



Genetically Modified/ Genome Edited Crop

Guiding your products to
a successful approval in Japan



**10 years' experience
in biotech regulation**

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SCC 
WE CARE FOR YOUR SUCCESS

GLOBAL GMO MARKET AND FUTURE TRENDS

Commercial cultivation of genetically modified (GM) crop started in the mid-1990s and has been steadily growing, reaching 191.7 Mio hectares globally in 2017 (a ~113-fold increase as compared to 1996). The total cultivation area in developing countries reached 103.1 million hectares in 2017 and exceeded that of developed countries. Among mega-countries growing over 50,000 hectares are the US, Brazil, Argentina, Canada and India.

Next to genetic engineering, genome editing has been increasingly used by plant breeders as an alternative technique to allow for a controlled alteration of a living organism's existing DNA for the purpose of creating varieties with desired characteristics. Genome editing is more precise than GM, easier to apply and less expensive.

Although GMO adoption in key cultivation countries is nearly 100%, the global adoption still does not exceed 50%, indicating that this sector has considerable potential to expand its market shares in the coming future. A global demand for increased production capacity, paired with limited existing resources and targeted reduction of pesticide use, will drive the demand for genetically modified and edited crop even further.

JAPAN'S GM CROP MARKET

Japan is one of the major grain importers in the world, with gradually decreasing food self-sufficiency (37% in 2018). In 2019, a total of 16 million tons of corn, twice as high as domestic rice production, was imported mainly from the US, Brazil and Argentina, predominantly for food and feed purposes. Another 3.5 million tons of soybeans were used for oil and feed production as well as soybean food, almost entirely imported from the US, Brazil, and also Canada.

How is the GM crop market in Japan regulated?

GMO regulation in Japan was implemented around 2000. In recent years, Japan's authorities have worked on simplification and streamlining of regulatory processes.

Producers of genome edited organisms are currently requested to consult with regulatory agencies before making them commercially available on the market. With data requirements for Japanese approvals being highly consistent with the US and other countries, seed developers can use study data acquired for previous market approvals for submissions in Japan.

Visit our website to learn more about our services:

<https://www.scc-gmbh.de/japan-genetically-modified-crop-compliance>

or contact our experts:

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Obtaining regulatory approval in Japan

To obtain regulatory approval for placing genetically modified or genetically edited crop on the Japanese market, the Japanese government requires complete safety assessments of GM or genetically edited crops under the regulation for food, feed and environment prior to their import, cultivation and use. All field trials need to be conducted in Japan.

The Ministry of Health, Labour and Welfare is responsible for food safety under the food sanitation law. Safety assessments are conducted by the Food Safety Commission of the Japanese Cabinet Office.

The Ministry of Agriculture, Forestry and Fisheries (MAFF) is responsible for feed safety under the feed safety law.

MAFF and the Ministry of Environment conduct biological risk assessments (environmental) jointly under the Cartagena law.

What are the key factors for regulatory success on Japan's GM market?

- Good knowledge of Japan's regulations and thorough understanding of how the regulatory framework works
- Developing successful global data strategies
- Hands-on experience in compiling a dossier

How can SCC help?

We offer regulatory and scientific support covering all aspects of the submission and approval process for genetically modified and genetically edited crop.

For Japan's unique requirement for in-country field trial (stage-3 trial), SCC liaises with local research organisations (CROs) able to conduct in-country field trials for GM crop. We coordinate and monitor these trials on behalf of our customers.

We help companies by providing guidance and follow-up with the respective authorities on the minimum data requirements for notifications.

SCC regulatory experts in Japan have more than 10 years' experience in biotech regulation and rely on a strong and broad network of key stakeholders in and outside the country.

OUR SERVICES

Genetically Modified Crop

- Providing advice on data requirements for food, feed and environmental safety assessments
- Coordinating and monitoring stage-3 field trials
- Preparing and submitting application dossiers
- Coordinating and communicating with the respective authorities, as well as preparing response letters to the authorities and technical committees

Genome Edited Crop

- Offering guidance on data requirements for notification to MHLW and MAFF
- Communicating with the respective authorities, including preparation of response letters to regulatory authorities and technical committees

