

Utensils, Containers, and Packaging (UCP) Regulation Updates

AICM会员分享

Japan

October 21, 2025

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Agenda

- 01 Japan UCPs Regulations Overview
- 02 Instruction of the Latest Positive List (PL) System
- 03 Guidelines for Applying to Add a New Substance to Japan's Positive List (PL)
- 04 Associations: JCII
- 05 Compliance Strategy

01

Japan UCPs Regulations Overview

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What Does UCP Standard for in Japan

Utensil

- Tableware
 - Cutting tool
 - Machinery, equipment, etc. that comes into direct contact with the food
- * The tools/equipment used for agriculture or fishing are **not** included.



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Containers and Packaging

Articles in which foods or food additives are offered when such products are wrapped, delivered.



Regulatory Authorities



**Ministry of Health,
Labour and Welfare
(MHLW)**

Compliance
Monitor &
Enforcer

**Consumer Affairs
Agency (CAA)**

Risk Manager &
Standard Setter

Administration transferred
from Apr. 1, 2024



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**Food Safety
Commission of Japan
(FSCJ)**

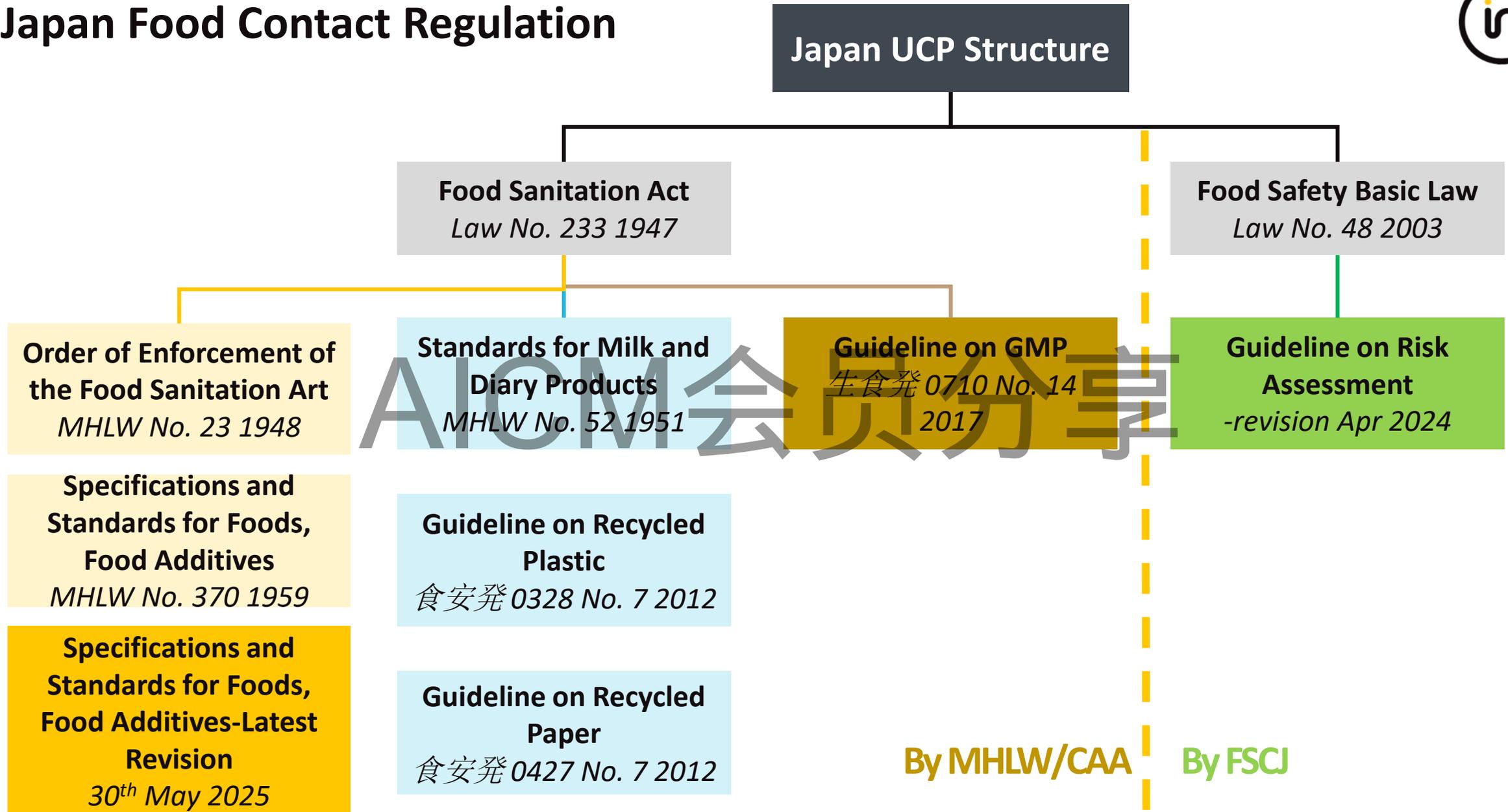
Independent
Scientific Assessor

**Industry Associations
(e.g., JCII, JAIA)**

The Industry
Bridge



Japan Food Contact Regulation





Food Sanitation Act – The Core Principles of UCP (Law No. 233, 1947)

Article 16 Utensils, containers and packaging which contains or bears toxic or harmful substances and is likely to cause harm to human health, or utensils, or containers and packaging which comes into contact with food or additives and has a harmful effect on them and which is likely to cause harm to human health **must not be sold, produced or imported for the purpose of sale, or used in business.**

Prohibition the use, sale etc. of toxic or harmful UCP

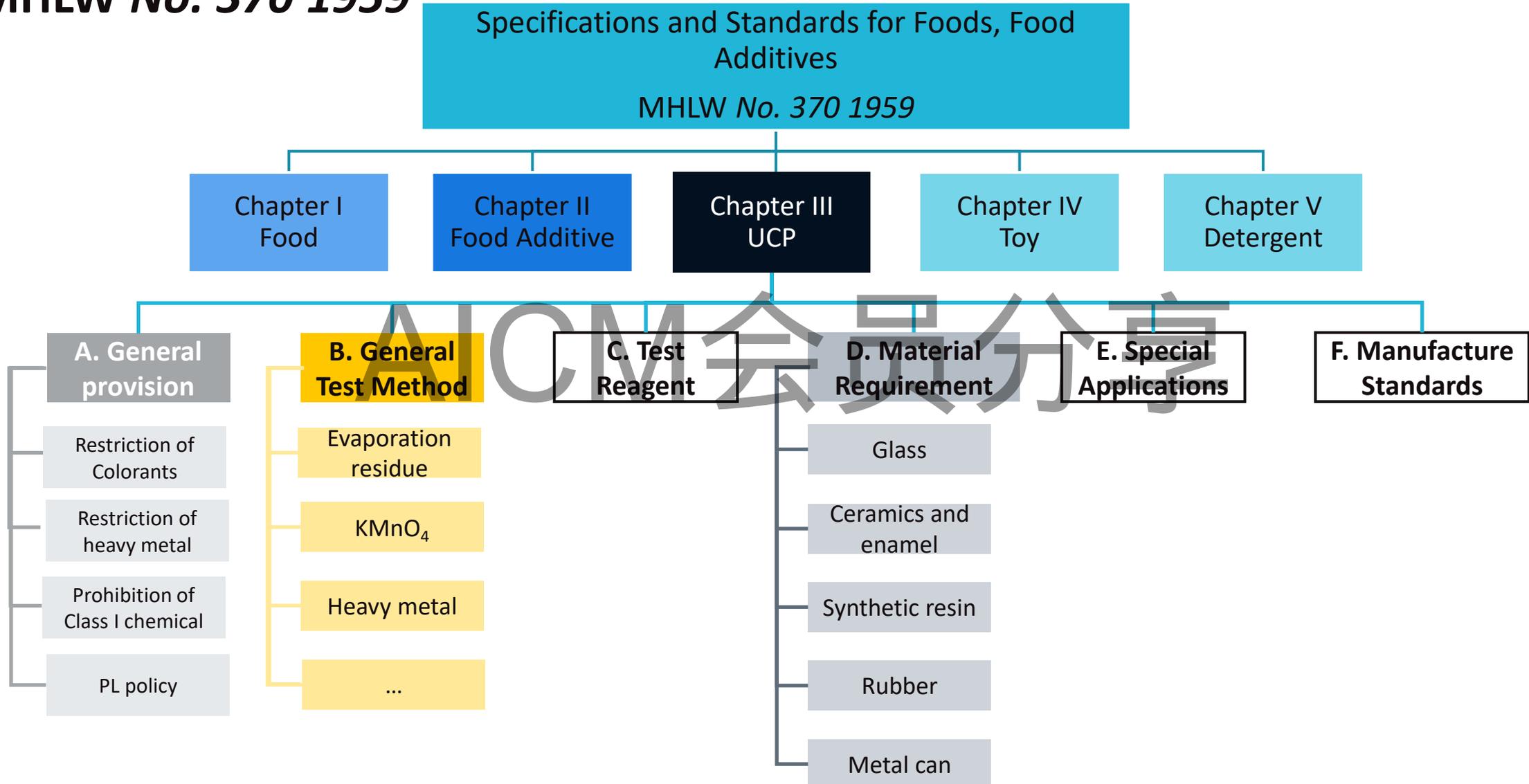
Article 18 (1) From the viewpoint of public health, the Minister of Health, Labour and Welfare may **establish standards for utensils, containers and packaging**, or the raw materials thereof to be served for the purpose of sale or to be used in business, or may **establish the criteria for the production methods** thereof, by hearing the opinions of the Food Sanitation Standards Council.

Establishment of specifications and standards

Article 18 (3) Substances (excluding substances generated by chemical change of the substances) as raw materials of materials specified by Cabinet Order by taking into consideration the impact on public health of the elution or seeping out of their components into food **must not be used for UCP**, where the quantity allowed to be contained in the UCP produced using the substances or the quantity allowed to be eluted or seep out into food from the UCP produced using the substances is **not specified in the standards established pursuant to paragraph (1) of the same Article**; provided, however, that this does not apply when UCP is processed so that those substances are unlikely to be eluted or seep out into food at levels exceeding the quantity specified by the Minister of Health, Labour and Welfare as unlikely to cause harm to human health by hearing the opinions of the Food Sanitation Standards Council (excluding the case where those substances are used in the part of UCP that comes into contact with food).

Positive List System

Specifications and Standards for Foods, Food Additives, MHLW No. 370 1959



02

Instruction of Japan latest Positive List (PL) System

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Introduction of a Positive List System for UCP

- Establishment of internationally harmonized hygiene regulations for UCP
- The use/sale of UCP made from raw materials not allowed will be prohibited, and only those that have been confirmed to be safe will be permitted for use.

Before Revision

In principle, the specific raw materials are allowed or forbidden to use.

Even if a substance is banned for use overseas, it cannot be regulated immediately.

Add PL system to manager under the original regulation

After Revision (PL system)

- Specify the substances with restrictions

- In principle, only could use the permitted substances
 - * Synthetic resin → **CAA**
- Establish manufacturing management standards
 - * General hygiene management for all manufacturers.
- Establish info. Transmission between businesses
 - * Synthetic resin manufacturers

→ **MHLW**

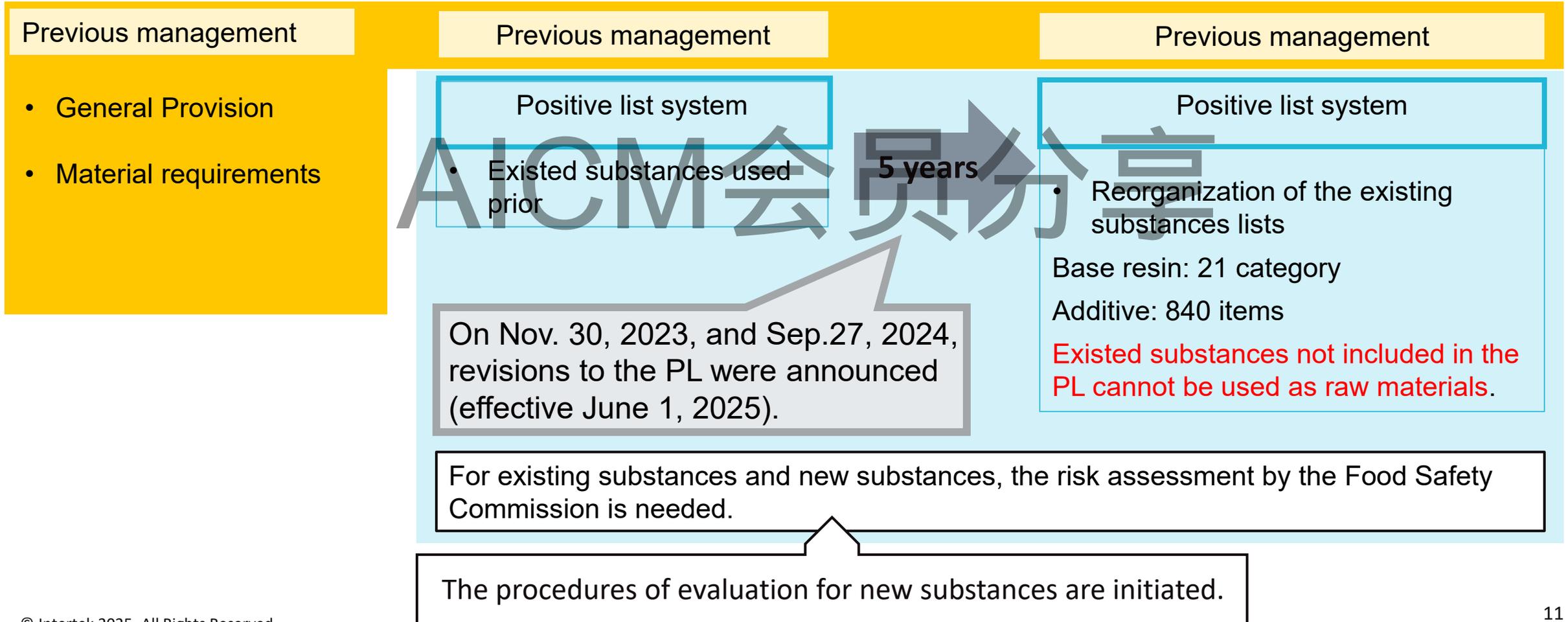
Positive List System for UCP



[Prior to enforcement]

[After enforcement]

[After full enforcement (June 1, 2025)]

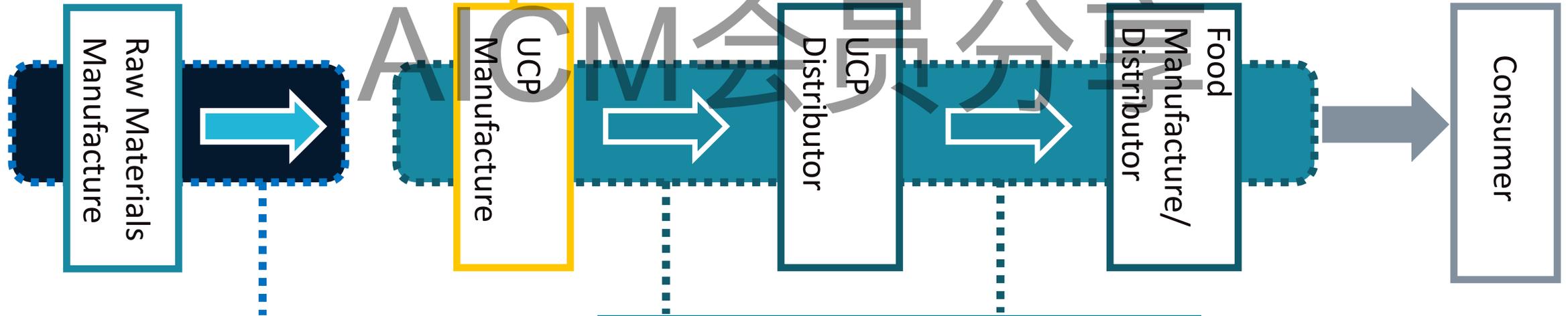


Manufacturing Management & Information Transmission



Manufacturing Management (GMP, Revised ordinance on 30 November 2023, effective 1 June 2025) and the information transfer

Confirmation of raw materials * Provision of information on product compliance with specifications * Keeping records of production



Upon request, **provide information** that can confirm compliance with the PL system (not mandatory)

Provision of information that can confirm compliance with the PL system (mandatory) (obligation)



Scope of Positive List

The latest version is published on Nov. 30, 2023 & Sep. 27, 2024.

❖ Classification of Synthetic Resins

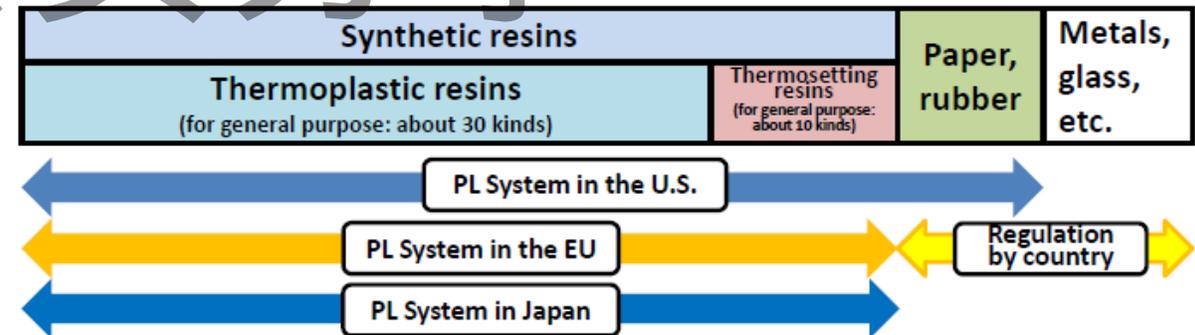
	Thermoplastic resins	Thermosetting resins
Plastic	Thermoplastics eg., PE, PS	Thermosetting plastics eg., melamine resin, phenol resin
Elastomer	Thermoplastic elastomer eg., polystyrene elastomer, styrene-block copolymer	Rubber (thermosetting elastomer) eg., butadiene rubber, nitrile rubber
Note	Without a cross-linking structure	With a cross-linking structure

*Blue in the scope

*Grey is not in the scope

Comparison:

- US: Synthetic resin, paper, rubber
- EU: Synthetic resin,
- EU members: Paper, rubber, metal, glass, etc.
- Japan: Synthetic resin



Positive List (PL) System _ Scope: Not Applicable



The substances are out of scope of PL, could be used based on the requirements of <Food Sanitation Act> and take the risk to ensure the safety.

- ✓ Substances that fall under the category of raw materials other than synthetic resins
 - Elastic that do not have thermoplastic properties (raw materials for rubber)
 - Inorganic substances
 - Nature products and it's reactants
- ✓ Substances released from UCP, which are intended to transfer to food with functions
- ✓ The liquid or powder substances in the surface of UCP with the purpose of Anti-static , anti-fogging, etc.
- ✓ Substances produced by chemical changes of substances contained in raw materials
- ✓ Substances that are not intended to remain in the final products

大分類	小分類	物質例	PL対象	
無機物質	金属	鉄、銅、アルミ	対象外	
	非金属	ケイ酸塩、炭酸塩等	対象外	
	未精製の無機物	岩石、土、砂	対象外	
有機物質	天然有機物	未精製の天然物	対象外	
		天然高分子物質	植物繊維	対象外
		精製された天然低分子物質	油脂、脂肪酸	第2表 (添加剤)
	合成有機物		ポリマー (合成樹脂)	第1表 (基材)
			ポリマー (ゴム)	対象外
			合成有機高分子物質 (液体)	PEG、ポリグリセロール
	合成有機低分子物質	—	第2表 (添加剤)	



Japan New Positive List (PL) System – Table 1

As a general rule, polymers in synthetic resins with a molecular weight \geq 1000 and solid form at room temperature and pressure are listed in Table 1.

- Specify the synthetic resin base material (polymer).
- Classified into **21** types based on ethylene bonds and carbonate bonds as the basic structure.
- Specifically, for each of the 21 substances, the permissible monomers and other chemical substances/chemical treatments are listed by application notification.

材質区分 1	ガラス転移温度若しくはボールプレッシャー温度が150℃以上の重合体又は架橋構造を有し、融点が150℃以上の重合体その他これに類するもの
材質区分 2	炭化水素を主なモノマーとする重合体
材質区分 3	ガラス転移温度及びボールプレッシャー温度が150℃未満の重合体その他これに類するもの 炭化水素を主なモノマーとする重合体であって重合体を構成する成分に対して、アクリル酸、アクリロニトリル、N-フェニル-マレイミド、無水マレイン酸及びメタクリル酸の合計が10%以上のもの
材質区分 4	塩素置換エチレンを主なモノマーとする重合体
材質区分 5	被膜形成時に化学反応を伴う塗膜用途の重合体

物質名	材質区分
イミド結合を主とする重合体	1
エーテル結合を主とする重合体	1
エステル結合を主とする重合体の架橋体	1
エポキシ化合物の架橋重合体	1
カーボネート結合を主とする重合体	1
シロキサン結合を主とする重合体	1
スルフィド結合を主とする重合体	1
フッ素置換エチレン類を主なモノマーとする重合体	1
ホルムアルデヒドを主なモノマーとする重合体	1
イオン交換能及び吸着能のうち一又は複数をも有する重合体	1又は3
ウレタン結合を主とする重合体	1又は3
エステル結合を主とする重合体	1又は3
アルケン類を主なモノマーとする重合体	2
共役ジエン炭化水素を主なモノマーとする重合体	2
芳香族炭化水素を主なモノマーとする重合体	2又は3
アクリル酸類を主なモノマーとする重合体	3
アミド結合を主とする重合体（アジリジン又は2-エチル-2-オキサゾリンを主なモノマーとする重合体を含む。）	3
グルコース単独重合体又は化学修飾処理されたセルロース	3
酢酸ビニルを主なモノマーとする重合体の加水分解物	3
塩素置換エチレンを主なモノマーとする重合体	4
被膜形成時に化学反応を伴う塗膜用途の重合体	4又は5

Grouping Rule for Resin



Polymer Group No. (NEW)	Standard of Classification	Essential Monomer
1	Polymers with a glass transition temperature or ball pressure temperature $\geq 150^{\circ}\text{C}$, or polymers having a cross-linked structure and with a melting point $\geq 150^{\circ}\text{C}$	imide bonds polymers, ether bonds polymers, etc
2	Polymers composed of hydrocarbons as the main monomer (except the polymer in group 4)	Ethylene, propylene, styrene etc.
3	Polymers with both glass transition temperature and ball pressure temperature $< 150^{\circ}\text{C}$ (excluding those correspond to polymer groups 2 and 4)	Acid, amine, alcohol, isocyanate etc.
4	Polymers composed of chlorine-substituted ethylene as the main monomer	Chloroethylene, Vinylidene Chloride
5	<p>Polymers that are used for coating involving chemical reaction during film formation.</p> <p>Substances for which the sum of vinylidene chloride and vinyl chloride in the polymer is 50% or more fall under polymer group 4; substances that are other than those categorized in group 4 fall under polymer group 5.</p>	Not specified



Japan New Positive List (PL) System – Table II

As a general rule, organic substance with a molecular weight <math>< 1000</math> and are intended to change the physical or chemical properties of the substrate and remain in the final product without a chemical reaction;

if the molecular weight ≥ 1000 and in liquid form at room temperature and pressure, or those that have a special functional group and the functional group exerts a unique effect on the substrate, are listed in Table 2 as additives.

- Additives for synthetic resins (840 items)
- The usage amount and specific requirements (molecular weight restrictions, other compliance requirements) are specified for each chemical substance.

別表第1 第2表

通し番号	物質名	材質区分別使用制限 (%)						特記事項
		材質区分1	材質区分2	材質区分3	材質区分4	材質区分5 (耐熱温度が150℃以上の重合体に限る。)	材質区分5 (耐熱温度が150℃未満の重合体に限る。)	
1	アクリル酸イソブチル	5.0	5.0	5.0	-	5.0	5.0	
2	アクリル酸2-エチルヘキシル	5.0	5.0	5.0	-	5.0	5.0	
3	アクリル酸及びエチレンを主な構成成分とする重合体	-	-	1.6	-	1.6	1.6	分子量1000未満のものに限る。
54	亜リン酸2-tert-ブチル-4-[1-(4-ヒドロキシ-3-tert-ブチルフェニル)-1-メチルエチル]フェニルビス(4-ニルフェニル)	1.4	1.4	1.4	1.4	1.4	1.4	<ul style="list-style-type: none"> ・材質区分4に使用する場合を除き、70℃を超える温度で食品に接触する部分に使用してはならない。 ・酒類に接触する部分に使用してはならない。
								特記事項で対象の食品を制限している場合もある。
108 (2)	第1表に該当する重合体	*	*	*	*	*	*	<ul style="list-style-type: none"> ・常温常圧で固形状でないものに限る。 ・通し番号412に該当するものを除く。 ・被膜形成時に化学反応を伴う塗膜用途の重合体を除く。 ・分子量1000以上のものに限る。
								基材の物質は原則として使用可能



Summary of Allowed Substances

- With regard to synthetic resins, the use of substances listed in Appendix 1 of the Standard Specifications Notice (Ministry of Health and Welfare Notice No. 370) is permitted.
- Regarding the non-contact layer of food, the amount determined by the Minister of Health, Labour and Welfare as an amount that is unlikely to harm human health (0.01 ppm) , it can be used.
- New substances not listed in Appendix 1 are subject to individual application and review procedures, such as safety reviews, before they can be used.

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03

Guidelines for Applying to Add a New Substance to Japan's Positive List (PL)





Guidelines for Applications Regarding Revisions to Standards for Substances Contained in Raw Materials for Food Contact Materials or Containers and Packaging

食品用器具又は容器包装の原材料に含まれる物質の
規格の改正等に係る申請等の手引

✓ Notice 357 issued by CAA on 28th May, revised on 5th Sep

✓ Guidelines for Food Health Impact Assessment Concerning Food Contact Materials and Packaging

✓ Information Regarding Leaching Tests and Dietary Concentrations Related to Requests for Food Health Impact Assessments

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食品用器具及び容器包装に関する
食品健康影響評価指針

令和7年5月28日

令和7年9月5日一部改正

消費者庁 食品衛生基準審査課

2019年5月
(2024年4月改正)

食品安全委員会

(参考) 食品健康影響評価の要請に係る溶出試験及び食事中濃度に関する情報について

食品健康影響評価を要請するに当たり、食品用器具及び容器包装に関する食品健康影響評価指針（以下「評価指針」という。）別紙2に定める方法に基づき溶出試験を実施し、食品への移行に係る知見を整理する際は、以下を参考に情報を整理する。

溶出試験関係

1) 溶出試験に用いる試料の情報

以下のとおり、溶出試験に用いる試料の情報を整理する。

項目	内容
試料の選定理由	<ul style="list-style-type: none"> 溶出試験に供した試料の選定理由（意図する使用条件の範囲、合成樹脂の物理的性質等を踏まえて記載する。） ※ 以下に該当する場合は、試料の代表性も考慮して選定理由を記載する。 <ul style="list-style-type: none"> 評価要請物質が添加剤であって、複数の種類の基ポリマーに適用するに当たって基ポリマー種類ごとの溶出試験を省略する場合 評価要請物質が基ポリマーであって、当該物質が属する合成樹脂グループ内で使用が認められている複数の添加剤を適用するに当たって添加剤ごとの溶出試験を省略する場合
試料作製に用いた合成樹脂	<ul style="list-style-type: none"> 試料作製に用いた合成樹脂に関する情報（合成樹脂グループ、合成樹脂の種類、基ポリマー名等多層構造の場合は、各層について記載する。）
試料の厚さ	<ul style="list-style-type: none"> 試料の厚さ（mm）（多層構造の場合は、各層について記載する。）
試料の形状	<ul style="list-style-type: none"> 試料の形状に関する情報
添加剤の配合組成	<ul style="list-style-type: none"> 評価要請物質に該当する添加剤のほか、試料作製の際に使用した全ての添加剤等の含有量（mg/g）

Types and Subjects of Petitions for PL Revisions, etc.

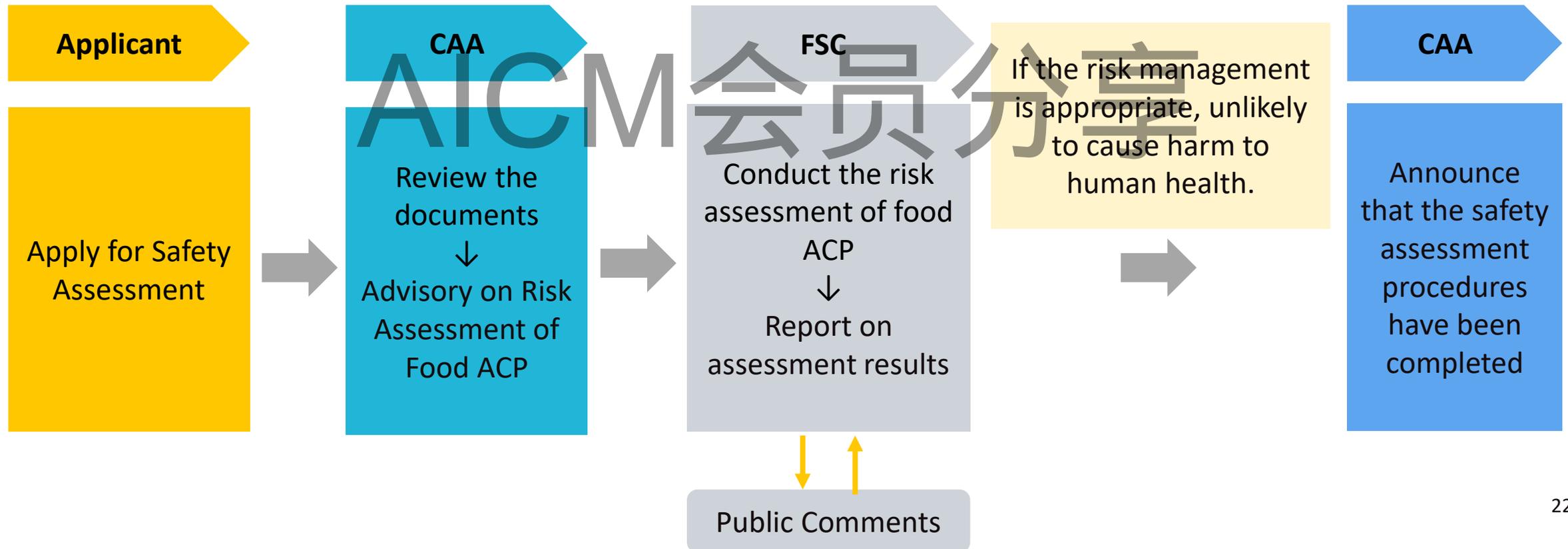


Types of Procedure	Main Subjects	General Requirements
Safety Assessment	Subject to those are appropriate to manage the risk by the method different from that specified in Appendix 1: The newly used substances are expected to be used for limited purposes.	1. Conduct a preliminary consultation (the type of application & the application materials)
Revision of Appendix 1 (PL)	Subject to those are appropriate to manage the risk by the method specified in Appendix 1: -Revisions of specifications (usage restrictions, amendment of requirements, etc.) in Table 2 (Additives); -Addition of new substances if applicable.	2. A person responsible for handling matters related to the application within Japan (Domestic Contact) must be clearly designated.
Revision of Monomer Notification	Subject to those attempting to add new monomers or use monomers beyond the specified range: Addition of new monomers, etc. to the Monomer Notification (Appendix 1-21) (essential monomer, optional substance, Essential chemical treatment, optional chemical treatments).	

Flow of Safety Assessment



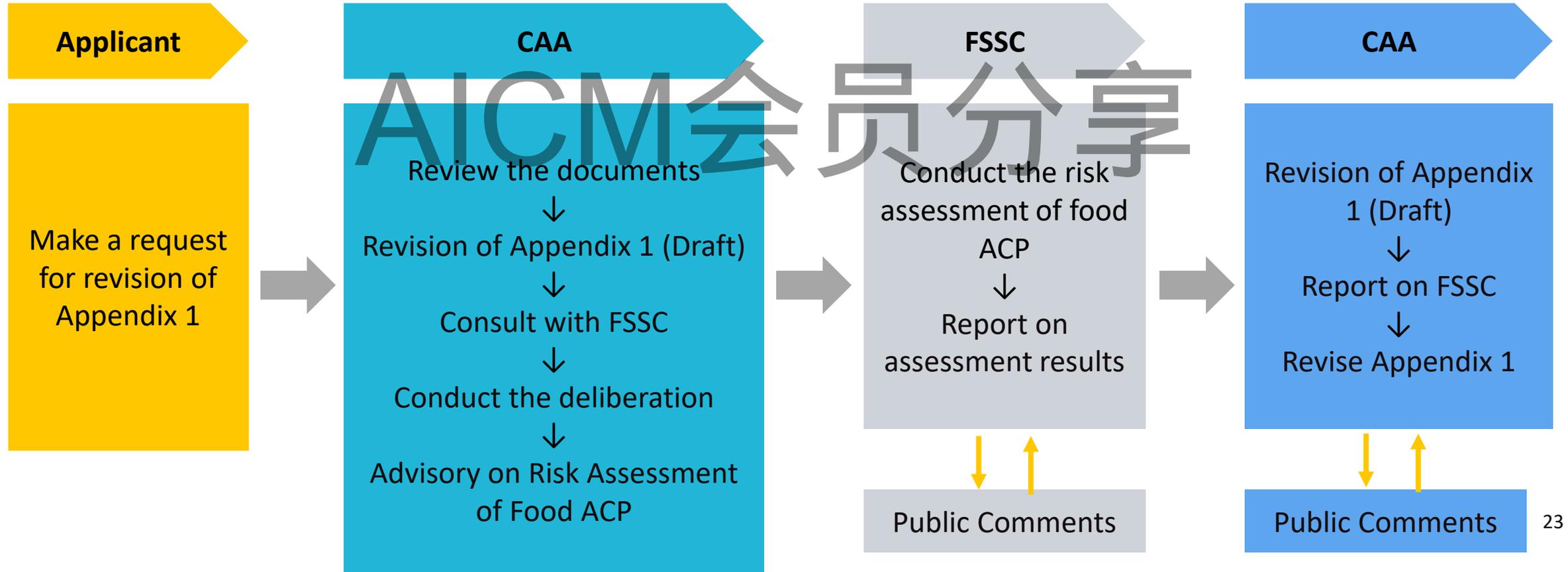
- Submit the application using the prescribed application form.
- The Food Sanitation Standard Review Division of CAA will review the documents and listen to the opinions of the Food Safety Committee regarding the safety assessment.



Flow of Revision of Appendix 1



- After verifying the relevant documents at the Food Sanitation Standard Review Division of CAA, and upon hearing the opinions of the Food Sanitation Standard Council and the Food Safety Commission, revisions will be made to the Specifications and Standards for Foods, Food Additives, Etc.



Required Data for Safety Assessment & Addition of New Substances to Appendix 1



1. Substance Information

1) Basic Information

- 1) Development background
- 2) Name, structure, etc.
- 3) Physical and chemical properties
- 4) Manufacturing method
- 5) Other (purity, impurities, etc.)

Need to clarify the data source, test or in silico evaluation

- 2) **Purpose and condition** of use (food category and temperature/time conditions, applicable groups and types of synthetic resin, range of amount in material, etc.)
- 3) **Draft proposed usage conditions (or Draft Specifications for Appendix 1 Revision)**
- 4) **Usage status and evaluation in Japan and overseas** (start date, usage amount, the existence of usage approval, etc.)
- 5) **Other information** (usage status in products other than UCPs)

2. Migration into food

- Migration test methods and validation
- Migration test results summary
- Tier of dietary concentration

Waive for the polymer with MW>1000Da with no other fractions below 1000Da.

3. Safety information (Toxicology)

- Outline of test items required for each Tier of DC
- Details of tests

4. The assessment result on health impacts

5. List of appendix

Required Data for Specification Revision Request to Appendix 1



1. Subject of the Request

- Specify whether the requested amendment pertains to Table 1 (Base Materials) or Table 2 (Additives).

2. Background of the Request

- Describe the background and reasons leading to the submission of this request.

3. Substance Information

- Substance name, structure, etc.
- Physical and chemical properties
- Other (purity, impurities, etc.)

4. Purpose and condition of use

- Purpose of use
- Conditions of use
- Usage status in Japan and overseas

5. Draft of the Proposed Specifications

- provide the proposed changes using a **comparison table** between the current and proposed versions.

6. Migration into Food

- Test conditions and results for migration testing
- Calculation conditions and results for dietary concentration
- Tier of dietary concentration

7. Safety information (Toxicology)

- Applicable for substances without a prior assessment for which new standards are being established, or for substances with existing standards where the amendment proposes a change to a higher tier of dietary concentration.

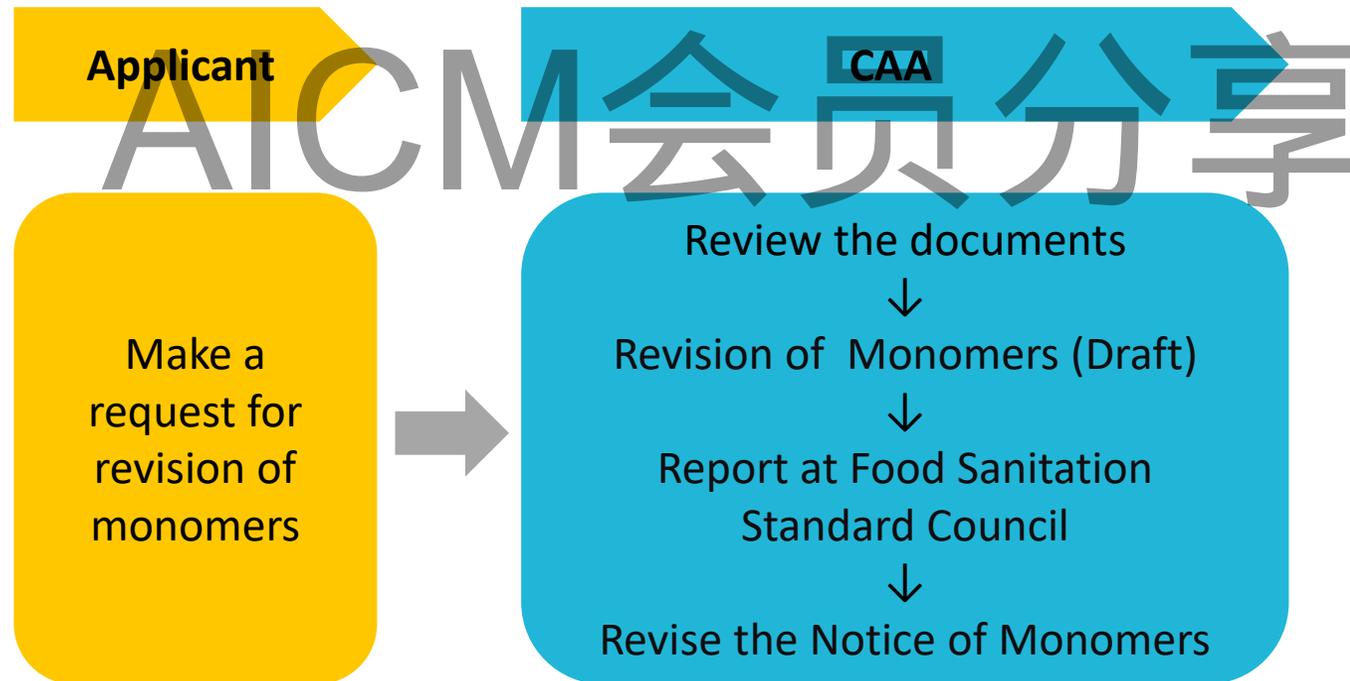
8. Other

- Provide the summary based on assessment guidance

Flows of Revision of Monomers



- The Food Sanitation Standard Review Division of CAA will review the documents. After the report at Food Sanitation Standard Council, the Notice of Monomers will be revised.





Required Data for Revision Request to Monomer Notification

1. Subject of the Request

- Specify the annex number and the specific item (e.g., Essential Monomer, Optional Substance, Chemical Treatment, etc.)

2. Background of the Request

- Describe the background and reasons leading to the submission of this request.

3. Information on the Target Substance and Base Polymer

- a. Substance: Name and Structure of the Monomer (etc.) and Polymer
- b. Physicochemical Properties of the Monomer (etc.) and Polymer:
- c. Other Information such as typical product purity, impurities; treatment information etc.

4. Purpose and condition of use

- Purpose of use for both monomer and polymer
- Conditions of use
- Usage status in Japan and overseas for both monomer and polymer, the **non UCP use** status

5. Draft of the proposed changes

- Provide the proposed changes using a **comparison table** between the current and proposed versions

6. Migration to Food

7. Safety information

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Withdraw the application

Submit a Notice of Withdrawal of Application, etc., using Form 3 to the Food Sanitation Standards Review Section.

- ✓ Substance name
- ✓ Application date
- ✓ Reason of withdraw

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04

Association: JCII

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History of JCII

1949 Established as the Celluloid Testing Association

Authorized as an inspecting organization under Export Control Law

.....

2012 Renamed as Japan Chemical Innovation and Inspection Institute (JCII)

Authorized as general incorporated foundation

2020 Food Contact Material Safety Center (FCMSC) was established within JCII

2021 FCMSC merged associations like Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA), Japan Hygienic PVC Association (JHPA), and Japan Hygienic Association of Vinylidene Chloride (JHAVDC) and took over all polymer and additive certification duties from JHOSPA as of April 1, 2021.

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Building a communication bridge between the government and enterprises and tries to collect the information through the supply chain to add more substances to the positive list during grace period.

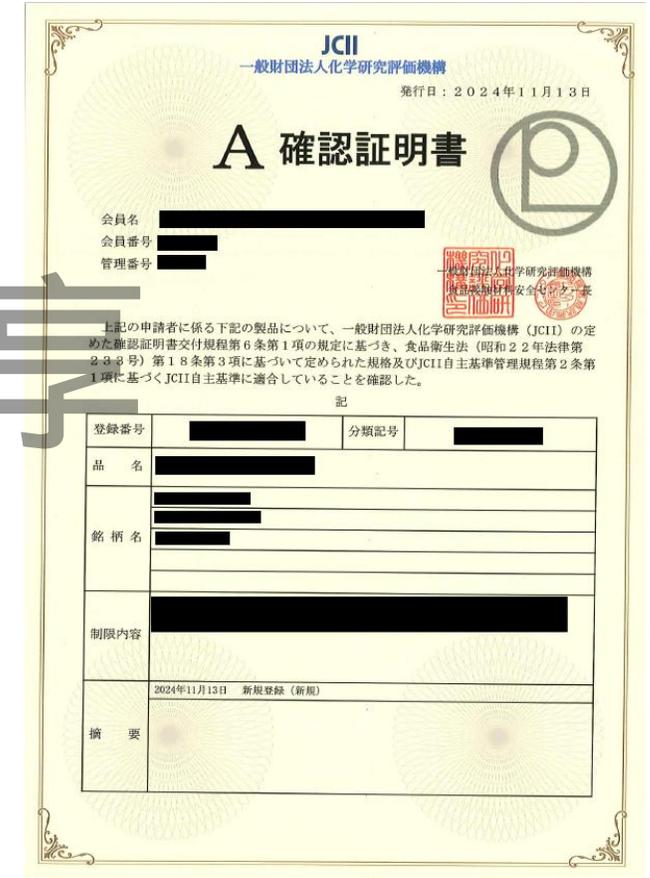
JCII has developed:

- Voluntary standards
- Positive lists (pigments)
- Evaluation standards & Test methods
- Certification systems for additives, resin and processed products



From legal perspective, compliance is voluntary, but it is often required by downstream customers.

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JCII Membership

Regular Members:

- 1) Engaged in the manufacture and sale of raw materials for food utensils and containers and packaging;
- 2) Engaged in the manufacture, processing, and sale of food utensils and containers and packaging;
- 3) Manufacture, processing, and sales of food products that use utensils, containers and packaging.

Associate Members:

Industry associations or organizations related to the safety and hygiene of food contact material products.

* Membership is open to businesses regardless of nationality. However, for foreign companies, having a local contact in Japan (such as agent or branch office) is required because all communications and documents will be in Japanese.



Benefits for Membership

Apply for certificates according to the national positive list

Submit opinions and requests to government

Regulation information and instructions related to the PL system can be provided and explained in a timely manner

Various information and materials related to the PL system can be obtained on the member's website

Members can preferentially participate in various briefings and projects organized by JCII

Members can consult without hesitation about the PL system and supply chain management

Consultation and support for new substances addition to the PL

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05

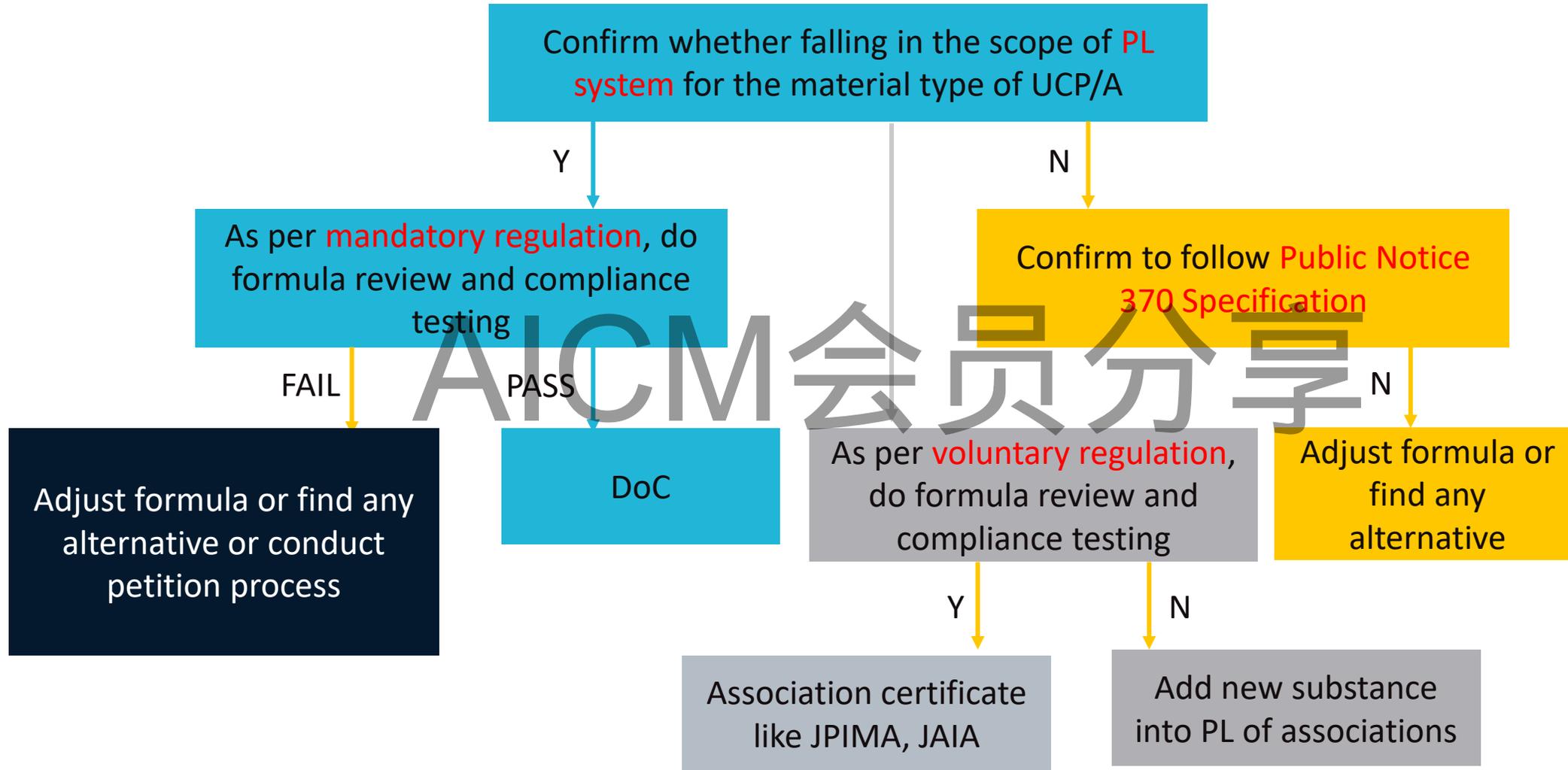
Compliance Strategy

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Japan Food Contact Compliance Strategy



Thank you!



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