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JAPAN FOOD CONTACT REGULATIONS AND POSITIVE LISTS

Caroline Yang/ INTERTEK ASSURIS CHINA

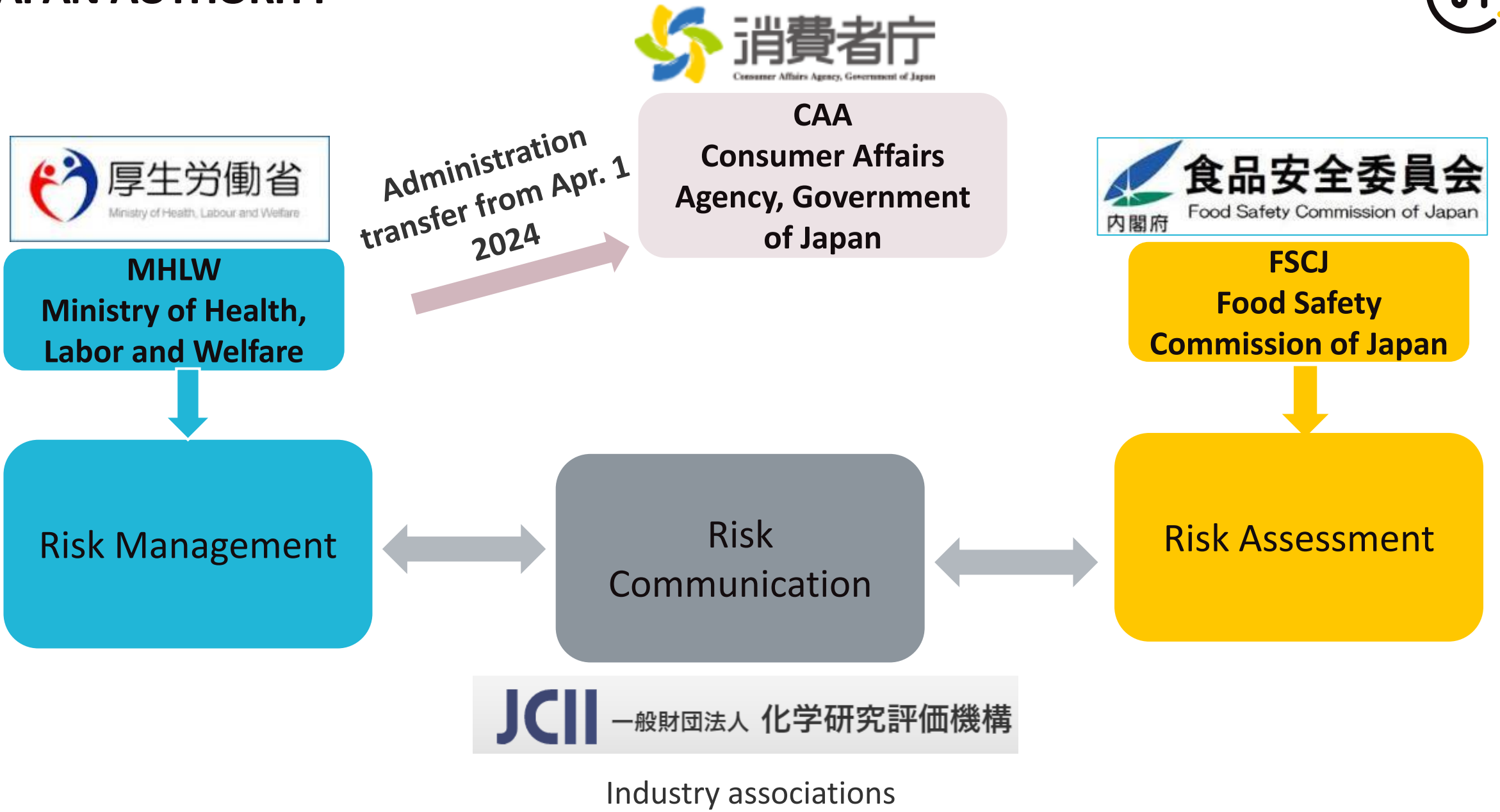
2024-12

CONTENT

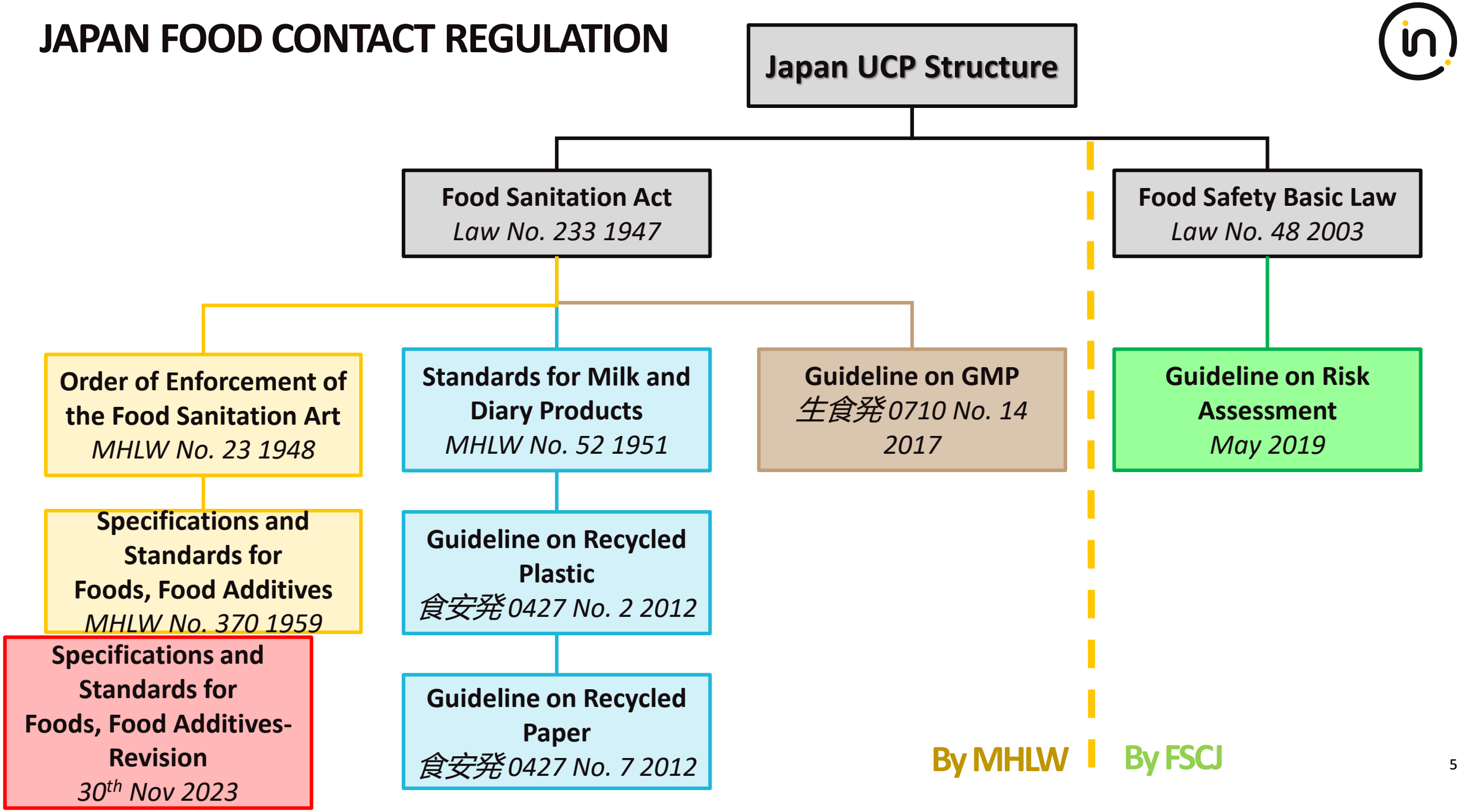
REGULATION OF FOOD PACKAGING IN JAPAN

01

JAPAN AUTHORITY



JAPAN FOOD CONTACT REGULATION



JAPAN: FOOD SANITATION ACT _ BASIC REQUIREMENTS

Article No.	Requirements
3	Practitioners of food contact materials (involving the manufacture, import, export, and sale of utensils and containers) are responsible for conducting independent inspections and take other necessary measures oof the products and their raw materials to ensure the safety of the food for sale.
15	UCP products must be manufactured or sold in a clean and hygienic environment
16	UCP that contain toxic or harmful substances and are likely to impair human health, or that may damage human health by coming into contact with food or additives and having harmful effects on them, shall not be sold, manufactured, imported, or used for sale.
18	The production or sale of UCP products shall comply with relevant laws and standards.

FOOD SANITATION ACT

❖ Chapter 3 Utensil, Container and Packaging (Article 15-18)

- **Article 17: The MHLW shall prohibit the manufacture or import the UCP product which is recognized that there is a risk of containing a considerable from the status of food hygiene management at the manufacturing site and other reasons and impairment to human health and other matters.**
- **Article 18 Substances used in UCP shall be manufactured by the raw material allowed.**

❖ Chapter 9 Production and Operation

- **Article 52**

GMP requirements for manufacturer of UCP products.

- **Article 53**

Information transfer and sharing through the whole supply chain (DoC).

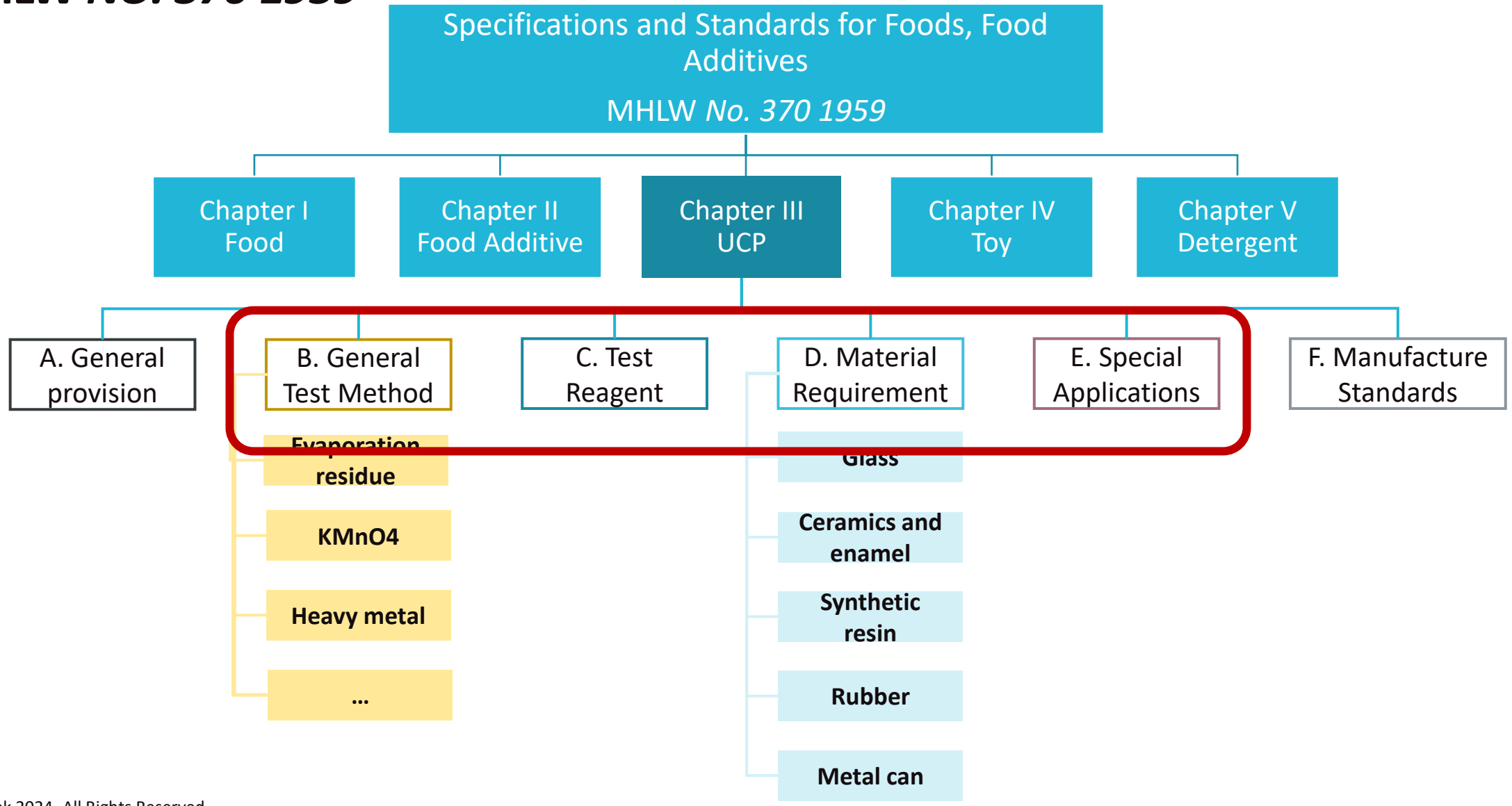
JAPAN: FOOD SANITATION ACT _ UCP

Chapter 1 (General Provisions), Article 4:

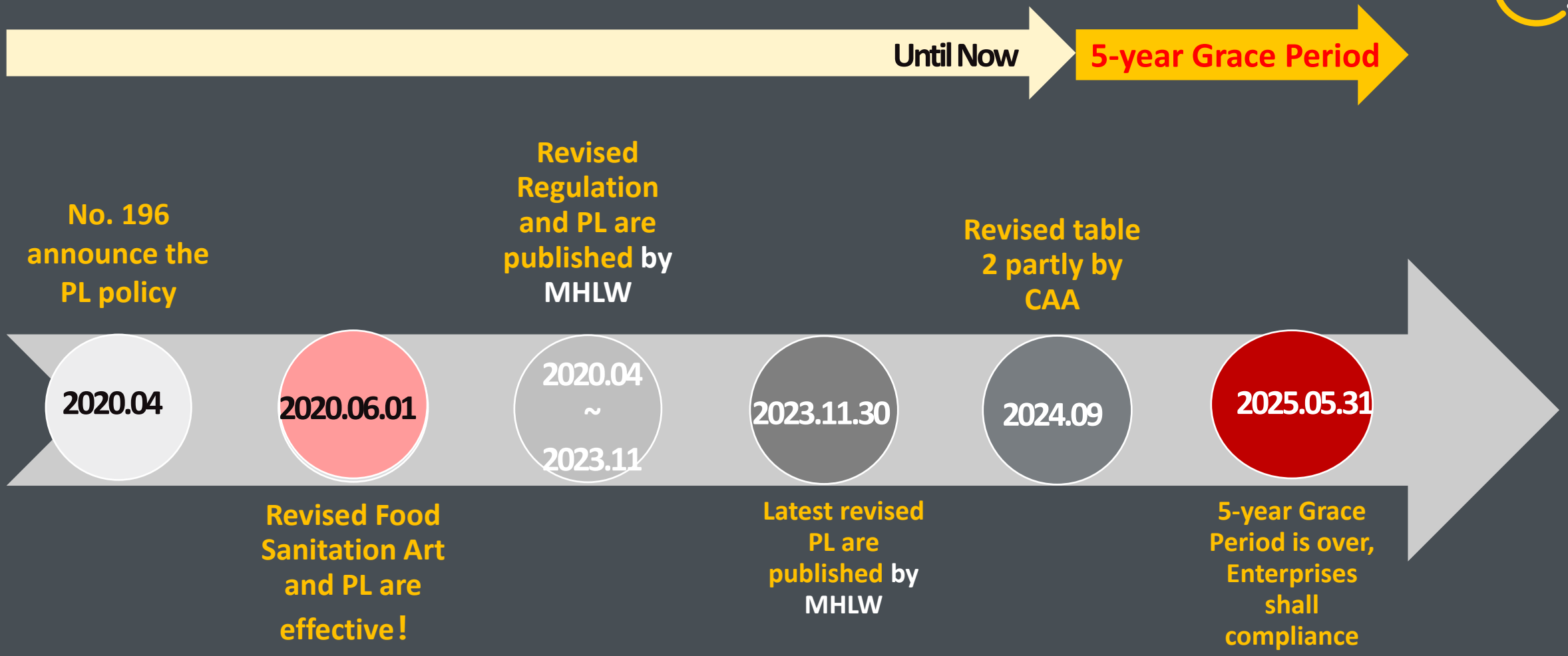
Utensils: Tableware, kitchen utensils, machines, implements, and other articles used to handle, manufacture, process, prepare, store, transport, display, deliver, or consume food or food additives, and which come into direct contact with food and food additives.

Containers and Packaging: Articles in which foods or food additives are offered when such products are delivered

SPECIFICATIONS AND STANDARDS FOR FOODS, FOOD ADDITIVES, MHLW *NO. 370 1959*

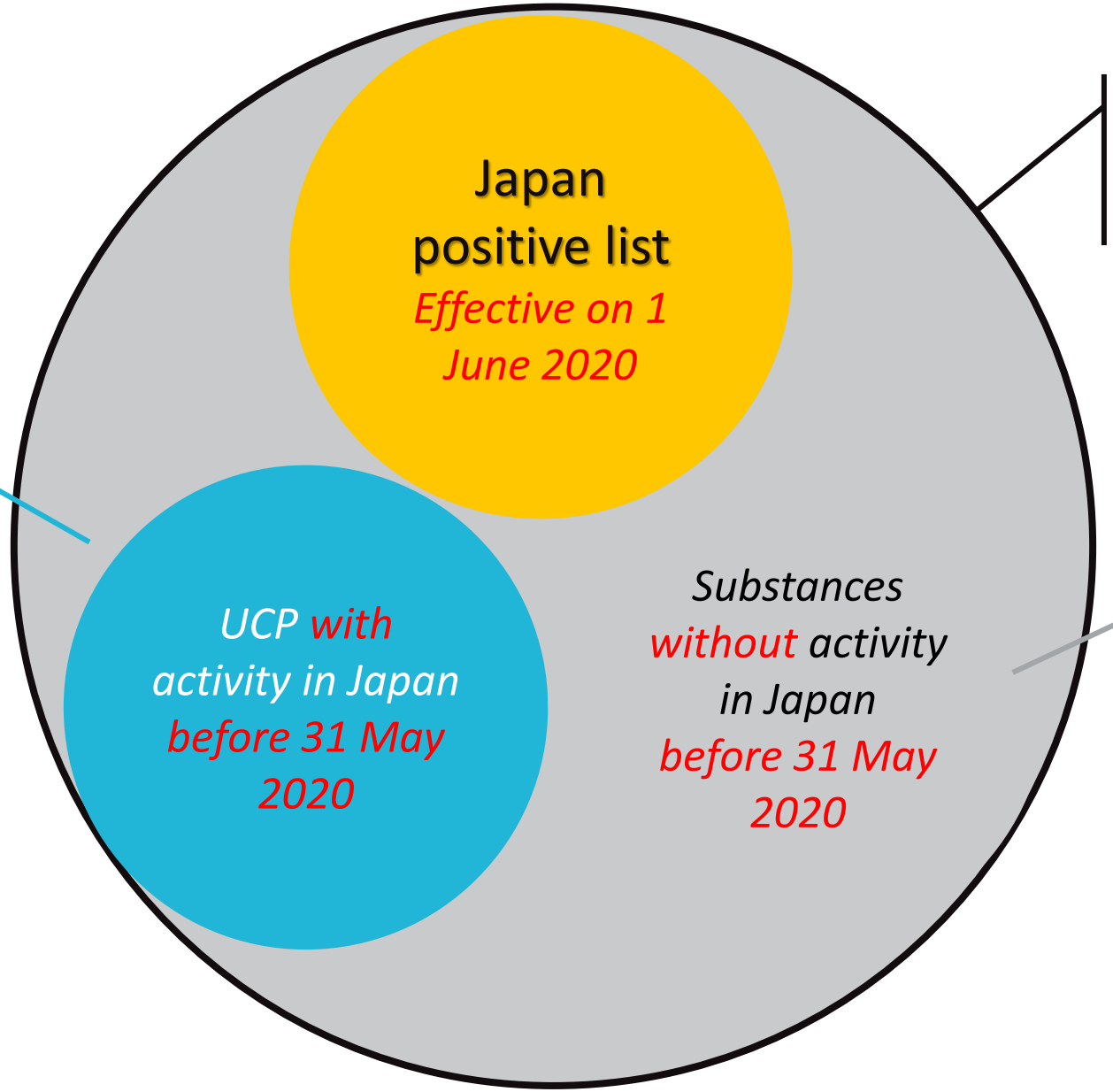


NEW POSITIVE LIST-TIMELINE



FOOD SANITATION ACT-REVISION, *NO. 196*

❖ **5-Year Grace Period**



All the substances intended to be food contact use!

The UCP could be sold and used in food contact during and after 5-year grace period.

Only substances added/approved to be listed in PL can be used for the manufacture and impot of UCP after transitional period.

DEVELOPMENT OF JAPAN NEW POSITIVE LIST (PL) SYSTEM

02

SCOPE OF POLISITVE LIST

❖ Classification of Synthetic Resins

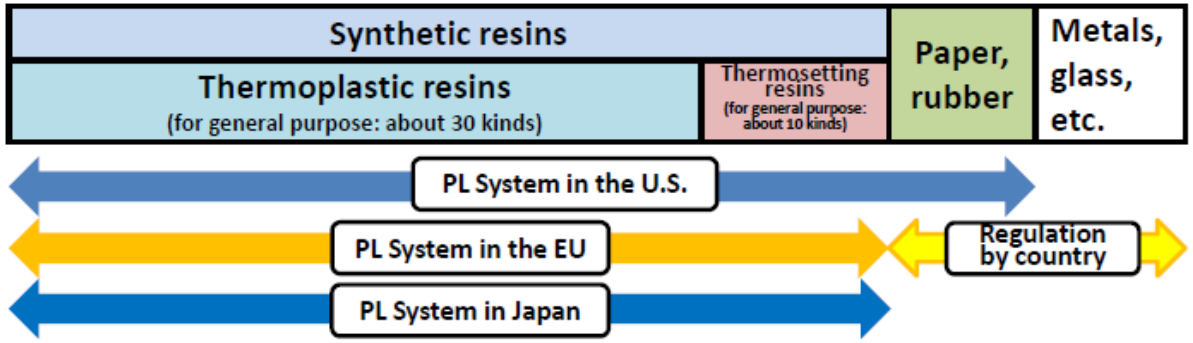
	Thermoplastic resins	*Thermosetting resins*
Plastic	*Thermoplastics* *eg., PE, PS*	*Thermosetting plastics* *eg., melamine resin, phenol resin*
Elastomer	*Thermoplastic elastomer* *eg., polystyrene elastomer, styrene-block copolymer*	*Rubber (thermosetting elastomer)* *eg., butadiene rubber, nitrile 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.

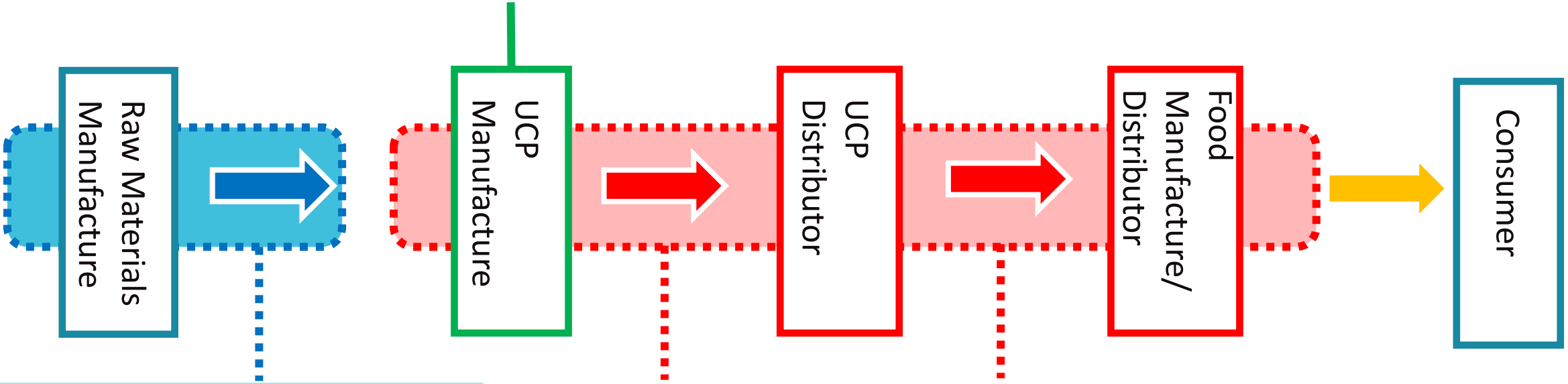
- ✓ Substances that fall under the category of raw materials other than synthetic resins
  - Elastic that do not have thermoplastic properties (raw materials for rubber)
  - Inorganic substances
  - Nature products and it's reactants
- ✓ Substances released from UCP, which are intended to transfer to 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	植物、抽出物	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	合成有機高分子物質（固体）	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	第２表（添加剤）
		合成有機低分子物質	ー	第２表（添加剤）

POSITIVE LIST (PL) SYSTEM _ SCOPE: SYNTHETIC RESIN

Good Manufacturing Practices (GMP)

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 (obligation)

Examples of Information Transmission Contents for Substances Subject to Transitional Measures

"The substance used in the product handled by the business operator is manufactured before the effective date. A substance that was used in UCP, and was not used. What is used within the range" etc.

JAPAN NEW POSITIVE LIST (PL) SYSTEM

The latest version is published on Sep. 27, 2024.

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

As a general rule, organic substance with a molecular weight < 1000 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.

	Appended Table 1		**Appended Table 2**
List No.	Table 1	Annex	
Speciality	Listed **5** polymer groups	21 annexes with essential substances and optional substances	More than 800 Additives used in different polymer groups

GROUPING RULE FOR RESIN

Polymer Group No. (NEW)	Standard of classification	Essential Monomer
1	**Polymers with a glass transition temperature or ball pressure temperature ≥ 150°C, or polymers having a cross-linked structure and with a melting point ≥150°C**	Specific in table 1
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°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	**Polymers that are used for coating involving chemical reaction during film formation.** 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.	**Not specified**

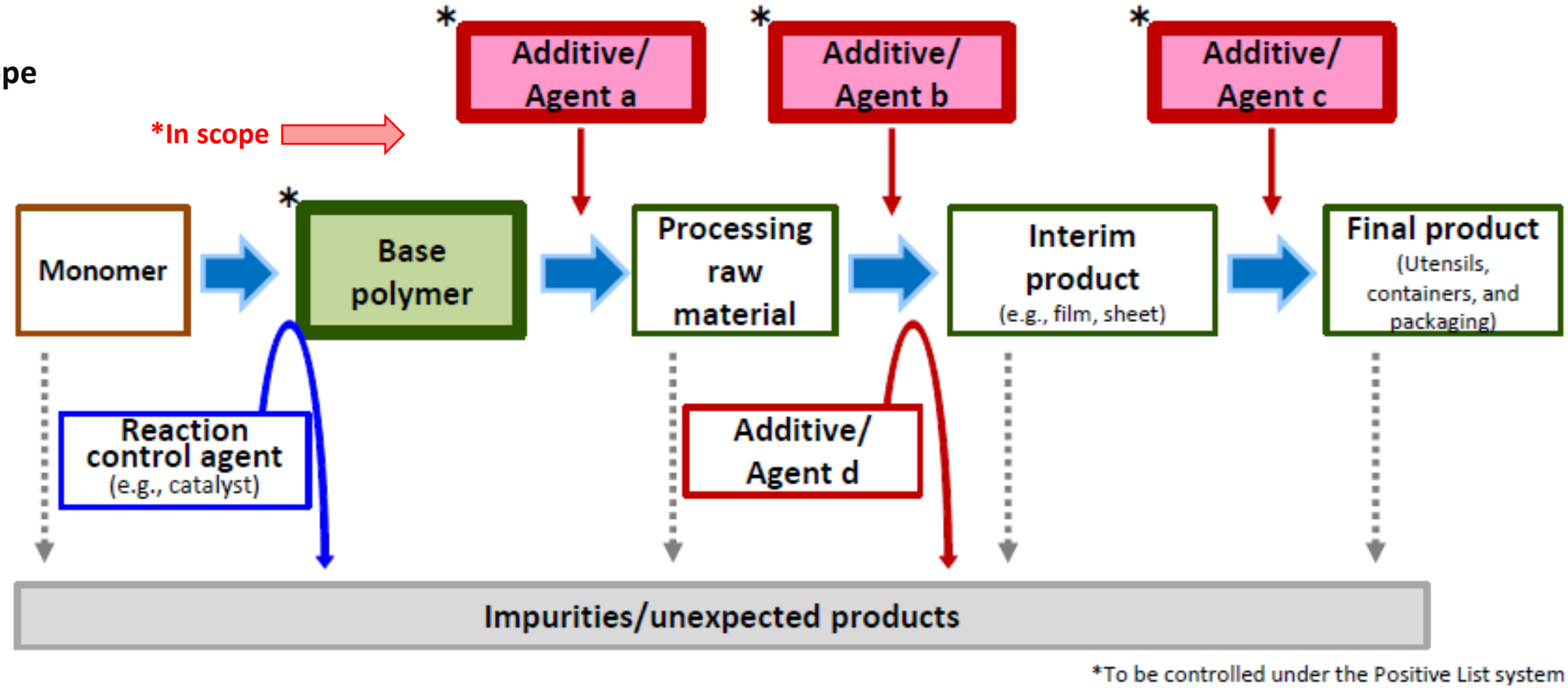
GROUPING RULE FOR RESIN

Annex 1~21: essential monomer, optional substances, restrictions, other requirements.

- Polymer mainly composed of imide bonds
- Polymer mainly composed of ether bonds
- Cross-linked polymer mainly composed of ester bonds
- Cross-linking polymer of epoxy compound
- Polymer mainly composed of carbonate bonds
- Polymer mainly composed of siloxane bonds
- Polymer mainly composed of sulfide bonds
- Polymer composed of fluorine-substituted ethylenes as the main monomer
- Polymer composed of formaldehyde as the main monomer
- Polymer with ion exchange ability and/or adsorption ability
- Polymer mainly composed of urethane bonds
- Polymer mainly composed of ester bonds
- Polymer composed of alkenes as the main monomer
- Polymer composed of conjugated diene hydrocarbon as the main monomer
- Polymer composed of aromatic hydrocarbons as the main monomer
- Polymer composed of acrylic acids as the main monomer
- Polymer mainly composed of amide link (including polymer composed of aziridine or 2-ethyl-2-oxazoline as the main monomer
- Glucose homopolymer or chemically modified cellulose
- Hydrolysates of polymer composed of vinyl acetate as the main monomer
- Polymer composed of chlorine-substituted ethylene as the main monomer
- Polymer used for coating that involves chemical reaction during film formation

SCOPE OF NEW DRAFT OF TABLE 2

❖ Scope



SCOPE OF NEW DRAFT OF TABLE 2

<table>
<tr><th colspan="3">Additives</th></tr>
<tr><th colspan="2">Additives covered by the PL System</th><th>Additives not covered by the PL System</th></tr>
<tr><td colspan="2">Substances that are used to physically or chemically change the properties of synthetic resins and that are intended to remain in UCP (final products)</td><td>• Substances that are incorporated into the structure of base polymer (e.g., cross-linking agents) or that are necessary for its polymerization
• Substances that are used for manufacturing synthetic resins but not intended to remain in the final products
• Substances that do not function for synthetic resins themselves, for example, those used to stabilize additives or for other purposes</td></tr>
<tr><td>Antiblocking agents
Antifoaming agents (those intended to remain in UCP)
Antifog agents
Antioxidants
Antistatic agents
Dispersants
Extender pigments
Fillers
Flame retardants
Foaming agents (those intended to remain in UCP)</td><td>Heat resistance enhancers
Lubricants
Mold release agents
Plasticizers
Preservatives (those intended to remain in UCP)
Reinforcing agents
Stabilizers
Surfactants
UV absorbing agents
Viscosity modifiers
Wetting agents, etc.</td><td>Antifoaming agents
Catalysts
Cross-linking agents
Impurities
pH Adjusters at polymerizing
Preservatives
Quenching agents
Reaction accelerators
Reaction residues
Solvents
Stabilizers for additives
Surface treatment agents for additives, etc.</td></tr>
</table>

HOW TO CALCULATE THE AMOUNTS OF ADDITIVES ADDED

第２表（添加剤）

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。
4	アクリル酸及びトリプロピレングリコールからなるジエステル	0.60	0.60	0.60	0.60	0.60	0.60	
5	アクリル酸及びプロポキシル化処理されたグリセロールからなるエステル	0.004	0.002	0.002	－	0.004	0.002	・プロピレンオキシドの付加数が４以上のものに限る。 ・分子量1000以上のものに限る。
6	アクリル酸及びプロポキシル化処理されたネオペンチルグリコールからなるジエステル	6.0	6.0	6.0	6.0	6.0	6.0	・プロピレンオキシドの付加数が４以上のものに限る。 ・分子量1000以上のものに限る。
7	アクリル酸２－［１－（２－ヒドロキシ－３，５－ジ－tert－ペンチルフェニル）エチル］－４，６－ジ－tert－ペンチルフェニル	1.0	1.5	1.0	0.20	1.5	1.5	
8	アクリル酸ブチル	5.0	5.0	5.0	－	5.0	5.0	
9	アクリル酸２－tert－ブチル－６－（２－ヒドロキシ－３－tert－ブチル－５－メチルベンジル）－４－メチルフェニル	0.50	8.0	0.50	0.50	8.0	8.0	
10	trans－アコニット酸	－	－	1.0	－	1.0	1.0	
11	アジピン酸	*	*	*	*	*	*	・通し番号412に該当するものを除く。 ・ナトリウム塩を含む。

- ❖ “-” indicates that the amount listed in the Restricted Use column by Material Classification is not available.
- ❖ “*” indicates that the substances in the table are to be used in the minimum amount that exhibits the intended properties for the substances shown in the Material Category column corresponding to Table 1, which is the amount to be set by the business operator's responsibility when designing the synthetic resin.
- ❖ When multiple substances are indicated in one serial number and there is no restriction on mixtures for the indicated substances, the serial number includes mixtures and compound salts of the multiple substances indicated. When mixtures or complex salts of more than one substance indicated in the serial number are used, the use restrictions by material category shall apply to the mixtures or complex salts. The use restrictions by material category shall apply to such mixtures or complex salts.

HOW TO CALCULATE THE AMOUNTS OF ADDITIVES ADDED

- The ratio of the weight of the additive to the total weight; for multi-layer, calculated for each layer

- The mixing substrates, is calculated from the weight ratio of the base material of each category. However, if the weight ratio of the substrate exceeds 50% of the total weight of the substrate, the material classification usage limit (%) of the material classification of the substrate that exceeds 50% can be applied as an upper limit.

The weight ratio calculation for Additive A

2 ✕20%+4 ✕80%=**3.6%**;
Or
Since resin 2 exceeds 50% of the total weight of the substrate, it is possible to adopt **4.0% directly**.

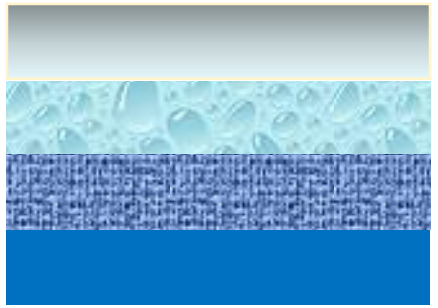
POSITIVE LIST (PL) SYSTEM _ SCOPE: MULTI-LAYER UCP

- ✓ All layers are synthetic resin, substances released from UCP, the amount specified by the MHLW as an amount that does not pose a risk of impairing human health for layers that do not come into contact with food shall be required. If it has been processed so that it is not miscible by eluting or leaching into food, it is not subject to the positive list.

- ✓ A layer in which the layer in contact with the food is composed of a material other than synthetic resin. If there is a synthetic resin layer on the non-food contact side, the synthetic resin layer is not subject to the positive list.

- ✓ If the layer that comes into contact with food is a layer of synthetic resin and there is a layer other than synthetic resin in the layer that does not come into contact with food, only the layer of synthetic resin from the layer other than the synthetic resin on the side of the food contact surface must be subject to the positive list. However, in accordance with the proviso to Article 18, Paragraph 3 of the Act, it may not be subject to the positive list.

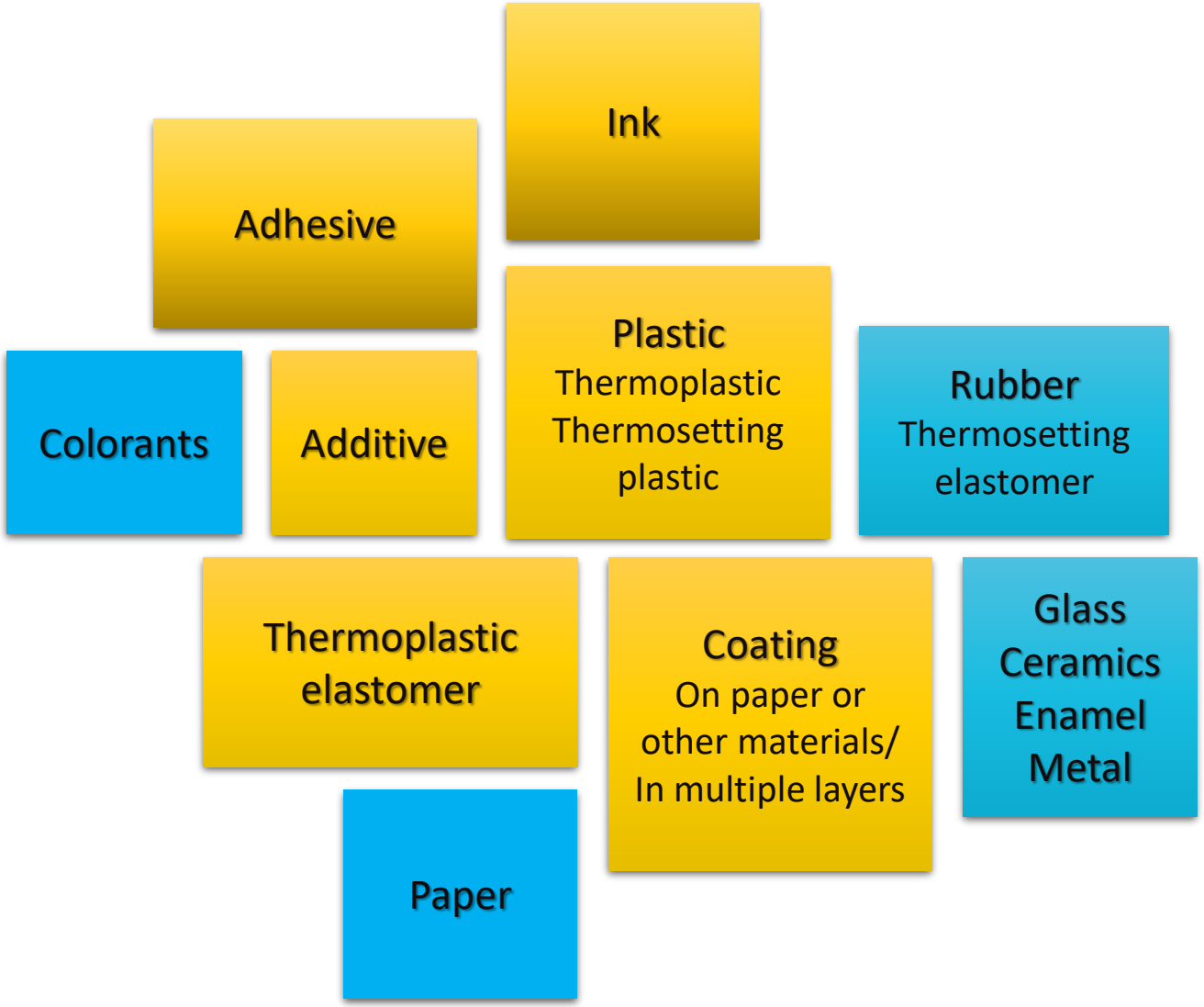
Resin A
Resin B
Resin C
Resin D (Food Contact)
Food



Resin E (printing ink)
Paper
Resin F
Resin G (Food Contact)
Food

Resin H
Metal
Resin I
Resin J (Food Contact)
Food

SCOPE OF JAPAN FOOD CONTACT REGULATION SYSTEM



ASSOCIATION-JCII

03

ROLE OF ASSOCATION

MHLW

Mandatory regulations

+

Industrial Associations

Voluntary standards

- **Food Sanitation Art-Revision**
- *Order of Enforcement of the Food Sanitation Art, MHLW No. 23 1948*
- *Specifications and Standards for Foods, Food Additives*
- *Guideline on GMP, 生食発0710 No. 14 2017*

- **JETRO**-Japan External Trade Organization
- Japan Chemical Innovation and Inspection Institute (JCII)
- **JPIMA**-Japan Printing Ink Makers Association
- **JPWIA**-Japan Petrolatum Wax Industry Association
- **JAIA**-Japan Adhesive Industry Association
- **JRMA**-Japan Rubber Manufacturers Association
- **JPA**-Japan Paper Association

JAPAN CHEMICAL INNOVATION AND INSPECTION INSTITUTE

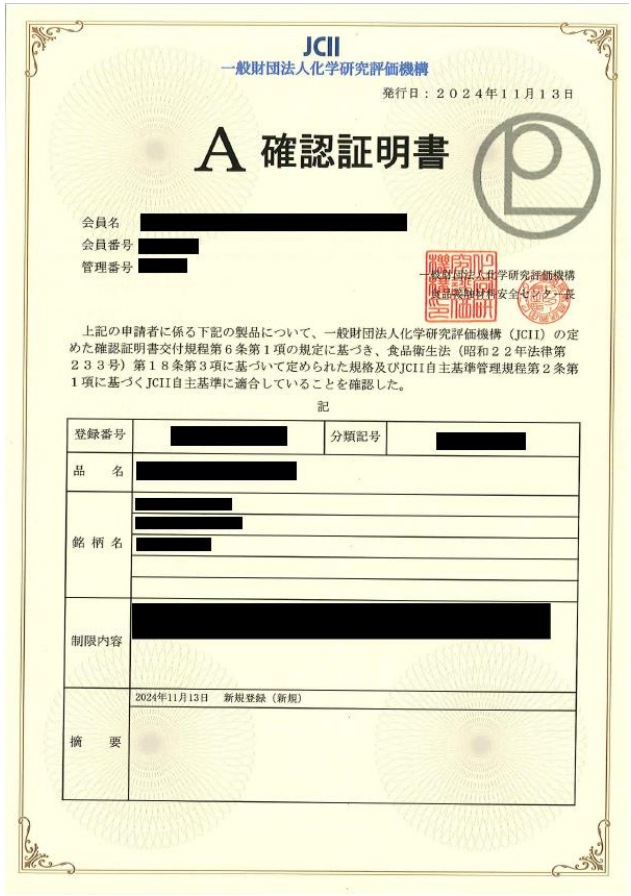
JCII 一般財団法人 化学研究評価機構

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

JCII has developed:

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

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



JCII
一般財団法人化学研究評価機構
発行日：２０２４年１１月１３日

A 確認証明書

会員名 [redacted]
会員番号 [redacted]
管理番号 [redacted]

一般財団法人化学研究評価機構
食品衛生法対応安全化学グループ長

上記の申請者に係る下記の製品について、一般財団法人化学研究評価機構（JCII）の定めた確認証明書交付規程第６条第１項の規定に基づき、食品衛生法（昭和２２年法律第２３３号）第１８条第３項に基づいて定められた規格及びJCII自主基準管理規程第２条第１項に基づくJCII自主基準に適合していることを確認した。

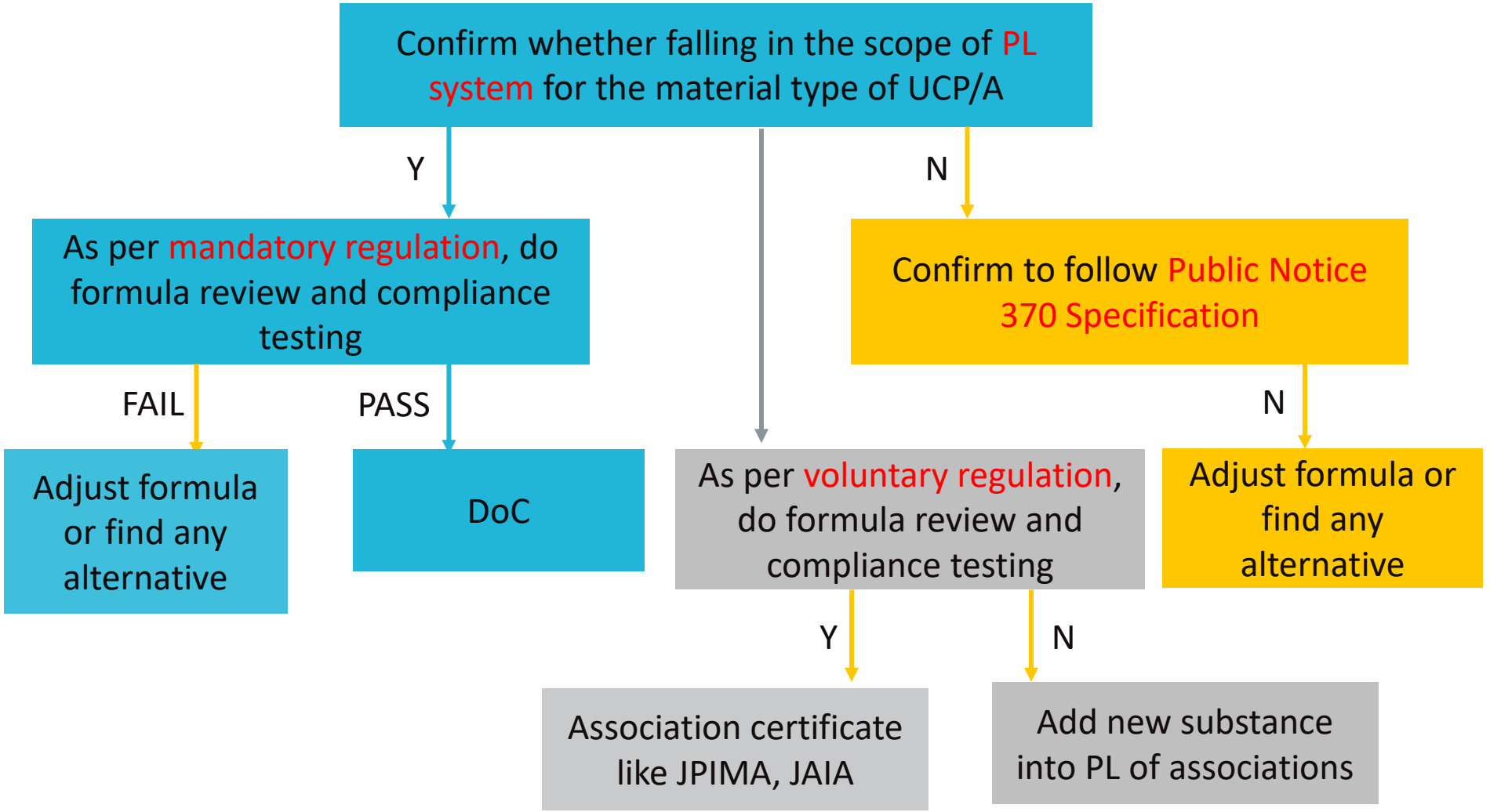
記

登録番号	[redacted]	分類記号	[redacted]
品　名	[redacted]		
銘柄名	[redacted]		
制限内容	[redacted]		
摘　要	2024年11月13日　新規登録（新規）		

COMPLIANCE STRATEGY

04

JAPAN FOOD CONTACT COMPLIANCE STRATEGY



COMPLIANCE STRATEGY

Formula review

- **MHLW Regulation: Annex I, Specifications and Standards for Foods, Food Additives-Revision, 30 Nov. 2023**
- Confirm the temperature limit and contact food types based on basic resin
- Confirm the max use content and other restrictions of additives

Compliance testing

- **MHLW Regulation: Specifications and Standards for Foods, Food Additives-Revision, 30 Nov. 2023**
- Including general tests, material tests, elution tests and etc.

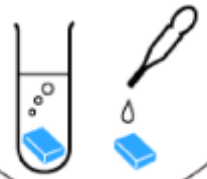
DoC

- **Law: Food Sanitation Art and its Revision**
- No requirements for format
- Claim the compliance status, but no need to clarify the details of formulation or use content

INTERTEK JAPAN FOOD CONTACT SERVICE

Formula review and compliance testing

衛生試験法



Declaration of Compliance

Compliance Certificate of associations, eg, JCII, JAIA

Submission on opinions of PL to MHLW

ポジティブリスト (PL)

Newsletter

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Thank you for your attention.

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