English version

Interim Report

June 2015

Committee for
Reviewing the Regulations on Food Utensils, Containers and Packaging

1. Introduction

Japan regulates food utensils, containers and packaging (UCP) based on specifications and standards established under Article 18 of the Food Sanitation Act (Act No. 233 of 1947, hereinafter referred to as “the Act”). The current regulations in Japan, however, different from those in the European Union and the United States, which are based on a positive list (PL), and are inconsistent with the international trend.

In line with that, the Committee for Reviewing the Regulations on Food Utensils, Containers and Packaging has been formed to investigate the domestic and overseas knowledge and technological advancement and to give consideration to the designing of new regulatory systems for UCP.

The Committee has deliberated on what a desirable regulatory system should be, including the introduction of a PL system and its legislation. However, smooth introduction of a PL system postulates environmental improvements, such as establishment of evaluation methods and operation systems in Japan and the gathering of a broad range of information on raw materials used in UCP. Needless to say, there are many issues involved with legislation, and the reviewing of them alone requires time.

The Interim Report summarizes the issues towards introduction of a PL system and immediate measures that are considered practicable and important.

2. Background of Review

In Japan, no major health hazards associated with UCP have occurred thanks to the contribution by the UCP industry to secure the product safety through production management, in addition to the legal regulations for assessing substances identified to have safety risk and setting specifications and standards for them.

However, contrary to the European Union and the United States where a PL system is

applied to chemical substances used in UCP, Japan has not officially introduced a PL system. Therefore, Japan cannot immediately enforce regulations when a chemical substance that is banned from use in other countries is used in UCP in Japan or imported. To regulate the use of chemical substances with safety risk under the current legal systems, legal actions are required, including the setting of specifications and standards through data collection, assessment by the Food Safety Commission of Japan, and deliberations by the Pharmaceutical Affairs and Food Sanitation Council.

Under such a situation, the Committee investigated the actual regulatory situation in the European Union and the United States and the contents of production management by the industry groups in Japan and deliberated on how chemical substances used in UCP should be controlled.

3. Regulatory Situation of Food Utensils, Containers and Packaging

(1) Current situation in Japan

Article 3 of the Act stipulates that UCP business operators and food business operators (hereinafter referred to as “business operators”) shall, on 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 stipulates that any UCP which involves a risk to human health, for instance, containing toxic or harmful substances, shall not be sold, or used for commercial purposes. Article 18 of the Act stipulates that any UCP which does not conform to the general specifications (e.g., regulations on the use of colorants, ban on the use of bis (2-ethylhexyl) phthalate for oily and fatty food) and material-specific specifications (e.g., those for synthetic resins (15 types), glass, rubber) shall not be sold.

Regarding synthetic resins, which are often used in UCP, specifications applicable to all resins (material tests for cadmium and lead, migration tests for heavy metals and potassium permanganate consumed) and individual specifications for testing depending on the property of the resin (e.g., migration tests for phenol in phenol resin) are established (see Reference 1).

Regarding thermoplastic resins, there are voluntary standards and a certification system (the system to approve the compliance with the voluntary standards*) established by the three trade organizations (the Japan Hygienic Olefin and Styrene Plastics Association, the Japan Hygienic PVC Association and the Japan

Hygienic Association of Vinylidene Chloride: hereafter referred to as the “Three Hygienic Associations”).

** A system where each of the Three Hygienic Associations summarizes various requirements of UCP and raw material synthetic resins, additives, etc. (e.g., polyolefin) into the voluntary standards, and a certificate is issued when the compliance with the voluntary standards is confirmed in each step from raw material to final articles according to the members’ request.*

Excerpt from Food Sanitation Act (Act No. 233 of 1947)

(Responsibility of food business operators)
Article 3

(1) A food business operator (meaning a person or juridical person who is engaged in collecting, producing, importing, processing, cooking, storing, transporting, or selling food or additives, or producing, importing, or selling utensils, containers or packaging, or a person or juridical person who provides food to many and unspecified persons on an ongoing basis at schools, hospitals or other facilities; the same shall apply hereinafter) shall, on his/her own responsibility, endeavor to ensure the safety of the food, additives, utensils, containers or packaging which he/she collects, produces, imports, processes, cooks, stores, transports, sells, provides to many and unspecified persons, or uses in business (hereinafter referred to as "food for sale, etc."), and for that purpose, he/she shall endeavor to obtain the knowledge and technologies necessary to ensure the safety of food for sale, etc., conduct voluntary inspections of food for sale, etc., and take other necessary measures.

(2) A food business operator shall endeavor to make a record of any necessary information such as the name of a person who has sold food for sale, etc. or the raw materials thereof to said food business operator and retain such record, within the limit necessary for preventing food sanitation hazards resulting from food for sale, etc.

(3) In order to prevent food sanitation hazards resulting from food for sale, etc., a food business operator shall endeavor to take any necessary measures appropriately and immediately, such as the provision of a record prescribed in the preceding paragraph to the State or prefectures, etc. and the disposal of the food for sale, etc. which had caused the food sanitation hazards.

(Principle of treatment for utensils, containers and packaging used in business)
Article 15

Utensils, containers and packaging used in business shall be clean and sanitary.

(Ban of sales, etc. of toxic or harmful Utensils, containers and packaging)
Article 16

Any utensil, container or packaging which contains or bears toxic or harmful substances and involves a risk to human health, or any utensil, container or

packaging which touches food or additives and has a harmful effect on them and involves a risk to human health shall not be sold, nor be produced or imported for the purpose of marketing, nor be used in business.

(Establishment of specifications and standards of utensils, containers and packaging)
Article 18

(1) From the viewpoint of public health, the Minister of Health, Labour and Welfare may establish specifications for the utensils, containers and packaging, or the raw materials thereof to serve for the purpose of marketing or to be used in business, or establish the standards for the production methods thereof, by hearing the opinions of the Pharmaceutical Affairs and Food Sanitation Council.

(2) When the specifications or standards have been established pursuant to the provisions of the preceding paragraph, any utensils, container or packaging which does not conform to such specifications shall not be sold, nor be produced or imported for the purpose of marketing, nor be used in business; raw materials which do not conform to such specifications shall not be used; and any container or packaging shall not be produced by methods that do not conform to such standards.

(2) Current situation in other countries

In the United States, a PL system was established in 1958 for synthetic resin, paper and rubber products, where only the chemical substances listed in the Code of Federal Regulations (CFR) can be used. For synthetic resins, usable monomers and additives, and their content are specified for each polymer type. Additionally, in 2000, the Food Contact Notification (FCN) was established to allow for the use only by the applicant for each individual product, in order to accelerate the process of accreditation.

In the European Union, a PL system was established for synthetic resins in 2010, where the acceptable migration amount, use conditions, and other important matters are stipulated for each monomer and additive. Additionally, there is a regulation on the total migration amount for the ingredients that constitute products and their materials.

In China, a PL system was established for synthetic resins and rubber in 1988. In 2014, measures to enhance the PL system were presented, and China has since been actively promoting legislation of the system.

ASEAN countries and South Korea, which have similar regulations to Japan, are interested in deliberations on a PL system that are taking place in Japan.

4. Summary of Issues pertaining to Regulations

Large majorities of UCP are manufactured from chemical substances such as synthetic resins, and therefore UCP must be properly manufactured and used taking into account the impact of materials used on human health associated with their toxicity or migration into food. In the European Union and the United States, a PL system is created after assessing the properties of chemical substances used in UCP, and the types and contents of usable chemical substances are specified.

In Japan, while a PL system is not adopted by the Act, the Three Hygienic Associations have created and operated PLs as voluntary initiatives. And it is necessary to deliberate on measures to enable business operators who are not members of the Three Hygienic Associations to carry out proper risk management. In addition, it has become necessary to give considerations to risk management of imported products as well as home manufactured products.

To that end, it is desirable to review the system towards the establishment of PL, taking into account the existing systems in other countries and the voluntary standards of the industry. The legislation of the PL system may have the following issues.

(a) Chemical substances that shall be subject to risk management

On creating PL, there is a necessity to stipulate the types of usable chemical substances subject to risk management and their contents in products, taking into account their toxicity and migration into food. However, information on necessary matters, including the types and toxicity of chemical substances used in UCP, has not yet been gathered comprehensively.

(b) Information exchange among companies

In many cases, companies manufacturing raw materials (upstream companies) are different from companies manufacturing the finished products (downstream companies), and many downstream companies are small- and medium-sized enterprises. Therefore, in order for a UCP manufacturer to confirm the product safety, there is a necessity for the information (e.g., names and amounts of ingredients used) on raw materials and chemical substances used at each company to be properly transmitted from upstream companies to downstream companies (see the top row of Reference 2).

(c) Proper production management by business operators and ensuring effective implementation

Since various chemical substances are used in the manufacturing of UCP, it is necessary for business operators to thoroughly implement proper production management, including not only proper planning for the types and quantities of substances used, based on the safety of raw materials of UCP and the amount of migration into food of chemical substances used for UCP, but also the prevention of contamination by unintended substances. Additionally, in order to realize proper implementation of such production management, there will be a necessity for the administrative bodies to confirm that management is appropriately implemented.

5. Responding to Issues and Considerations

(1) Chemical substances to be subject to risk management

It is necessary to gather and summarize a broad range of information on chemical substances used in Japan and in other countries taking into account the implementation status of PL systems in other countries, for the purpose of helping

business operators to voluntarily confirm the safety of raw materials and for the purpose of considering the establishment of the future system.

For that, it is necessary for the Ministry of Health, Labour and Welfare (MHLW) to compile a list of chemical substances subject to the voluntary standards of the Three Hygienic Associations, and to gather information on other countries and on the business operators that are not affiliated to the three Hygienic Associations.

In implementing proper risk management, there is a necessity to gather and scrutinize information that will be required for scientific evaluation of substances subject to risk management, and to define the range of necessary information so that information collection can be effectively carried out.

There are two methods for risk management: a method based on the amount of migration of substances into food and a method based on the content of substances in the product. Management by the content is considered practical as a management method by business operators. Meanwhile, it is essential to know the maximum migration amount for the safety assessment of substances, and it is important to review methods to ensure that information on the migration amount is gathered.

There were specific opinions on the desirable PL system, which requires further deliberations.

- While risk management should cover various materials including synthetic resins, paper, rubber, metals, glass, the focus should be placed first on synthetic resins that are widely used (see the bottom row of Reference 2).
- Some monomers are hazardous; they should be listed.
- Substances used for manufacturing polymers (polymerization aids, such as catalysts) are generally used in extremely small amounts, and they may be excluded from the subjects in principle and be handled individually as necessary.
- While additives should be subject to risk management in principle, there is a shortage of information on colorants, adhesives, coating agents and printing inks. Considering that the EU is to review regulations on these substances, information on them should continue to be gathered to review whether they should be listed as necessary.

- While there is a possibility for additives to undergo chemical reactions and

transform into unintentional products during manufacturing process, generation of unintentional products is case-dependent and they should not be included as the subjects. Considerations should be given instead on measures to ensure the product safety, for instance, regulating the maximum allowed concentrations of additives and amount of residue on evaporation, as necessary.

- The types and maximum allowed concentrations of additives should be specified for each type of resin. Furthermore, if the migration amount can be converted to the content, considerations shall be given on regulating both the migration amount and the content. In this case, there is a necessity to consider the conversion method for each type of resin.
- Considerations should be given to handling of thermosetting resins, since information on chemical substances used in them is insufficient.

(2) Information exchange among companies

In order for UCP manufacturers to ensure product safety, there is a necessity to properly transmit information on chemical substances used in their products, while protecting trade secrets.

To that end, UCP business operators may conclude an agreement, for instance, on the provision of information on purchasing of raw materials from raw material business operators. As a method to transmit the safety information of raw materials while protecting trade secrets, a method utilizing the certification system of the Three Hygienic Associations may be used (see Reference 3).

(3) Proper production management by business operators and ensuring effective implementation

In order to implement proper production management and to ensure its effective implementation, it is important that each business operator carries out proper production management including management of raw materials used, development of procedural manuals and retention of records. It also is important that the administrative bodies correctly learn the activities implemented by business operators concerning production management.

In order to further promote such production management, administrative bodies may present guidelines on matters that business operators should work on.

Development of analysis methods for commonly used additives and additives with

safety concerns based on the latest international standards may enable effective testing.

Regarding the handling of imported products, it is necessary to consider formulating a system to ensure effective implementation, such as requesting importers to submit test results that allow for objective assessment.

(4) Other

It is necessary to learn some information necessary to help design a regulatory system for UCP in Japan. Specifically, the information includes other countries' information (how other countries operate their own PL Systems and how they handle UCP imported into the countries) as well as domestic information (the migration of ingredients from UCP, the scale of individual business operators and the total number of the operators, risk management carried out for home-manufactured and imported products, and how member business operators the Three Hygienic Associations carry out risk management of their products) and voluntary activities conducted by Japanese business operators to ensure product safety .

If a PL System is introduced, there will be a necessity to give proper considerations on the protection of trade secrets. Since the system will not allow the use of substances until they are listed, there will be a necessity to pay attention for the system not to pose a disadvantage in the marketing of new products.

6. Immediate Measures

Reviewing the legal systems towards introduction of PL is desirable as a measure to ensure the safety of UCP. However, as described above, there are many issues including, for example, the fact that sufficient information on the raw materials of UCP is not available. Therefore, it is considered advisable to revise the current specifications and standards and newly establish specifications and standards for synthetic resins in response to technological advancement in UCP, and to promote the measures below in the view of introducing a PL system in the future.

(a) Deliberate on the formulation of guidelines for production management related to production management methods and information transmission for the purpose of further promoting production management by business operators. The guidelines should include provisions for the use of raw materials deemed safe by business operators through proper assessment methods, the creation of procedural manuals and the retention of records. As information useful for

production management, it is advisable for the MHLW to compile a list of chemical substances subject to the voluntary standards by the Three Hygienic Associations and attach it to the guidelines as a reference.

(b) Collect and summarize domestic and overseas information on the chemical substances to be subject to risk management, including systems in other countries, facts on the use of them in raw materials of UCP, information on relevant business operators and the activities implemented by the business operators.

(c) Develop simplified methods to determine the amount of migration into food of chemical substances used in UCP and define the range of data necessary for scientific evaluation to enable proper assessment of human health impacts.

(d) Promote the development of simultaneous analysis methods for commonly used additives and additives of safety concerns, in order to effectively and efficiently implement proper production management.

Members of Committee

	Name	Post
	Hiroshi AKIYAMA	Head, Division of Foods, National Institute of Health Sciences
	Yukihiro GODA	Head, Division of Drugs, National Institute of Health Sciences
	Kazuhiko TAKEUCHI	Research Institute for Chemical Process Technology, The National Institute of Advanced Industrial Science and Technology
	Hiroyuki NAKAZAWA	Professor Emeritus of Hoshi university
	Nobuhumi Nakamura	Department of Biotechnology and Life Science, Tokyo University of Agriculture and Technology Professor
	Toshiyuki HAYAKAWA	Safety Policy Service, Japanese Consumers' Co-operative Union
○	Akihiko HIROSE	Director, Division of Risk Assessment, National Institute of Health Sciences
	Masakazu HORIE	Department of Food Science, Faculty of Home Economics, Otsuma Women's University
	Motoh MUTSUGA	Section Chief, Division of Food-Additives, National Institute of Health Sciences

○ Chairman

Dates of the committee meetings held

1st: July 24, 2012
2nd: March 26, 2013
3rd: June 26, 2013
4th: March 12, 2014
5th: June 26, 2014
6th: December 18, 2014
7th: January 29, 2015
8th: March 11, 2015

【Reference1】Specifications and Standards for UCP Made from Synthetic Resins

		Material Test[1]	Migration Test[2]
General Specifications		Cd, Pb	Heavy metal, $KMnO_4$ consumption
Individual Specifications	Phenol	—	Phenol, Formaldehyde, Evaporation residue
	Melamine	—	Phenol, Formaldehyde, Evaporation residue
	Urea resin	—	Phenol, Formaldehyde, Evaporation residue
	Polyvinyl chloride	Dibutyltin compounds, Tricresol phosphate, Vinyl chloride	Evaporation residue
	Polyethylene	—	Evaporation residue
	Polypropylene	—	Evaporation residue
	Polystyrene	Volatile substance	Evaporation residue
	Polyvinylidene chloride	Barium, Vinylidene chloride	Evaporation residue
	Polyethylene terephthalate	—	Antimony, Germanium, Evaporation residue
	Polymethyl methacrylate	—	Methyl methacrylate, Evaporation residue
	Nylon	—	Caprolactam, Evaporation residue
	Polymethyl pentene	—	Evaporation residue
	Polycarbonate	Bisphenol A, Diphenyl carbonate, Amines	Bisphenol A, Evaporation residue
	Polyvinyl alcohol	—	Evaporation residue
	Polylactic acid	—	Total lactic acid, Evaporation residue

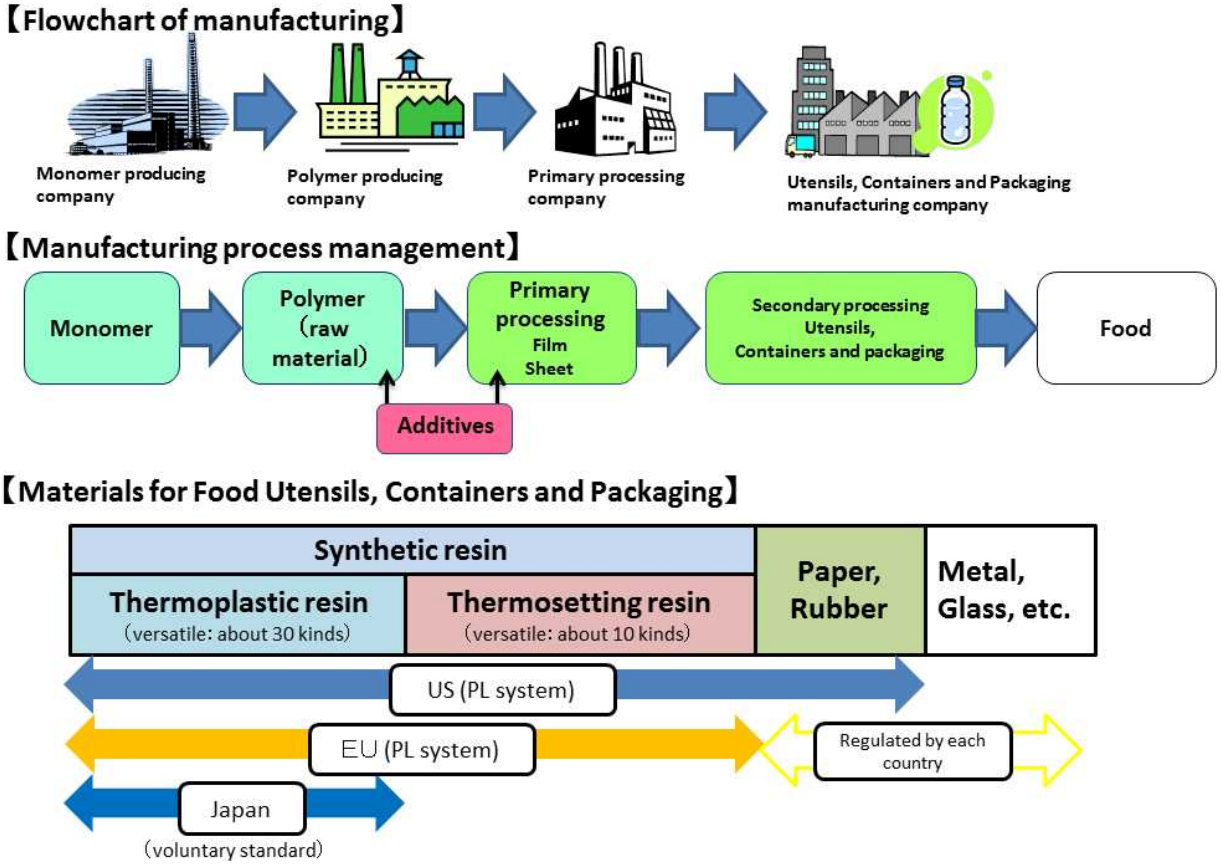
Note

1. The material test determines the total amount of a substance in the sample.
2. Migration test determines the total amount of a substance which migrates from the sample into the specified simulant under the specified conditions.

Specifications and standards are also established for synthetic resins made from formaldehyde.

Extract from *Specifications and Standards for Food and Food Additives, etc.* Ministry of Health and Welfare Notification No.370, December 1959)

【Reference 2】Current situation of Food Utensils, Containers and Packaging



【Reference3 】Certification system by Three Hygienic Associations