

**Revision of Specifications and Standards for Apparatus, Containers/Packages, Toys, and Detergents (Revision of Test Methods)**

**Purpose**

The Minister of Health, Labour and Welfare may establish specifications and standards for apparatus and containers/packages based on Article 18 Paragraph 1 of the Food Sanitation Law and for toys and detergents based on Article 11 Paragraph 1 in accordance with Article 62 Paragraphs 1 and 2. Where specifications and standards are established under the law, products that do not meet the standards or specifications are prohibited from being used or marketed.

This activity is to make the existing specifications (test methods and related requirements) meet the present scientific standards. The activity places importance on the replacement of harmful reagents and the improvement in analytical accuracy. This revision is based on a series of studies on the safety assurance of food apparatus and containers/packages, which were conducted between fiscals 2001 and 2003 in the Health Labour Science Research Program.

In response to consultation by the Minister of Health, Labour and Welfare, the Subcommittee on Apparatus and Containers/Packages under the Food Sanitation Committee under the Pharmaceutical Affairs and Food Sanitation Council has discussed the adequacy of the revision of the test methods for apparatus, containers/packages, toys, and detergents. The draft revised test methods are outlined in the attachment.

Attachment

**Summary**  
**Revision of Specifications and Standards**  
**on Apparatus, Containers/Packages, Toys, and Detergents**

**1. Specifications and standards on apparatus, containers/packages, toys, detergents**

The Food Sanitation Law regulates not only food but also food apparatus, containers/packages, toys for young children, and food detergents. The Food Sanitation Law defines “apparatus” as articles that are used for manufacturing, processing, consuming, or otherwise treating foods or food additives and that come in direct contact with the foods and food additives. It defines “container and package” as articles in which foods or food additives are contained or with which they are wrapped. For toys, the Law is applied to articles designated by the Minister of Health, Labour and Welfare as those that may pose health hazards to young children through direct contact with children. Toys include pacifiers, rattles, and building blocks. For detergents the law covers washing agents for vegetables, fruits, and eating utensils.

The Law specifies specifications and standards for apparatus, containers/packages, toys, and detergents in the Ministry of Health and Welfare Announcement, No. 370, December 28, 1959. The Announcement provides specifications and standards for apparatus, containers/packages roughly in five sections: General Specifications, General Test Methods, Specifications by Material, Specifications by Application, and Standards for Manufacturing. The Announcement also provides material specifications and manufacturing standards for toys, and compositional specifications and use standards for detergents.

**2. Outline of revision****A. Apparatus and containers/packages**

(1) Discontinuance of the use of harmful regents, including mercury and carbon tetrachloride

- Polarography as the quantitative method for metals, including lead and cadmium, will be completely removed to stop the use of mercury.
- The current arsenic test method will be modified to stop the use of mercury bromide test paper.
- In the tests of cresol ester phosphate and dibutyl tin compounds as additives for polyvinyl chloride, the extracting solvents will be changed from a mixture of carbon tetrachloride and methanol to a mixture of acetone and hexane for the dibutyl tin compounds test and to acetonitrile for the cresol ester phosphate test.

- In the test of vinylidene chloride as the monomer of polyvinylidene chloride, the extracting solvent will be changed from a mixture of carbon tetrachloride and tetrahydrofuran to N,N-dimethylacetamide
  - The current test of germanium as a catalyst for polyethylene terephthalate will be removed to stop the use of carbon tetrachloride. Instead, the use of both Atomic Absorption Spectrophotometry (AAS) and Inductively Coupled Plasma Atomic Emission Spectrometry (IPC-AES) will be enabled for the revised germanium test.
- (2) Improvement in analytical accuracy, such as the adoption of methods which have higher reproducibility
- The electrothermal type will be added to AAS in the General Test Methods since the current method only allows the flame type. This will make it possible to analyze metals, such as lead, cadmium, and antimony, with higher accuracy. The antimony test, which currently makes use of colorimetry, will be removed from the Additives Test Methods in the General Test Methods.
  - ICP-AES will be adopted as a metal test method in the General Test Methods and the individual sections in the Specifications by Material. This method is capable of determining plural metals at a time.
  - The capillary column will be adopted to heighten the resolution for the monomer tests in the General Test Methods. Also, operating conditions for the qualitative and quantitative tests will be changed.
  - The phenol test for plastics made of formaldehyde in the Specifications by Material will be changed from the bromine method to the 4-aminoantipyrine method.
  - The identification test method for dibutyl tin compounds in plastics made of polyvinyl chloride will be changed from paper chromatography to GC/MS (gas chromatography/mass spectrometry).
  - Hydrochloric acid treatment will be added to the preparation of the test solution in order to reduce the interference by barium and calcium in the tests of cadmium and lead in the Materials Tests, General Specification, Plastic Apparatus and Packages, Specifications by Material.
- (3) Addition of heavy metals tests, arsenic test, ICP-AES, and phenol test to the General Test Methods
- Heavy metals tests and arsenic test will be newly added to the General Test Methods. Currently, these tests are conducted using the methods specified for food additives in Announcement No. 370. In this activity the two tests will be established as those exclusively for apparatus and containers/packages and reagents used in these tests will be added.

- IPC-AES will be added. See section (2) above.
  - The phenol test (the 4-aminoantipyrine method) will be newly added in the Monomers Tests in the General Test Methods. This test is compiled and improved from the current phenol tests, which are individually specified at plural sections, including plastic and rubber apparatus containers/packages and metal cans.
- (4) Change of the leaching solutions used for apparatus and plastics made of formaldehyde (including both apparatus and containers/packages) in the residue on evaporation test.
- In the Residue on Evaporation Test Methods in the General Test Methods, the leaching solutions specified are different between apparatus and containers/packages. For container and packages, leaching solutions are specified by the type of foods intended to be contained in them by taking account of properties of the food. For example, *n*-heptan should be used for containers and packages for fat or oil, 20% ethanol for alcoholic products, 4% acetic acid for acidic foods, and water for other foods. However, for apparatus, only one leaching solution (4% acetic acid) is specified, regardless of use. The draft revised specifications specify more appropriate leaching solutions, which can correspond to the use of each apparatus. The similar change will be made in the residue on evaporation test for plastic products made of formaldehyde in the Specifications by Material. Currently, 4% acetic acid should be used as the leaching solution for these plastic products.
- (5) Clarification of limit values
- Limit values will be given in individual tests in order to clarify limitation. In some of the current tests, including the leaching tests for plastics, the determination of conformity with each specification is conducted by comparing with the standard solutions specified, and limit values are not given in individual tests. The draft revised specifications indicate the limit values to make it easy to understand specifications.
- (6) Use of methods equivalent or superior to the official methods
- The draft revised specifications enables the use of methods equivalent or superior in accuracy to the established official methods. The handling of other comparable methods is in accordance with the manner for food additives, which are specified in the same Announcement.  
The application of methods other than official methods follows the concept for the official test methods for food additives.
- (7) Other matters
- The way of the description of reagent names and test operations will align with the

Japan Industrial Standards.

- Other minor changes will be made to descriptions.

## B. Toys

### (1) Replacement of test methods making use of mercury

- The revised arsenic test for apparatus and containers/packages will be applied to toys. The current test is conducted using the method specified for food additives, which makes use of mercury bromide test paper
- Polarography as the test method of cadmium for polyvinyl chloride paints will be replaced with AAS and ICP-AES to stop the use of mercury.

(2) Application of the heavy metals tests, test of consumption of potassium permanganate, and residue on evaporation tests for apparatus and containers/packages to toys.

### (3) Clarification of limit values

- Limit values will be given in individual tests in order to clarify limitation. In some of the current tests, the determination of conformity with each specification is conducted by comparing with the standard solutions specified, and limit values are not given in individual tests. The draft revised specifications indicate the limit values to make it easy to understand specifications.

### (4) Use of methods comparable or superior to the official methods

- The draft revised specifications enables the use of methods equivalent or superior in accuracy to the established official methods. The handling of other comparable methods is in accordance with the manner for food additives, which are specified in the same Announcement.

## C. Detergents

The revised arsenic test for apparatus and containers/packages will be applied to detergents. The current test is conducted using the method specified for food additives, which makes use of mercury bromide test paper