial review of this determination may be sought by the Sustainability Council or others.

Questions

- Why was this application not notified?
- Delay notifying applicants until approach confirmed and information is ready.
- Are AgResearch or any other applicants planning any proactive comms?

- What is our approach to informing Ngā Kaihautū Tikanga Taiao?
- Do we need an engagement lens on this?
- What comms tools can we use to explain the science in a simple and effective way for a general audience?
- What level of involvement is the Minister likely to want?
- Any input from MfE required?

Recommended next steps

- The HSNO General Manager and Chief Executive consider the benefits and risks of taking either a reactive, low-key or a more high-profile approach to proactively communicating about this determination and advises the Communications of their preferred approach.
- The Minister's office is advised of the planned communications approach when they receive a briefing on the determination.
- Release the determination to the applicants after we have developed clear, plain language communications to ensure that the general public can understand this decision.
- Comms could prepare background information relating to our approach to GMOs more generally (this could possibly be reused on our website in future).

Communications plan: null segregants

17/01/2024

Context

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'.

A null segregant is the offspring of any genetically modified organism – but the offspring does not contain any genetic modifications from either parent. 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.

On 11 January 2024, the EPA recommended to a decision-making (DMC) committee that null segregants are not genetically modified organisms for the purpose of the Hazardous Substances and New Organisms Act 1996 (HSNO Act). On 18 January 2024, the DMC made a statutory determination that a null segregant is not a genetically modified organism under the Act.

MPI (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.

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. 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. It is possible that a judicial review of this latest determination may be sought by the Sustainability Council or others.

We have 30 working days to notify/gazette this determination.

Communications approach

As outlined in the [Comms options null segregants.docx](#), there are pros and cons to each approach. This plan has been prepared on the basis that a moderate proactive communications approach will likely be taken, meaning:

We will proactively announce the determination via media release, LinkedIn, posts and via our newsletter/s.

Communication objectives

- Highlight how we are making decisions that benefit New Zealanders and our economy while still taking a precautionary approach to GMOs.
- Clearly explain the law and science behind this determination and what this decision means in practice.
- Ensure our messaging addresses likely questions upfront, anticipating speculation/opinions being provided by other parties.
- Demonstrate transparency in our decision-making process by proactively releasing this information.
- Increase trust and confidence in the EPA as an effective regulator of GMOs.
- Increase public awareness of the EPA's role.

Audiences

- Agricultural sector
- Science and research sector
- Groups opposed to GE
 - Sustainability Council
 - GE-Free NZ
- Iwi/hapū
- Government
 - MPI, MfE, DOC, MBIE, Food Standards Australia New Zealand (FSANZ), PM's Chief Science Advisor
- General public
- The applicants

Key messages

- The Environmental Protection Authority (EPA) is providing certainty for researchers in New Zealand's primary industries by clarifying that certain organisms are not genetically modified organisms under the Hazardous Substances and New Organisms Act 1996.
- These organisms, known as null segregants, are 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, plants or animals or other organisms which are descended from genetically modified organisms may not inherit their parents' specific genetic modifications, meaning they do not contain any genetic modifications themselves.

- The EPA's decision brings New Zealand into line with other countries in the OECD, such as Australia and the United States, and will help New Zealand scientists keep pace with international research.
- 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, selective breeding work can then be done with the genetically modified rapidly flowering plants in secure research facilities. When the researcher achieves a desirable new variety (using traditional, non-GM selective breeding techniques), null segregant offspring can be created and then commercialised. This would vastly reduce the amount of time to bring a new variety to market.
- 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 containment.
- This determination does not change the regulations for food that contains genetically modified organisms or ingredients derived from genetically modified organisms. These come under the Food Standards Code, overseen by Food Standards Australia New Zealand (FSANZ).
- As Aotearoa New Zealand's environmental regulator, we balance social, economic, safety, and environmental factors in every decision we make to safeguard people and the environment now and into the future.
- We take a precautionary approach, and our experts make independent, evidence-based decisions that take into account the latest research and international best practice.

Risks and mitigations

Issue	Mitigation
Media learn about the issue from another source and run a story focussing on others' key messages and potentially use inaccurate information.	Time our release of the determination to the applicants so it is a day or two before the general release. This may allow us to be the first out with the news so we can set the tone, and gives us more scope to develop clear, plain language communications to ensure that the general public can understand this decision. We can provide the applicants with an embargoed copy of the media release to help set the narrative with our own key messages.
General public struggle to understand the science and the determination.	<p>Clear, concise, plain language information will be provided.</p> <p>Provide information to trusted experts under embargo, who will then be in a position to speak reassuringly to the public / the media when the decision is released.</p>
We are criticised about the time taken to make the determination.	Messaging explaining how rigorous our processes are. Prepare back pocket responses to likely queries so we have answers to hand.
This determination is seen as covert criticism of the Government's position on GMO regulation.	Propose a moderate proactive comms approach.
Opposition MPs and others claim the decision has been influenced by the Government's policy on GMOs.	Explain the timeline and independent process for the determination.
The announcement prompts questions about the Government's policy on GMOs, including its plan for a biotechnology regulator.	Ministers are briefed on the determination.

Question about GMOs entering the food chain.	Highlight role of Food Standards Australia New Zealand (FSANZ) and that there will still be case by case verification before null segregants (which are not considered GMOs) are released.
Possible questions about why there was no public consultation.	Prepare back pocket messaging around different types of application processes under HSNO.

Back pocket Q&As

Why make this determination now?

- The determination is the culmination of a three-year process. Under the HSNO Act, the EPA must assess and decide any application for an approval or request for a statutory determination that it receives. The determination has been made following the completion of the review, evaluation, and the rigorous decision-making process undertaken by the EPA.

Did the Government influence the decision or the timing?

- Neither this government, nor the previous one had any input into this assessment or decision. The EPA is an independent regulator, and our experts make evidence-based decisions that take into account the latest research and international best practice. Once we have assessed all the information, we make a recommendation to our independent decision-making committee. The committee reviews the information and then advises us of their decision.

Why has it taken so long to make this determination?

- Requests for determination have no statutory timeframes associated with them. The request was submitted just before the COVID-19 pandemic reached New Zealand's shores. As such, priority was given to pandemic-related work, such as the Pfizer vaccine determination, as well as other time-bound activities required of the EPA.

What were the steps and who was involved in making this determination?

- After we receive a request for a determination, we evaluate it against the relevant criteria of the HSNO Act. This process includes reviewing information in the context of the relevant criteria of the HSNO Act. We also seek input from other government agencies. Once we have assessed all the information, we make a recommendation to

our independent decision-making committee. The committee reviews the information and then advises us of their decision.

Did you hold a public consultation before making this determination?

- The determination process is not an application for an approval from the EPA. It is a process defined under the HSNO Act to determine whether or not any organism is a new organism. This means it is a determination of fact, involving the evaluation of the type of organism against the relevant criteria set out in the Act. These determinations do not require public notification under the HSNO Act.

Does this mean New Zealand is relaxing the rules for GMOs?

- The EPA has determined that a null segregant cannot be a GMO because it doesn't meet the definition of a GMO in the HSNO Act. New Zealand's regulations about GMOs are unchanged.

How does this fit with the Government's policy on GMOs?

- As a null segregant cannot be a GMO based on existing criteria in the HSNO Act, this decision cannot be considered to relate to the government's policy on GMOs.

Does this decision mean the HSNO Act is fit for purpose for GMOs?

- This decision is about organisms that are *not* GMOs. Therefore, the decision does not reflect on the regulation of GMOs under the HSNO Act, which is unchanged.

Will this damage New Zealand's reputation for being GE-free?

- Null segregants have been determined to be not GMOs and must be verified to confirm they do not contain any genetic modifications before any possible future use in the environment.

What will this mean for consumers?

- The EPA has noted some potential practical uses of null segregants in its evaluation of such organisms. The EPA can't predict what null segregants, if any, might be used in New Zealand. However, before any null segregants can be used in New Zealand they will require verification that they do not contain any genetic modifications.

Can gene-edited organisms be null segregants?

- Any gene edits, including gene deletions, are considered GMOs – so cannot be a null segregant.

Can a person be a null segregant?

- Human beings are not considered to be organisms for the purpose of the HSNO Act. Heritable genetic modifications to human beings are prohibited under the Human-Assisted Reproductive Technologies Act.

What about null segregants that are new organisms even if not genetically modified?

- Such organisms would not be GMOs, but they would still be new organisms because they meet other parts of the new organism definition.

What about organisms with genetic modifications that are undetected, or do not cause any outwardly detectable change in the organism?

- Such organisms would still be GMOs, because it is the presence of the genetic modification, and not any effects that the genetic modification might cause that is the defining criterion. There is a variety of well-established detection methods that can be used to detect genetic modifications, both known and unknown.

How will presumed null segregants be verified?

- 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 containment facility.

Will there be any food labelling requirements for null segregants?

- 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).

Are these proposals changing the regulations for food that contains GMOs or ingredients derived from GMOs?

- The regulatory requirements for food that contain GMOs, or ingredients derived from GMOs, come under the Food Standards Code, overseen by Food Standards Australia New Zealand (FSANZ).

Do other countries allow null segregants?

- This determination will bring us into line with other countries in the OECD. For example, both Australia and the United States do not view null segregants as GMOs.

Has the EPA exercised appropriate precaution?

- Yes. the EPA exercised caution by the careful selection of criteria that set boundaries on what a null segregant is. These criteria make it clear that organisms with modifications resulting from techniques not exempted in regulation remain GMOs. This includes all gene editing techniques. Additionally, verification methods will need to be developed to confirm the null segregant status of organisms.

Did the EPA give preferential treatment to the Sustainability Council with its letter?

- The section 26 determination is not a notified process under the HSNO Act. The Sustainability Council submission was unsolicited. However, as it was information pertinent to the consideration, the EPA deemed it the best approach to assess the information and provide advice to the Decision-making Committee regarding it, in addition to the letter and attached file.

When does this determination come into effect?

- The determination comes into effect once the decision is published in the New Zealand Gazette.

How does this determination relate to the Proposed changes to Aotearoa New Zealand's GMO regulations being undertaken by MfE? [Improving-GMO-regulations-Snapshot-of-the-consultation-and-FAQs.pdf \(environment.govt.nz\)](#)

- This determination has been made using the existing criteria of the HSNO Act, and it only relates to organisms that are not GMOs under the Act. As such, it is unrelated to any proposed changes to our GMO regulations.

If a null segregant breeds with another ordinary plant/animal in the environment, is it possible that the offspring might inherit any genetic modifications?

- As null segregants do not carry any genetic modifications as defined in the HSNO Act, the offspring can't inherit any genetic modifications.

Media release

Focus on how this determination will create opportunities for research. Highlight that any possible future null segregants will be verified by MPI.

Social media

Post to LinkedIn. Short statement and image, linking to the PR.

Visual storytelling

- Use an image similar to those used in the Plant and Food animation, or of allele punnett square /other relevant image to accompany press release (our own design if time permits or possibly reuse if there is a creative commons image available).
- Alternatively, use stock images suitable for LinkedIn post.

GMO website landing page

Front foot potential queries by developing a GMO landing page for the website, with context on New Zealand's GMO rules. Suggest also creating a separate null segregant webpage.

EPA roles and responsibilities

- Briefing Minister/s – Government Engagement – Annie
- Briefing Board – Allan
- Briefing/advising key agencies/stakeholders ahead of the release i.e. in addition to the standard notification email: Nga Kaihautū Tikanga Taiao, MfE, MPI, DoC, MoH, MBIE, Food Standards Australia New Zealand (FSANZ), PM's Chief Science Advisor and Forum, Office of the Gene Technology Regulator, applicants – Chris, Erica and Tim
- Briefing MPI, MfE comms, FSANZ – EPA Comms, Alisa
- Briefing any extra industry bodies – Chris
- Final sign off and EPA spokesperson - Chris

Important dates

- Select Committee date 15 February.
- Tim away 30 Jan – Feb 1
- Alisa away 2 February
- We have 30 working days (1 March) to Gazette and publish decision on website.
- Waitangi Day- 6 February 2024

Communications activity plan

What	When	Who	More detail (i.e. how we will do this)
Comms plan signed off	25 Jan	Alisa, Tim, Marina, Erina, Paula, Chris	
Draft press release, LinkedIn post, back pockets, image	23 Jan onwards	Alisa, Tim, Sarah	Sarah Laing to create infographic/illustration explaining null segregants (use graphics to create video if time)
Briefing to Minister, Board, Nga Kaihautū Tikanga Taiao (share with MfE, MPI, DoC, MoH, MBIE, Food Standards Australia New Zealand (FSANZ) operations and or policy teams)	TBC 26 Jan?	Annie, Allan, Chris, Tim	Could use briefing to Minister as basis for emails to others
Get sign-off for comms content	29 Jan	Marina, Erina, CH, Allan	
Advise Chief Science Advisors Forum (TBC)	31 Jan	Erica	Send embargoed copy of media release two days before release
Advise comms managers at MPI, MfE, MBIE, Health, FSANZ	31 Jan	Alisa/Erina	Heads up one week in advance and send advance copy of press release under embargo
Contact centre	31 Jan	Alisa	Heads up and copy of media release under embargo

Prepare spokesperson	5 Feb	Alisa, Tim, Chris	Media prep session. Calendar reserved for post-release responses.
Applicants advised	2 Feb	Tim/Chris	Send embargoed copy of media release
Update web publishers	5 Feb	Alisa	Alert webmaster at least 48 hours before intended publication
Embargoed copy of media release sent to Board, NKKT	5 Feb	Allan/Board admin/Erica	
Embargoed copy of media release sent to Chief Science Advisors Forum (TBC)	5 Feb	Erica	
Send embargoed copy of media release to independent science experts e.g. via Science Media Centre (TBC)	5 Feb	Alisa	
Update HSNO database	6 Feb	Diane	Update CRM, link organism register (information will publish to the HSNO database overnight). This will show the outcome of the decision.
Determination docs loaded to website	7 Feb 9 am	Diane	Will need links for these to include in press release (should appear on website fairly directly)

Send 'standard' notification emails	7 Feb 9 am	NO team	Email out standard advisement of decision (applicant, DOC and MPI) with additional note about information being embargoed until 11 am
Embargoed copy of media release sent to Te Herenga, Wai 262 project team	7 Feb 10.30am	KKT	
Office of the Gene Technology Regulator	7 Feb	Tim	
Issue determination comms	7 Feb 12pm	Alisa, webmaster. Engagement	Media release, web content, LinkedIn post. Consider if there are any other groups/people we should notify – engagement team.
Contact Sustainability Council to advise	7 Feb 12pm	Tim/Chris?	
EPA internal comms		Alisa	Short EPA home article linking to media release as soon as media release is published on website
Respond to media and public queries		Alisa, Tim, Erina, Chris	Comms to handle media queries, all others to NO
Gazette the decision		Diane	Pre-loaded into the Gazette publishing for release on 9 Feb.
Publish in EPA external publications	Feb onwards	Alisa	Consider Te Pūtara, annual report

Review and report back	Feb	Alisa, Tim	Let management, the board and other staff know the results of this work, and capture any lessons learned.
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Null seg media prep

Key messages:

- Our work is all about protecting the environment - helping foster a safe and sustainable way of life for all New Zealanders.
- Part of our role is to enforce the current rules around genetically modified organisms and make decisions about what is defined as a GMO.
- We received an application to clarify the rules around whether null segregants should be considered genetically modified organisms.
- Null segregants are plants and animals which are descended from a genetically modified organism but do not inherit the genetic modification themselves.
- This can occur when one parent has the genetic modification and the other parent does not. Some of the offspring of these parents will not have the genetic modification and these are called null segregants.
- One possible use of null segregants is for accelerated breeding in horticulture by using a genetic modification that makes plants produce fruit much sooner than would normally occur. This in turn allows desirable traits, such as resistance to a particular disease, to be developed much faster.
- Our scientists looked at the research on this topic and international best practise, then considered the GMO status of null segregants in light of current rules.
- We've now clarified that "null segregants" are not genetically modified organisms.
- Any specific null segregant will still need to be verified on a case-by-case basis by the Ministry for Primary Industries before being released into the environment.
- This decision brings New Zealand into line with other countries, like Australia and the United States.
- It also provides certainty for scientists in New Zealand's primary industries, helping them to keep pace with international research.

Back pocket Q&As

Why make this determination now?

- The determination is the culmination of a three-year process. Under the HSNO Act, the EPA must assess and decide any application for an approval or request for a statutory determination that it receives. The determination has been made following the completion of the review, evaluation, and the rigorous decision-making process undertaken by the EPA.

Did the Government influence the decision or the timing?

- Neither this government, nor the previous one had any input into this assessment or decision. The EPA is an independent regulator, and our experts make evidence-based decisions that take into account the latest research and international best practice. Once we have assessed all the information, we make a recommendation to our independent decision-making committee. The committee reviews the information and then advises us of their decision.

Why has it taken so long to make this determination?

- Requests for determination have no statutory timeframes associated with them. The request was submitted just before the COVID-19 pandemic reached New Zealand's shores. As such, priority was given to pandemic-related work, such as the Pfizer vaccine determination, as well as other time-bound activities required of the EPA.

What were the steps and who was involved in making this determination?

- After we receive a request for a determination, we evaluate it against the relevant criteria of the HSNO Act. This process includes reviewing information in the context of the relevant criteria of the HSNO Act. We also seek input from other government agencies. Once we have assessed all the information, we make a recommendation to our independent decision-making committee. The committee reviews the information and then advises us of their decision.

Did you hold a public consultation before making this determination?

- The determination process is not an application for an approval from the EPA. It is a process defined under the HSNO Act to determine whether or not any organism is a new organism. This means it is a determination of fact, involving the evaluation of the type of organism against the relevant criteria set out in the Act. These determinations do not require public notification under the HSNO Act.

Does this mean New Zealand is relaxing the rules for GMOs?

- The EPA has determined that a null segregant cannot be a GMO because it doesn't meet the definition of a GMO in the HSNO Act. New Zealand's regulations about GMOs are unchanged.

How does this fit with the Government's policy on GMOs?

- As a null segregant cannot be a GMO based on existing criteria in the HSNO Act, this decision cannot be considered to relate to the government's policy on GMOs.

Does this decision mean the HSNO Act is fit for purpose for GMOs?

- This decision is about organisms that are *not* GMOs. Therefore, the decision does not reflect on the regulation of GMOs under the HSNO Act, which is unchanged.

Will this damage New Zealand's reputation for being GE-free?

- Null segregants have been determined to be not GMOs and must be verified to confirm they do not contain any genetic modifications before any possible future use in the environment.

What will this mean for consumers?

- The EPA has noted some potential practical uses of null segregants in its evaluation of such organisms. The EPA can't predict what null segregants, if any, might be used in New Zealand. However, before any null segregants can be used in New Zealand they will require verification that they do not contain any genetic modifications.

Can gene-edited organisms be null segregants?

- Any gene edits, including gene deletions, are considered GMOs – so cannot be a null segregant.

Can a person be a null segregant?

- Human beings are not considered to be organisms for the purpose of the HSNO Act. Heritable genetic modifications to human beings are prohibited under the Human-Assisted Reproductive Technologies Act.

What about null segregants that are new organisms even if not genetically modified?

- Such organisms would not be GMOs, but they would still be new organisms because they meet other parts of the new organism definition.

What about organisms with genetic modifications that are undetected, or do not cause any outwardly detectable change in the organism?

- Such organisms would still be GMOs, because it is the presence of the genetic modification, and not any effects that the genetic modification might cause that is the defining criterion. There is a variety of well-established detection methods that can be used to detect genetic modifications, both known and unknown.

How will presumed null segregants be verified?

- 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 containment facility. We work very closely with MPI as they are responsible for ensuring compliance with the HSNO Act.

Will there be any food labelling requirements for null segregants?

- 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).

Are these proposals changing the regulations for food that contains GMOs or ingredients derived from GMOs?

- The regulatory requirements for food that contain GMOs, or ingredients derived from GMOs, come under the Food Standards Code, overseen by Food Standards Australia New Zealand (FSANZ).

Do other countries allow null segregants?

- This determination will bring us into line with other countries in the OECD. For example, both Australia and the United States do not view null segregants as GMOs.

Has the EPA exercised appropriate precaution?

- Yes. the EPA exercised caution by the careful selection of criteria that set boundaries on what a null segregant is. These criteria make it clear that organisms with modifications resulting from techniques not exempted in regulation remain GMOs. This includes all gene editing techniques. Additionally, verification methods will need to be developed to confirm the null segregant status of organisms.

Did the EPA give preferential treatment to the Sustainability Council with its letter?

- The section 26 determination is not a notified process under the HSNO Act. The Sustainability Council submission was unsolicited. However, as it was information pertinent to the consideration, the EPA deemed it the best approach to assess the information and provide advice to the Decision-making Committee regarding it, in addition to the letter and attached file.

When does this determination come into effect?

- The determination comes into effect once the decision is published in the New Zealand Gazette.

How does this determination relate to the Proposed changes to Aotearoa New Zealand's GMO regulations being undertaken by MfE? [Improving-GMO-regulations-Snapshot-of-the-consultation-and-FAQs.pdf \(environment.govt.nz\)](#)

- This determination has been made using the existing criteria of the HSNO Act, and it only relates to organisms that are not GMOs under the Act. As such, it is unrelated to any proposed changes to our GMO regulations.

If a null segregant breeds with another ordinary plant/animal in the environment, is it possible that the offspring might inherit any genetic modifications?

- As null segregants do not carry any genetic modifications as defined in the HSNO Act, the offspring can't inherit any genetic modifications.

Notes for null segregants post-decision

What is a null segregant under the HSNO Act?

NB: The following definition of a null segregant is only applicable in the context of the HSNO Act.

A null segregant is defined for the purpose of this statutory determination as – any living eukaryotic organism (other than a human being) that:

1. is descended from one or more genetically modified organisms that are new organisms solely by virtue of being GMOs as defined in the Act, and

Point 1 is meant to cover the possibility that a GMO could be a new organism for another reason, such as not being present in New Zealand immediately before 29 July 1998. Any organism that is a new organism before it was a GMO remains a new organism.

2. is descended via sexual reproduction from its GMO parent(s) and allelic segregation from its GMO sibling(s), or

Point 2 is ensures that a supposed null segregant arose as a result of breeding, and allelic segregation as described above, and not some other way of removing the in vitro-manipulated genes or other genetic material.

3. is descended or otherwise derived, whether sexually or asexually, through any number of replications, from a null segregant progenitor(s), and

Point 3 clarifies that the offspring of null segregants are also not GMOs, so long as they are not bred with another GMO.

4. that does not contain *in vitro*-modified genes or other genetic material that is not exempted in regulation and that defined its ancestor(s) as a GMO(s)

Point 4 clarifies that the presumed null segregant must be free of any modifications that are not exempted in the HSNO (Organisms Not Genetically Modified) Regulations 1998. This includes modifications resulting from all gene editing techniques.

Such organisms do not meet the definition of a GMO in the HSNO Act, and can't be considered to be new organisms solely on this basis.

Why has this determination been made?

There are a number of uses of advanced GM technology that can benefit New Zealand's primary sectors and consumers, and/or address animal welfare issues. Some immediate

uses include so-called accelerated breeding, in which a genetic modification can be used to make plants like apples or kiwifruit flower much earlier than they normally would. Traditional breeding work can be done with such plants in containment, and when a desirable new variety is achieved, null segregants can be created from the rapid flowering plants and subsequently commercialised. This will aid in keeping the horticultural and forestry sectors internationally competitive.

Another example is sex selection in chickens. Currently male chicks from layer hen breeds are not suitable for either laying or meat production, so 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. Hens are null segregants in this case, so neither they nor the eggs they lay would contain genetic modifications.

Can gene-edited organisms be null segregants?

No. Gene-edited organisms are not exempt from regulation as GMOs. Therefore, any gene edits, including gene deletions, must not be present in order for an organism to be a null segregant.

Can a person be a null segregant?

No. Human beings are not considered to be organisms for the purpose of the HSNO Act. Heritable genetic modifications to human beings are prohibited under the Human-Assisted Reproductive Technologies Act.

What about null segregants that would be new organisms even if not genetically modified?

Such organisms would not be GMOs, but they would still be new organisms because they meet other parts of the new organism definition.

What about organisms with genetic modifications that are undetected, or do not cause any outwardly detectable change in the organism?

Such organisms would still be considered to be GMOs, because it is the presence of the genetic modification, and not any effects that the genetic modification might cause that is the defining criterion.

How will presumed null segregants be verified?

Verification of presumed null segregants will need to be done on a case-by-case basis, and may involve a variety of tests.

Who will regulate null segregants and what might this regime look like?

Other than the above, will there be any other barriers to null segregants being released into the environment?

Will there be any food labelling requirements for null segregants?

Are these proposals changing the regulations for food that contains GMOs or ingredients derived from GMOs?

No. The regulatory requirements for food that contain GMOs, or ingredients derived from GMOs, come under the Food Standards Code, which are overseen by Food Standards Australia New Zealand (FSANZ). Read more about the Food Standards code and FSANZ

I sell products that are marketed as GM free. Would I still be able to use this label if I sell products from null segregants or products that are null segregants?

If a null segregant breeds with another ordinary plant/animal in the environment, is it possible that the offspring might inherit any genetic changes?

How does this application relate to the AgResearch rye grass trials?

Do other countries allow null segregants?

This determination will bring us into line with many other countries in the OECD. For example, both Australia and the United States do not define null segregants as GMOs.

Has the EPA exercised appropriate precaution?

Yes. the EPA exercised caution by the careful selection of criteria that set boundaries on what a null segregant is. These criteria make it clear that organisms with modifications resulting from techniques not exempted in regulation remain GMOs. This includes all gene editing techniques. Additionally, the EPA acknowledges that verification methods will need to be developed to confirm the null segregant status of organisms.

What is the EPA's approach to regulating GMOs?

Say something here about our precautionary approach but how we do approve things in containment etc so research can still progress. Could reference proposed GMO regulation changes here...

Why was there no public consultation on this determination?

Did the EPA give preferential treatment to the Sustainability Council with its letter?

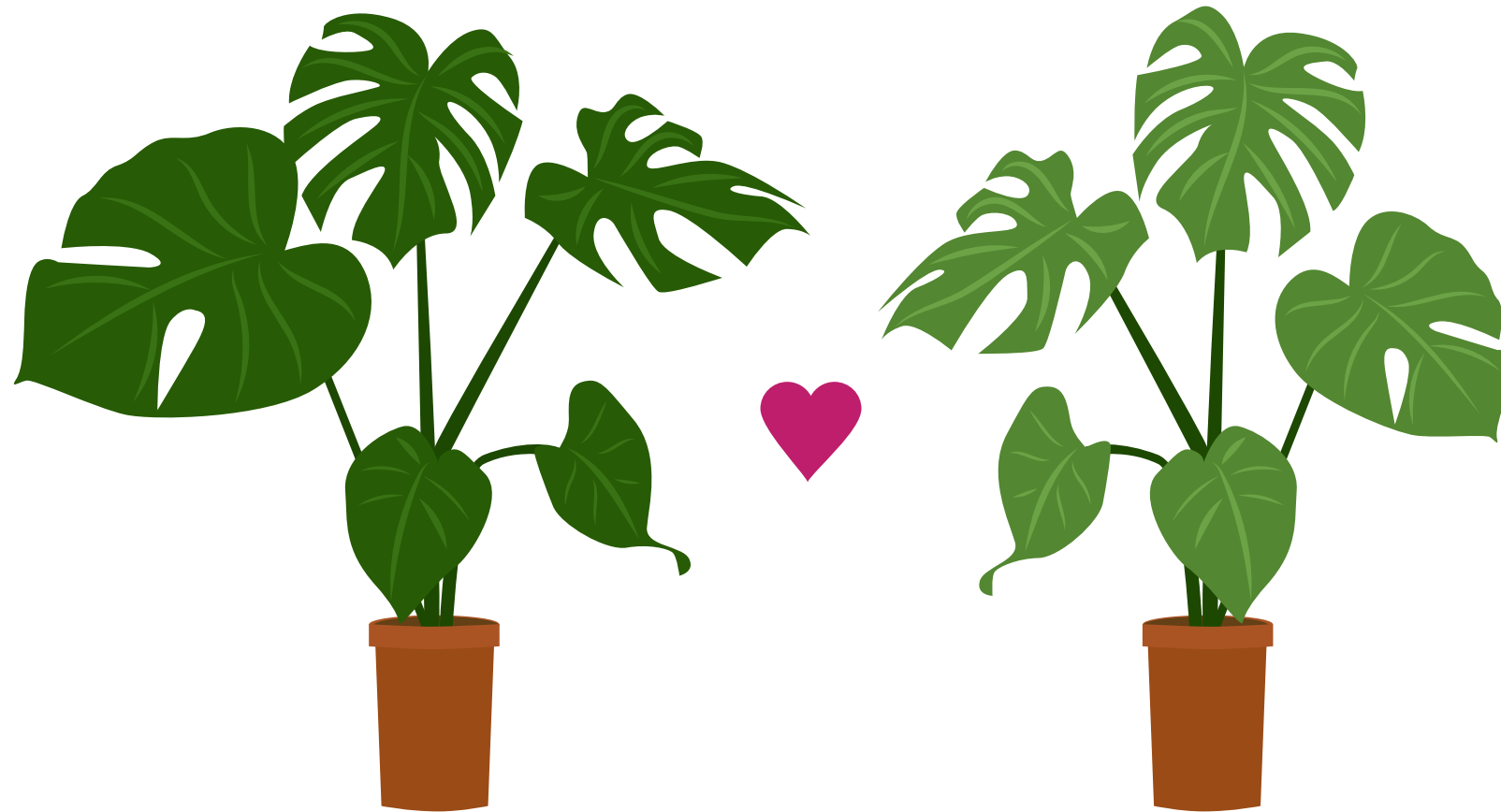
No. The section 26 determination is not a notified process under the HSNO Act. The Sustainability Council submission was unsolicited. However, as it was information pertinent to the consideration, the EPA deemed it the best approach to assess the information and provide advice to the Decision-making Committee regarding it, in addition to the later and attached file.

When does this determination come into effect?

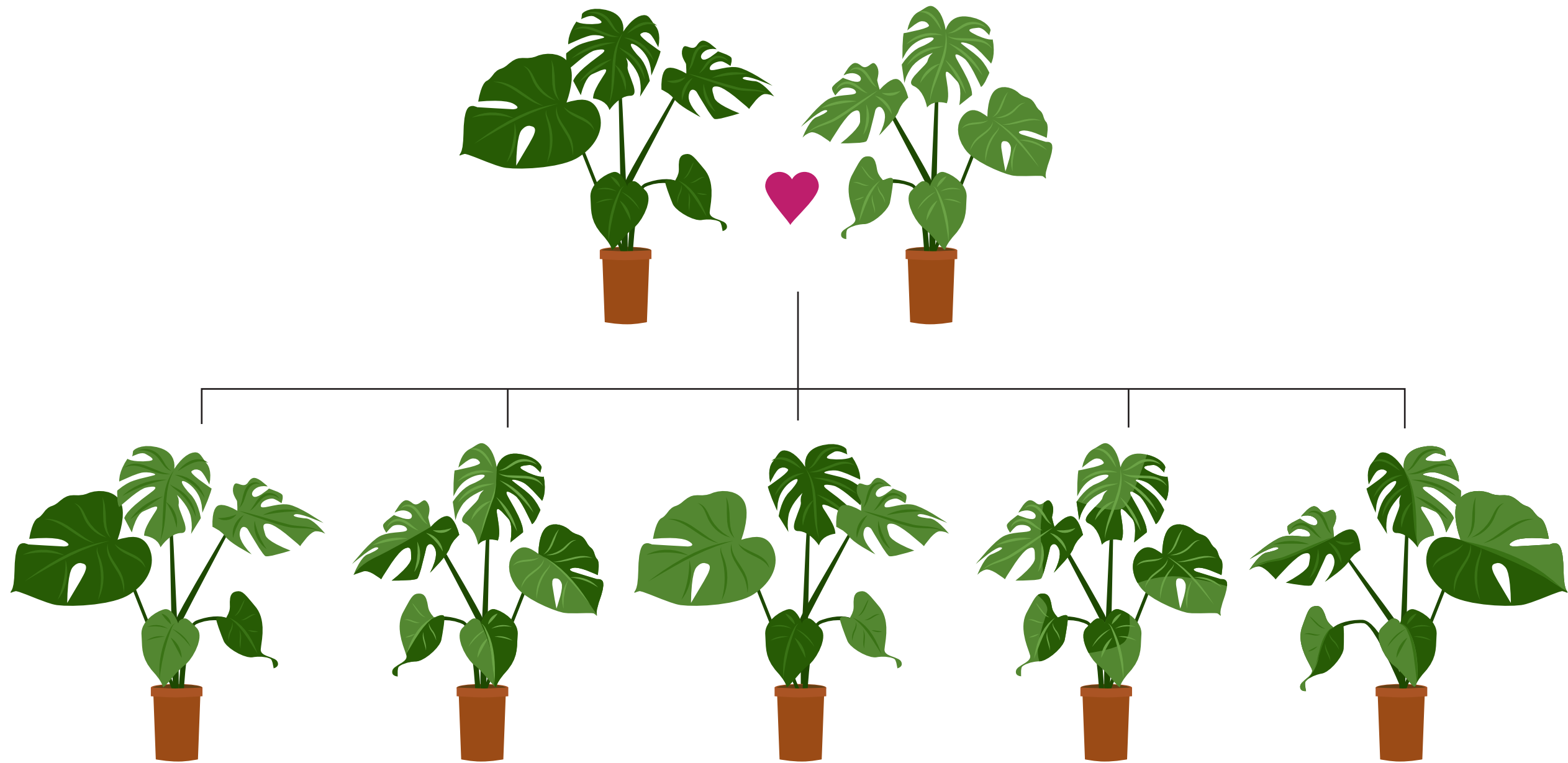
Why did it take so long for this determination to be made?

How does this determination relate to the Proposed changes to Aotearoa New Zealand's GMO regulations ([Improving-GMO-regulations-Snapshot-of-the-consultation-and-FAQs.pdf \(environment.govt.nz\)](#)) being undertaken by MfE?

Does this determination mean that HSNO Act is fit for purpose?



When you cross two parents



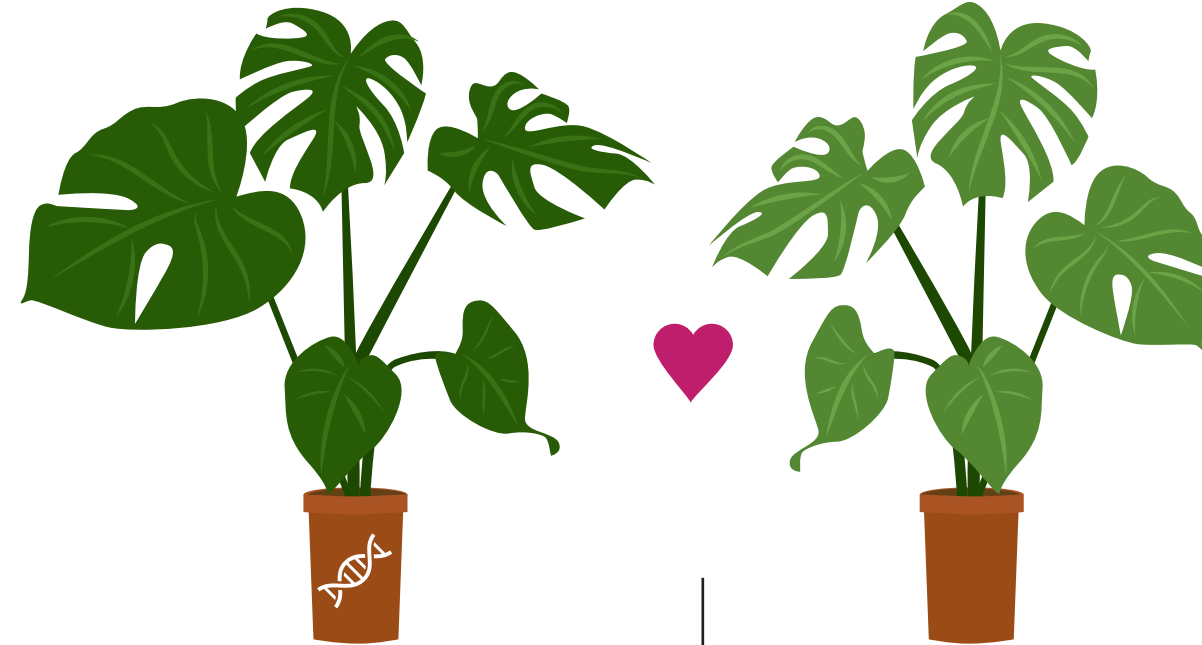
the offspring inherit half of their genes from each parent.
The mix will be different for each offspring.

delete first two plants, give third a star

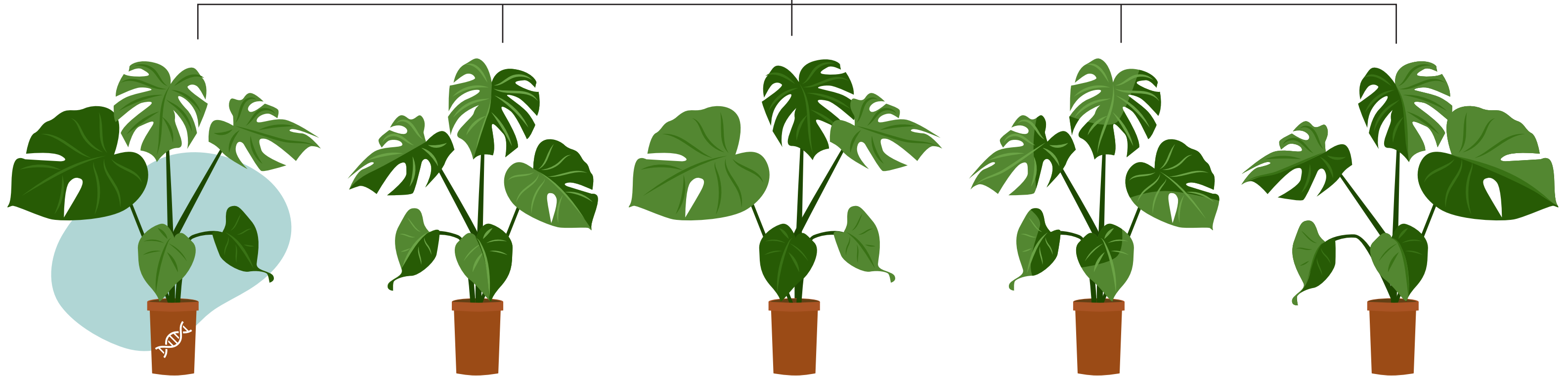


In the traditional practice of non-GM selective breeding, breeders select the offspring with desirable traits, like disease resistance, represented here by the

~~In the current practice of selective breeding, plant breeders use this current understanding and over a number of generations breed for desired traits, like disease resistance.~~



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If one of the parents has a modified gene ^{such as rapid flowering,} ~~for a specific trait,~~ represented here by the flower, some offspring ~~will inherit the trait and some will not inherit the modified gene or the trait.~~

will inherit the desirable trait but not the modified gene. Using rapidly flowering plants allows breeders to identify desired traits much more quickly as these plants take much less time to mature.



give this one a star



take away flower



give this one a star



give this one a star





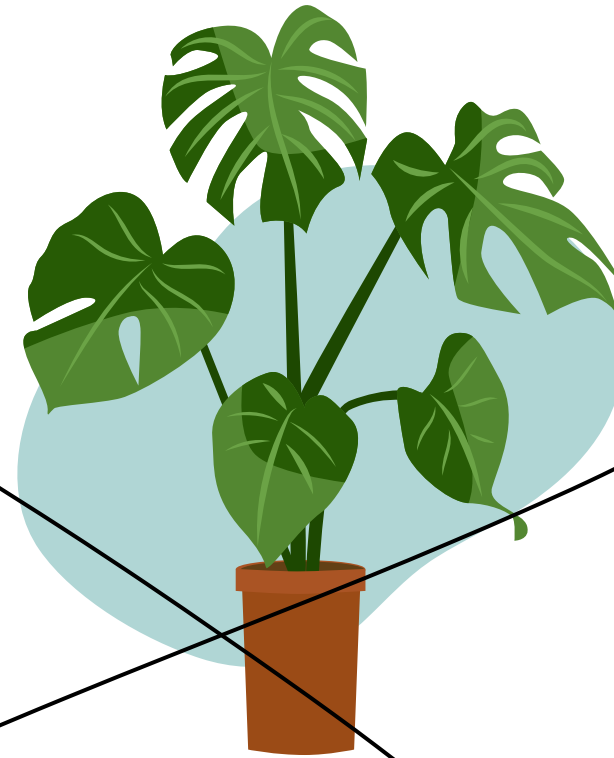
give these both stars



These are called null segregants.

Null segregants do not contain any genetic modifications, just the desirable trait.

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Null segregants do not contain any extra or modified DNA, just modified genes from both parents.



Null segregants decision: contact centre brief

7 February 2024

Background and summary

- The EPA is releasing a decision on whether null segregants are genetically modified organisms. This is a determination decision (a finding of fact), not an application decision (an approval for use).
- Null segregants have been determined to not be genetically modified organisms, within set parameters (**this information is embargoed until midday 7 February 2024**).
- The decision was made by an independent decision-making committee. The process was managed by the New Organisms team.
- There is likely to be a narrow number of customers impacted, however, there will be a media release, so potentially wider public interest in the decision.
- As with anything to do with genetically modified organisms, people hold a range of views on the topic, including some strong views.

Key words and phrases

- Null segregants
- Not GMOs
- Decision about the GM plants (plants are being used as an example in the decision)
- s26 or section 26 decision

Key messages or actions

- All of the documents associated with this decision will be available on the website from 7 February.
- Compliance of any possible specific null segregants will be on case-by-case basis, and sits with Ministry of Primary Industries
- Further questions can be emailed to the New Organisms team.
- Null segregants are descended from genetically modified organisms but do not contain genetic modifications themselves.
- Just as a brown-eyed parent may have a blue-eyed child who did not inherit the gene for brown eyes, plants, animals or other organisms that are descended from genetically modified organisms may not inherit their parents' genetic modifications.

Points of contact

- In the first instance, people should email their questions to NewOrganisms@epa.govt.nz (general enquiries) or Ministerials@epa.govt.nz (requests for information/demands for explanation), or media@epa.govt.nz (media requests only).
- For phone requests, ideally get them to send an email. If they really need to speak to someone, calls should be directed to Miriam Robertson (apart from media).

- More generally, Dr Tim Strabala is the lead on this decision. Miriam Robertson as backup.
- Media queries should go to media@epa.govt.nz. Alisa Yong is the lead in Comms.

Important dates and any important next steps

- 7 February 2024 – Decision release published on website. Media release issued at 12pm
- 9 February 2024 – Decision comes into effect

Links to further information

Please provide links to any relevant documents, media releases, webpages and indicate whether they're able to be shared with customers