CHR. HANSEN SUBMISSION

1ST CALL FOR SUBMISSIONS- PROPOSAL P1055

DEFINITION FOR GENE TECHNOLOGY AND NEW BREEDING TECHNIQUES

03 December 2021

PREFACE

Chr. Hansen is a leading, global bioscience company that develops natural ingredient solutions for the food, nutritional, pharmaceutical, and agricultural industries.

With the vision to improve food and health, our innovative solutions and adoption of natural ingredients in addressing global challenges enabled our partners and customers to produce more with less, while also reducing the use of chemicals.

At Chr. Hansen, we are uniquely positioned to drive positive change through our sustainable microbial solutions and enable a future that values nature as the foundation of a healthy society.

For more than 145 years, we have worked to enable sustainable agriculture, cleaner labels, and healthier living for more people around the world. With more than one billion people consuming products containing our natural ingredients every day, we are proud, and will continue striving to create natural solutions that advance food, health, and productivity for the benefit of all. That is also the reason why, at the heart of our Strategy, is our purpose- To Grow a Better World. Naturally.

Chr. Hansen welcomes the opportunity to make the submission in response to Food Standards Australia New Zealand (FSANZ) Call for Submission on Proposal P1055- Definition for gene technology and new breeding techniques. Our comments for submission are contained in the enclosed dossier.

We thank FSANZ for its consideration of our Submission. If you have any questions or require further information, please contact [redacted]

Yours Sincerely,

[redacted]

SUMMARY

P1055 is a proposal to amend the definitions for 'food produced using gene technology' and 'gene technology' in the Australia New Zealand Food Standards Code (the Code). These definitions determine what foods are classed as genetically modified (GM) food under the Code. Currently, all GM food available for sale in Australia and New Zealand must have been assessed for safety by FSANZ and be expressly permitted and listed in relevant Code schedules.

COMMENTS

We appreciate the initiative taken by FSANZ to address the regulatory issues arising from New Breeding Techniques (NBT) in relations to Genetically Modified (GM) food and Pre-market assessment.

The proposed hybrid approach through the re-definition of "gene technology" to include NBT-derived food such as GM food in combination with pragmatic, subsequent product-based exclusion from GM food for regulatory purposes, will modernize the legislation and appears to be a good approach in ensuring regulatory certainty and consumer safety moving forward.

With reference to microorganisms used in food production, we noted that in the current situation, as well as through the proposed new definition of "gene technology", classical mutagenesis is excluded from the scope of the regulation. However, NBTs which could introduce identical changes to the genome, would still result in the classification as GM food.

The exclusion criteria for GM food and refined ingredients refer to the absence of "foreign DNA" or "novel DNA or novel protein", respectively. The term "foreign DNA" clearly excludes genome changes, resulting in modifications which are indistinguishable from classical mutagenesis. This would align with the current situation for mutagenesis and conventional breeding.
However, the term "novel DNA" or "novel protein" leaves room for interpretation, which may lead to regulatory uncertainty.

In the proposal, FSANZ provided the following example:

"Food derived from an organism which does not contain foreign or recombinant DNA as a result of gene technology, would still be captured if it was unable to meet all of the other criteria. For example, if genome editing had been used to alter the endogenous allergen content of a food. While no novel DNA or novel protein would be present in the food for sale (because foreign or recombinant DNA would be absent from the organism from which the food is derived), such food would not meet criterion (v) and therefore would require an application to FSANZ."

The example mentioned "While no novel DNA or novel protein would be present in the food for sale (because foreign or recombinant DNA would be absent from the organism from which the food is derived)", implies that novel DNA or novel protein is

dependent on the presence of “foreign or recombinant DNA”, thus would exclude changes made to the DNA via genome editing.

Consequently, microorganisms modified via gene editing would not contain novel DNA or novel protein, thus be excluded from pre-market safety assessment as GM food. This is supported by Chr. Hansen and we would recommend for this to be clearly stipulated in the regulation to deliver a conclusive and well-defined regulatory environment for innovative products.

FSANZ proposes comparability to existing food or equivalence to existing refined ingredients in addition to the absence of “foreign DNA,” “novel DNA” or “novel protein” for exclusion from the GM food pre-market assessment. This would, in our opinion, create uncertainty and hinder innovation, as novel foods or ingredients could not be produced using state of the art technology without being regulated as GM foods, while indistinguishable products could be developed using classical methods and subsequently follow other regulations for pre-market assessment (e.g., as novel foods or processing aids).

CONCLUSION

Chr. Hansen would like to request FSANZ to consider stating clearly, that genomic changes indistinguishable from classical mutagenesis or conventional breeding cannot lead to novel DNA or novel protein in the final food product and would thus, not be a cause for regulation as GM food.

Moreover, we recommend FSANZ to consider and assess the requirements for exclusion from the GM food regulation and the applicable pre-market safety assessment regulations to allow the use of modern methods and the generation of innovative food without unnecessarily labelling it GM food.