Report by the Committee on the Regulation of Food Utensils, Containers and Packaging

June 16, 2017

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I. Introduction

In Japan, the safety of food utensils, containers and packaging (UCP) has been secured mainly by regulation by the national government and the voluntary management by trade organizations. Under regulation by the national government, the use of only substances with specifications and standards is restricted under the Food Sanitation Act (Act No. 233 of 1947).

However, regulations in Japan are based on the system of restricting the use of substances on which the government stipulates individual specifications and standards (Negative List system), which means the substances whose use is not permitted in foreign countries, such the European Union (EU) countries and the United States cannot be regulated immediately unless individual specifications and standards are set.

On the other hand, the EU countries and the United States apply a national system for the management of UCP that are made mainly of synthetic resins based on the mechanism of essentially prohibiting the use of substances other than those that have been approved for use as the result of a safety assessment (Positive List system). Also, in countries of Asia, management based on the Positive List system has been introduced or is being examined with introduction in view.

In light of recent developments including the diversification of products and an increase in imports, as well as global trends, Japan needs to examine the mechanism for ensuring the safety of UCP in Japan with an eye on the design of new institutional arrangements and other factors.

Consequently, the Ministry of Health, Labour and Welfare has investigated and examined the knowledge, technological advancements and other conditions in Japan and the rest of the world. These efforts resulted in the release in June 2015 of the “Interim Report by the Committee for Reviewing the Regulations on Food Utensils, Containers and Packaging.”

Based on these developments, the committee examined the vision of regulations and future direction of UCP in Japan after organizing the current conditions and challenges associated with UCP, sharing information on the situation in other countries, and hearing from trade organizations and business operators.

Ⅱ Current Situation and Challenges

1. Current situation in Japan

(Current system)

Article 3 of the Food Sanitation Act (the Act) stipulates that business operators engaged in the sale, etc. of UCP shall, at their own responsibility, endeavor to ensure the safety of raw materials, etc.

Article 15 of the Act stipulates that UCP used in business shall be clean and sanitary. Article 16 of the Act prohibits the sale, etc. of UCP which pose potential health hazard to humans including those that contain toxic or harmful substances. Article 18 of the Act prohibits the sale, etc. of UCP that do not comply with the established specifications and standards.

Business license based on the Act is not mandatory for business operators that engage in the sale, etc. of UCP in Japan. However, about one fourth of the local governments, including prefectures, cities in which public health centers are established and special districts, keep track of such business operators based on ordinances, etc.

The local governments provide supervision and guidance on UCP that are distributed inside the country, regardless of whether they are domestically produced or imported.

In line with Article 27 of the Act, a business operator importing UCP from other countries must submit, for each import, the information on whether the item comes under the utensil, container or packaging category and the material used in UCP to the Minister of Health, Labour and Welfare. For container and packaging items that hold food, the information on the material of packaging must be submitted. Regarding inspection at the time of import, necessary inspections are conducted (guidance inspection) at the time of the initial import after which other inspections are conducted as necessary (including monitoring inspection by the Quarantine Stations).

(Voluntary management of the industry)

In addition to regulations based on the Act outlined above, voluntary management by trade organizations are being implemented.

For instance, regarding thermoplastic synthetic resins, a list of substances approved for use has been drawn up based on voluntary standards set by the trade organizations following an assessment from the safety perspective. The list provides requirements on each approved substance regarding the content in or quantity added to the product, amount of migration into food (amount of elusion), purpose of use and other items. Also, business operators utilize the

“confirmation certification system,” under which certificates are issued by trade organizations when a product is found to comply with voluntary standards based on applications from member companies for each stage of handling from raw material to the end product. In addition, certain voluntary standards on hygiene control (voluntary standards on hygiene control) are established for flexible packaging materials that are made of thermoplastic synthetic resins, and a factory accreditation system based on these standards is in operation.

Each industry has its own voluntary measures based on the characteristics of the material used. As for thermosetting synthetic resins, trade organizations have developed voluntary standards, which designate a list of substances that can be used as raw materials. For metals, organizations established voluntary hygiene standards for coating agents and sealants used in canned foods. For paper, organizations established a list of chemical substances banned for use in manufacturing of paper.

(Current situation on UCP)

UCP are indispensable in the collection, manufacturing, processing, cooking, consumption, transportation, delivery, etc. of food. Also, UCP are expected to fulfill various roles and functions including sanitary conditions of UCP themselves, the preservation of quality of food, prevention of microbial contamination, extension of the period from manufacturing or processing date to the best-before date, enhanced convenience for consumers and reduction of environmental load. A wide range of products are being manufactured by combining various additives and other agents to accommodate these roles and functions.

The volume of shipment for all packaging materials decreased between 1995 and 2009, after which it picked up slightly. The proportion, by packaging materials, of paper, paper board and plastic products has increased in terms of shipping quantity. Imports of UCP in the past ten years expanded from 770,000 tons to 810,000 tons in weight, and from 210,000 to 520,000 in the number of import notifications.

2. Situation in other countries

(System in other countries)

In the United States, a Positive List system was established in 1958 for synthetic resins, paper and rubber products, which confined the chemical substances that can be used to those listed in the Code of Federal Regulations (CFR). For synthetic resins, the CFR prescribes the monomers and additives that can be used, as well as their content, etc. for each type of polymer. Also, the Food Contact Notification (FCN), a premarket notification for food contact substances,

was established in 2000, which limits their use to the notifier for each product, in order to accelerate the process of inclusion in the Positive List.

In the EU countries, a Positive List system was established for synthetic resins in 2010, under which limits on the elusion amount, use conditions, and other necessary matters are stipulated for each monomer and additive. Additionally, the system also regulates the total elusion amount of ingredients contained in the products and their materials.

Also, the issuance of “declaration of compliance,” which certifies the compliance of raw materials and products with the Positive List, is mandated. The declaration functions as a communication tool among business operators.

Also, in countries of Asia, the Positive List system has already been introduced in China, while the system is being examined with introduction in view in other countries including South Korea and Thailand.

(Response to imported products in other countries)

Regarding UCP products imported into the United States, importers may require, depending on the contract signed between business operators, the disclosure of information on material composition, or the submission of certification of compliance with the Positive List (a certificate of analysis by a third-party organization in many cases), an opinion letter or other documents prepared by a law firm.

As the issuance of declaration of compliance is mandated for imports into the EU countries, the availability of proper documents that support the declaration of compliance must be provided upon request from the authorities. The declaration of compliance must be submitted to the authorities as needed as it is not normally included in the documents to be submitted at the time of import. The name of substances intentionally used in the manufacture must be noted in the declaration of compliance, but when information disclosure is difficult for purposes of trade secret protection, there may be cases where certification is provided by a domestic third-party organization after compliance is verified from a neutral standpoint.

3. Issues in Japan

Since many of the UCP products are made of chemical substances such as synthetic resins, they must be manufactured and used properly by considering the toxicity of the substances used, impact of their elusion on humans and other factors.

Under the mechanisms adopted in other countries including the EU countries and the United States, the use of substances other than those whose safety has

been assessed is not permitted. However, substances that are not approved for use in the EU countries or the United States can be used in Japan under its regulatory mechanism, and such substances cannot be regulated immediately unless individual specifications and standards are set.

Although voluntary management by trade organizations have played a certain role in securing safety in the past, business operators that do not affiliate to any trade organization fall outside the framework of such measures. For this reason, there is a need to examine the desired shape of the regulatory system for safety assurance that encompasses such business operators as well as imports.

In light of these points, the introduction of a Positive List system should be examined by considering the institutions in other countries, voluntary standards of the industry and other elements.

The issues identified include the following:

- Formulation of basic policy and course of action on how to secure the safety of UCP in Japan
- In case of introducing the Positive List system, the UCP material (synthetic resins, metals, paper, ceramics, etc.) applicable to the Positive List system, types of substances (additives, etc.), methods of risk management, etc.
- The mechanism of information sharing among business operators, which is designed to guarantee that the raw material or product is compliant with the Positive List
- The mechanism that guarantees good manufacturing practice (GMP) including the management of raw materials, and creation and retention of records with the aim of supporting the functioning of Positive List system and enhancing measures for safety assurance by business operators
- Ideas on the supervision and guidance by local governments in case of introducing the Positive List system

III. Hearing from trade organizations and business operators

The committee conducted hearing from trade organizations and business operators to identify the current situation of the related industries for the examination of regulations on UCP.

Major comments and other information obtained by the interview surveys are as follows:

[Synthetic resins]

(Measures being taken)

- A list of substances approved for use by trade organizations, confirmation certification system and voluntary standards on GMP about equipment criteria, raw material selection criteria, etc. are established. A product registration system is established for recycled materials.
- Manufacturers select raw materials appropriately by obtaining information on the substances after concluding a non-disclosure agreement and acquiring a confirmation certificate, certificate of analysis or other documents in addition to utilizing voluntary standards set by trade organizations. Their exercise of GMP is based on International Organization for Standardization (ISO) standards, etc. and hygiene controls that respond to the different needs of manufacturers of food products, etc.
- Confirmation certificate, certificate of analysis and other documents that verify compliance, in addition to restrictions of use, etc., are provided to manufacturers of food products, etc. A mark that indicates compliance with the list of substances approved for use may be stamped on the product.

(Major comments)

- The current voluntary regulations established by the trade organizations have contributed to the assurance of safety by developing a list of restrictions on resin composition and the volume of additives, transferring information by considering the protection of corporate secrets and other means. These regulations should be utilized.
- Measures on GMP, which vary among different business operators, should be standardized by notifying the voluntary management guidelines.
- The assessment, permission and authorization of substances should be carried out promptly.
- The burden of business operators should be minimized.

[Paper]

(Measures being taken)

- Trade organizations apply voluntary standards for paper and paper board that are designed to come in contact with food. They apply a list of substances that cannot be used for manufacturing and voluntary specifications involving the elusion amount of heavy metals. Also, they conduct periodic surveys on the condition of contamination by unintentional additives that are contained in or elute from paper.
- Trade organizations promote measures that include the registration of substances with a track record on their database and organization of substances by classifying them according to purpose and method of use.

(Major comments)

- A Positive List system that enables the sharing of information not only among members of the trade organization but also within the supply chain should be introduced to promote better communication.

[Metals]

(Measures being taken)

- Trade organizations apply hygiene test methods established by themselves and a list of substances approved for use as coating agents or sealants for canned foods.
- Manufacturers use substances listed in trade organizations' voluntary standards in the manufacturing of coating agents and sealants, and refer to the Japanese Industrial Standards for metal materials.

(Major comments)

- The current voluntary restraints and restraints similar to those in the United States should be continued for the establishment of a Positive List system for synthetic resins.
- Considering that a Negative List system for heavy metals has been introduced under the Act for metal materials used in cans, continuing the Negative List system-based management would be desirable.

[Silicone rubbers]

(Measures being taken)

- Trade organizations apply a list of substances approved for use for silicone rubbers that come in contact with food.
- In addition to the utilization of voluntary standards set by trade organizations, manufacturers provide Positive List compliance certificates in the United States and Germany or confirmation certificates issued by the Japan Hygienic Olefin and Styrene Plastics Association for silicones and related products used as an additive for synthetic resins.

(Major comments)

- Since management by elusion amount is expected to require enormous effort and time, management by the volume of additives would be more desirable.
- There is a need to guarantee trade secrets on the substances used and

exercise safety management not only for trade organization members but also by the entire supply chain.

[Manufacturers of food products, etc.]

(Measures being taken)

- When business operators procure UCP, there are cases that they cannot obtain information on their raw material composition, in which case they confirm safety by specifications, hygiene certification, confirmation certificates or other documents. Also, they conduct inspections on products including imported items and quality assessment with considerations to food and container/packaging combinations.

(Major comments)

- A system that supports rational judgment on the amount of elusion into food and that avoids barriers to improvement and development of container/packaging should be introduced.
- Transfer of information on compliance from UCP manufacturers to manufacturers of food products, etc. should be mandated. A mechanism that can be managed by small- and medium-scale business operators, including ensuring consistency among items listed in certificates, is necessary. Also, an analysis method to verify compliance should be in place.
- Efforts to disseminate and spread knowledge on regulations should be made in other countries to facilitate the management of imported products in the same way as domestic products.

IV. Management system

1. Basic concept (Regulation and course of action)

In Japan, the safety of UCP has been secured mainly by regulation by the national government and the voluntary management by trade organizations. Under regulation by the national government, the use of only substances with specifications and standards is restricted.

In light of the diversification of products, an increase in imports and other moves in recent years, Japan's UCP system should be founded on the policy of essentially banning all substances except those that have been approved for use by way of safety assessment (Positive List system) to secure and improve the safety of UCP. Also,

(1) The government needs to set common rules to ensure the safety of the entire UCP binding all people including non-members of trade organizations

(2) Japan needs to ensure consistency with global trends on the UCP system to secure the safety of all UCP including imported products at levels on a par with other countries. This is because management of UCP in other countries including those in the EU countries and the United States is based on the mechanism of essentially prohibiting the use of all substances except those that have been approved for use by way of safety assessment (Positive List system).

In this regard, Japan needs to study the institutional necessity for each material, prioritize the issues and gradually adopt the new system based on the properties of materials and situation in other countries.

In the design of specific frameworks, Japan needs to make substantial efforts to collect and analyze information on substances, etc. approved for use in other countries including the EU countries and the United States and to achieve consistency with global trends so that the mechanism may be utilized as common rules for import and export.

Also, considering the current situation where voluntary management by trade organizations have worked to ensure safety, specific frameworks should be examined with reference to the measures adopted by such organizations.

2. Specific frameworks

(1) Materials to which the Positive List system should apply

The introduction of the Positive List system should start with synthetic resins. Points to note regarding materials subject to the system include:

- The material is widely used in UCP
- There is a possibility that the addition of additives, etc. to the material results in the elution of various substances
- The material is managed under the Positive List system in other countries including the EU countries and the United States
- In Japan, voluntary management by trade organizations based on the list of substances approved for use have become established to a certain degree and played a certain role in safety assurance.

Also, sufficient considerations should be given to the period and policy of system introduction for thermosetting resins based on the situation in other countries, condition of voluntary management by trade organizations, and other factors.

With regard to products that are made of a combination of synthetic resins and other materials, they should be covered by the Positive List system if synthetic resins are used in sections that come in contact with food.

The examination of necessities and priorities should be continued for materials other than synthetic resins including metals, paper, printing inks and adhesives with an eye on:

- The need to launch safety assurance measures based on the type and scale of potential risks for each material
- The need to identify the current situation in Japan and other countries

(2) Scope of substances subject to risk management, method of risk management, etc.

(Scope of substances subject to risk management)

When a decision is made that the Positive List system targets synthetic resins, because various substances are used in synthetic resins, the extent of regulation should be examined for monomers, base polymers, additives and other agents.

More detailed studies will be required in future on the coverage of substances subject to risk management based on the situation in other countries, condition of voluntary management by trade organizations, and other factors.

(Method of risk management)

When a decision is made that the Positive List system targets synthetic resins, further technological studies on risk management method are required from the viewpoint of:

- Risk assessment based on the extent of elusion into food, data on toxicity and other attributes
- Establishment of maximum volume and method of use that consider elusion into food based on risk assessment
- Method of verifying the compliance of raw materials and products in each stage of distribution

In doing so, the concrete mechanism should be examined by considering specific risk management methods that include management by the amount of migration (elution amount) into food as exercised in the EU countries, management by the product content (amount added) as adopted in the United States and measures launched by trade organizations in Japan, with an eye on achieving consistency with global trends and actual conditions in Japan.

In both the EU countries and the United States, toxicity assessment according to dietary concentration is conducted as risk assessment for inclusion in the Positive List.

The United States has the mechanism of Food Contact Notification (FCN), a premarket notification system for food contact substances, which limits their use to the notifier for each product. There is a need to sort out the ideas on such mechanisms.

(Parts subject to the Positive List system coverage)

When a decision is made that the Positive List system targets synthetic resins, synthetic resins used for parts that come in contact with food should be covered by the system. Also, layers other than food-contact surfaces in multi-layered products should be subject to the Positive List system if components of the layers are likely to migrate into food.

For products that are processed in ways that prevent the elution, leaching and migration of the substance used into food, their handling should be examined based on the judgment criteria that precludes the possibility of migration, risk assessment method, consistency with global trends and other factors.

(Risk assessment)

While risk assessment is conducted by the Food Safety Commission of Japan, consistency with global trends should be considered for the assessment method and data required for assessment. Risk assessment is an extremely important element in including a substance in the Positive List. A rational and scientific risk assessment method that is consistent with global trends should be established urgently. As the number of candidates for prospective inclusion in the list is expected to be substantial, that process would enable the risk assessment of such substances within a certain period of time.

(Others)

As for substances that are currently used, considerations should be made to allow their continued use, provided that certain requirements (for instance, the substance is listed in the Positive List of a country outside Japan or its use is permitted in trade organization’s voluntary standards and its safety is ensured) are met, given the traditional use of various substances in UCP and the absence of serious health damages reported.

Existing risk management methods should be maintained for substances with significant toxicity such as heavy metals, unintentionally generated impurities, reaction products and others.

(3) Details on the mechanism of information sharing among business operators

The act of UCP manufacturers to confirm that the raw materials comply with the Positive List, when they procure and use raw materials, should be regarded as part of manufacturing practice.

The mechanism should enable manufacturers of raw materials to provide appropriate information required for the manufacturing of products that comply with the Positive List upon a request from UCP manufacturers.

In doing so, the focus should be placed on encouraging the utilization of conventional frameworks including authentication by a third-party organization and agreements among business operators while taking the protection of trade secrets into consideration.

Also, the mechanism should be designed to enable the provision of necessary information from manufacturers of UCP to distributors of UCP so that UCP distributors or business operators that manufacture food products using the UCP are able to ensure that the product complies with the Positive List.

Specifically, the mechanism should be designed to enable UCP manufacturers to verify the compliance of their own products and provide the necessary information to UCP distributors by referring to the mechanism of declaration of compliance in the EU countries, confirmation certification system by trade organizations in Japan, and other means.

Also, measures to support the utilization of verification, etc. by a third-party organization should be examined to enable the smooth operation of such mechanisms.

(4) Details on the mechanism that guarantees Good Manufacturing Practice (GMP)

In view of the importance of proper management of raw materials and prevention of contamination by unintended substances, etc., under the Positive List system, business operators that manufacture UCP made of materials subject to the Positive List system need to adopt the system of Good Manufacturing Practice (GMP) for these measures.

Also, business operators engaged in the manufacturing of UCP made of materials not subject to the Positive List system are also advised to promote voluntary measures for GMP.

During this process, environmental improvements should be executed, for example, including support for GMP in collaboration with trade organizations by utilizing the “voluntary management guideline” to be prepared by the Ministry of Health, Labour and Welfare, while giving sufficient considerations to small- and

medium-scale business operators.

Today, a number of large-scale business operators have acquired quality management certifications such as the ISO. These private certifications may also be utilized to promote measures under this mechanism.

(5) Identity information on business operators and supervision/guidance by local governments

The current Act does not have a mechanism for local governments to ensure the identity of UCP manufacturers. Since inspection of all substances is not realistic under the Positive List system, an effective approach for supervision and guidance would be to check whether proper raw materials are used and whether the business operators are taking steps to confirm safety.

A mechanism based on notification, etc. is required to enable local governments to ensure the identity of UCP manufacturers.

Supervision and guidance by local governments should be provided to the UCP manufacturers based on information obtained on identity and production management.

As for supervision and guidance through product inspection, etc., inspections should be prioritized by giving priority to the inspection of materials with significant toxicity such as heavy metals, while paying attention to ongoing regulations, inspection technology, personnel and other factors.

(6) Others

From the perspective of ensuring the safety of UCP items in distribution in Japan, the Positive List system should be applied to importers, etc. for imported products in the same way as for domestic products. Also, the method of verification at the time of import should be examined with reference to mechanisms, etc. in other countries.

V. Challenges for the future

Examinations should be made on steps including the promotion of voluntary measures that would make it easier for business operators and consumers who use UCP to check an item’s compliance with the Positive List system.

Regarding the introduction of Positive List system and making GMP mandatory, efforts to maximize efficiency should be made while considering the potential increase in the burden of business operators in terms of paperwork.

Also, a preparatory period of sufficient length should be set as part of considerations to small- and medium-scale business operators.

Moreover, efforts for dissemination should be launched through risk communication, etc. for business operators and consumers prior to the introduction of the Positive List system. Information should be provided proactively through various opportunities, in particular, to small- and medium-scale business operators in Japan, manufacturers in other countries, importers, etc. so that they are able to obtain the necessary information accurately.

Measures to ensure safety should be examined regarding the handling of recycled materials based on the guideline of the Ministry of Health, Labour and Welfare, voluntary standards of trade organizations and situation in other countries.

Measures to ensure safety should be examined regarding the handling of active substances designed to sustain, improve or otherwise alter the condition of food, intelligent substances armed with functions to monitor the condition of packaged food, and nano substances based on the situation in Japan and other countries.

The specifications and standards for UCP stipulated in the Ministerial Ordinance on Milk and Milk products Concerning Compositional Standards, etc. should be integrated with the specifications and standards for other UCP at the time of the introduction of the Positive List system.

[Major Developments of the Committee]

August 23, 2016	Session 1	Explanation of the current situation of UCP in Japan and other countries; Organization of major points at issue
September 30, 2016	Session 2	Hearing from trade organizations and discussions
November 1, 2016	Session 3	Hearing from trade organizations and discussions
December 13, 2016	Session 4	Hearing from trade organizations and discussions
January 17, 2017	Session 5	Hearing from trade organizations and discussions
February 8, 2017	Session 6	Hearing from trade organizations and discussions
March 1, 2017	Session 7	Discussion on the outline of a drafted report
From March 17 to April 15, 2017	Calls for public comments on the drafted report	
May 25, 2017	Session 8	Hearing from trade organizations and discussions on the finalized draft report
June 16, 2017	Announcement of the final report	

[List of members] (in Japanese alphabetical order; honorifics omitted)

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Kazuo Onitake	Head of Unit, Safety Policy Service, Japanese Consumers' Co-operative Union
Kazuya Ono	Chairman of Senior Technical Committee, Japan Association of Milk Packaging and Machinery (general incorporated association)
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◎: Chair ○: Acting chair