

Voluntary Report – Voluntary - Public Distribution

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Report Name: MHLW Updates Genome Editing Handling Procedures for Crossbred Progeny

Country: Japan

Post: Tokyo

Report Category: Biotechnology and Other New Production Technologies, Biotechnology - Plants and Animals

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Report Highlights:

On December 23, the Ministry of Health, Labour, and Welfare (MHLW) amended the handling procedures for products that are derived from the crossbreeding of genome edited varieties which have already been notified to MHLW. Developers of these products are no longer expected to undergo MHLW's consultation process.

General Information

On December 7, the Ministry of Health, Labour, and Welfare's (MHLW) Research Committee for Newly Developed Foods (Committee) approved the decision by the Research Sub-Committee for Genetically Modified Foods (Sub-Committee) to amend the language in MHLW's Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology so that products that are derived from the crossbreeding of genome edited varieties which have already been notified to MHLW are not expected to consult with MHLW prior to commercialization. On December 23, MHLW officially amended the Handling Procedures to reflect this change and the change is effective immediately, for more see MHLW's [website](#) (in Japanese). The updated Handling Procedures are also attached to this report (in Japanese).

When first released in September 2019, the Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology indicated all crossbred progeny products with at least one genome edited parent would be expected to undergo the consultation process with MHLW, for more see [JA2019-0011](#). On September 15, the Sub-Committee held the first in a series of meetings to hear expert testimony about the requirements for food products derived from crossbred progeny. After three meetings, the Sub-Committee unanimously decided to recommend the handling procedures be updated to reflect the below changes.

Version	Crossbred Progeny Language in MHLW Handling Procedures
September 2019	<p>For a crossbred progeny product obtained using a conventional breeding technique between a traditional breed etc. and a breed whose notification to the MHLW as a genome editing technology derived food was published and is intended to be marketed, the MHLW will continue to consider the handling of the product.</p> <p>The developer etc. of the crossbred progeny should conduct prior consultation with the MHLW by the time when a measure is established by the MHLW.</p>
December 2020	<p>For crossbred progeny obtained through a traditional breeding technique between a conventional breed etc.* and a breed made known to the public as a product notified to the MHLW as a food derived from genome editing technology, the developer etc. concerned is not required to consult with the MHLW in advance and to notify the MHLW of the obtained product.</p> <p>* A conventional breed etc. means: (i) a conventional breed, (ii) a breed made known to the public as a product notified to the MHLW as a food derived from genome editing technology, or (iii) a breed made known to the public as a product evaluated to be safe as a food derived from recombinant DNA technology.</p>

References

MHLW – Food derived from genome editing technology

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryoushokuhin/bio/genomed/index_00012.html

Materials and minutes from the Research Sub-Committee for Genetically Modified Food meetings:

https://www.mhlw.go.jp/stf/shingi/shingi-yakuji_148834.html (in Japanese)

Materials and minutes from the Research Committee for Newly Developed Food meetings:

https://www.mhlw.go.jp/stf/shingi/shingi-yakuji_127893.html (in Japanese)

Attachments:

[MHLW Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology.pdf](#)