NEWSLETTER

Latest Regulatory Update on Cell-Cultured Foods in Japan (Part 2)
-Based on the 2nd Meeting of the FY2025 Food Sanitation Standards Council, Novel Foods Subcommittee-

Agri-Food Newsletter

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Author:
Hideki Katagiri
h.katagiri@nishimura.com

1. Introduction

On September 29, 2025, the Subcommittee on Novel Foods under the Food Sanitation Standards Council ("Subcommittee") convened its second meeting of FY2025 to discuss the ongoing development of guidelines and the regulatory framework for cell-cultured foods in Japan.[1] This newsletter provides an overview of the key points discussed at the latest Subcommittee meeting regarding (i) the scope of foods covered by the guidelines and the nomenclature used to describe such foods, and (ii) the regulatory framework, i.e., the legal structure and administrative procedures by which product safety is ensured.[2] In particular, this article takes a closer look at the regulatory framework, as it directly affects the specific processes by which food business operators can bring cell-cultured foods to market.[3]

2. Scope and Nomenclature of Foods under the Guidelines

(1) Background

As reflected in previous meetings and materials, the Subcommittee has primarily focused on animal cell-based products. However, the latest meeting also addressed whether the guidelines should cover plant cell-based products produced using cell culture technology (e.g., materials such as those used for chocolate or coffee-based products). The discussion included whether the considerations for animal and plant cell applications differ and how these differences should be reflected in the guidelines.

(2) Secretariat's Proposal and Subcommittee's Deliberations

The Secretariat of the Office for Novel Foods, Food Sanitation Standards Division, Consumer Affairs Agency ("Secretariat") proposed that the safety procedures under discussion should apply to products manufactured using animal (including fish) cells via cell culture technology. Regarding nomenclature, the Secretariat proposed that, for the time being, the term "animal cell-cultured foods / 動物性細胞培養食品" (provisional name) be used

[1] For details on the background and previous discussions of the Subcommittee, please refer to my article "Latest Regulatory Update on Cultivated Meat and Fish in Japan" dated July 29, 2025.

[2] There were no significant updates regarding the hazards and risk control points discussed at the previous meeting on July 25, 2025; these matters remain under consideration, and further developments will need to be followed.

[3] The author watched the live webcast of the latest Subcommittee meeting and incorporated its contents into this newsletter. However, as noted on the CAA's website, the webcast does not constitute an official record, and the official minutes will be published later. Until the final regulatory framework and/or guidelines are released, the information in this article remains subject to change.

by the Subcommittee.

Based on the discussions at the latest Subcommittee meeting, it was agreed that while the guidelines may potentially apply to applications involving plant cells and other non-animal cells, the focus of their consideration will remain on animal cells (including seafood) in order to maintain the pace of deliberations.[4] Regarding nomenclature, since there is no international precedent for limiting the name to products derived from animal cells (such as "animal cell-cultured foods") when referring to this category of foods in general, it was agreed not to impose such a restriction, and to use the provisional term "cell-cultured foods / 細胞培養食品".[5]

(3) Author's Perspective

There remains some uncertainty regarding how products derived from plant cells will ultimately be treated. This issue is closely related to the timing of the discussion at the latest Subcommittee meeting. It is expected that, as the guidelines are finalized, the extent to which applications involving non-animal cells may deviate from those involving animal cells will be considered, and any necessary exceptions or special considerations will be specified accordingly (for example, the guidelines may note that different considerations are required for plant cell-derived products). Therefore, it is unlikely that products made from cultured plant cells will be categorically excluded from the scope of the guidelines or that applications from food business operators will be automatically rejected on that basis. In any case, as the Secretariat is expected to present a revised draft reflecting the latest discussions, it will be necessary to await that document.

3. Regulatory Framework for Ensuring Safety

(1) Overview

First, the Secretariat explained that domestic regulatory frameworks (not limited to the food sector) can be classified into the following four types.

Type	Description	Examples
1. Individual Product Review by Authorities	Authorities review and approve each product based on established standards and guidelines.	Pharmaceuticals, certain medical devices, genetically modified foods
2. Third-Party Certification	Third-party organizations certify products' compliance with standards.	JIS/JAS-marked products, some medical devices
3. Notification System	Companies notify authorities of products that comply with standards; authorities may review before acceptance.	General medical devices, cosmetics, genome-edited foods
4. Self-Management	Companies are responsible for ensuring their compliance with standards.	Nutritional function foods

[4] In the discussion on the scope of application, it was noted that the Subcommittee's initial focus was on "alternative proteins." There was also a comment that different considerations may be required when examining other types of products. However, this should not be interpreted as an intention to exclude applications involving animal cells other than proteins, such as fat, from the scope of the guidelines—especially given that both the Subcommittee members and the Secretariat recognize that there are already approved cases and ongoing discussions in other countries regarding such applications.

[5] For this reason, while the previous Newsletter used the term "cultivated meat and fish," this Newsletter uses the term "cell-cultured foods". Incidentally, as the discussions at the Subcommittee were conducted exclusively in Japanese, the official English nomenclature has not yet been determined. Therefore, please note that the term "cell-cultured foods" used in this newsletter is the author's own translation based on the agreed Japanese term, and is not an official English designation.

Next, the Secretariat explained the regulatory situation in several foreign jurisdictions (specifically Singapore, the EU, Australia/New Zealand, the UK, and the US), describing both the responsible authorities and the process for market approval (i.e., how products are reviewed by those authorities). While the forms of approval vary, it was noted that, in principle, regulatory authorities in these countries are involved in the review and approval of individual products, which corresponds to "Type 1" in the classification presented above.

(2) Subcommittee Discussion

Based on the explanations above, the following exchanges took place between the Subcommittee members and the Secretariat:

First, regarding Type 2, it was noted that establishing third-party certification bodies would require their designation as registered certification organizations under the law, and a legal basis for such organizations would be necessary. Therefore, this approach was considered unworkable in relation to the process currently being pursued.

Regarding Type 3, the example of genome-edited foods was referenced. However, the notification system for genome-edited foods applies only when certain technical requirements are met (specifically, when genes are not introduced from external sources) and when the final product does not differ from naturally occurring mutants. Given these various prerequisites, the notification system is permitted only as an exception, and many members expressed skepticism about applying this approach to cell-cultured foods, as it is unclear whether similar prerequisites exist.

Many members pointed out that, since cell-cultured foods are considered "novel foods," a pre-market review system (Type 1) should be implemented, and that it is necessary to carefully consider the extent to which risk assessment should be delegated to the Food Safety Commission. The Secretariat responded that, as the guidelines are developed, discussions with the Food Safety Commission will be held.[6]

On the other hand, regarding Type 1, while acknowledging the complexity of cell-cultured foods, it was also pointed out that these are food ingredients such as proteins, and the level of risk differs from that of pharmaceuticals. Concerns were also raised about the lengthy time required for commercialization,[7] and it was emphasized that even if Type 1 is adopted, careful consideration of the scope and depth of the review would be necessary.

Additionally, referring to the practical experience of regulatory procedure with pre-market approval for genetically modified foods, it was noted that the burden on food business operators could become excessive (in practice, this has meant that only multinational corporations have been able to comply with the requirements, while startups have found it difficult to submit an application). Therefore, depending on the contents of the guidelines, even if Type 1 is adopted, the burden on food business operators must be considered.[8]

Based on these discussions, it was agreed that the Secretariat will continue to consider the regulatory framework, including by consulting with the Food Safety Commission as necessary regarding the scope of its

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[6] In addition, regardless of which regulatory type is ultimately adopted, the Secretariat indicated that a process will be established to allow the Food Safety Commission to be consulted for risk assessment opinions as needed.

[7] One member pointed out that, in some of the foreign jurisdictions cited at the latest Subcommittee meeting, there are long queues for applications and cases where it takes a considerable amount of time for products to reach the market.

[8] Some members expressed a hybrid view, suggesting that while Type 1 should be used for the time being, it may be appropriate to shift to a lighter procedure such as Type 3 once more is known about cell-cultured foods. On the other hand, it was pointed out that, although similar discussions have taken place regarding genetically modified foods, in practice, once strict standards and procedures have been established, it is difficult to simplify them later.

involvement.

(3) Author's Perspective

First, it is important to recognize that these discussions regarding the regulatory framework are occurring before the contents of the guidelines have been finalized. As several Subcommittee members pointed out, the perception that cell-cultured foods inherently carry unknown risks may change as the guidelines are further developed (at least from the perspective of food safety).[9] In this context, the fact that the Consumer Affairs Agency has made the regulatory framework a topic for discussion at the latest Subcommittee meeting and provided related information can be seen as a starting point for the Agency's full-scale consideration of the regulatory framework.

In Japan, "novel foods" (i.e., foods without a history of human consumption) are generally not subject to pre-market approval requirements. Rather, the legal system is based on post-market regulation.[10] This is not a matter of legal formality, and reflects the legal culture and framework that Japan has developed over time, balancing food safety with various other considerations, including economic, cultural, and social factors. In this context, it is also important to take into account that Japan's flexible approach to novel foods has enabled the creation of innovation and diverse food cultures.[11] The legal stability fostered under this system will continue to serve as a foundation for considering new regulatory frameworks.[12]

Currently, only genetically modified foods are subject to a pre-market approval process in Japan.[13] This framework was established after extensive debate regarding foods produced using recombinant DNA technology, and is distinct from other categories. As noted in footnote 10, the post-market regulatory framework for novel foods under Article 7, Paragraph 1 of the Food Sanitation Act was already in place when these rules

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9 In other words, it is not necessary to eliminate every unknown aspect of cell-cultured foods purely from a scientific standpoint; rather, what is required is to address risks from the perspective of food safety. For example, if hazards can be managed through measures such as heat treatment or by controlling residual levels in the final product, then even if our understanding of all hazards is not complete, as long as clear solutions exist, it can be considered that adequate risk control has been achieved from a food safety perspective. In this sense, such products may no longer be regarded as "unknown foods."

10 Specifically, Article 7, Paragraph 1 of the Food Sanitation Act stipulates that, for "substances not generally consumed as food," the authorities may prohibit their sale if certain requirements are met. Although this provision does not provide a detailed definition as seen in some foreign jurisdictions, it can be regarded as establishing a post-market regulatory framework for novel foods. Notably, since this provision was enacted in 1972, it is clear that the concept of novel foods was not absent from Japanese law; rather, Japan was ahead of many other countries in recognizing the risks associated with novel foods and, after considering various factors, adopted a restrained legal system based on post-market regulation.

11 To the best of my knowledge, there has not been any specific research conducted to verify or demonstrate that Japan's regulatory environment has been intentionally designed to promote innovation in the food sector, nor to assess the effects of such an approach. Nevertheless, it is noteworthy that Japan has maintained a high standard of food safety while adopting a legal framework that allows for flexible handling of novel foods.

12 In connection with this, at the latest Subcommittee meeting, one member remarked that even when scientific review involves government participation, there is a significant difference between a process that ultimately requires formal government approval and one that proceeds through consultation with the authorities. The member commented that, even if the authorities are involved in the safety review of individual products (Type 1), requiring formal government approval would be a significant decision. In my view, this reflects the need to carefully consider the potential burden on food business operators.

13 As was pointed out at the latest Subcommittee meeting, "Foods for Specified Health Uses" (FOSHU) also require pre-market approval. However, this category is primarily intended to allow health claims to be made for foods as an exception, and the main focus is on verifying whether such health functions exist. Furthermore, the legal basis for FOSHU is the Health Promotion Act, not the Food Sanitation Act. Therefore, although food safety is also reviewed as one of the key criteria in the FOSHU approval process, FOSHU should not be considered equivalent to pre-market approval from the perspective of general food safety regulation.

were created, and genetically modified foods were regulated as a separate category.
Therefore, while both cell-cultured foods and genetically modified foods share the common feature of being produced using new technologies, they are distinct categories. Therefore, when considering Japan's overall legal system, it is not necessarily appropriate to use the regulatory framework for genetically modified foods as a benchmark for cell-cultured foods. Moreover, it is important to recognize that, in the major foreign jurisdictions referenced at the latest Subcommittee meeting, these two fields are currently regulated under different frameworks that reflect their respective characteristics.
In light of the matters above, it should be kept in mind that establishing specific regulations for cell-cultured foods would be an exceptional measure. Rather than focusing excessively on the novelty of cell-cultured foods, it is appropriate to construct a framework in which food business operators provide sufficient information (such as the necessary data sets and supporting evidence demonstrating food safety from a risk assessment perspective) and the government verifies this information, intervening as necessary. Such a framework would ensure consistency with Japan's overall legal system and the legal culture that has been cultivated to date.

End.

Public Relations Section, Nishimura & Asahi newsletter@nishimura.com