



Your FCM Expert
for Japan

Food Contact Materials in Japan

Helping you overcome your regulatory
challenges in Japan

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SCC 
WE CARE FOR YOUR SUCCESS

Since the establishment of the food sanitation law in 1947 and the standards for food and additives (Ministry of Health and Welfare Notification no. 370 in 1959), Japan has legally worked with a negative list system for setting safety criteria for food contact materials.

Most of the world, including USA, EU, Australia, New Zealand, China, India, and Indonesia, prefers using a positive list system for setting criteria.

FOOD SANITATION ACT AMENDMENT

In attempt to develop an internationally consistent regulation for food contact materials, Japan revised its food sanitation law and has been transitioning to a positive list system. In June 2018, the Japanese food sanitation act amendment was published. One of the changes implemented was the introduction of a “positive list system” for plastic food contact materials, similar to the EU. Starting June 1, 2020, only substances whose safety have been evaluated under the new system and published on the positive list are allowed to be used.

The Japan Chemical Innovation and Inspection institute (JCII) has been appointed as the notified body for food contact plastic evaluations (high polymer test & evaluation center).

A 5-year transition period was set until May 31, 2025. During this transition period, products not

complying with the new requirement can continue to be sold, if they were manufactured or imported before the implementation of the new amendment.

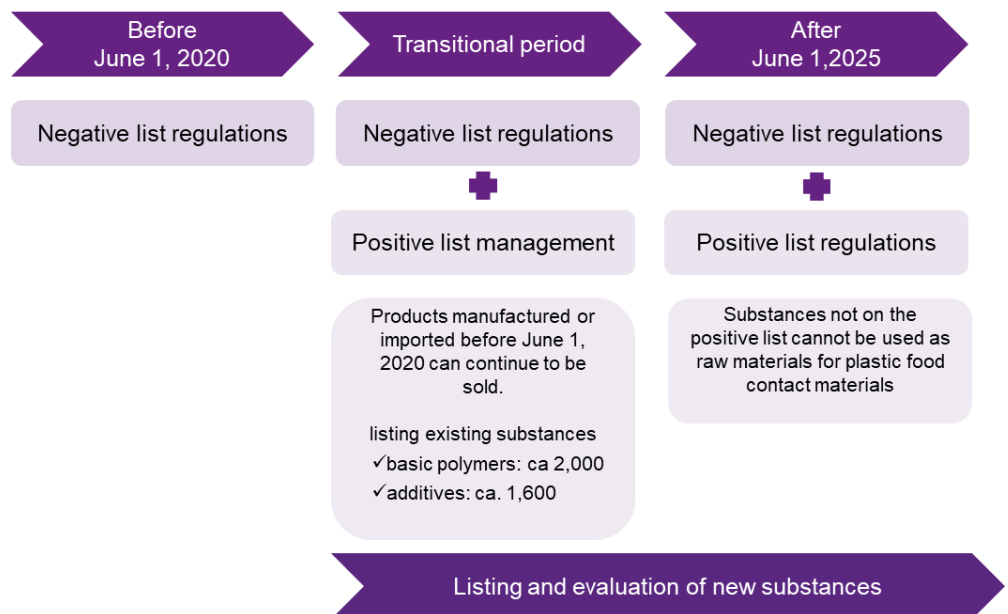
However, such products, still require an approval by the Japanese authorities based on the evidence that they were manufactured or imported before June 1, 2020.

Important note: The negative list system will remain in place and continue to be enforced by the Japanese government, also after the transition period.

POSITIVE LIST

On December 23, 2019, a draft list of existing substances for inclusion on the positive list was released. At the same time, the Japanese authorities initiated a consultation calling for inclusion or revision of information on substances used as raw materials for food contact materials and set a deadline of June 1, 2025, by when all relevant substances in the product must be included in the positive list.

The establishment of the Food Contact Materials Safety Center (FCMSC) on June 1, 2020 brought together the public and private sectors with the goal of developing the framework for a new sanitation management system and a horizontal organisation that can respond appropriately and efficiently to the new positive list system.



SUPPLY CHAIN COMMUNICATION

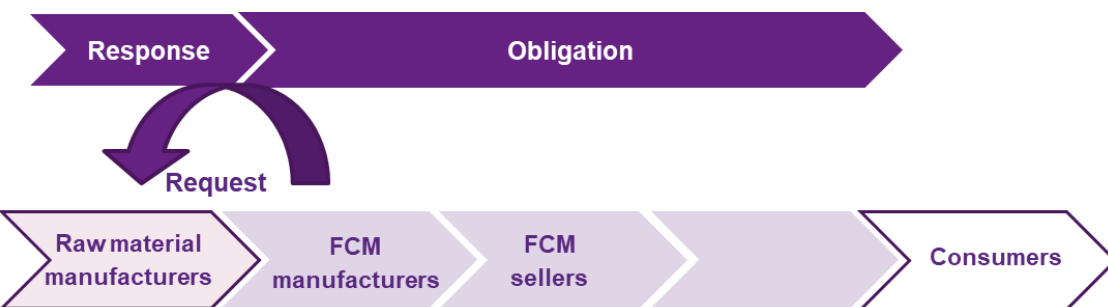
All plastic food contact materials must comply with the positive list system and can only be manufactured using materials containing the listed substances. All supply chain actors need to communicate and confirm that materials and products supplied for the manufacturing of food contact materials comply with the positive list system. Raw material suppliers are obliged to make every effort to ensure raw materials not suitable for food contact, are not sold or used for the manufacturing of food contact materials.

There will be no obligation to share ingredient or formulation information on raw materials or products. The Japanese authorities are developing guidance on how compliance must be confirmed within the supply chain.

Information Transfer in the Supply Chain

Providing information confirming the compliance with the positive list, via:

- Specifications
- Quality certificates
- Declaration of Conformity



*FCM: Food Contact Materials

Manufacturing quality control according to Good Manufacturing Practice (GMP)

SHOWING COMPLIANCE

Anyone manufacturing or selling food contact materials, are legally bound to verify if raw materials and products are suitable and safe for food contact and comply with the positive list. A certificate of compliance can be issued by the Food Contact Material Safety Center (FCMSC) of the Japan Chemical Innovation and Inspection Institute (JCII).

As a member of the FCMSC, SCC can help you enter the Japanese market, ensure your product complies with the positive list and obtain the certificate of compliance accepted by the Japanese authorities.

OUR SERVICES

- Evaluating the conformity of your food contact material with the latest requirements and the positive list
- Defining and initiating hygiene test strategies
- Designing and monitoring safety studies
- Preparing and submitting notifications
- Follow up with the responsible authorities



Contact our experts