

File ref APP204173

25 March 2024

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Dear Claire

Letter seeking a reassessment of null segregants decision

In your letter dated 15 March 2024 you have requested I initiate a reassessment of APP204173. A section 26 determination cannot be reassessed. There is the ability to revoke or reissue a determination if further information is received (under section 26(6) of the Hazardous Substances and New Organisms Act 1996 (the HSNO Act)). However, no further information has been received to justify this, as I explain below.

It is very clear in the APP204173 decision and in the staff advice that the recessive or dominant nature of any trait conferred by a genetic modification is not relevant to the determination. Rather, the relevant criterion for the determination in this regard is the presence of *in vitro*-modified genes or other genetic material that is created or transferred by a technique not exempted in the HSNO (Organisms Not Genetically Modified) Regulations 1998 (the Not-GM regulations).

The determination is also very clear that any presumed null segregants will need to be verified as not containing any modifications, regardless of whether these were intentional modifications or not. As the compliance agency for new organisms, the Ministry of Primary Industries is most appropriately placed to verify that an organism meets all the determination's relevant requirements as a null segregant before it may be released into the environment. Until such verification is done, the presumed null segregant must be treated as a GMO.

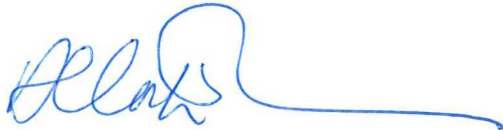
The footnote and glossary entry regarding null segregants in the Evaluation and Review document supporting the GMF06002 decision are therefore completely consistent with the determination made in APP204173. Because the presumed null segregants used under the GMF06002 approval were never verified to lack all *in vitro*-modified genes or other genetic material, ERMA treated these as GMOs. Therefore, there is no change of interpretation between 2006 and today as to what a null segregant is.

You are correct that there is no specific exemption for null segregants in the Not-GM regulations. However, the determination made in APP204173 is based solely on the definitional requirements of the HSNO Act, with the added requirement for verification. The EPA carefully considered its definition of a null segregant against all the relevant definitional requirements of the HSNO Act for any organism to be considered a GMO, and found that a null segregant did not match any of these definitional requirements. The EPA therefore determined that any organism that met EPA's definition of a null segregant could not be considered to be a GMO. Therefore, there is no reason to specifically exempt null segregants either in the Not-GM regulations or the HSNO Act itself, because the definitions in the HSNO Act make it clear that a null segregant cannot be a GMO.

Under its section 97A(5), the HSNO Act specifically provides that the agency that is responsible for ensuring compliance under the Biosecurity Act 1993 is also responsible for ensuring compliance under the HSNO Act. This agency is MPI. On this basis, I confirm that the EPA has not delegated responsibility to MPI for ensuring verification of presumed null segregants. Rather, the HSNO Act requires that MPI is the agency responsible for such verification as part of its compliance function.

Thank you for taking the time to provide this letter and meet with us, hopefully this has clarified the points you have raised.

Yours sincerely



Dr Allan L Freeth
Chief Executive