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Japan Takes Step Forward to Improve its GE Product Review Process

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Biotechnology - GE Plants and Animals

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Report Highlights:
On January 28, 2014, the Government of Japan (GOJ) proposed two revisions to the review process of GE products: exemption of the review process for food and food additives produced using microorganisms considered as self-cloning or natural-occurrence; and the exemption of stacked GE events using pre-approved single events from scientific review, provided the cross does not affect the metabolic system of the hosts. The proposal is likely to have a significant positive impact for the industry. The proposal will be effective after a domestic comment period and publication in the GOJ's official gazette (KANPO).

General Information:

Summary

On January 28, 2014, the Government of Japan (GOJ) proposed two revisions to the review process of GE products. One of the two revisions is to exempt from the scientific review foods and food additives produced using microorganisms considered as self-cloning or natural-occurrence. Though industry still would need to consult regulators with the information and data proving the product is from microorganisms considered as self-cloning or natural-occurrence, they will be exempted from the lengthy scientific review process.

The other revision is to exempt stacked GE events with pre-approved single events from scientific review, provided the breeding cross does not affect the metabolic system of the hosts. Currently, only the food safety approval process requires "full scientific review" for stacked events, whereas feed and environmental review requires only notification and/or report for stacked event approval. Considering the majority of commercial GE crops being released to growers are stacked, the proposed revision is expected to have a positive impact, such as saving regulatory resources for technical providers, more precise prediction of product release, and timely availability of the latest technology to U.S. growers.

As the proposal is not to make current regulation more restrictive, the GOJ will not notify the WTO regarding these two revisions but is expected to hold a domestic public comment period, which is usually 30 to 60 days. After the domestic public comment period, the GOJ will officially announce the new review process in the GOJ's Official Gazette (KANPO).

Partial Revision of Safety Assessment Procedure for Genetically Modified Foods and Food Additives

The Government of Japan is planning to partially revise the provisions concerning genetically modified foods and food additives stipulated in Ministry of Health, Labor and Welfare Notifications No. 370 and No. 233.

1. **Background**

Current regulation

Any food or food additive for which specifications or standards have been established based on Article 11 of the Food Sanitation Act of Japan (Act No. 233, 1947) and specified in Ministry of Health, Labor and Welfare Notification No. 370 (1959, hereafter referred to as Notification No. 370) shall not be used or marketed unless it meets the standards or specifications.

Foods and food additives produced by recombinant DNA Techniques (genetically modified foods and food additives) shall receive safety assessment of the Ministry of Health, Labor and Welfare (MHLW), according to the Procedure for the Safety Assessment of Foods and Food Additives Produced by Recombinant DNA Techniques (Ministry of Health, Labor and Welfare Notification No. 233, 2000, hereafter referred to as the “Assessment Procedure”) established based on Notification No. 370, and

shall be published by the MHLW as those that have passed the safety assessment.

MHLW and FSC carry out a scientific review on each individual event, even if the inserted gene is the same.

Handling of self-cloning and natural occurrence

The MHLW asks the FSC to assess health effects of these products to hear its opinion when receiving an application from businesses.

However, foods and food additives produced using microorganisms considered as self-cloning or natural-occurrence are not specified in the Standards for the Safety Assessment of Genetically Modified Food (microorganisms) and the Standards for the Safety Assessment of Food Additives Produced Using Genetically Modified Microorganisms as those requiring an assessment of the health effects by the FSC. (Here, "self-cloning" refers to cases where the DNA ultimately introduced into a host—a living cell into which DNA is inserted by recombinant DNA techniques—is DNA only from microorganisms belonging to the same species as the host (taxonomically). "Natural occurrence" refers to cases where the recombinant—a host containing recombinant DNA—is equivalent in genetic composition to naturally occurring microorganisms.) FSC does not require safety review of food and food additives from microorganisms considered as self-cloning or natural-occurrence. Based on the FSC's decision, the MHLW considers them to not be categorized as genetically modified foods and food additives under Article 3, Paragraph 5 of the Assessment Procedure.

Consumers and businesses indicate that the current assessment procedure for genetically modified products is very hard to understand. As a result, there have been compliance violations as a result of companies skipping the regulatory consultation, even though there was no requirement for a full scientific review.

In foreign countries, such as the United States and the European Union, foods and food additives produced by self-cloned microorganisms or microorganisms considered as natural-occurrence are not classified as genetically modified foods and food additives. Businesses voluntarily confirm whether products are produced by such microorganisms.

Handling of stacked events produced by conventionally crossing multiple events that passed safety assessment

When events are published as having passed the safety assessment of the MHLW and the traits newly developed in these events by recombinant DNA techniques do not have any effect on the metabolic system of the hosts, new events produced by conventionally crossing these events (parental events) are considered as genetically modified foods. Therefore, based on current regulation and practice, MHLW requests the FSC conduct a full food safety review of stacked events. However, FSC has concluded that products from the conventional cross of genetically modified plants, where the parental events have already been determined to be safe and to have no effect on the metabolic system of the host, do not require safety assessments.

In the United States, events produced by the crossing do not require safety assessment for the reason that there is no safety concern.

2. **Outline of revision**

Self-cloning and natural occurrence

The cases considered as "self-cloning" and "natural occurrence" will be excluded from the definition of recombinant DNA techniques, and these cases will not fall under the recombinant DNA techniques that require safety assessment. (The underlined parts will be newly added.)

<Definition of recombinant DNA techniques>
"Recombinant DNA techniques" is defined as a series of techniques to join DNA fragments by mainly enzymatic breakage and rejoining to create recombinant DNA molecules, and then to insert them into living cells and proliferate them. However, this excludes cases that are clearly determined to fall into following A or B.

A. The DNA ultimately introduced into a host is DNA only from microorganisms belonging to taxonomically the same species as the host.
B. The recombinant is equivalent in genetic composition to naturally occurring microorganisms.

Note: The MHLW will publish criteria to determine whether cases fall into A or B above. As the result of determination based on the criteria, if cases cannot be clearly determined to fall into either of them, they will be considered to require safety assessment.

Stacked events produced by conventionally crossing multiple events that passed safety assessment

When events are published as having passed the safety assessment of the MHLW and the traits newly developed in these events by recombinant DNA techniques do not have any effect on the metabolic system of the hosts, new events produced by conventionally crossing these events are considered to be granted the official safety approval of MHLW if the following conditions are met.

A. Traits newly developed by recombinant DNA techniques do not change even in events produced by crossing.
B. Crossing between subspecies does not take place.
C. There are no change in conditions, including amount consumed, edible portion, and processing methods, between the events used for crossing and the events produced by crossing.

Note: For events used for crossing, during the health effect assessment, the FSC determines whether the traits newly developed by recombinant DNA techniques do not have any effect on the metabolic system of the hosts. The result is published.

The events produced by conventionally crossing plural events published as having passed the safety assessment are treated in the same manner as for “events produced by crossing between events published as having passed safety assessment and non-GM species using conventional breeding methods” that are specified in Article 5 of the Assessment Procedure.