

Guideline for safety assurance in the manufacture etc. of food utensils, containers and packaging

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This document is the English translation of “食品用器具及び容器包装の製造等における安全性確保に関する指針（ガイドライン）.” The Ministry of Health, Labour and Welfare offers this translation as a service to a broad international audience/readers. While the ministry has attempted to obtain translation that is as faithful as possible to the Japanese version, we recognize that the translated version may not be as precise, clear, or complete as the original version. The official version of this document is the Japanese version.

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Chapter 1 General provisions

1. Purpose

The purpose of this guideline is to make clear the basic matters concerning manufacturing management, information sharing concerning the imported, distributed or used products and other activities that the business operators conduct by themselves for safety assurance of food utensils, containers and packaging (UCP) stipulated in the Food Sanitation Act (Act No. 233 of 1947, (Act)), Article 3, Section 1 and thus to promote voluntary management of the business operators.

2. Basic concept

With regard to UCP, standards are established in accordance with the Article 18 of the Act for safety assurance. However, further safety assurance is considered to be acquired by thoroughly conducting process control in each stage of manufacturing, import, distribution and usage in addition to complying with the standards.

Specifics include proper control of employees, facilities and equipment in manufacturing sites, etc, establishment of a cooperative structure to provide necessary and sufficient guarantee or to share information between the business operators with regard to the management activities of the business operators and the quality of products in each stage of the supply chains and insurance of traceability for identification of the causes, prevention of spread, etc. of the health damage in case of food sanitation incidents.

Based on such a concept, it is conceivable that a supply system of safer products will be ensured when the business operators engaged in manufacture of UCP have shared awareness and aim at thoroughness of control based on the actual situation, etc. of circulation of food, etc. under the responsibility of their own.

3. Scope of application

This guideline is applied to the business operators dealing with UCP who manufacture, import, distribute or use synthetic resin UCP or UCP whose food contact surfaces are processed with synthetic resin.

However, it is desirable that the business operators dealing with UCP made of other raw materials than synthetic resin also make effort to ensure further safety by correspondingly applying the activities stated in this guideline. In addition, it is expected that the manufacturing or distribution business operators of raw materials of UCP will cooperate with the manufacturing or distribution business operators of UCP for safety assurance.

4. Definition of terms

(1) Raw material

Raw material refers to the starting material, material, chemical agent or interim product procured from other business operators to be used in the manufacturing processes of each of the business operators.

(2) Product (final product, interim product)

Product refers to the final output of the manufacturing processes of each of the business operators.

The product of the final stage of manufacturing in condition usable in direct contact with food or in condition already in contact with food is termed as the final product. The product to be further processed or deformed by other business operators before becoming the final product is termed as the interim product.

(3) Traceability

Traceability refers to the capability of confirming the history of circulation of the objective products (or parts or raw materials thereof).

(4) Supply chain

Supply chain refers to the domestic and overseas route of supply for manufacturing of UCP including from raw materials to usage.

(5) Food chain

Food chain refers to a series of domestic and overseas route of supply of food and services including from production of agricultural and marine products to distribution of food.

(6) Hazard

Hazard refers to a biological, physical or chemical factor that may cause development of food sanitation-related harm attributable to contamination by harmful living things, microorganisms, dust or dirt, mixing-in of unintended substances, use or migration to food of chemical substances, raw material, etc. likely to cause health damages, use of final products not in conformity with the purpose or the intended range of application or to any other causes.

(7) Acceptable level

Acceptable level refers to a voluntary standard or specification established for the purpose to confirm or guarantee that the product manufactured, imported, distributed or used is appropriate for use for food, comprising of restrictions and limit values of kinds and amount of use, etc. of chemical substances contained in raw materials or manufactured products.

Chapter 2 Specific activities for safety assurance

For safety assurance of UCP by the voluntary management such as manufacturing management and information sharing, it is necessary that management systems based on the fourpoints of view i.e. 1) management of employees, facilities and equipment, 2) design and quality check of safe products, 3) seamless information sharing through the supply chains and 4) provision of countermeasures in case of occurrence of health hazards, etc. are properly established by the business operators who manufacture, import, distribute or use UCP based on the contents and scale of their businesses and on the grasped hazard and that such management systems are effectively and efficiently operated.

1. Management of employees, facilities and equipment

Business operators (or responsible persons) should provide necessary employees, facilities and equipment and should control the employees, specifics of work, facilities, equipment, etc. for proper manufacturing or usage of products so that contamination or quality deterioration is prevented during manufacturing, etc.

2. Design and quality check of safe products

With regard to the safety (or quality) of products, business operators (or responsible persons) should specify the extent (or contents) thereof that they can take responsibility for, execute the management appropriate to the extent (or contents) and confirm that the products to be shipped are safe (having appropriate quality for use for food).

To this end, control should be carried out so that products satisfying the acceptable level and ensuring safety are always supplied to the downstream business operators by setting the acceptable level and the management method to cope with the hazard contained in the products, designing the products and the manufacturing processes so as to satisfy the acceptable level and by checking the quality of products, etc.

3. Information sharing through supply chains

With regard to the safety (or quality) of products, business operators (or responsible persons) should correctly communicate with the downstream business operators the extent (or contents) of their responsibility and guarantee and, in cooperation with the upstream and downstream business operators within the supply chains and the food chains, should establish and maintain a frame that would make it possible to ensure information sharing concerning the hazard.

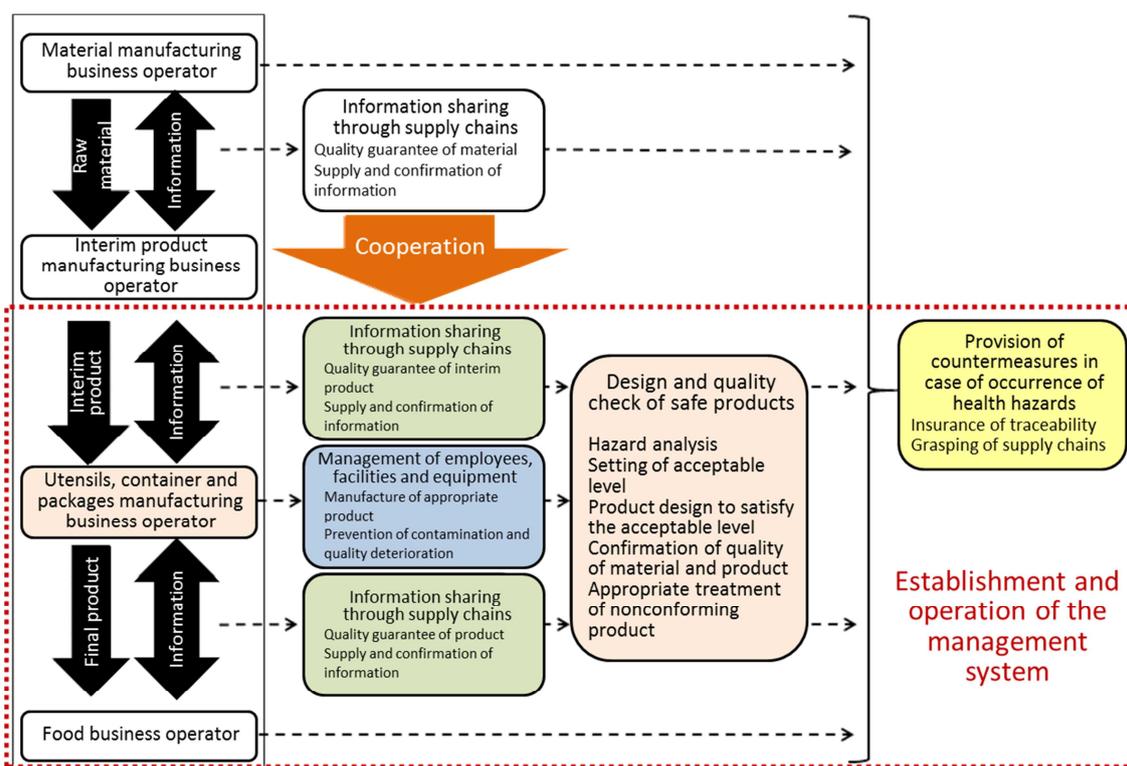
In particular, information exchange with the destinations of products (business operators in the downstream by one step) and suppliers of raw materials (business operators in the upstream by one step) is important. In addition, to make the information exchange ensured, it is necessary that the business

operators (or the responsible persons) grasp their own positions and roles in the supply chains and the food chains.

4. Provision of countermeasures in case of occurrence of health hazards, etc.

Business operators (or responsible persons) should secure the traceability and develop a framework which, in case of occurrence of health damage, food sanitation incidents or emergence of products not satisfying various requirements, etc., would make it possible to identify the business operator or the process causing the occurrence in every point of supply chains and food chains and to promptly distinguish and recover the products.

Chapter 3 Image diagram of activities for safety assurance (Manufacturing business operators as the main character)



Chapter 4 1. Specific examples of activities for safety assurance

Establishment and operation of the management system (general)

- Business operators should clarify and make the employees understand the policy of activities, the target and the responsibility-taking system relating to the safety of products.
- Business operators should provide employees, facilities and equipment necessary for implementation of the activities.
- Business operators or responsible persons should set up the specifics of activities, the efficient and effective methods and the procedure to review them and should review them at regular intervals.
- Business operators or responsible persons should record and retain the specifics of activities and the results in a verifiable fashion.
- Business operators or responsible persons should confirm that necessary activities are implemented also in the outsourced works.

(1) Management of employees, facilities and equipment (particular)

- Sanitary management and health management of the employees engaged in the work should be conducted.
- Buildings, facilities and utilities (air, water energy, etc.) should be of such structures that can prevent products from contamination by mixing-in of dust, dirt, microorganisms, etc. for adequate conditions to be maintained.
- Maintenance of clean working environment should be aimed at as well as adequately implementing cleaning, washing, maintenance and inspection of the facilities and equipment.
- Facilities, working spaces and sanitary equipment necessary for the employees engaged in the work should be arranged properly.
- Work procedures, requirements, etc. should be prepared and made understood by the employees engaged in the work for implementation of the work according to the work procedures, requirements, etc.
- Education and trainings should be implemented for the persons responsible for the management and the employees engaged in the work, and information and activities for safety assurance should be shared between the persons involved.

(2) Design and quality check of safe products (particular)

- Collected information on the hazard should be examined carefully and the hazard which require proper control should be identified.

- With regard to the hazard which require proper control, appropriate acceptable levels and control methods thereof should be set up respectively for the products.
- Raw materials suitable for manufacture of the products for use for food should be selected and used.
- It should be verified that the designed products and the manufacturing processes thereof are suitable for the products for use for food.
- It should be confirmed that the raw materials and manufactured products satisfy the set-up acceptable levels.
- Methods of treatment of products not satisfying the acceptable levels (nonconforming products), collected products, claims, etc. should be set up for the treatment to be done accordingly.

(3) Information sharing through supply chains (particular)

- A situation should be established where information sharing concerning the hazard (properties, components, historical trails of used raw materials or manufactured products, laws, regulations, etc. concerning food sanitation, restrictions and cautions for use when manufactured into the final products, etc.) is possible between business operators.
- The information on the purpose and method of use, etc. of the raw materials (or products) to be used should be shared with the upstream business operators in addition to that the information on the hazard, restrictions and cautions for use when manufactured into the final products, etc. concerning the received raw materials should be obtained from the upstream business operators.
- The information on the purpose and method of use, etc. of the manufactured products should be confirmed from the downstream business operators in addition to that the information on the hazard, restrictions and cautions for use when manufactured into the final products, etc. concerning the shipped products should be shared with the downstream business operators.
- In the case where change is made to the provided information, revision should be made without delay and be shared with the business operators concerned.
- Positions and roles in the supply chains and food chains should be recognized by each business operator.

(4) Provision of countermeasures in case of occurrence of health hazards (Building up of traceability) (particular)

- Information on the incoming raw material (name of supplying business operator, responsible person, product lot, date of manufacture, place of manufacture, date of arrival, etc.) and storage, usage and disposal of the raw material should be recorded and properly retained.

- Manufacture, storage, shipment or delivery, disposal, etc. of the product should be recorded and properly retained.
- Information on the shipped product (name of supplied business operator, responsible person, product lot, date of manufacture, place of manufacture, date of shipment, etc.) should be recorded and properly retained.
- When required, part of the used raw material or manufactured product should be retained.
- Method of treating the problems, when occurred, should be established and treatment should be done according to the established procedure.

Chapter 4 2. Points to note

Establishment and operation of the management system

- In response to the contents and scale of the business, specifics of activities and scope of activities should be planned and set up.
- Even the activities not shown in specific examples should be proactively approached when considered necessary for food safety assurance.
- Consideration should be given to the trade secrets between the business operators and request should not be made to other business operators more than is necessary.
- In the case where sufficient activities are already undertaken by individual business operators or industry groups by establishing voluntary standards or acquisition of international certifications, it is possible that such activities are undertaken in continuation.

(1) Management of employees, facilities and equipment

- Management and activities should be such that the products manufactured by the business operator and the methods of use by the downstream business operators, etc. are taken into consideration.

(2) Design and quality control of safe products

- Food business operators, import business operators and distribution business operators dealing with UCP should confirm that the traded products are suitable for use for food and should carry out the works of storage, distribution, usage, etc. in a sanitary manner so as not to spoil safety and the quality required for food.
- Taking the possibility of food sanitation risk caused by the hazard into consideration, necessity of management should be judged. In the case where it is judged that there is no necessity of management, the reason for the judgment should be recorded and retained.

- The acceptable levels and the management methods should be set up by the judgment of each business operator. It is possible to make reference to the application limit values, etc. set up by the industry groups or specified by laws or regulations in Europe or in the U. S.
- As the means to prove that the products satisfy the acceptable levels, it is conceivable to adopt the certification of confirmation, etc. issued by relevant industry groups such as quality certificates of relevant business operators, certificates of the third party organizations, etc. In addition, conceivable is creation of a situation where agreement is reached between the business operators as to the safety (or quality) of the products.
- If satisfaction of the above acceptable levels can be guaranteed, it is not especially necessary to carry out instrumental analyses, etc.
- Downstream business operators (mainly, the food business operators) should not make requests to upstream business operators more than is necessary (mainly, UCP business operators).
- With regard to the adequateness of imported raw materials or products for use for food, the business operators who import them should, in principle, be held responsible to confirm the adequateness based on the information shared from the business operators who export them. However, this statement does not apply when an agreement is concluded between the importing business operator and the exporting business operator by certificates or contracts and it is made clear that the accountability belongs to the exporting business operator.

(3) Information sharing through supply chains

- With regard to the part not covered by the management or guarantee concerning safety of products, information sharing should be thoroughly carried out between business operators to avoid differences of awareness by such means as to call attention of the others concerning latent hazards and efforts should be made so that safe final products are manufactured, imported, distributed and used.
- As the means of information sharing, use of specifications etc. made at the time of conclusion of contract between the business operators, quality certificates etc. received at the time of arrival of articles, certification of confirmation etc. of the industry groups is conceivable.
- Food business operators, import business operators and distribution business operators dealing with UCP should also recognize that they are taking partial charge of supply chains and food chains.

(4) Provision of countermeasures in case of occurrence of health hazards etc.

- Records of information should be made which allow identification (of the correlation between the lot of used raw material and the lot of manufactured product, etc.) shared not only between the business operators but also within the relevant business operator.