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Japan's Positive List System for Utensils, Containers, and Packaging Intended for Food Use (Effective from June 1, 2025)

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Following the amendment of the Food Sanitation Act in 2018, the so-called Positive List System was introduced to regulate utensils, containers, and packaging intended for food use. This system, which came into force on June 1, 2020, allows the use of only those substances that have been evaluated as safe to use. Pursuant to Article 18, Paragraph 3 of the Act, synthetic resins used in such products must consist solely of substances listed in the Positive List. In principle, the use of substances not included in the list is prohibited.

This system applies to all businesses engaged in food-related operations, regardless of their scale. Violations are subject to penalties meaning the system has a significant impact within the industry[1]. Additional attention will be required after June 1, 2025, as this marks the expiration of the transitional period and a revision of the Positive List itself.

This newsletter outlines the framework of the Positive List System, including the transitional measures, and introduces the scope of materials covered under the system - highlighting changes made to the Positive List. Unless otherwise stated, all legal provisions cited herein are current as of the time of writing.

1. Overview of the Positive List System for Food Utensils, Containers, and Packaging

(1) Background and Purpose of the Positive List System

Most utensils, containers, and packaging intended for food use are manufactured using synthetic resins and other chemical substances. Given the potential toxicity of such materials and the risk of harmful substances leaching into food, it is essential that they are produced and used in a controlled and appropriate manner.

Under the previous Food Sanitation Act, a Negative List System was in place - only explicitly prohibited substances were listed. However, this approach made it difficult to address the emergence of new harmful substances, as unlisted materials could technically be used until added to the list. In an age where new chemical substances are constantly being developed, the Negative List System posed inherent limitations in ensuring food safety.

[1] Violations of the Positive List System may result in **criminal penalties**, including **imprisonment for up to one year** or **a fine of up to one million yen** (Article 83, Item 1 of the Food Sanitation Act), as well as **administrative sanctions** such as business suspension (Article 60 of the same Act).

Consequently, Japan adopted a Positive List System as has already been implemented in many other countries[2]. Under this new system, only substances that are included in the Positive List after undergoing a safety assessment may be used. Substances not listed are, by default, prohibited. Moreover, the list specifies conditions such as maximum permissible usage and migration limits, making it more precise in regulating material use[3].

It should be noted that, even before the 2018 legal amendment, certain thermoplastic resins were already subject to voluntary Positive Lists developed by industry organizations such as the Polyolefin Hygienic Council, the PVC Food Sanitation Council, and the PVDC Hygienic Council. These were operated under a voluntary verification system.

Therefore, the significance of the legislative change lies in two key aspects:
1. From a market perspective, the law ensures that businesses not affiliated with these industry organizations, including importers, are also subject to government-led safety evaluations.
2. From a coverage perspective, the amendment expands the scope of regulation to include not only thermoplastic resins but also thermosetting resins, aligning Japan's framework with international standards.

(2) Overview of the Positive List System for Utensils, Containers, and Packaging Intended for Food Use

This section provides a general overview of the Positive List System as it applies to food-related utensils, containers, and packaging.

① Scope of Application of the Positive List System

Article 18, Paragraph 3 of the Food Sanitation Act stipulates that for raw materials of designated types specified by Cabinet Order[4], any substance not conforming to the prescribed standards - namely, the amount permitted to remain in or migrate into food from the utensils or containers made from such materials – is prohibited. These prescribed standards are referred to as the *Positive List*.

Under the Enforcement Order of the Food Sanitation Act (Article 1), the designated raw materials are defined as "synthetic resins." Furthermore, administrative guidance clarifies that rubber - an elastomer that lacks thermoplastic properties - is not included within this definition of synthetic resins[5].
Accordingly, the Positive List System applies to the following types of synthetic resins:

(i) **Thermoplastic resins**,
(ii) **Thermosetting resins**, and
(iii) **Thermoplastic elastomers**
but **excludes**
(iv) **Thermosetting elastomers (rubber)**.

Utensils, containers, and packaging made of or containing any of the above synthetic resins fall within the scope of this regulatory system. Additionally, products made from materials other than synthetic resins may also fall under the Positive List System if their food-contact surfaces are laminated with synthetic resin.

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[2] The Positive List System is not unique to Japan. The United States introduced a comparable system in **1958** and the European Union in **2010**. Additionally, other jurisdictions—such as **China, India, and Vietnam**—have also implemented similar regulatory frameworks.

[3] It is important to note that the concept of a Positive List System is **not new under Japanese food law**. In fact, a positive list regulation concerning pesticide residues was introduced through the **2003 amendment to the Food Sanitation Act**. That aim of that system is to prohibit the distribution of food products containing residues of agricultural chemicals, feed additives, or veterinary drugs exceeding specified limits. The **2018 amendment** to the Food Sanitation Act extended this regulatory approach to **utensils, containers, and packaging** intended for food use.

[4] Food Sanitation Act, Article 18, Paragraph 1, Ministry of Health and Welfare Notification No. 370 of 1959

[5] **"Establishment of Related Ministerial and Ordinance Regulations Following the Enforcement of the Partial Amendment to the Food Sanitation Act"**
(Notification No. 1, Bureau of Food Safety, November 7, 2019)

While food utensils and packaging may be made from a variety of materials such as glass, plastic, paper, and rubber, the decision to apply the Positive List System to synthetic resins initially was based on several considerations[6]:

- Their widespread use in diverse food-related applications and corresponding potential impact on public health,
- International practices in jurisdictions such as Europe and North America, where similar systems are already in place,
- The existence of established industry-led self-regulation efforts in Japan.

However, it remains possible that the scope of the system will be expanded in the future to encompass materials beyond synthetic resins[7].
In conjunction with the end of the transitional period, revisions will be made to clarify and refine the scope of materials subject to the Positive List[8]. A more detailed explanation of the updated scope will be provided later in this newsletter.
As an exception to the general rule, substances not included in the Positive List may be used in parts of utensils or containers that do not come into contact with food, provided they are processed in such a way that the migration of such substances into food does not exceed the established threshold for safety. According to the proviso of Article 18, Paragraph 3 of the Act, this is defined as **not more than 0.01 mg per kg of food**[9]. If this criterion is met, the use of non-listed substances is permissible.

② Manufacturing Controls

Article 52 of the Food Sanitation Act imposes general sanitation management obligations on businesses engaged in the manufacture of food utensils and packaging. In addition, manufacturers of synthetic resin-based utensils and containers must comply with *Good Manufacturing Practice (GMP)* standards[10]. These standards are designed to ensure proper control over the manufacturing process.

③ Information Sharing Among Businesses

Under Article 53 of the Act, businesses engaged in the sale, manufacture, or import of synthetic resin-based food utensils or containers are required to explain to their business partners that either:

- The raw materials conform to the standards (i.e., the substances are listed in the Positive List), or
- If substances not listed are used, that they are not used in food-contact surfaces and are processed in a way that prevents migration into food in quantities exceeding safe levels.

In addition, manufacturers of raw materials are under a duty to make reasonable efforts to provide information on compliance when requested by manufacturers of utensils or containers[11].
This explanation must be delivered in writing with businesses required to maintain appropriate documentation (such as specifications) to ensure that compliance can be verified retrospectively.

④ Notification Requirements

Article 57 of the Food Sanitation Act requires any business engaged in the manufacture of synthetic resin-based food utensils or packaging to notify the relevant local government authority.
Furthermore, under Article 58, if a business must recall products due to non-compliance - or potential non-compliance - with standards or the Positive List, a notification must be submitted to the governor of the relevant prefecture.

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[6] **"Final Report of the Study Group on Regulation of Utensils and Food Packaging"** (June 16, 2017, page 8)
[7] **Supplementary Resolution No. 4 of the 2018 Amendment to the Food Sanitation Act**, recommending consideration of a Positive List System for materials other than synthetic resins, based on risk levels and international trends
[8] **Partial Amendments to the Standards for Food, Additives, etc.** (Notice No. 1130-4 by the Director of the Health and Safety Bureau, November 30, 2023; latest revision: Notice No. 224, September 27, 2024)
[9] **Notification No. 195 of 2020**, issued by the Ministry of Health, Labour and Welfare, defining the threshold level of "no appreciable risk to human health" as stipulated in the proviso of Article 18, Paragraph 3
[10] **Detailed obligations related to manufacturing management**: Article 66-5 of the Enforcement Regulations of the Food Sanitation Act
[11] **Detailed obligations regarding information disclosure**: Article 66-6 of the same regulations

(3) Transitional Measures

As noted above, the Positive List System included transitional measures to ease the shift from the previous regulatory framework. Accordingly, for a period of five years from the system's enforcement date - i.e., from **June 1, 2020, to May 31, 2025 -** it remained permissible to use substances that had been approved under the previous *Negative List System*, provided their use was consistent with historical applications[12].

Specific Provisions of the Transitional Measures	
①	**Continued Use of Non-Listed Substances Previously in Use** If a substance not included in the Positive List was already being sold, manufactured, imported, or used in utensils, containers, or packaging for food-related business purposes prior to **June 1, 2020**, it could continue to be used, but **only within the same scope of application** as before.
②	**New Use of Non-Listed Substances** If a substance not included in the Positive List was first sold, manufactured, imported, or otherwise introduced *after* **June 1, 2020**, **a formal request for inclusion** in the Positive List was required before its use would be permitted.
③	**Expanded Use of Preexisting Non-Listed Substances** Even for substances that had been used prior to **June 1, 2020**, any expansion beyond the original scope of use - such as using the additive at a higher concentration or applying it to a new category of food - required a **request for revision of the applicable standards**.

No Transitional Measures for Manufacturing Controls and Information Disclosure
It is important to note that **no transitional grace period** was provided for the obligations set forth in:

- Article 52 (Manufacturing Controls), and
- Article 53 (Information Disclosure) of the Food Sanitation Act.

For instance, even during the transitional period, businesses were required to demonstrate that their use of non-listed substances remained within previously established boundaries, through documentation such as manufacturing records or import data.

2. The Positive List

(1) Finalization of the Positive List

In conjunction with the enforcement of the Positive List System on **June 1, 2020**, the **2020 Cabinet Notification**[13] established the initial version of the Positive List, which also came into effect on the same date.
The list itself appears in **Annex Table 1** of the 2020 Notification. In **Table 1** of this annex, categories such as "Food Category," "Maximum Temperature," and "Type of Synthetic Resin" were defined according to each base material. **Table 2** set forth the permitted uses and restrictions applicable to additives incorporated into synthetic resins, categorized by resin type.
However, the content of the 2020 Notification, which detailed the framework of the Positive List System, was intended only as a **provisional measure**. It was established that, during the transitional period of the system, the list would be revised and finalized based on the actual usage data of substances employed up until that point.
This **finalization** was implemented through the issue of the **2023 Cabinet Notification**[14], which also amended **Annex Table 1** accordingly[15].
Therefore, beginning **June 1, 2025**, from when the Positive List System is fully implemented without transitional exceptions, businesses must refer to the **revised Annex Table 1 issued under the 2023 Notification** and ensure full compliance with the updated requirements.

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[12] **Partial Amendments to the Standards for Food, Additives, etc.**
(Ministry of Health, Labour and Welfare Notification No. 196 of 2020 and Notification No. 324 of 2023)
[13] **Partial Amendments to the Standards for Food, Additives, etc.**
(Ministry of Health, Labour and Welfare Notification No. 196 of 2020)
[14] **Partial Amendments to the Standards for Food, Additives, etc.**
(Ministry of Health, Labour and Welfare Notification No. 324 of 2023)
[15] https://www.caa.go.jp/policies/policy/standards_evaluation/appliance/positive_list_new/assets/standards_cms101_240927_08.pdf

(2) Content of the Positive List as Revised by the 2023 Notification

The primary elements of the **2023 Cabinet Notification** include:

1. Reorganization of Table 1 (Base Polymers);
2. Revision of Table 2 (Additives); and
3. Clarification of the scope of the Positive List.

Key Revisions under the 2023 Notification:	
①	**Table 1 of Annex Table 1** was revised to define *base polymers* as synthetic resin polymers with a molecular weight of **1,000 or more** that are **solid at normal temperature and pressure**. Additionally, columns for applicable food categories, usage temperatures, and special notes were removed.
②	**Table 2 of Annex Table 1** now primarily lists *additives*, defined as **organic low-molecular-weight substances** (generally with a molecular weight below 1,000) that are used to alter the physical or chemical properties of base polymers and are intended to remain unreacted in the final product. However, substances with a molecular weight of 1,000 or more are also included as additives if they are **liquid at room temperature** or **possess specific functional groups** that impart distinctive effects on the base polymer.
③	A number of **necessary adjustments** were made to the Positive List, including **removal of certain substances**, **unification of substance names**, and **modification of use restrictions**, reflecting a clarification of the scope of substances subject to Positive List management.

Focus on the Clarification of Scope
Point 3 above - the clarification of the applicable scope of the Positive List - is particularly noteworthy. As a Positive List System, the regulatory regime permits only substances **explicitly listed in Annex Table 1**. However, an important caveat exists: **if a substance falls outside the scope of the system**, then it may be used **even if it is not listed in Annex Table 1**. Conversely, **if a substance is within the scope**, then it may not be used unless it is explicitly listed.
So how is the distinction made between substances that fall within or are outside the scope of the Positive List System? The 2023 Notification clarifies this as follows:

Substances outside the Scope of the Positive List System
Substances not derived from synthetic resins, including:

- Elastomers lacking thermoplastic properties (e.g., raw materials for rubber),
- Inorganic substances,
- Natural materials (e.g., rosin, naphtha extracts/distillates), *excluding purified individual constituents and defined substance groups*,
- Chemical derivatives of natural materials (*excluding chemically modified cellulose*).

Substances intentionally released from utensils or containers to interact with food.
Liquids or powders applied to the surface of raw materials for anti-static, anti-fogging, or similar purposes.
Substances formed via chemical changes of raw materials during processing.
Incidental residues not intended to remain in the final product.

For example, **inorganic substances** were previously listed in Table 2 and thus permitted for use. Under the revised Notification, they are **no longer listed** in Annex Table 1. This might appear to prohibit their use; however, since inorganic substances have been **explicitly excluded from the scope** of the Positive List System, **they may still be used** despite not being listed - **as they are now considered outside the scope of regulation**.

Responsibilities and Future Considerations
While substances excluded from the scope of the Positive List System may be used even if not listed, **business operators remain responsible for ensuring product safety** under **Article 16 of the Food Sanitation Act**. They must continue to implement safety controls equivalent to previous standards.
Moreover, should new scientific evidence emerge in the future indicating that an *out-of-scope* substance poses risks to human health, **additional regulations or specifications may be introduced as necessary**.

Finally, in **May 2025**, the **Consumer Affairs Agency** issued an official *Q&A* on the Positive List System for utensils and food containers[16]. For matters not addressed in this newsletter, readers are encouraged to consult that resource as well.

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[16] https://www.caa.go.jp/policies/policy/standards_evaluation/appliance/positive_list_new/assets/standards_cms101_250515_01.pdf

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