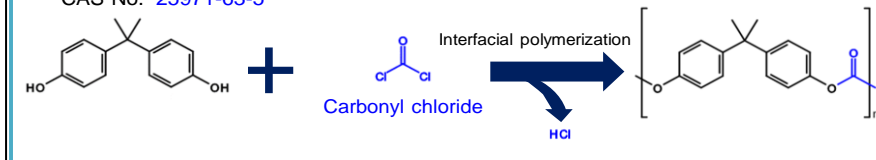
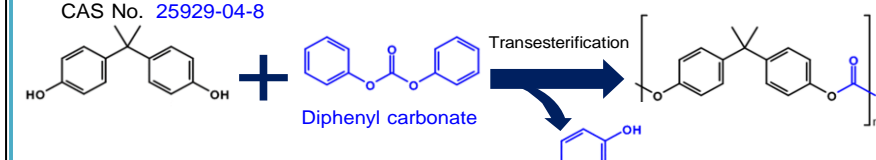
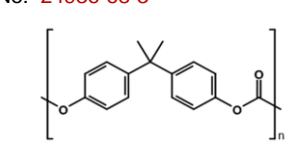


NO.	Question	Answer															
1	Which synthetic resins are subject to the Positive List (PL) System specified by the Cabinet Order?	<p>Under the PL System, synthetic resins refer to high molecular compounds categorized as (1) thermoplastic resins, (2) thermosetting resins, and (3) thermoplastic elastomers. Thermosetting elastomers (rubbers) are not included. (Synthetic resins subject to the PL System: (1), (2), and (3).)</p> <div data-bbox="844 362 1619 911" data-label="Diagram"> <table border="1"> <thead> <tr> <th colspan="3">Classification of synthetic resins (overview)</th> </tr> <tr> <th></th> <th>Thermoplastic</th> <th>Non-thermoplastic</th> </tr> </thead> <tbody> <tr> <th>Plastic</th> <td>Thermoplastics e.g., polyethylene, polystyrene</td> <td>Thermosetting plastics e.g., melamine resin, phenol resin</td> </tr> <tr> <th>Elastomer</th> <td>Thermoplastic elastomers e.g., polystyrene elastomer, styrene-block copolymer</td> <td>Rubbers (thermosetting elastomers) e.g., butadiene rubber, nitrile rubber</td> </tr> </tbody> </table> </div>	Classification of synthetic resins (overview)				Thermoplastic	Non-thermoplastic	Plastic	Thermoplastics e.g., polyethylene, polystyrene	Thermosetting plastics e.g., melamine resin, phenol resin	Elastomer	Thermoplastic elastomers e.g., polystyrene elastomer, styrene-block copolymer	Rubbers (thermosetting elastomers) e.g., butadiene rubber, nitrile rubber			
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2	Of raw materials of synthetic resins, which substances are subject to the PL System?	<p>The PL System covers Base polymers (Table 1) and Additives and Coating agents (Table 2) specified in Appended Table 1 of the Specifications and Standards for Food, Food Additives, Etc. (Public Notice of the Ministry of Health and Welfare No. 370 of 1959; hereinafter referred to as the “Notice”) as well as Coloring agents (see Q3) specified in Chapter III-A-5 of the Notice.</p> <p>In Tables 1 and 2 of Appended Table 1, substances that are intended to remain in Utensils, or Containers and Packaging (UCPs) are listed as substances subject to the PL System.</p> <p>Table 1 lists constituent monomers, cross-linking agents, etc. for base polymers that are incorporated into the structure of synthetic resins and form the foundation.</p> <p>Table 2 lists additives and coating agents. They are used with the intention to remain in UCPs for the purpose of changing the physical or chemical properties of synthetic resins.</p> <p>Meanwhile, substances that are used during a manufacturing process but not intended to remain in the final products (including substances that are used but intended to be removed during a manufacturing process, such as catalysts, polymerization aids, and solvents) are not subject to the PL System. (For the basic idea about which additives are subject to the PL System, please see the following Table.)</p> <p>Additionally, substances that exist unintentionally in a manufacturing process (such as impurities in constituent monomers or additives) are not subject to the PL System.</p> <p>Please note that even when substances not subject to the PL System are used in UCPs, the UCPs need to comply with the general standards for raw materials, specifications by material type, specifications by application, and manufacturing standards specified by the Notice.</p> <p>Note: A period of transitional measures is set for five years after the enforcement date of the PL System. During this period, substances used in products similar to UCPs already distributed before the enforcement date are regarded as being included in Appended Table 1 (see Q18).</p> <div data-bbox="852 2003 1631 2552" data-label="Table"> <table border="1"> <thead> <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> </thead> <tbody> <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> <ul style="list-style-type: none"> 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> <tr> <td colspan="3"> Notes: Neutralizers, hydrophilizing agents, appearance modifiers, adhesion promoters, adhesion aids, film-forming aids, masking agents, spreading agents, etc. require individual judgments concerning whether the additives are covered or not covered by the PL System. </td> </tr> </tbody> </table> </div>	Additives			Additives covered by the PL System		Additives not covered by the PL System	Substances that are used to physically or chemically change the properties of synthetic resins and that are intended to remain in UCP (final products)		<ul style="list-style-type: none"> 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 	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)	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.	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.	Notes: Neutralizers, hydrophilizing agents, appearance modifiers, adhesion promoters, adhesion aids, film-forming aids, masking agents, spreading agents, etc. require individual judgments concerning whether the additives are covered or not covered by the PL System.		
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3	How does the PL System regulate coloring agents used in synthetic resin UCPs?	<p>Coloring agents that are used only for the purpose of coloring UCPs are not specified in Appended Table 1, because provisions are already given in Chapter III. Utensils, Containers and Packaging, Section A. General Specifications for Utensils, Containers, and Packaging or Their Raw Materials, Item 5 of the Notice. Coloring agents need to comply with the provisions.</p> <p>If a substance that is generally used as a coloring agent is used for a purpose other than coloring (e.g., as a filler), such substance is listed in Appended Table 1 for the use.</p>																															
4	If a UCP is mainly made of a material other than synthetic resin (e.g., paper or wood) but the food contact part of the UCP is coated with a synthetic resin, is the synthetic resin subject to the PL System?	<p>Even if a UCP is mainly made of a material other than synthetic resin, when a layer of synthetic resin is formed in a part coming into contact with foods, the synthetic resin is subject to the PL System. Meanwhile, synthetic resins used in non-food contact parts are not subject to the PL System.</p>																															
5	If a UCP is mainly made of a material other than synthetic resin (e.g., paper or wood) but a synthetic resin is mixed in the material, is the material including the synthetic resin subject to the PL System?	<p>If the main ingredient of a UCP is a material other than synthetic resin (e.g., paper or wood), even if a synthetic resin is mixed in the material, the material of the UCP is not regarded as synthetic resin and the material including the synthetic resin is not subject to the PL System (e.g., a material that mainly consists of talc, wood flour, pulp, etc. and contains a synthetic resin).</p>																															
6	If a resin is manufactured by mixing base polymers listed in Table 1 of Appended Table 1, is the resulting resin regarded as conforming to the PL System?	<p>If base polymers listed in Table 1 of Appended Table 1 are mixed, the resulting resin does not have to be listed in Table 1 as long as all the base polymers before mixing are listed in the Table. However, if a chemical reaction occurs as a result of mixing, the resulting substance after the chemical reaction needs to be specified in the Table.</p> <p>Note that the restrictions for each base polymer before mixing (food category, maximum temperature, use amount of additives, etc.) also apply to the resulting resin. Specifically, when a base polymer with lenient restrictions is mixed with a base polymer with severe restrictions, in principle, the severe restrictions apply to the resulting resin (For example, when a base polymer with maximum temperature II and a base polymer with maximum temperature III are mixed, maximum temperature II applies to the resulting resin). However, in some cases, lenient restrictions may apply; such cases (cases outside the principle of mixture rules) are described in the Requirements column of the Table.</p> <div data-bbox="793 1492 1570 2039" data-label="Complex-Block"> <p style="text-align: center;">Mixture of Synthetic Resins</p> <p>Summary</p> <ul style="list-style-type: none"> When multiple polymers listed in the PL are mixed, basically the restrictions for the each polymer before mixture (food category, maximum temperature, etc.) apply to the resulting resin. In general, the severest conditions for the polymers apply to the resin. In some case, more lenient restrictions may apply when a polymer with lenient restrictions is mixed with small amounts of a polymer with severe restrictions. Example: If a resin consists of small amounts of a polymer with maximum temperature II (severe) and a polymer with maximum temperature III (lenient), the temperature III is applied to the maximum temperature of the resin. Such resins are managed based on descriptions given in the Requirements column, which clarify exceptions for the mixture rule. <p>Example</p> <table border="1"> <thead> <tr> <th rowspan="2">No</th> <th colspan="2">Substance</th> <th rowspan="2">CAS No.</th> <th colspan="5">Food category</th> <th rowspan="2">Max. temperature I: ≤ 70°C II: ≤ 100°C III: > 100°C</th> <th rowspan="2">Group</th> <th rowspan="2">Requirements</th> </tr> <tr> <th>Japanese name</th> <th>English name</th> <th>Acidic</th> <th>Fat/oil and fatty/oil</th> <th>Milk/milk product</th> <th>Alcoholic beverage</th> <th>Others</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>メタクリル酸メチル単独重合体</td> <td>methyl methacrylate homopolymer</td> <td>9011-14-7</td> <td>○</td> <td>○</td> <td>○</td> <td>○</td> <td>○</td> <td>II</td> <td>3</td> <td>When mixed with a base polymer in Synthetic Resin Group 4 at not more than 5%, the maximum temperature: III.</td> </tr> </tbody> </table> </div>	No	Substance		CAS No.	Food category					Max. temperature I: ≤ 70°C II: ≤ 100°C III: > 100°C	Group	Requirements	Japanese name	English name	Acidic	Fat/oil and fatty/oil	Milk/milk product	Alcoholic beverage	Others	1	メタクリル酸メチル単独重合体	methyl methacrylate homopolymer	9011-14-7	○	○	○	○	○	II	3	When mixed with a base polymer in Synthetic Resin Group 4 at not more than 5%, the maximum temperature: III.
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7	How can a substance be identified if no CAS Registry Number is shown in the Japanese/English bilingual version of Appended Table 1?	<p>The substances subject to the PL System are specified by substance names. Additionally, as supplementary information for identifying substances, the Japanese/English bilingual version of Appended Table 1 including the English name and CAS Registry Number for each substance is available on the website of the MHLW.</p> <p>Usually, whether a substance is regarded as being listed in Appended Table 1 or not should be determined by using the information of the Japanese/English bilingual version of Appended Table 1. However, if CAS Registry Number is not provided for the substance you want to identify, the substance name will be the primary source of identification while referencing other information.</p> <p>For substances that currently do not have CAS Registry Numbers in the Japanese/English bilingual version of Appended Table 1, the MHLW plans to add CAS Registry Numbers once it is identified.</p>																															

8	How is it checked in Appended Table 1 whether an additive can be used and how the additive is regulated?	<p>Additives listed in Table 2 of Appended Table 1 can be used. For each additive, the synthetic resin groups in which the additive can be used and the maximum use level (%) are specified in the Use Limit by Synthetic Resin Group (%) column. You should identify the synthetic resin group of the base polymer to be used by checking it in Table 1 of Appended Table 1, and then use the additive at or below the maximum use level (%) for the group. Note that in additions to the use limit, specific requirements apply to some additives. Such requirements are given in the Requirements column. Make sure to check the notes in the column.</p> <p>Note: A period of transitional measures is set for five years after the enforcement date of the PL System. During this period, substances used in products similar to UCPs already distributed before the enforcement date are regarded as being included in Appended Table 1 (see Q18).</p>												
9	How are base polymers specified in Table 1 of Appended Table 1?	<p>Base polymers are categorized by source-based names to distinguish the differences in starting monomers. Therefore, the categorization may inevitably reflect differences in manufacturing method, arising from differences in starting monomers. However, if polymers with the same structure are manufactured using the same starting monomer, the polymers are basically categorized under the same substance name, even if the manufacturing methods are different.</p> <div data-bbox="800 839 1591 1397" style="border: 1px solid black; padding: 5px;"> <p style="text-align: center;">Specifications of Base Polymers</p> <p>Summary</p> <ul style="list-style-type: none"> When starting monomers and manufacturing method differ, the polymers shall generally be treated as different base polymers even if the synthesized base polymer structures are the same. Base polymers with different source-based names shall be listed separately in the Positive List even if they have the same structure-based name. <p>Example: Polycarbonates</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>No</th> <th>Polymers</th> <th>English name</th> <th>CAS No.</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>2, 2-bis (4-hydroxyphenyl) propane, carbonyl chloride copolymer</td> <td>Carbonic dichloride, polymer with 4,4'-(1-methylethylidene)bis[phenol]</td> <td>25971-63-5 24936-68-3</td> </tr> <tr> <td>2</td> <td>2, 2-bis (4-hydroxyphenyl) propane, diphenyl carbonate copolymer</td> <td>Carbonic acid, diphenyl ester, polymer with 4,4'-(1-methylethylidene)bis[phenol]</td> <td>25929-04-8 24936-68-3</td> </tr> </tbody> </table> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="width: 45%;"> <p>Source-based name</p> <p>(1) 2, 2-bis (4-hydroxyphenyl) propane, carbonyl chloride copolymer CAS No. 25971-63-5</p>  <p>(2) 2, 2-bis (4-hydroxyphenyl) propane, diphenyl carbonate copolymer CAS No. 25929-04-8</p>  </div> <div style="width: 45%; border: 1px solid red; padding: 5px;"> <p>Structure-based name</p> <ul style="list-style-type: none"> Poly [oxycarbonyloxy-1,4-phenylene (dimethylmethylen) -1,4-phenylene] CAS No. 24936-68-3  <p>Source-based name Name based on the ingredient monomer.</p> <p>Structure-based name Name based on the chemical structure of the polymer's repeating unit.</p> </div> </div> </div>	No	Polymers	English name	CAS No.	1	2, 2-bis (4-hydroxyphenyl) propane, carbonyl chloride copolymer	Carbonic dichloride, polymer with 4,4'-(1-methylethylidene)bis[phenol]	25971-63-5 24936-68-3	2	2, 2-bis (4-hydroxyphenyl) propane, diphenyl carbonate copolymer	Carbonic acid, diphenyl ester, polymer with 4,4'-(1-methylethylidene)bis[phenol]	25929-04-8 24936-68-3
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10	If multiple CAS Registry Numbers are provided in the CAS Registry Number column of the Japanese/English bilingual version of Appended Table 1, does the level (%) in the Use Limit column apply to each substance?	Percentage of additives to be added applies to each substance in the Substance column. For example, some substances with different salt types are classified as the same substance and when such substances are used in one resin at the same time, the specified use level applies to the total amount of the resin and the substances.												
11	For substances with isomers, if a substance in the Substance column is not distinguished by isomer, can all the isomers for the substance be used?	If isomers are not specifically stated, substances are not distinguished by isomers in Appended Table 1. Similarly, cis/trans isomers can be used without distinguishing them if not specifically stated.												
12	Are all parts made of synthetic resin subject to the PL System, like the handle of chopsticks and the outer part of food manufacturing machine that do not come in contact with food?	If the parts in question do not come in contact with food under normal use, such parts are not subject to the PL System.												
13	Do surface treatment agents used in manufacturing glass fibers, etc. that are added to a synthetic resin need to be listed in Table 2 of Appended Table 1? Also, are surface treatment agents included in coloring agents?	Surface treatment agents used for glass fibers, for example, are regarded as part of the glass fibers and they can be used as glass fibers, without being listed in Table 2 of Appended Table 1. For coloring agents, usually pigments that underwent surface treatment, etc. are functioning for the purpose of coloring. Therefore, the entire coloring agent including surface treatment agents, etc. is regarded as a coloring agent. However, substances other than coloring agents (e.g., base polymers or dispersants) in a masterbatch etc. are required to be individually listed in Appended Table 1.												
14	When a masterbatch is used, do restrictions on use level, etc. of additives apply to the base resin of the masterbatch?	Restrictions on use level of additives apply to the resin as the final material for UCPs, not to the base resin for masterbatches to which the additives are added. Note that, in accordance with the concept of mixture rules, it should be confirmed that the mixture of a masterbatch and a target resin satisfies the use restriction.												

15	If a cross section of a multi-layer film may come in contact with food, do substances contained in all the layers have to be listed in Appended Table 1?																																																		
16	For additives that are used in the non-food contact layer in a multi-layer film, etc., is the use limit by synthetic resin group determined by (1) the group of synthetic resin to which the additives are added or by (2) the group of synthetic resin in the food-contact layer?																																																		
17	<p>What kind of restrictions apply to UCPs made from synthetic resin when chemical substances are released from the UCPs for the purpose of having an effect on food?</p> <p>Chemical substances contained in such UCPs are regulated as substances subject to the PL System as raw materials of UCPs, regardless of their effects on food. In addition, chemical substances released from UCPs for the purpose of working on food need to be designated as food additives, regardless of their migration amounts. Therefore, in this case, chemical substances need to be listed in Table 2 of Appended Table 1 as substances that satisfy the food additive standards. That means, the words "food additive" must be stated in the Substance column and the Requirements column must state "Follow the stipulations in "Chapter 2. Food Additives" of Ministry of Health and Welfare Notification No. 370" regarding the use restrictions. (Notification No.370 is same as the Notice.) For that reason, even if a substance listed in Table 2 of Appended Table 1 has the same name as a food additive, unless the substance is listed in the same Table as a substance that satisfies the food additive standards, it must not be used by being released from UCPs with the purpose of having an effect on food.</p> <div style="display: flex; justify-content: space-around;"> <div data-bbox="682 1121 1245 1516"> <p>Functional Materials (Active and Intelligent Materials)</p> <p>Summary</p> <ul style="list-style-type: none"> The EU regulates food contact materials (e.g., active and intelligent materials) based on its regulations. <ul style="list-style-type: none"> Active materials are defined as "materials that are intended to extend the shelf-life or to maintain or improve the condition of packaged food" through releasing or absorbing specific substances. Intelligent materials are defined as "materials that monitor the condition of packaged food or the environment surrounding of the food." In Japan, these substances are handled as follows: <ul style="list-style-type: none"> Chemical substances contained in UCP are subject to the PL System as raw ingredients of UCP, regardless of their effects on food. Chemical substances released from UCP with the intention to have effects on food are treated as food additives and are also subject to the regulation of food additives, regardless of their migration amounts (in a state that the substances remain in UCP, they are treated as raw materials of UCP). *UCP: utensils, containers and packaging *the PL System: the Positive List System <table border="1"> <thead> <tr> <th>Classification</th> <th>Regulatory framework</th> <th>Example</th> </tr> </thead> <tbody> <tr> <td>Absorbing type</td> <td>Managed as substances subject to the PL System for UCP</td> <td>Oxygen scavenger Drip absorber</td> </tr> <tr> <td rowspan="2">Releasing type</td> <td>Managed as substances subject to the PL System for UCP and also managed as food additives (However, food substances are raw materials of material categories of UCP before being released from the UCP)</td> <td>Freshness keeping agents that release model cheese (that additive)</td> </tr> <tr> <td>Managed as substances subject to the PL System for UCP</td> <td></td> </tr> <tr> <td rowspan="2">Immobilized type</td> <td>Managed as substances subject to the PL System for UCP</td> <td>Anti-microbial products that contain silver ions</td> </tr> <tr> <td>Managed as substances subject to the PL System for UCP</td> <td>Temperature indicators</td> </tr> </tbody> </table> </div> <div data-bbox="1287 1121 1850 1516"> <p>When food additives are used as raw materials of utensils, containers and packaging (UCP) for the purpose of working on foods</p> <ul style="list-style-type: none"> To use a substance released from UCP for the purpose of working on foods, the substance shall be listed in the PL as the substance satisfying the standards for food additive. The use amount of the substance is not specified in the PL; however, it shall satisfy the use restriction as a food additive. Even if a substance listed in the PL for UCP has the same name as a food additive, unless it is listed in the PL as the substance satisfying the standards, it must not be used by being released from UCPs with the purpose of having an effect on food. <p>Example</p> <div style="display: flex; justify-content: space-around;"> <div style="text-align: center;"> <p>● Calcium hydroxide (food additive)</p> <p>Can be used with the purpose of having an effect on food (Shall satisfy the food additive standards)</p> </div> <div style="text-align: center;"> <p>● Calcium hydroxide</p> <p>Can not be used with the purpose of having an effect on food</p> </div> </div> <p>Descriptions in Table 2 of Appended Table 1</p> <p>● Additives, coating agents, etc.</p> <table border="1"> <thead> <tr> <th rowspan="2">Substance</th> <th colspan="7">Use Limit by Synthetic Resin Group (%)</th> <th rowspan="2">Requirements</th> </tr> <tr> <th>1</th> <th>2</th> <th>3</th> <th>4</th> <th>5</th> <th>6</th> <th>7</th> </tr> </thead> <tbody> <tr> <td>1 Calcium hydroxide (food additive)</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td> <td>-</td> <td>Follow the stipulations in "Chapter 2. 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1 Calcium hydroxide (food additive)	-	-	-	-	-	-	-	Follow the stipulations in "Chapter 2. Food Additives" of Ministry of Health and Welfare Notification No. 370.																																											
2 Calcium hydroxide	30	30	30	5	30	30	0.01																																												

<p>18 What are the transitional measures that have been newly specified in the Notice? Also, what kind of information should be shared as confirmation of conformance to the PL System?</p>	<p>The MHLW established transitional measures under which, if products similar to UCPs* being manufactured, imported, etc. before the enforcement date of the PL System are manufactured or imported for the purpose of marketing during the period of five years from the enforcement date (until May 31, 2025), raw materials of such UCPs are regarded as being included in Appended Table 1. During the period of transitional measures, manufacturing, etc. can be continued using substances not included in Appended Table 1 as long as the substances are used within the range in which they were used in UCPs being manufactured before the enforcement date. During the period of transitional measures, regarding information sharing related to conformance to the PL System as stipulated in Article 53 of the Food Sanitation Act, the following explanation can be shared as an example, taking into account the content of the transitional measures.</p> <p>A substance that was used in a UCP being manufactured before the enforcement date is used within the range of the previous use in the product the business operator handles.</p> <p>Note: The notification No. 1107-1 dated November 7, 2019, titled “Establishment of Relevant Cabinet Orders and Ministerial Ordinances Associated with Enforcement of the Act Partially Amending the Food Sanitation Act Etc.,” stipulates matters to information sharing as follows:</p> <ul style="list-style-type: none"> • Each business operator should understand the necessity of information sharing through supply chains of UCPs and convey appropriate information with awareness of each position and role. • The information sharing system specified in the ministerial ordinances has been established considering the communication between business operators. • The information is required just to confirm conformity to the PL and not required to disclose individual substances. • The way to convey information has not been specifically stipulated. However, it is necessary to secure a means to confirm it at a later date, for example, by business operators’ recording and storage of the information. • Information usable to convey includes specifications upon executing a contract between business operators, quality assurance certificates upon delivery, confirmation certificates issued by a trade association, and documents supporting conformity to provisions of Article 18, paragraph (3). • Information sharing specified in Article 66-6 of the Ordinance for Enforcement of the Food Sanitation Act is communication carried out to the other party who purchases the finished products by the business operators who market, manufacture, and import UCPs made from synthetic resin or UCPs made from other materials whose food-contact surfaces are formed as a synthetic resin layer. <p>* The term “a product/products similar to a UCP/UCPs” used in this FAQ means any UCP that is manufactured using substances (raw materials of synthetic resin) that had been used in UCP being sold, manufactured or imported for the purpose of marketing, or used in business before June 1, 2020 within the range in which the substances had been used; or means any import of the UCPs that are manufactured using such substances within such range.</p>
<p>19 What kind of action needs to be taken if a substance contained in a UCP that was being used before the enforcement date is subject to the PL System but not listed in Appended Table 1, or if it does not satisfy the use conditions, etc. specified in Appended Table 1?</p>	<p>If a substance that was being used before the enforcement date is not listed in Appended Table 1, or does not satisfy the use conditions, etc., please provide required information to the Standards and Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW. Please note that information will not be accepted if the information fails to provide clear evidence of the history of use before the enforcement date.</p> <p>Details on how to provide information will be published on the MHLW website at a later date. Please be aware that substances not listed in Appended Table 1 will become unusable after the expiration of the transitional measures period running five years from the enforcement date.</p>

20	What procedure should be taken to use a new substances in UCPs newly manufactured after the enforcement?	To enable the use of a new substance after the enforcement, the substance needs to be added to Appended Table 1. A guide to request the listing of new substances will be published on the MHLW website at a later date.
21	How can the substances listed in the draft Positive List (as of December 23, 2019) be identified in Appended Table 1?	Substances are given same reference numbers in the draft Positive List and Appended Table 1 to enable to identify the same substances. For substances deleted in the process of preparing Appended Table 1 from the draft Positive List due to duplicates, etc., descriptions to that effect are provided in the Japanese/English bilingual version of Appended Table 1.
22	The handling of preforms for PET bottles seems to have been put in order this time. Is it correct that import notification is not required for import of preforms after the enforcement of the amended Food Sanitation Act?	Preforms for PET bottles are regarded as materials of food UCPs, and notification is not required at import.
23	When a product similar to a UCP being sold, manufactured, imported, or used in business since before the enforcement date (June 1, 2020) is manufactured or imported during the transitional measures period, can the product be sold on or after the date (June 1, 2025) of five years from the enforcement date?	<p>The amended Food Sanitation Act is not applied to UCPs being actually sold, manufactured, imported or used in business at point of the enforcement of the Act Partially Amending the Food Sanitation Act, Etc. (Act No. 46 of 2018; hereinafter referred to as "the Amendment Act") under Article 4 of the Supplementary Provisions of the Amendment Act.</p> <p>Therefore, when a product similar to a UCP being sold, manufactured, imported, or used in business since before June 1, 2020 is manufactured or imported during the transitional measures period, the product is judged to be manufactured using substances regarded as conforming to the PL System and can be sold or used in business on and after June 1, 2025.</p> <p>After the expiry date of the transitional measures period, even products similar to UCPs being sold, manufactured, imported or used in business since before the enforcement date cannot be manufactured or imported if substances as raw materials of synthetic resins used in the products are not listed in Appended Table 1. Procedures including filing an application are required to list such substances in Appended Table 1.</p>
24	<p><u>Specifications for bis(2-ethylhexyl) phthalate</u></p> <p>For synthetic resin UCP consists mainly of polyvinyl chloride (PVC) in which bis(2-ethylhexyl) phthalate is used as raw material, have regulations on such UCP changed with the issuance of the Public Notice of the MHLW No. 196, April 28, 2020: Matters on Partially Amendment to the Specifications and Standards for Foods, Food Additives, Etc.?</p>	<p>Regulations on such UCP have not changed. With the issuance of the Public Notice No. 196, Chapter III-A-7 of the Specifications and Standards for Food, Food Additives, Etc. was deleted. The specifications that were stipulated in Chapter III-A-7 have been stipulated in Table 2 of Appended Table 1 as the requirements for serial No. 1320 bis(2-ethylhexyl). The Appended Table 1 has been prepared pursuant to Chapter III-A-8, which was newly added with the issuance of the Public Notice No. 196.</p> <p>See the Notice 食基発 No. 0802001, August 2, 2002 for the details. (The Notice was issued as “食品、添加物等の規格基準の一部改正について。” Japanese text only.)</p> <p>https://www.mhlw.go.jp/web/t_doc?dataId=00ta6136&dataType=1&pageNo=1</p>
25	Which notice explains how to calculate the use amount of an additive in synthetic resin?	<p>Please refer to IV., 1., E. of the Notice Namashoku No. 0501-6, May 1, 2020: Preparations of related public notices following the enforcement of paragraph (3) of Article 18 of the Amended Food Sanitation Act amended by the Act Partially Amending the Food Sanitation Act, Etc.</p> <p>https://www.mhlw.go.jp/content/000651038.pdf</p>