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### **Report Highlights:**

This report provides the latest status of consumption, regulation, public perception, research, development, production, and use of agricultural biotechnology in Japan. In general, Japan uses a science-based process for evaluating and granting approval for import and production of genetically engineered products. Japan is a major importer and consumer of crops derived from biotechnology, but domestic production remains extremely limited. Japanese regulators have established handling procedures for genome edited food and agricultural products. Three genome edited products developed by Japanese companies have completed the necessary consultation and notification processes and are being produced and distributed in the domestic market.

## **Executive Summary**

Japan is a major importer of food and feed produced using modern biotechnologies. The United States is the top exporter of genetically engineered (GE) products, primarily grains and oilseeds, to Japan, but other major suppliers include Canada, Brazil, and Argentina. In Marketing Year (MY) 2021/2022, Japan imported 15 million metric tons of corn, 3.5 million tons of soybeans, and 2.1 million tons of canola. Japan also imports billions of dollars of processed foods that contain GE-derived oils, sugars, yeasts, enzymes, and additives. Conversely, Japanese farmers do not cultivate any genetically engineered food or feed products, despite broad regulatory approval by national authorities. As of September 2023, the Government of Japan (GOJ) has approved 200 products for environmental safety, including 151 approvals for domestic cultivation. The GOJ requires domestic field trials for the approval of GE grains and oilseeds.

The GOJ's regulatory approval of GE crops is important for U.S. agriculture and global food production and distribution. As a significant importer of agricultural products, GE exports not approved by the GOJ could result in significant trade disruption. The GOJ's GE regulations are largely science-based and transparent, and regulators generally review and approve new events within time periods that align with industry expectations for market release. As of September 2023, regulators have approved 333 products for food use.

The GOJ completed the handling guidelines and product labeling policies for genome edited food in 2020. The Ministry of Agriculture, Forestry, and Fisheries (MAFF) is the competent authority for overseeing animal feed and biodiversity handling procedures and the Ministry of Health, Labour and Welfare (MHLW) oversees handling procedures for food products. As of September 2023, three companies have notified the GOJ about five non-GE genome edited food products.

## Useful Acronyms

AMC: Agricultural Material Committee

CAA: Consumer Affairs Agency

CAS9: CRISPR Associated Protein 9

CRISPR: Clustered Regularly Interspaced Short Palindromic Repeats

FSC: Food Safety Commission

GE: Genetically Engineered

GOJ: Government of Japan

IP: Identity Preservation, Identity Preserved

JETRO: Japan Export Trade Organization

JFY: Japan Fiscal Year

LMO: Living Modified Organisms

MAFF: Ministry of Agriculture, Forestry, and Fisheries

MEXT: Ministry of Education, Culture, Sports, Science and Technology

MHLW: Ministry of Health, Labour and Welfare

MOE: Ministry of Environment

NIAS: National Institute of Agro-biological Sciences

ST-3FT: Stage 3 Field Trial

TALLEN: Transcription Activator-Like Effector Nuclease

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## CHAPTER I: PLANT BIOTECHNOLOGY

### PART A: Production and Trade

#### *a) RESEARCH AND PRODUCT DEVELOPMENT*

In Japan, although there are a number of private seed companies, agricultural biotechnology research is done predominantly by public sector; government research institutes and public universities. Research progresses at a slower pace than in the United States as there is limited demand for domestic application. Japanese farmers and food companies are reluctant to handle GE varieties as many GE food products come with mandatory labeling requirements and concerns persist over public perception. Annual GOJ polling shows public concern about GE products has fallen significantly over the last 10 years. However, without demand signals for commercial GE products, product developers have little reason to seek commercialization of GE varieties.

The GOJ's national project for science and technology innovation, the Cross-Ministerial Strategic Innovation Promotion Program (SIP), encouraged research of genome editing technology ([JA6050](#)). In December 2020, [Sanatech Seed](#), an agricultural biotechnology company founded in 2018, was the first organization to complete the GOJ's voluntary notification and consultation process for genome edited products. The product, a nutritionally enhanced tomato, is now commercially available in Japan. USDA Animal Plant Health Inspection Service (APHIS) has also [determined](#) that the tomato product is not regulated under 7 CFR part 340.

Public and private sector researchers, as well as joint public-private research, continue to develop genome edited products in Japan. For example, researchers at Osaka University have been developing [a genome edited potato](#) to reduce toxicity levels. In 2021, The group started [experimental field trials](#) at a confined field plot with public outreach activities and open field days for the public.

A number of potential new products have been studied and developed in the lab, and study results have been published by public research institutions and academia on products including, but not limited to, [high yield rice with less fertilizer](#), [environmental stress tolerant rice](#), [wheat with reduced pre-harvest sprouting of grains on spikes](#), and [pollen-free Japanese cedar](#) (to combat hay fever). However, as reluctance to handle GE products still prevails in Japanese industry and society in general, it is uncertain if/when these studies will translate into marketable commercial products.

#### *b) COMMERCIAL PRODUCTION*

There is no commercial production of GE food or feed products in Japan, despite MAFF approval for the cultivation of 151 GE agricultural products. A lack of GE products developed for the Japan market combine with burdensome federal and local GE cultivation regulations to make it almost impossible for Japanese farmers to cultivate GE agricultural products. There is a limited domestic cultivation of GE ornamental and pharmaceutical crops, however, neither the government nor the private sector release information on the scale of production.

Sanatech Seed began online sales of its nutritionally enhanced, genome edited fresh tomato after completing Japan's voluntary consultation and notification process in 2020. The tomato had been available to consumers only through online sales and at select restaurants since 2021, however, in 2023, a few grocery stores in Tokyo started to sell the tomato. They also sell tomato puree made from the

genome edited tomato. The company has also made another voluntary notification to GOJ for their second high GABA tomato product ([notification to MHLW](#), in Japanese).

As of September 2023, there are [three non-GE genome edited crops notified to GOJ](#), including [a waxy corn product from Corteva Agriscience](#), non-Japanese developer.

#### *c) EXPORTS*

There are no GE agricultural products exported from Japan. In CY2022, Japan exported \$9.5 billion of food and agricultural products, including processed products (\$3.4 billion). Exported processed products may contain GE ingredients (USD=149 JPY, [Link to MAFF's home page](#), in Japanese).

#### *d) IMPORTS*

##### Grains and Oilseeds

Japan imports almost 100 percent of its corn and over 95 percent of its oilseeds supply, much of which is GE soybean and canola. In MY2022, Japan imported 15 million tons of corn, approximately a third of which was for food use. FAS/Tokyo estimates nearly half to two-thirds of corn for food use imported by Japan is non-segregated or GE, but there are no official statistics available. For more information on the import of grains and oilseeds see [JA2023-0021](#) and [JA2023-0031](#).

##### Fresh Produce

The “Rainbow Papaya,” a GE papaya grown in Hawaii, is the only fresh GE product exported from the United States to Japan ([JA1048](#)).

#### *e) FOOD AID*

In 2022, Japan provided approximately \$52 million food aid, mainly with Japanese Government reserve rice, to 25 countries and regions. For more, see [Ministry of Foreign Affairs](#) (in Japanese).

#### *f) TRADE BARRIERS*

Japan is one of the world's largest per-capita importers of GE products and has no significant trade barriers.

### PART B: Policy

#### *a) REGULATORY FRAMEWORK*

##### Regulatory Process

The GOJ requires regulatory approval prior to the commercialization of GE plant products for use as food, feed and/or for environmental release depending on the nature and use of product. Four ministries play a role in the regulatory framework: MAFF, MHLW, Ministry of Environment (MOE), and the Ministry of Education, Culture, Sports, Science and Technology (MEXT). These ministries are also involved in environmental protection and regulating lab studies. The Food Safety Commission (FSC), an independent risk-assessment body under the Cabinet Office, performs food safety risk assessments for MHLW and feed-safety risk assessments (in terms of human consumption of livestock products grown with GE feed) for MAFF.

It is customary for regulators to first approve products for food, followed by feed, and then environment. The actual time needed for full approval varies significantly depending on each event and the familiarity

of the product and trait. Approval is generally granted within eighteen months of formal acceptance of the dossier for food, feed, and/or environmental release if regulators characterize the product as familiar. For a detailed diagram of the food, feed, and biodiversity approval process, see Figure 1.

Responsible ministries use external advisors to provide scientific review and risk assessment of GE products for which developers seek approval in Japan. The advisory committees and expert panels primarily consist of researchers, academics, and representatives from public research universities, and they report their findings and recommendations to the responsible ministries for final approval.

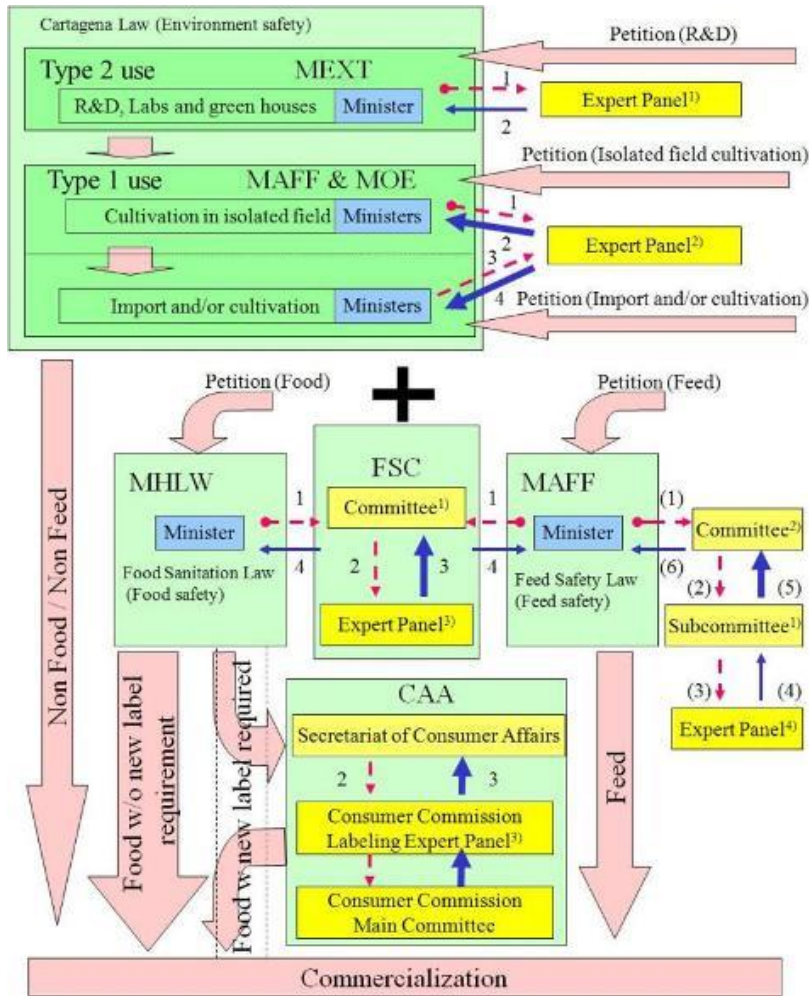
**Table 1: GE Product Safety Review by Approval Type**

Type of Approval	Examining body	Jurisdiction	Legal Basis	Main Points Considered
Food Safety	FSC	Cabinet Office	Food Safety Basic Law	<ul style="list-style-type: none"> <li>• Safety of host plants, genes used in the modification, and the vectors</li> <li>• Safety of proteins produced because of genetic modification, particularly their allergenicity</li> <li>• Potential for unexpected transformations as the result of genetic modification</li> <li>• Potential for significant changes in the nutrient content of food</li> </ul>
Feed Safety	Agricultural Materials Council	MAFF Animal Product Safety Division	Law Concerning the Safety and Quality Improvement of Feed (the Feed Safety Law)	<ul style="list-style-type: none"> <li>• Any significant changes in feed use compared with existing traditional crops</li> <li>• Potential to produce toxic substances (especially with regard to interactions between the transformation and the metabolic system of the animal)</li> </ul>
Environment/Impact on Biodiversity	Biodiversity Impact Assessment Group	MAFF Plant Product Safety Division	Law Concerning Securing of Biological Diversity (Regulation of the Use of Genetically Modified Organisms)	<ul style="list-style-type: none"> <li>• Competitive superiority</li> <li>• Potential production of toxic substances</li> <li>• Cross-pollination</li> </ul>

Note: MHLW and MEXT are not involved in conducting risk assessments; they are risk management bodies and/or contact points for applications.



**Figure 1: Approval Process for GE Products**



- Type 1 Use: The use of living modified organisms (LMOs, therefore not limited to plants) outside facilities, equipment, or other constructions without containment measures
- Type 2 Use: The use of living modified organisms (LMOs, therefore not limited in plants) with containment measures
- Expert Panel 1: Expert Panel on Recombinant DNA Technology, Bioethics and Biosafety Commission, Council for Science and Technology, MEXT
- Expert Panel 2: Experts with special knowledge and experience concerning adverse effect on biological diversity selected by MAFF/MOE Ministers
- Expert Panel 3: Genetically Modified Foods Expert Committee, FSC
- Expert Panel 4: Expert Panel on Recombinant DNA Organisms, Agricultural Materials Council, MAFF
- Committee 1: Food Safety Commission
- Committee 2: Feed Committee, Agricultural Materials Council, MAFF
- Subcommittee 1: Safety Subcommittee, Feed Committee, Agricultural Materials Council, MAFF
- Red (broken) arrow: Request for review or risk assessment
- Blue (solid) arrow: Recommendation or risk assessment results (thick arrows: with public comment periods)
- Numbers beside the arrows indicate the order of requests/recommendations within the respective ministries.

### *Food Safety*

The MHLW must approve GE plants intended for food use prior to commercialization in Japan. Upon receiving a petition for review from an applicant, MHLW will undertake a preliminary check of the application then request that FSC complete a food-safety risk assessment. Within the FSC, there is a “Genetically Modified Foods Expert Committee” that consists of scientists from universities and public research institutes who conduct the scientific review. Upon completion, the FSC provides its conclusions to the MHLW Minister for the official announcement of review completion. FSC publishes the risk assessment results of GE foods in English on [its website](#). FSC set the standard processing time, from the receipt of dossier to the completion of review, at 12 months.

In September 2022, the GOJ announced a plan to shift food safety standard administration from the MHLW to the CAA as part of an overall effort to streamline the Government of Japan’s response to health-related emergencies. In May 2023, the "Act on Improvement of Relevant Laws to Strengthen the Functions of Public Health Administration" was passed and enacted. The act mandates the shift of food safety standard administration from the MHLW to the Cabinet Office, which oversees the CAA. The official shift will occur on April 1, 2024. Recent preparation status can be found on [MHLW’s homepage](#) (link in Japanese).

### *Feed Safety*

Under the Feed Safety Act, the MAFF must approve all GE products intended for feed use prior to commercialization. When MAFF receives a petition, MAFF asks the Expert Panel on Recombinant DNA Organisms, part of the MAFF-affiliated Agricultural Materials Committee (AMC), to review the GE crops for feed use. The Expert Panel evaluates feed safety for livestock animals and then the AMC reviews the evaluation. The MAFF Minister also asks the FSC’s Genetically Modified Foods Expert Committee to review human health effects from consuming livestock products from animals fed the GE crop under review. Based on the AMC and FSC reviews, the MAFF Minister approves the feed safety of the GE events.

### *Impact on Biodiversity*

In 2003, Japan ratified the Cartagena Protocol on Biosafety. In 2004, Japan adopted the “Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms,” commonly referred to as the “Cartagena Law,” to implement the Protocol. Under this law, MEXT requires Minister-level approval before performing early stage agricultural biotechnology studies in laboratories and greenhouses. MAFF and MOE require joint approvals for the use of GE plants in greenhouses or labs as part of their assessment on biodiversity.

MAFF requires product developers to perform isolated field trials in Japan to collect scientific data as part of the approval process for biodiversity. MAFF and MOE must give developers permission to begin field trials required for the environmental risk assessment for the event. A joint MAFF and MOE expert panel conducts the environmental safety evaluations. MAFF set the standard processing time, from the receipt of the dossier to approval to begin field trials, at six months. More information can be found on [MAFF’s website](#) (link in Japanese). However, the “clock” for the standard processing time stops when the applicant revises the dossier, receives questions from MAFF, and prepares the response. The preliminary consultation, confined field trial, and administrative handling for an official notification is a prolonged process.

The GOJ does not charge fees for the review of GE products.

**Table 2: Relevant Terminology**

<b>Legal Term (in local language)</b>	<b>Legal Term (in English)</b>	<b>Laws and Regulations where Term is Used</b>	<b>Legal Definition (in English)</b>
遺伝子組換え技術 (Idenshi Kumikae)	Genetic engineering	<a href="#">Law Concerning Securing of Biological Diversity</a>	Technology for processing nucleic acids outside the cell Technology to fuse cells of organisms belonging to different taxonomic families
組換えDNA技術 (Kumikae Di Enu Ei Gijyutsu)	Recombinant DNA technique	<a href="#">Standards for the Safety Assessment of Genetically Modified Foods</a>	Technique that recombinant DNA molecules prepared by cleavage and recombination of DNA using enzymes or other methods are transferred to living cells for proliferation (the term refers to the techniques that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection)
遺伝子組換え生物 (Idenshi Kumikae Seibutsu)	Living Modified Organism (LMO)	Law Concerning Securing of Biological Diversity	Living organisms created by genetic engineering
第二種使用 (Dai Nishu Sihyou)	Type 2 Use	Law Concerning Securing of Biological Diversity	Use with the intention of preventing the spread of the LMO into the air, water, or soil outside of facilities, equipment, or other structures
第一種使用 (Dai Isshu Shiyou)	Type 1 Use	Law Concerning Securing of Biological Diversity	Use of LMO without measures in Type 2 use (e.g., open field cultivation)

宿主 (Shukushu)	Host	Standards for the Safety Assessment of Genetically Modified Foods	A living cell or individual organism into which DNA is transferred through recombinant DNA techniques
ベクター (Bekuta)	Vector	Standards for the Safety Assessment of Genetically Modified Foods	A carrier DNA that transfers the target genes or DNA fragment into the host for its proliferation or gene expression
ドナー (Donah)	Donor	Standards for the Safety Assessment of Genetically Modified Foods	A microbe, animal or plant that supplies the inserted DNA
ゲノム編集技術 (Genomu Henshuu Gijyutsu)	Genome Editing Technology	<a href="#">Food Hygiene Handling Procedures for Food and Additives Derived from Genome Editing Technology</a>	A technology to modify a specific site of a specific base sequence on a chromosome using an enzyme recognizing the base sequence in order to provide specific functions

#### *b) APPROVALS/AUTHORIZATIONS*

As of September 2023, Japan has approved over 333 GE products for food, 196 for feed, and 200 for environment; including 151 for environmental release, including cultivation. The 333 products approved for food does not include 36 stacked events, which are no longer subject to the safety review process. See the reference section at the end of this report for links to lists of approved products.

#### *c) STACKED OR PYRAMIDED EVENT APPROVALS/AUTHORIZATIONS*

The GOJ requires separate environmental approvals for stacked products. MHLW exempts from review GE stacked products that use previously approved single events if the crossing of single events does not affect the metabolic pathway of the host, for more details see the FSC [website](#) (in Japanese). As of September 2023, MHLW has exempted 36 stacked products (5 soybean, 15 corn, 4 canola, and 12 cotton) from review, for more information see MHLW's [website](#). For details on the approved stacks, please see the links contained in the reference section at the end of this report. For additional details on previous improvements made in the handling of stacked product approvals, see [JA7138](#).

#### *d) FIELD TESTING*

The GOJ requires domestic field trials for GE products, even those with no foreseeable opportunity for environmental release or commercial cultivation. In December 2014, MAFF excluded crops that do not have wild relatives in Japan (like corn), with traits of sufficient familiarity (i.e., herbicide tolerance, insect resistance) from mandatory field trial requirements. In March 2019, MAFF added cotton with

traits of sufficient familiarity to the list of products excluded from domestic field trials, for more information on this change see MAFF’s [website](#) (in Japanese). For additional information on field trials, see [JA6050](#).

*e) INNOVATIVE TECHNOLOGIES*

The GOJ has three separate handling procedures for genome edited food and agricultural products that cover food, feed, and biodiversity safety. MHLW oversees the procedures for food and food additives, while MAFF is responsible for both feed and feed additives as well as biodiversity safety for products under its authority. For more on genome editing handling procedures in Japan, see [JA2021-0106](#). MHLW and MAFF amended procedures for pre-market consultations and notifications for products derived from genome edited crossbred progeny in December 2020 and April 2021, see [JA2020-0214](#) and [JA2021-0073](#) for more information.

CAA determined that genome edited foods that do not contain foreign DNA are not subject to the Food Labeling Standard. However, CAA guidance recommends food manufacturers voluntarily label genome edited foods. Similarly, food manufacturers may also disclose that their products are not derived from genome edited ingredients, but CAA advises that manufacturers should be able to verify their product’s authenticity of ingredients throughout supply chain. For more on CAA’s labeling guidance, see [JA2019-0174](#).

*f) COEXISTENCE*

A 2004 MAFF guideline requires that before product developers can begin a field trial, they publicly disclose detailed information about the field trial online and host meetings with nearby residents. MAFF also requires the establishment of buffer zones to prevent related plant species in the surrounding area from cross-pollinating, see Table 3. These requirements, restrictive local regulations, and perceived public resistance has made the planting of GE crops difficult. For additional detail, please see the guidelines for cultivation of GE crops on the MAFF [website](#) (link in Japanese).

**Table 3: Required Buffer Zone for GE Crops in Open Fields**

<b>Plant</b>	<b>Minimum Isolation Distance</b>
Rice	30 meters
Soybeans	10 meters
Corn (applicable for food and feed safety approvals)	600 meters or 300 meters with the presence of a windbreak
Rapeseed (applicable for food and feed safety approvals)	600 meters or 400 meters if non-recombinant rapeseed is planted to flower at the same time of the field-tested rapeseed. A width of 1.5 meters surrounding field tested plants as a trap for pollens and pollinating insects

Local Government Regulations

There are 15 local governments with regulations for the planting of GE products for research and/or commercial purposes. Local governments established many of these rules between 2004 and 2009 with limited changes since. In addition, some local governments, for example [Imabari City](#) (link in Japanese), argue that foods containing GE ingredients should not be used in the school lunch program.

In July 2022, the Hokkaido Prefectural Government (HPG) amended a rule that requires prefectural approval before planting GE products. The HPG amended the ordinance and exempted pot-grown ornamental plants following MAFF's approval of a GE phalaenopsis orchid developed by [Ishihara Sangyo](#) (link in Japanese). In March, MAFF completed the biodiversity risk assessment for the orchid, with enhanced blue color (OECD UI: ISK-311NR-4), and commercial distribution began in June 2022. HPG's ordinance requires prospective farmers and gardeners apply for permission from the HPG to cultivate approved GE products. The application process includes requirements to host explanatory community meetings and establish measures to prevent crossbreeding. The HPG has never granted prefectural level approvals for GE cultivation. See [JA2019-0219](#) for more information on other local regulations.

#### *g) LABELING AND TRACEABILITY*

Processed product manufacturers, importers, and/or retailers can make three types of GE claims on food labels in Japan: GE, non-segregated (i.e., without identity preservation), and non-GE. CAA requires GE and non-segregated product labeling. If a product is GE IP, CAA requires the food label contain a GE label. If a retailer distributes a non-IP product for which approved GE varieties exist (e.g., grains, oilseeds), CAA requires the food label to contain a non-segregated label (regardless of the percentage of GE or non-GE in the product).

CAA requires food labels to identify GE products and/or ingredients when the GE ingredient is among the top three ingredients and accounts for at least five percent of the product.

In March 2019, CAA revised labeling policy for GE foods, effective on April 1, 2023. Under the revised labeling regulation, the products need to be distributed under an IP system and have no detectable GE content; effectively establishing a zero tolerance for GE components. Although some consumer groups complained to CAA that manufacturers are effectively unable to use "non-GE" labeling, post has not observed any significant market impact. To highlight industry efforts to obtain non-GE ingredients at five percent or lower with IP handling, some manufacturer use description such as "identity preserved". For more information, please see [CAA website](#) (in Japanese). FAS/Tokyo has submitted multiple reports on the review process (see, e.g., [JA7067](#), [JA7093](#), [JA7121](#), [JA8014](#), and [JA9055](#)).

#### *h) MONITORING AND TESTING*

The GOJ monitors volunteer plants to assess the effect on biodiversity of environmental release of a GE crop. MAFF's most recent [report](#) on environmental release includes a survey conducted in the vicinity of ports where canola and soybeans were unloaded from vessels. MAFF found no significant impact on biodiversity. MAFF looked for indicators that GE plants are affecting biodiversity, such as by surviving through multiple generations, or crossbreeding of GE soy with *Glycine soja*, a Japanese domestic wild plant and the closest living relative of soybean.

MAFF, acting as a state trading enterprise, conducts tests for GE wheat and rice shipments from some export markets, including the United States. MAFF conducts these tests to ensure compliance with MHLW's low-level presence policy. MAFF publishes tests results annually on its [website](#) (in Japanese).

#### *i) LOW-LEVEL PRESENCE (LLP) POLICY*

Japan has a zero-tolerance policy for unapproved GE events in food and the environment, and it is explicitly illegal to import GE-derived foods that MHLW has not approved, regardless of the amount, form, or their known safety outside of Japan. For this reason, LLP of unapproved GE crops has the potential to disrupt agricultural trade with Japan. For more on Japan's LLP policy, see [JA6050](#).

As of September 2023, MHLW monitors imported foods for the following items:

- PRSV-YK, PRSV-SC, and PRSV-HN (papaya and its processed products if papaya can be isolated for analysis. Monitors 119 cases annually.)
- 63Bt, NNBt, and CpTI (rice and its processed product with rice as a main ingredient, such as rice flour, rice noodle, etc., when products are unheated or mildly heated. Monitors 299 cases annually.)
- RT73 *B. rapa* (canola and its processed products. Monitored 29 cases annually.)
- MON71100/MON71300, MON71700 and MON71800 (U.S. wheat. Monitors 59 cases annually. Also, regulatory authority, MHLW and/or port officials, may request inspection of specific shipments.)
- MON71200 (Canadian wheat. Monitors 59 cases annually. Also, regulatory authority, MHLW and/or port officials, may request inspection to specific shipments)
- F10 and J3 (potato and its processed products, of potato as a main ingredient, such as French fries, potato chips, etc. Monitors 299 cases annually)
- AquAdvantage (salmon and its processed products, such as salmon flakes, from Canada, Panama, and the United States. Monitors 59 cases annually).

#### *j) ADDITIONAL REGULATORY REQUIREMENT*

Although GE products receive regulatory approval for commercial planting, GE products with herbicide resistance may need to have the relevant chemical registered in Japan.

#### *k) INTELLECTUAL PROPERTY RIGHTS (IPR)*

Japan provides strong IPR protection and enforcement. Japanese IPR covers genetic engineering of agricultural crops, including but not limited to, the gene, seeds, and name of varieties. Japan's Patent Office is responsible for IPR.

#### *l) CARTAGENA PROTOCOL RATIFICATION*

Japan ratified the Cartagena Protocol on Biosafety in November 2003 and implemented the "Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms." In December 2017, Japan ratified the "Nagoya-Kuala Lumpur Supplemental Protocol on Liability and Redress to the Cartagena Protocol on Biodiversity." This and other laws implementing the protocol may be found on the Japan Biosafety Clearing House (J-BCH) [website](#).

#### *m) INTERNATIONAL TREATIES AND FORUMS*

The Japan Bioindustry Association has prepared [guidelines](#) on Access and Benefit Sharing. Their target, however, are the pharmaceutical and medical industries and not agriculture.

Japan is also actively involved in the harmonization of regulatory oversight in biotechnology at the Organization for Economic Co-operation and Development (OECD).

*n) RELATED ISSUES*

None.

PART C: Marketing

*a) PUBLIC/PRIVATE OPINIONS*

Although GOJ polling shows public concern about GE products has fallen significantly over the last 10 years, Japanese food companies and retailers are reluctant to handle GE varieties as many GE food products come with mandatory labeling requirements and concerns over public perception remain. Without assurance that GE crop will be purchased, farmers cannot take the risk of using GE crops. In addition, local government regulation adds another hurdle for local farmers to cultivate GE crops.

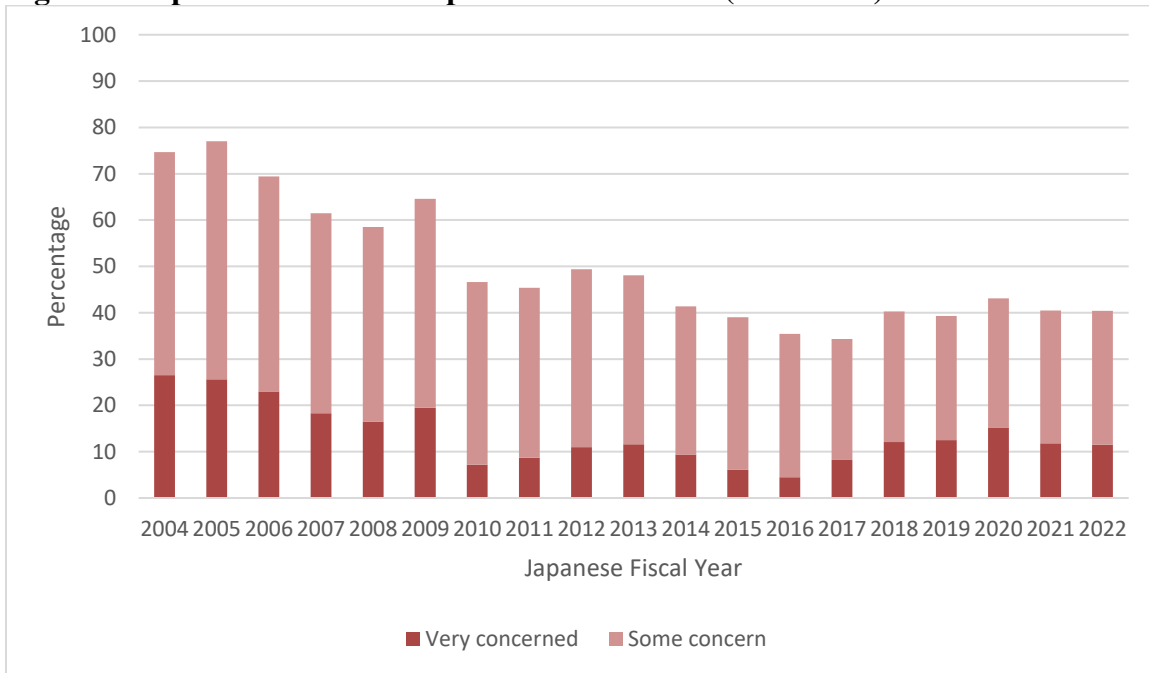
At the same time, a new movement toward forward-leaning engagement on agricultural biotechnology has occurred among some Japanese farmers. A group of like-minded local farmers has started to openly claim an urgent need for agricultural biotechnology by Japanese farmers. In April 2023, a group of like-minded farmers established the Japan Biotech Crop Network ([JBCN](#), in Japanese and English). Their goal is to have biotechnology crops in the hand of Japanese farmers. In addition, JBCN claims these crops will reduce the burden on the environment caused by agriculture and support sustainable agriculture.

*b) MARKET ACCEPTANCE/STUDIES*

Although there are still consumer groups actively campaigning against products derived from biotechnology, the public perception of GE-derived products has changed. Recent GOJ survey results show that consumers concerned with GE food are now in the minority. In a 2006 Japan Fiscal Year (JFY), [survey conducted by FSC](#) (in Japanese) 75 percent of participants were “highly concerned” or “concerned” about GE foods. However, in the JFY2022 survey, only 40 percent of respondents were “highly concerned” or “concerned,” marking a notable change in the public’s concern about GE products. GE foods last appeared in the top seven food-safety concerns for survey respondents in 2009. For non-GE genome edited food products, 11 percent responded that they are “highly concerned,” and 31 percent “concerned. For more information on the FSC’s annual survey, see the Appendix in this report.



**Figure 2: Japan Consumer Acceptance of GE Foods (2004-2022)**



Source: [FSC Food Safety Monitoring](#) (in Japanese)

## CHAPTER 2: ANIMAL BIOTECHNOLOGY

### PART D: Production and Trade

#### *a) RESEARCH AND PRODUCT DEVELOPMENT*

In Japan, most molecular biology researchers focus on medical and pharmaceutical applications. As with plants, universities and public research institutions conduct much of the limited animal biotechnology research pertaining to food and agriculture.

In 2019, a largely academic research team behind a genome edited sea bream and pufferfish founded a startup company called [Regional Fish](#), with private sector financial support. Regional Fish aims to revive the Japanese aquaculture industry and address a shortage of protein sources through the commercialization of genome edited aquaculture products. For more scientific and technical information on the new genome edited products, see their [publication](#). Regional Fish also recently [announced](#) a partnership with JETRO, a quasi-governmental export assistance organization, as well as an Indonesian company, to bring their genome editing technology to Indonesia. Regional Fish and Nippon Telegraph and Telephone Corporation also announced the use of epigenetics for the commercialization of Japanese flounder (*Paralichthys olivaceus*) with high temperature tolerance ([Nikkei](#), in Japanese).

Kyushu University and the Karatsu City Government are partnering to develop a genome edited chub mackerel with reduced aggression, which increases aquaculture productivity ([Nature](#)).

Researchers at Hiroshima University and Kewpie Corporation have been working on lowering allergens in chicken egg. The team created a chicken lacking ovomucoid, the most predominant allergen protein, and performed a safety study ([publication](#) in Food and Chemical Toxicity).

Japan's National Institute of Agrobiological Sciences (NIAS) continues to develop GE silkworm varieties for value-added silk production; however, its commercial application remains limited. As of September 2023, Japan has approved [10 GE silkworms for commercial use](#).

Interest in animal cloning appears to have waned in Japan and activity has been steadily decreasing since the late 1990's. There have been no new births since 2018, and currently there is only one cattle from a fertilized-egg clone and five cattle from somatic cell cloning in Japan. For more details, see the [MAFF website](#) (link in Japanese).

#### *b) COMMERCIAL PRODUCTION*

Currently, there is no commercial production of GE animals or cloned animals for the purpose of agricultural production except for limited production of value added silk and protein by [GE silkworms](#).

As of September 2023, one company, Regional Fish, has notified MHLW of two types of animal food products from genome editing technology. Two lines of sea bream with increased edible skeletal muscle and two lines of fast-growing puffer fish. More details in [MHLW website](#) (in Japanese).

#### *c) EXPORTS*

None.

*d) IMPORTS*

None.

*e) TRADE BARRIERS*

None.

PART E: Policy

*a) REGULATORY FRAMEWORK*

GOJ regulators apply the same regulation for GE plants to the commercialization of GE livestock animals and insects. For production or environmental release of GE animals, MAFF will apply its “Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms.” The Food Sanitation Act, under MHLW’s supervision, covers the food safety aspect of GE animals.

In general, the technical terms used for animals are the same as for plants.

*b) APPROVALS/AUTHORIZATIONS*

**Table 4: GE Animals for Commercial Use in Open Environment**

Organisms	Product	Developer	Date of Approval
Silkworm	Green fluorescent emitting protein producing silkworm (HC-EGFP, <i>Bombyx mor</i> ) (HC-EGFP Gunma, HC-EGFP 200, HC-EGFP Gunma x HC-EGFP 200, and their progenies)	<a href="#">National Agriculture and Food Research Organization</a>	September 22, 2017
Silkworm	Green fluorescent emitting protein producing silkworm (HC-EGFP, <i>Bombyx mor</i> ) (HC-EGFP Gunma (including progeny with Gunma), HC-EGFP 200 (including progeny with 200, HC-EGFP Gunma x HC-EGFP 200, HC-EGFP Gunma x 200, Gunma x HC-EGFP 200)	National Agriculture and Food Research Organization	September 12, 2019
Silkworm	Blue Fluorescent emitting protein	National Agriculture and Food Research	August 21, 2020

	producing silkworm (HC-Sirius, <i>Bombyx mori</i> ), (GN13, GCS13, GN13 x GCS13, GN13 x MCS4, GN13 x Shi 146, Nichi 137 x GCS13)	Organization	
Silkworm	High staining property silkworm (modified Fibroin H, <i>Bombyx mori</i> ), (GCS500, GCS508, Chu515 x GCS500, CHu 517 x GCS508)	National Agriculture and Food Research Organization	August 21, 2020

*c) INNOVATIVE BIOTECHNOLOGIES*

The regulatory policies and guidelines developed by MHLW for food and MAFF for biodiversity explained in Chapter 1 apply to animals derived from genome editing technology with some exceptions.

MHLW decided that due to differences between fish raised for aquaculture versus crops and livestock (such as a shorter breeding history, greater genetic variation in species, and genetic mosaicism with CRISPR/Cas9), it would change its genome edited product consultation and notification process for fish. MHLW finalized a report titled “Note on the Handling of Fishes Obtained via Genome Editing Technology.” For more detail, please see [JA2021-0132](#).

*d) LABELING AND TRACEABILITY*

The labeling requirement for GE animals is the same as for plants. There is no mandatory labeling requirement for non-GE, genome edited products. For products derived from a cloned animal, CAA requires products to carry a cloned label. FAS/Tokyo is not aware of any commercial product with a “cloned” label.

*e) ADDITIONAL REGULATORY REQUIREMENTS*

*f) INTELLECTUAL PROPERTY RIGHTS (IPR)*

Same as for plants.

*g) INTERNATIONAL TREATIES/FORA*

Japan ratified the Cartagena Protocol on Biosafety in 2003.

*h) RELATED ISSUES*

In September 2017, the GOJ implemented monitoring for GE salmon and processed salmon products, such as salmon flakes. For additional details, please see [JA7112](#).

PART F: Marketing

*a) PUBLIC/PRIVATE OPINIONS*

At this moment, there is no commercial distribution of GE animals in Japan except for a few products, such as the silkworm used to make protein for medical diagnostic agent. It is not clear how much, if any, public interest there would be in consuming meat from GE or cloned animals.

*b) MARKET ACCEPTANCE/STUDIES*

There are no market acceptance studies specific to animal biotechnology.

## CHAPTER 3: MICROBIAL BIOTECHNOLOGY

### PART G: Production and Trade

#### *a) COMMERCIAL PRODUCTION*

Japan has several traditional foods that rely on fermentation, including soy sauce, *natto* (fermented soybeans), *miso* (soybean paste), and *sake* (rice wine). Other products common in the modern Japanese diet that use fermentation include yogurt, cheese, and bread. Despite widespread use, there is little public information on the scale of production for products derived from microbial biotechnology. The food industry in Japan is sensitive to consumer reaction to the use of biotechnology and labeling rules exempt the products in this category from required GE labeling, so there is little incentive to indicate if a product uses microbial biotechnology.

Industry values Japan's 2021 enzyme and yeast markets at approximately 49 billion yen (340 million USD) but there is no specific value available for enzyme and yeast derived from biotechnology.

Manufacturers of products that use microbial biotechnology (e.g., GE enzymes) are a mix of international and domestic companies. MHLW has given approval to a number of companies to use microbial biotechnology, including, Novozyme, Danisco U.S., Ezaki Glico and several other domestic companies. Lists of approved products and applicants can be found on [MHLW's website](#).

Japanese companies make up most applicants for self-cloning, natural occurrence, and highly purified products (e.g., L-glutamine). See [MHLW's website](#) (link in Japanese) for a list of approved products and applicants.

Product developers have introduced a limited number of alternative meat products in the Japan market. Most alternative meat products available on the Japanese market are soy-based. In October 2020, MAFF held its first "[Council for Public-Private Partnership in Food Technology](#)" (link in Japanese) for the promotion of cross-sectorial collaboration, but the conference was not open to the general public. The Center for Rule-Making Strategies at Tama University established [Japan Association for Cellular Agriculture](#) in 2020 to promote activities and communication among stakeholders in industry, regulators, policy makers, and academia about the commercial application of cellular agriculture for medical/pharmaceutical, food, and materials industry, etc... The [Japan Bioindustry Association](#) also launched a working group for cultured meat and held its first workshop in July 2023. So far, meat analogue products from bacteria or single cell-based proteins are not in commercial distribution in Japan.

#### *b) EXPORTS*

In 2022, Japan exported 5,871 MT of enzymes (HS code 3507), valued at \$298 million, which may include products derived from microbial biotechnology.

**Table 5: Japan Enzyme Exports (HS3507, CY2022)**

Country	Volume (Metric Ton)	Value (Million USD)
Denmark	1,459	14
United States	1,159	90
China	817	45
Germany	390	19
France	370	15
Others	1,676	115
<b>Total</b>	<b>5,871</b>	<b>298</b>

Source: [Trade Data Monitor Inc.](#)

*c) IMPORTS*

In 2022, Japan imported 4,950 MT of enzymes (HS code 3507), valued at \$95 million, which may contain products derived from microbial biotechnology.

**Table 6: Japan Enzyme Imports (HS3507, CY2022)**

Country	Volume (Metric Ton)	Value (Million USD)
Denmark	1,521	24
China	1,451	15
United States	791	22
Singapore	357	2
Finland	249	2
Others	581	43
<b>Total</b>	<b>4,950</b>	<b>108</b>

Source: [Trade Data Monitor Inc.](#)

*d) TRADE BARRIERS*

None.

PART H: Policy

*a) REGULATORY FRAMEWORK*

Japan's Food Sanitation Act defines food additives as (i) substances used in or on food in the process of manufacturing food, or (ii) substances used for the purpose of processing or preserving food. The GOJ considers most microbial biotechnology products as food additives. More information can be found on [MHLW's website](#).

If product manufacturers only use the GE microorganism and its products in a contained environment for food production, the manufacturer must only seek food safety approval from MHLW. The approval

process is the same as the GE food safety review process for plant and animal products. After MHLW completes a preliminary review it sends the application to FSC for the safety risk assessment. For more information on the process, please see [FSC's website](#).

MHLW exempts food additives from the safety review when they are highly purified and do not contain foreign GE material. MHLW and FSC can exempt microorganisms from the safety review if they agree that they are self-cloning or natural occurrence. FSC has published their Safety Assessment Standards for [microorganisms](#), [food additives](#), and [highly purified end-products](#). More information can be found on [MHLW's website](#) (in Japanese).

The Newly Developed Food Survey Subcommittee in MHLW held the first listening session for industry in March 2023 and the second in August to learn about current status of research and development of foods derived from cell culture technologies. The listening session was not open to the public. MHLW announced that they will continue such events with the industry. As of September 2023, GOJ has not published any regulatory policy for the handling of food products derived from cell culture technologies.

#### *b) APPROVALS/AUTHORIZATIONS*

As of September 2023, Japan has approved 80 food additive ingredients derived from GE technologies. Approved products can be found on [MHLW's website](#) and are listed below:

- Alpha amylase: 19 products
- Rennet: 5
- Pullulanase: 4
- Lipase: 6
- Riboflavin: 2
- Glucoamylase: 5
- Alpha-glucosyltransferase: 4
- CGTase: 2
- Asparaginase: 1
- Phospholipase: 7
- Beta-amylase: 1
- Exomalt tetraohydrolase: 2
- Acid phosphatase: 1
- Glucose oxidase: 3
- Protease: 4
- Hemicellulase: 2
- Xylanase: 5
- Beta-galactosidase: 1
- Psicose epimerase: 1
- Terpene hydrocarbons: 1
- Aminopeptidase: 1
- Alpha-Glucosidase: 1
- Carboxypeptidase: 1
- Pectinase: 1

As of September 2023, MHLW has approved 88 products as highly purified substances, products of natural occurrence, or self-cloning. [MHLW's website](#) (link in Japanese) has the complete list of



products.

*c) LABELING and TRACEABILITY*

CAA requires food labels to identify GE products and/or ingredients when the GE ingredient is among the top three ingredients and accounts for at least five percent of the product.

CAA does not require food labels to contain GE labeling for food additives. CAA does have other food additive labeling requirements, for more see [JA2019-0216](#).

*d) MONITORING AND TESTING*

No specific testing for products from microbial biotechnology.

*e) ADDITIONAL REGULATORY REQUIREMENTS*

None.

*f) INTELLECTUAL PROPERTY RIGHTS (IPR)*

Same as for plants and animals.

*g) RELATED ISSUES*

None.

PART I: Marketing

*a) PUBLIC/PRIVATE OPINIONS*

Public awareness of microbial biotechnology use by the food industry is limited.

*b) MARKET ACCEPTANCE/STUDIES*

There are no significant market acceptance studies available.

## Reference

### Risk assessment standards of genetically engineered food

Food Safety Commission

[http://www.fsc.go.jp/english/standardsforriskassessment/gm\\_kijun\\_english.pdf](http://www.fsc.go.jp/english/standardsforriskassessment/gm_kijun_english.pdf)

### Information related to GE food regulations

Ministry of Health, Labor and Welfare

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\\_iryoushokuhin/bio/index\\_00013.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryoushokuhin/bio/index_00013.html)

### Information on GE Food Labeling

Consumer Affairs Agency (the agency responsible for labeling regulations, including GE)

<http://www.caa.go.jp/en/> (English)

Food Labeling Law, Government Ordinance, Ministerial Ordinance and Notifications (in Japanese only)

[https://www.caa.go.jp/policies/policy/food\\_labeling/food\\_labeling\\_act/](https://www.caa.go.jp/policies/policy/food_labeling/food_labeling_act/)

The information on the Food Labeling Law is still not available in English. Please refer to [JA7078](#) for additional details on the law.

Useful resources on agricultural biotechnology by Japan Biosafety Clearing House (Japan)

[http://www.biodic.go.jp/bch/english/e\\_index.html](http://www.biodic.go.jp/bch/english/e_index.html)

### Approved events for commercial use

Approved events for food use (in English):

<https://www.mhlw.go.jp/english/topics/food/pdf/sec01-2.pdf>

Approved stacked events for food use (exempted from review, in Japanese):

<https://www.mhlw.go.jp/content/11130500/001120178.xlsx>

Approved events for feed use (in English):

[http://www.famic.go.jp/ffis/feed/r\\_safety/r\\_feeds\\_safety33.html](http://www.famic.go.jp/ffis/feed/r_safety/r_feeds_safety33.html)

Approved events for environmental release (in Japanese):

<https://www.maff.go.jp/j/syouan/nouan/carta/torikumi/attach/pdf/index-49.pdf>

Japan Biosafety Clearing House – List of approved living modified organisms under Cartagena Protocol domestic Law (in English):

[http://www.biodic.go.jp/bch/english/e\\_index.html](http://www.biodic.go.jp/bch/english/e_index.html)

### Genome editing technology

MHLW – Foods derived from genome editing technology (in Japanese)

[https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\\_iryoushokuhin/bio/genomed/index\\_00012.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryoushokuhin/bio/genomed/index_00012.html)

MAFF – Handling of living organisms derived from new breeding technique under Cartagena Law (in Japanese)

<http://www.maff.go.jp/j/syouan/nouan/carta/tetuduki/nbt.html>

MAFF – Safety of Feeds and Pet Foods (in English)

[https://www.maff.go.jp/e/policies/ap\\_health/petfood/index.html](https://www.maff.go.jp/e/policies/ap_health/petfood/index.html)

CAA – Information for the labeling of genome edited foods (in Japanese)

[https://www.caa.go.jp/policies/policy/food\\_labeling/quality/genome/](https://www.caa.go.jp/policies/policy/food_labeling/quality/genome/)

## Appendix

**Table: Degree of Concern for Each Hazard Perceived in Terms of Food Safety (Top 7 responses, by percentage, answering "very anxious" and "somewhat anxious") (Provisional Translation)**

	#1	#2	#3	#4	#5	#6	#7
2004	Contaminants (cadmium, methylmercury, arsenic, etc.) (91.7%)	Pesticide Residue (89.7%)	Antibiotics for livestock (83.5%)	Food poisoning from harmful microorganisms, viruses (80.9%)	Food Additives (76.4%)	Genetically Modified (74.7%)	BSE (74.5%)
2009	Food poisoning from harmful microorganisms, viruses (79.6%)	Contaminants (cadmium, methylmercury, arsenic, etc.) (78.1%)	Pesticide Residue (73.1%)	Antibiotics for livestock (68.2%)	Elution of chemicals from utensils, containers and packaging (67.5%)	Genetically Modified (64.6%)	Food Additives (62.5%)
2014	Food poisoning from harmful microorganisms, viruses (78.5%)	Radioactive material (64.1%)	Health food claims (64.1%)	Pesticide Residue (58.8%)	Antibiotics for livestock (55.4%)	Contaminants (cadmium, methylmercury, arsenic, etc.) (53.6%)	Food Additives (50.4%)
2016	Food poisoning from harmful microorganisms, viruses (82.8%)	Health food claims (61.7%)	Mold toxicity (61.5%)	Drug-resistant bacteria by antibiotics for livestock (59.1%)	Radioactive material (56.5%)	Foods containing allergenic substances (55.7%)	Contaminants (cadmium, methylmercury, arsenic, etc.) (51.9%)
2017	Food poisoning from harmful microorganisms, viruses (83.4%)	Health food claims (63.6%)	Mold toxicity (62.0%)	Drug-resistant bacteria by antibiotics for livestock (59.1%)	Foods containing allergenic substances (57.5%)	Radioactive material (51.5%)	Contaminants (cadmium, methylmercury, arsenic, etc.) (49.9%)
2018	Food poisoning from harmful microorganisms, viruses (86.7%)	Drug-resistant bacteria by antibiotics for livestock (66.9%)	Health food claims (64.9%)	Mold toxicity (64.6%)	Foods containing allergenic substances (61.8%)	Contaminants (cadmium, methylmercury, arsenic, etc.) (60.9%)	Radioactive material (54.0%)
2019	Food poisoning from harmful microorganisms, viruses (85.1%)	Drug-resistant bacteria by antibiotics for livestock (66.1%)	Health food claims (62.6%)	Mold toxicity (61.9%)	Foods containing allergens (59.9%)	Contaminants (cadmium, methylmercury, arsenic, etc.) (53.9%)	Elution of chemicals from utensils, containers and packaging (52.8%)
2020	Food poisoning from harmful microorganisms, viruses (83.2%)	Mold toxicity (72.5%)	Health food claims (60.5%)	Contaminants (cadmium, methylmercury, arsenic, etc.) (59.4%)	Drug-resistant bacteria by antibiotics for livestock (57.4%)	Pesticide Residue (56.3%)	Elution of chemicals from utensils, containers and packaging (55.5%)
2021	Food poisoning from harmful microorganisms, viruses (80.5%)	Mold toxicity (64.1%)	Drug-resistant bacteria by antibiotics for livestock (63.9%)	Health food claims (62.9%)	Contaminants (cadmium, methylmercury, arsenic, etc.) (61.4%)	Foods containing allergens (60.5%)	Radioactive material (54.9%)
2022	Food poisoning from harmful microorganisms, viruses (79.5%)	Health food claims (66.8%)	Mold toxicity (65.6%)	Contaminants (cadmium, methylmercury, arsenic, etc.) (62.1%)	Drug-resistant bacteria by antibiotics for livestock (59.4%)	Foods containing allergens (58.2%)	Radioactive material (51.3%)

Source: [Food Safety Commission of Japan](#)

**Attachments:**

No Attachments

**Attachments:**

No Attachments