



Voluntary Report - Voluntary - Public Distribution

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## **Report Name:** Japan Determines Genome Edited Tomato Will Not be Regulated as GE

Country: Japan

Post: Tokyo

Report Category: Biotechnology and Other New Production Technologies

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## **Report Highlights:**

On December 11, Japan's Ministry of Health, Labour, and Welfare (MHLW) and Ministry of Agriculture, Forestry, and Fisheries (MAFF) announced their determination that a genome edited tomato will not be regulated as a genetically engineered (GE) product. This is the first product to complete either ministry's voluntary notification process for verification of whether a genome edited product should be regulated as a GE product. The tomato was developed in Japan by a joint venture between a public university and a private company and is intended for commercial distribution. The developer used CRISPR-Cas9 technology to increase the gamma-aminobutyric acid (GABA) content in the tomato.

THIS REPORT CONTAINS ASSESSMENTS OF COMMODITY AND TRADE ISSUES MADE BY USDA STAFF AND NOT NECESSARILY STATEMENTS OF OFFICIAL U.S. GOVERNMENT POLICY

## **General Information**

The genome edited tomato product was developed by a joint venture between the University of Tsukuba and Sanatech Seed, a private company, using CRISPR-Cas9 technology to enhance the gamma-aminobutyric acid (GABA) content in the tomato. GABA is a nonproteogenic amino acid effective in lowering blood pressure.

Japan's Ministry of Health, Labour, and Welfare (MHLW) and Ministry of Agriculture, Forestry, and Fisheries (MAFF) biotechnology regulators request that all genome edited products undergo a consultation and notification process prior to their commercialization in Japan, for more see JA2020-0184. On December 11, MHLW and the two MAFF regulatory authorities determined that the genome edited tomato would not be regulated as genetically engineered (GE) and is therefore not required to undergo the GE safety review process. For more on their decisions, see below (Japanese only):

- <u>MHLW Food safety</u>
- <u>MAFF Feed safety</u>
- <u>MAFF Biodiversity</u>

The genome edited GABA tomato was developed using, in part, resources from the Government of Japan's Cross-ministerial Strategic Innovation Promotion Program (SIP), which promoted and funded research and development of genome editing technology, for more see <u>JA2019-0219</u>.

Sanatech Seeds plans to begin distribution of the product in the spring/summer of 2021 and will be made available in Japan only. Sanatech Seed intends to voluntarily label their product as genome edited, for more on Japan's labeling requirements see JA2019-0174.

## Attachments:

No Attachments.