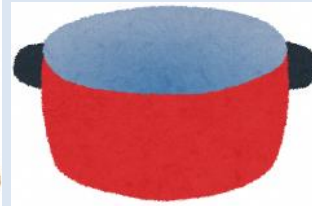


# Japan's Positive List System for Food Apparatus, Containers and Packaging

## Apparatus

tableware



kitchen utensils



## Containers and Packaging



Food Safety Standards and Evaluation Division  
Pharmaceutical Safety and Environmental Health Bureau  
Ministry of Health, Labour and Welfare, Japan

# The amended Food Sanitation Act

## Specifications for ACP and the level unlikely to cause harm to human health

Article 18 (Paragraph (3) was newly added.)

the Enforcement Date

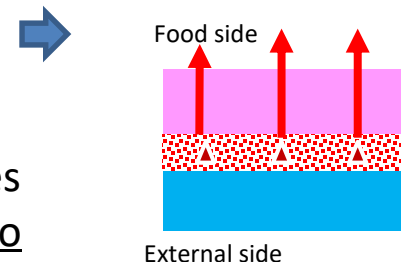
June 1, 2020 for the enforcement

(3) Substances (excluding substances generated by chemical change of those substances) constituting **material categories specified by Cabinet Order** by taking into consideration the impact on public health through the elution or seeping out of ingredients into food, for which the standards prescribed in paragraph 1 have not been established in terms of **the amount allowed to be contained in Apparatus or containers and packaging manufactured using the substances** or the amount allowed to be eluted or seep out into food from Apparatus or containers and packaging manufactured using the substances, shall not be used in any Apparatus or containers and packaging.

➡ Synthetic resin

However, this shall not apply when Apparatus or containers and packaging have been processed so that the substances are not eluted or do not seep out into food at an **amount exceeding the level** that the Minister of Health, Labour and Welfare specifies as **unlikely to cause harm to human health** by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council (excluding cases where the substances are used in parts of Apparatus or containers and packaging that come into contact with food).

➡ 0.01mg/kg of food



ACP: Apparatus, containers, and packaging

# Positive List System for Apparatus, Containers, and Packaging

## Establishment of specifications pursuant to the Article 18, paragraph (3) of the amended Food Sanitation Act

Before the enforcement date  
(June 1, 2020)

After the enforcement date

After full enforcement (June 1, 2025)

**Conventional management**  
(Regulation based on the Negative List)

### General specifications

Migration of coloring agents, content of metals (e.g., lead and tin), etc.

### Specifications by material type

Material test, Migration test, Residue test, etc.

**Conventional management**  
(Regulation based on the Negative List)

### **Introduction of management based on the Positive List**

(Listing the substances constituting synthetic resin)

### **Listing of the existing substances**

Base polymers: **about 2,000** substances

Additives: **about 1,600** substances

### **Specifications:**

Food category, usable maximum temperature, use limit, etc.

In the transitional measure period, collect information of substances being used before the enforcement (thousands of substances expected to be listed)

**5 Years**

**Conventional management**  
(Regulation based on the Negative List)

### **Management based on the Positive List**

(Listing the substances constituting synthetic resin)

### **Completion of the listing of the existing substances**

Base polymers: xxx substances

Additives: yyy substances

### **Specifications:**

Food category, usable maximum temperature, use limit, etc.

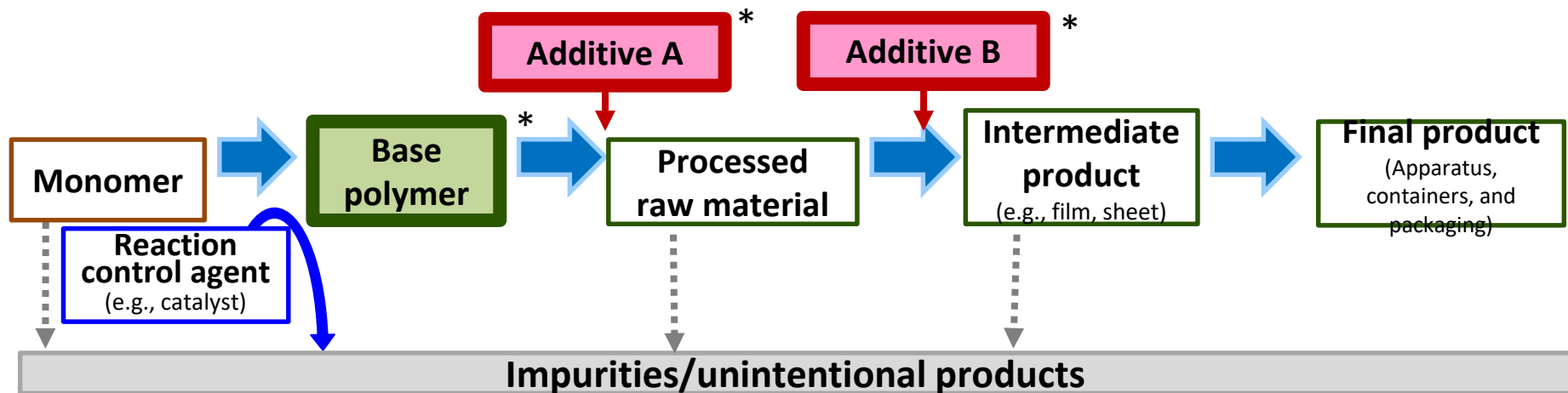
**After the completion, the use of non-listed substances as raw materials is prohibited.**

**Ask Japan's Food Safety Commission to assess the risk of the existing and new substances**

**Start the listing procedure and assessment of new substances**

**Continue the listing of new substances**

Additional base polymers and additives



\* For additives and base polymers, establish specifications under the Positive List System. **3**

# EU's Positive List

(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)	(11)
FCM substance No	Ref. No	CAS No	Substance name	Use as additive or polymer production aid (yes/no)	Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no)	FRF applicable (yes/no)	SML [mg/kg]	SML(T) [mg/kg] (Group restriction No)	Restrictions and specifications	Notes on verification of compliance
1	12310	0266309-43-7	albumin	no	yes	no				
2	12340	—	albumin, coagulated by formaldehyde	no	yes	no				
3	12375	—	alcohols, aliphatic, monohydric, saturated, linear, primary (C <sub>4</sub> -C <sub>22</sub> )	no	yes	no				
4	22332	—	mixture of (40 % w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60 % w/w) 2,4,4-trimethylhexane-1,6-diisocyanate	no	yes	no		(17)	1 mg/kg in final product expressed as isocyanate moiety.	(10)
5	25360	—	trialkyl(C <sub>5</sub> -C <sub>15</sub> )acetic acid, 2,3-epoxypropyl ester	no	yes	no	ND		1 mg/kg in final product expressed as epoxygroup. Molecular weight is 43 Da.	
6	25380	—	trialkyl acetic acid (C <sub>7</sub> -C <sub>17</sub> ), vinyl esters	no	yes	no	0,05			(1)
7	30370	—	acetylacetic acid, salts	yes	no	no				
8	30401	—	acetylated mono- and diglycerides of fatty acids	yes	no	no		(32)		
9	30610	—	acids, C <sub>2</sub> -C <sub>24</sub> , aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)	yes	no	no				
10	30612	—	acids, C <sub>2</sub> -C <sub>24</sub> , aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters	yes	no	no				

# The format of new draft of the Positive List

## 【New draft of Table 1 (Base Materials)] (Molecular weight: 1,000 or more)

### 1a. polymer composed of formaldehyde as the main monomer

Numbers by polymer group

物質code Substance Code	材質区分 Polymer Group	ポリマー分類 Polymer Class	モノマー分類 Monomer Class	モノマー番号 Monomer No.	物質名 Substance Name (JP)	物質名 Substance Name (EN)	CAS登録番号 CAS RN	特記事項 Requirements (JP)	特記事項 Requirements (EN)
1a-xxx	1	1a	—	—	ホルムアルデヒドを主なモノマーとする重合体	polymer composed of formaldehyde as the main monomer		以下の必須モノマー（1種以上）と任意のモノマー（1種以上）からなる重合体	Polymer composed of following one or more essential monomers and following one or more optional substances
1a-1xx	1	1a	1	—	必須モノマー	essential monomer			
1a-101	1	1a	1	1	1, 3, 5-トリオキサン	1,3,5-trioxane	0000110-88		
1a-102	1	1a	1	2	ホルムアルデヒド	formaldehyde	0000050-00		
1a-7xx	1	1a	7	—	任意の物質	optional substance			Molecular weight of the part composed only of the following substances: Less than 1,000.
1a-701	1	1a	7	1	エチレングリコール又はオキシラン	ethyleneglycol or oxirane	0000075-21 0000107-21 0000111-46 0000112-27 0025322-68	重合体の構成成分に対して 6% 以下であること。	Not more than 6% in the polymer components.
1a-710	1	1a	7	10	キシレン	xylene	0001330-20		
1a-702	1	1a	7	2	1, 3-ジオキサシクロヘプタン	1,3-dioxacycloheptane	0000505-65	重合体の構成成分に対して 6% 以下であること。	Not more than 6% in the polymer components.
1a-703	1	1a	7	3	1, 3-ジオキサラン	1,3-dioxolane	0000646-06	重合体の構成成分に対して 6% 以下であること。	Not more than 6% in the polymer components.
1a-704	1	1a	7	4	尿素	urea	0000057-13		
1a-705	1	1a	7	5	フェノール	phenol	0000108-95		
1a-706	1	1a	7	6	1, 4-ブタンジオールのジグリシジルエーテル	diglycidyl ether of 1,4-butanediol	0002425-79	重合体の構成成分に対して 6% 以下であること。	Not more than 6% in the polymer components.
1a-707	1	1a	7	7	ベンゾグアミン	benzoguanamine	0000091-76		
1a-708	1	1a	7	8	4-メチルベンゼンスルホン酸アミド	4-methylbenzenesulfonamide	0000070-55		
1a-709	1	1a	7	9	メラミン	melamine	0000108-78		
1b-9xx	1	1a	9	—	任意の化学処理	optional chemical treatment		重合体の処理に限る。	Can be applied only for polymer.
1b-901	1	1a	9	1	メチル化処理	methylated			

## 【New draft of Table 2 (Additives)] (Molecular weight: less than 1,000)

通し番号 Serial No.	物質名 Substance Name (JP)	物質名 Substance Name (EN)	CAS登録番号 CAS RN	特記事項 Requirements (JP)	特記事項 Requirements (EN)	材質区分 1 Polymer Group 1	材質区分 2 Polymer Group 2	材質区分 3 Polymer Group 3	材質区分 4 Polymer Group 4
948	セバシン酸ビス（2, 2, 6, 6-テトラメチル-4-ピペリジル） sebacate	bis(2,2,6,6-tetramethyl-4-piperidiny) sebacate	0052829-07-9	材質区分4に限り、100℃を超える温度で溶剤類に接触する部分に使用してはならない。	Only for Polymer Groups 4, not allowed to be used in the parts coming into contact with food at over 100°C	5	5	5	0.5
1666	食品衛生法施行規則（昭和23年厚生省令第23号）別表第1又は既存添加物名簿（平成8年厚生省告示第120号）に記載する添加物	Additives listed in Appendix Table 1 of Regulations for Enforcement of the Food Sanitation Act (Order of the Ministry of Health and Welfare No. 23, 1948) or the List of Existing Food Additives (Public Notice of the Ministry of Health and Welfare No. 120)	—			適量 proper dose	適量 proper dose	適量 proper dose	適量 proper dose

# Inviting applications for the Positive List

テーマ別を探す	報道・広報	政策について	厚生労働省について	統計情報・白書	所管の法令等	申請・募集・情報公開
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ホーム > 政策について > 分野別の政策一覧 > 健康・医療 > 食品 > Utensils, Containers, and Packaging

健康・医療

## Utensils, Containers, and Packaging

- Important Notice
- The Positive List System for Food Utensils, Containers, and Packaging
- Manufacturing management
- Regulations

To ensure the safety of utensils, containers, packaging, toys and detergent, the MHLW establishes specifications and standards for these products. The MHLW also prohibits the use of materials that do not meet the specifications and the manufacturing of them by using methods that do not meet standards.

### Important Notice

May 30, 2022

On April 26, 2022 the MHLW started inviting applications for the substances listed in the Positive List. Please check [Inviting applications for the Positive List \(Appended Table 1\)](#) for the details. The application period is until July 15, 2022.

(English) [The guide to submitting application about the new draft of the Positive List](#) [3MB]

[ページの先頭へ戻る](#)

## The Positive List System for Food Utensils, Containers, and Packaging

### The guide to submitting application about the new draft of the Positive List



## Inviting applications for the Positive List (Appended Table 1)

### Inviting application for requests about the draft of the Positive List

After the enforcement of Positive List (PL) System concerning food apparatus, containers, and packaging (ACP) on June 1, 2020, the MHLW invited requests on the substances listed in the PL from July to October 2020. Based on the requests from the businesses concerned including trade associations, on December 24, 2021, the MHLW published draft lists to modify the PL.

The Committee on Apparatus, Containers, and Packaging deliberated on the PL on December 21, 2020 and March 23, 2022; and concluded that the PL should be reorganized. Based on the committee's conclusion, the MHLW worked to reorganize the draft lists published on December 24, 2021.

This time, the MHLW published the reorganized draft lists of the PL as the new drafts of Tables 1 and 2, and started inviting requests on the substances that have been commercially used as raw materials of food ACP since before the enforcement date of the PL System, June 1, 2020 (substances subject to transitional measures).

If businesses have any requests such as for additional listing to the PL, please submit the application, according to "How to submit application" below, to the Office of Apparatus, Containers, and Packaging, Food Safety Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW.

政策について
分野別の政策一覧
健康・医療
健康
食品
医療
医療保険
医薬品・医療機器
生活衛生
水道
子ども・子育て

# Inviting applications for the Positive List

## Application period

April 26, 2022–July 15, 2022

If there are plural applications, submit them in the order they are ready.

## How to submit application

1. Please see “the guide to submitting application about the new draft of the Positive List” (the “guide”) and check whether the substance concerned is properly listed in the new draft of Table 1 or 2.
  - ▶ [The guide to submitting application about the new draft of the Positive List](#) [3MB]
2. Fill out an appropriate application form, and send it as an attachment by email to the following addresses as directed below.



Thank you for your attention.



### **Public Notice of the MHLW No. 196 (an excerpt)**

(Omitted) when products similar to ACP\* that have been sold, manufactured or imported for the purpose of marketing, or used in business since before the effective date of this public notice are manufactured or imported for the purpose of marketing until the date after five years from the effective date, substances used in the products and constituting material categories specified by Article 1 of the Order for Enforcement of the Food Sanitation Act can be considered to be those listed in Appended Table 1 of the Specifications and Standards for Foods, Food Additives, Etc. amended by this public notice.

#### **\*The term “products similar to”**

The term “products similar to” means the ACP that are manufactured using substances (raw materials of synthetic resin) the same as those used in the ACP being sold, manufactured or imported for the purpose of marketing, or used in business before June 1, 2020 within the range in which those substances were used; or means the imported ACP that are manufactured using substances within such range.

### **Information Sharing During the Period of the Transitional Measures**

Based on provisions on the transitional measures, business operators **may**, when they share information on conformance to the Positive List System prescribed in Article 53 of the Food Sanitation Act, **explain that products they handle are “similar to” ACP being manufactured before the effective date.**