Chapter III: Apparatus, Containers and Packaging

A. General Specifications for Apparatus, Containers and Packaging, and their Materials

1. Apparatus must NOT have a structure that might allow copper, lead, or their alloys to be scraped off the surface.
2. Tin which is electroplated onto the surface that will directly touch food must NOT contain more than 0.1 % of lead.
3. Any part of a food utensil, container, or packaging that will directly touch food must NOT be made or repaired using the metal containing more than 0.1 % of lead or 5 % or more of antimony.
4. Solder which is applied to make or repair any part of a food utensil, container, or packaging that will directly touch food must NOT contain more than 0.2 % of lead.
5. Apparatus, containers and packaging must NOT contain any chemically synthesized colorant other than those listed in Appended Table 1, the Ordinance for Enforcement of the Food Sanitation Act (Ordinance of the Ministry of Health and Welfare No. 23, 1948). Note that this requirement shall NOT apply to the case where the apparatus, container, or packaging is made to prevent artificial colorant from being eluted or seeping into food.
6. Apparatuswith a built-in device that passes an electric current directly through food must NOT use the electrodes made of metal other than iron, aluminum, platinum, and titanium. Note that if the electric current is very small, the use of stainless steel electrodes is acceptable.
7. For the apparatus, containers, and packaging that will directly touch the food containing oil and fat or high-fat products, the synthetic resins whose main component is polyvinyl chloride containing bis(2-ethylhexyl) phthalate must NOT be used as their raw material. Note that this requirement shall NOT apply to the case where the appratus, container, or packaging is made to prevent bis(2-ethylhexyl) phthalate from being eluted or seeping into food.
8. For the apparatus, containers, or packaging that are made of paper (which includes paper board; this applies to all the paper described in this section) and used for applications that will significantly increase their water/oil content, or for applications that will expose them to heat for a long time, waste paper must NOT be used as their raw material. Note that this requirement shall NOT apply to the case where the apparatus, container, or packaging is made to prevent the harmful substances contained in the paper material from being eluted or seeping into food.

B. General Limit Tests for Apparatus, Containers, or Packaging

The limit tests not listed below shall refer to *Chapter II: Additives, Section B*. General Limit Tests. If there is an alternative test to the specified test, and if the alternative test provides higher accuracy than the specified test, then that alternative test may be used. Note that if the results based on the alternative test are questionable, the final determination shall be made based on the specified test.

1. Potassium Permanganate Consumption Limit Test

The Potassium Permanganate Consumption Limit Test is a method to measure the amounts of substances contained in the sample by oxidizing them with potassium permanganate. These substances migrate from the sample to water when treated by a predetermined method.

Test Procedure

Put 100 ml of water, 5 ml of sulfuric acid (1 in 3), and 5 ml of 0.002 mol/l-potassium permanganate solution in a conical flask. Boil the solution for 5 min and discard it, and then wash the conical flask with water. Put 100 ml of the test solution in this conical flask, add 5 ml of sulfuric acid (1 in 3), and add 10 ml of 0.002 mol/l-potassium permanganate solution. Heat and boil the solution for 5 min. Immediately after stopping heating, add 10 ml of 0.005 mol/l-sodium oxalate solution to decolorize the solution, and titrate it with 0.002 mol/l-potassium permanganate solution until the faint red color remains without disappearing. Separately, conduct a blank test using the same method, and obtain potassium permanganate consumption using the following formula:
[Potassium Permanganate Consumption] (μg/ml) = [(a – b) x 0.316 x f x 1,000] / 100
where

a: The volume of 0.002 mol/l-potassium permanganate solution consumed in the main test (ml)
b: The volume of 0.002 mol/l-potassium permanganate solution consumed in the blank test (ml)
f: The factor of 0.002 mol/l-potassium permanganate solution

2. Strength Limit Test

Continuous Pressure Limit Test

Fill the container/packaging with dilute sulfuric acid (for continuous pressure test use) to 95 % of its internal volume. Put sodium hydrogen carbonate inside the container/packaging at a rate of 1.5 g per 100 ml of dilute sulfuric acid, in a way that will not allow the carbonate to touch the solution. After capping/sealing the container/packaging tightly, let the sodium hydrogen carbonate dissolve completely in the solution. Keep the container/packaging in warm water at 45±2ºC for 2 hr. Then check for gas leaks.

Continuous Depressurization Limit Test

Fill up the container/packaging with hot water heated to the temperature at which the product is filled. Immediately after that, cap/seal the container/packaging tightly. Put the container/packaging in methylene blue TS (for pinhole test use) at 25±5°C. Leave the container/packaging for 2 hr, and take it out for washing with water.
Using a pipette, put 25 ml of the water in the container/packaging in a 50 ml Nessler tube. Observe the tube against a white background from above and the side, checking that the water is not colored methylene blue.

Pressure Limit Test

Make a hole with a diameter of 5 to 10 mm on the sealed container/packaging. Insert an air-supply nozzle into the hole in a way that will not allow air to leak. Connect the air-supply nozzle to a pressure gauge and a compressor. Start the compressor and pressurize the container/packaging to 294 kPa. Then check for air leaks.

Compression Limit Test

As shown in Figure A, set up the sealed container/packaging that is filled up with its content or water. Depending on its gross weight as listed in the first column of the following table, exert the corresponding load, which is listed in the second column, on the container/packaging for 1 min. Then check that the content or water is not leaking. Note that if the container/packaging is box-shaped, set it up as shown in Figure B.

Figure A

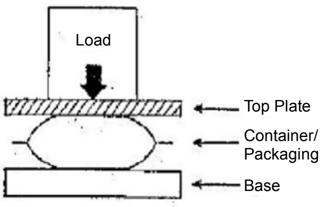
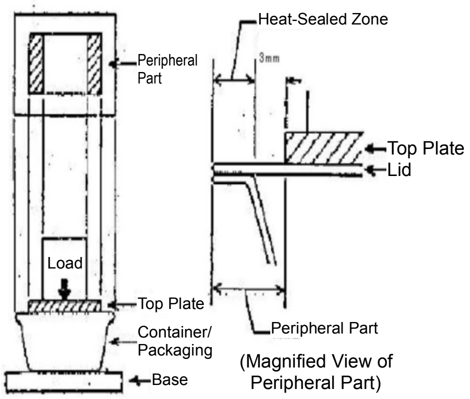


Figure B



1st Col.	2nd Col.
GW<100 g	20 kg
100 g≤GW< 400 g	40 kg
400 g≤GW<2,000 g	60 kg
2,000 g≤GW	80 kg

Depressurization Limit Test

Insert the needle of a vacuum gauge into the tightly capped/sealed container/packaging. Fix the vacuum gauge securely in a way that will not allow air to leak, and connect it to a vacuum pump. Start the vacuum pump to reduce pressure to 26.7 kPa. Then check for air leaks.

Sticking Strength Limit Test

Set the test sample on the holder. Stick a 1.0 mm-diameter needle with a 0.5 mm-radius hemicircle point into the sample surface at a rate of 50±5 mm/min. Measure the maximum sticking load until the needle penetrates through the test sample.

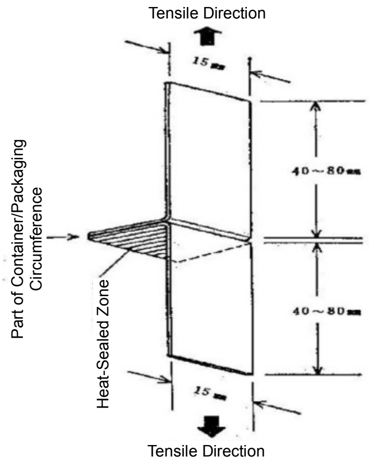
Internal Pressure Limit Test

Insert a needle into the tightly sealed container/packaging filled up with its content or water. Fix the needle securely in a way that will not allow air to leak, and connect it to a pressure gauge and a compressor.

Start the compressor to supply air into the container/packaging at a rate of 1±0.2 L/min. Read the maximum internal pressure until the container/packaging bursts.

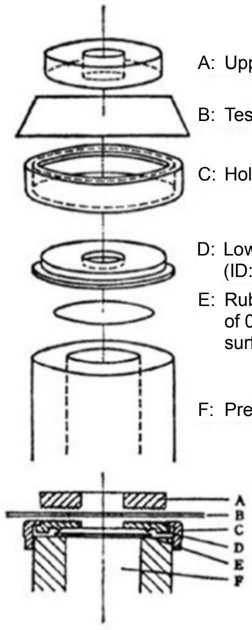
Heat-Seal Strength Limit Test

Cut out a test strip from the heat-sealed zone of the sealed container/packaging. Peel off the test strip as shown in the following figure. Hold both ends and pull them apart at a rate of 300±20 mm/min. Measure the maximum load until the heat-sealed zone peels off.



Burst Strength Limit Test

As shown in the figure below, set the test sample securely on the base. Inject glycerin into the pressure chamber at a rate of 95±10 ml/min. Measure the maximum pressure value until the test sample tears.



A: Upper Clamping Ring (ID: 30.48±0.03 mm)

B: Test Sample

C: Holding Ring

D: Lower Clamping Ring
(ID: 31.75±0.25 mm, thickness of 3.18mm)

E: Rubber Diaphragm (A pure rubber diaphragm with a thickness of 0.84 to 0.89 mm, which inflates to about 9.5 mm above the surface of B at a pressure of 34.3 to 44.1 kPa.)

F: Pressure Chamber

Pinhole Test

Fill up the container/packaging with methylene blue TS (for pinhole test use). Leave it for 30 min and check for pinholes.

Seal Limit Test

Make a hole 5–10 mm in diameter on the side wall or at the center of the bottom face of the sealed container/packaging. Attach an air-supply nozzle to the hole in a way that will not allow air to leak. Connect the air-supply nozzle to a pressure gauge and a compressor. Start the compressor and pressurize the container/packaging to 13.3 kPa in 10 sec. Then check for air leaks.

Drop Limit Test

Drop the capped/sealed container/packaging that is filled up with its content or water from a specified drop height onto a concrete floor. Based on the gross weight listed in the first column of the following table, select the corresponding drop height for the container/packaging from the second column. Drop the container/packaging so that it will hit the concrete floor on its bottom face or flat face. Repeat this drop test twice, and check that its content or water is not leaking.

1st Col.	2nd Col.
GW<100 g	80 cm
100 g≤GW<400 g	50 cm
400 g≤GW<2,000 g	30 cm
2,000 g≤GW	25 cm

Water Leak Limit Test

Leave the capped/sealed container/packaging filled up with its content in a constant-temperature oven at 45±2ºC for 24 hr. In this case, place the container/packaging on its side in the oven. Then check that the content is not leaking.

3. Atomic Absorption Spectrophotometry

Atomic absorption spectrophotometry is an analytical method to measure the concentration of a particular element (analyte) contained in a test solution. This method utilizes the phenomenon that when light passes through free atoms in the gaseous state, the atoms in the ground state absorb light with a specific wavelength.

Instrumentation

In general, atomic absorption spectrometers consist of the light source, the sample atomizer, the spectroscope, the detector, and the recording unit. The light source uses a hollow cathode lamp. The sample atomizer for the flame atomization type (direct spray type) consists of the burner and the gas flow regulator. The sample atomizer for the electrothermal atomization type consists of the electric heating furnace and the power source unit. The spectrometer consists of the diffraction grating or the interference filter. The spectroscope consists of the detector and the signal processor. The recording unit consists of the display and the recorder.

Standard Solution

Unless otherwise specified, use standard solutions recommended for the analyte.

Test Procedure

Unless otherwise specified, use one of the following procedures.

(1) Flame Atomization Type (direct spray type): Turn ON the light-source lamp (a hollow cathode lamp recommended for the analyte must be chosen). Adjust the spectroscope to the analytical wavelength recommended for the analyte. Select an appropriate electric current and slit width. Light the gas (acetylene or hydrogen), and adjust the flow rates of the gas and compressed air. Spray the solvent into the flame to make a zero-point adjustment. Then spray the test solution or the standard solution of the analyte into the flame to measure its absorbance.

(2) Electrothermal Atomization Type: Turn ON the light-source lamp (a hollow cathode lamp recommended for the analyte must be chosen). Adjust the spectroscope to the analytical wavelength recommended for the analyte. Select an appropriate electric current and slit width. Inject a certain amount of the test solution or the standard solution of the analyte into the electric heating furnace. Flow carrier gas at an appropriate rate, and dry the solution under appropriately set conditions including temperature, duration, and heating mode. After ashing the residue, atomize the ash to measure the absorbance.

For absorbance measurements, the following wavelengths must be used depending on the analyte: 213.9 nm for zinc, 217.6 nm antimony, 228.8 nm cadmium, 265.2 nm germanium, 283.3 nm lead, and 553.6 nm barium.

The absorbance of the test solution must NOT be greater than the absorbance of the standard solution of the analyte, which was obtained in the same way as for the test solution.

4. Heavy Metals Limit Test

The Heavy Metals Limit Test is a method to ensure that the amounts of heavy metals eluted from samples are less than their maximum permissible limits. Heavy metals measured in these tests are those metallic substances that will exhibit a dark color in response to sodium sulfide TS in an acidic environment. The amounts of these heavy metals are expressed by a lead (Pb) equivalent amount.

Test Procedure

Put 20 ml of the test solution in a Nessler tube, and add water to make a 50 ml solution. Separately, put 2 ml of the lead standard solution (for heavy metal test use) in a Nessler tube, and add 20 ml of an eluting solution and water, making a 50 ml standard control solution. Add two drops of sodium sulfide TS in each of the two solutions and mix them well. After leaving them for 5 min, observe both tubes against a white background from above and the side. The color exhibited by the test solution must NOT be darker than that exhibited by the standard control solution. In the case where the eluting solution is water, before adding two drops of sodium sulfide TS, add 5 ml of 4 % acetic acid and then water to each of the test solution and the lead standard solution, making them 50 ml in volume.

5. Evaporation Residue Limit Test

The Evaporation Residue Limit Test is a method to measure the amounts of the substances that migrate from the sample to the eluting solution when treated by a predetermined method.

Test Procedure

Unless otherwise specified, apparatus, containers or packaging which directly touch the food listed in the first column of the following table must receive the test described below. This test uses the test solution that contains the solvent listed in the second column as its eluting solution.

1st Col.		2nd Col.
Oil & fat and high-fat products		Heptane
Alcoholic beverages		20 % ethanol
Foods other than oil & fat, high-fat products and alcoholic beverages	pH 5 <	Water
	≤ pH 5	4 % acetic acid

Put 200–300 ml of the test solution on a platinum, quartz, or heat-resistant glass evaporation dish, which was dried at 105ºC in advance and whose weight is known. (In the case where heptane is used as an eluting solution, put 200–300 ml of the test solution in an eggplant-shaped flask, and concentrate it to a volume of several milliliters under reduced pressure. Wash the flask twice with about 5 ml of heptane each time. Put the condensed solution and washings on the evaporation dish.) Evaporate and dry the solution on a water bath. Dry the residue at 105ºC for 2 hr and let it cool in a desiccator. After the residue cools down, measure the weight of the evaporation dish. Then calculate the difference in the weight before and after evaporation: a (mg). Calculate the amount of the evaporation residue using the following formula:

[Evaporation Residue (µg/ml)] = [(a – b) x 1,000] / [Volume of Collected Test Solution (ml)]

where b: the blank value obtained using the same volume of the eluting solution as the test solution (mg)

6. Additives Limit Test

Amines (only triethylamine and tributylamine)

(1) Preparation of Calibration Curves

Precisely measure about 10 mg each of triethylamine and tributylamine. Put them in a 100 ml measuring flask, and add dichloromethane to make a 100 ml solution. Put 4 ml of this solution in a 100 ml measuring flask, and add dichloromethane to make a 100 ml solution. Put 1 ml, 2 ml, 3 ml, 4 ml, and 5 ml each of this solution in a 20 ml measuring flask, and add dichloromethane to make 5 different 20 ml standard solutions (whose concentrations are 0.2 µg/ml, 0.4 µg/ml, 0.6 µg/ml, 0.8 µg/ml, and 1.0 µg/ml, respectively). In accordance with the following operating condition, conduct gas chromatography analyses using 1 µl each of these standard solutions. Obtain the respective peak heights/areas of triethylamine and tributylamine from the resulting gas chromatograms, and prepare the corresponding calibration curves.

Operating Condition

Columns: Use narrow borosilicate glass tubes with an inner diameter of 0.32 mm and a length of 30 m, coated with 5 µm-thick dimethylpolysiloxane.
Column temperatures: Keep the column at 150ºC for 5 min, and increase the temperature at a rate of 20ºC/min. After it reaches 250ºC, keep that temperature for 5 min.
Inlet temperature of test solution: 200ºC
Detector: Use an alkali flame ionization detector or a high-sensitivity nitrogen-phosphorus detector. Operate the detector at around 250ºC. Adjust the amounts of air and hydrogen so that detection sensitivity can be maximized.
Injection system: Split injection (15:1)
Carrier gas: Helium. Adjust the gas flow rate so that triethylamine will flow out in 3 to 4 min.

(2) Test

Conduct a gas chromatography analysis using 1 µl of the test solution under the same operating condition as described in *(1) Preparation of Calibration Curves*. Measure the respective peak heights/areas from the resulting gas chromatogram. Obtain the concentration of triethylamine and tributylamine contained in the test solution using the corresponding calibration curves. Calculate the content in the sample material using the following formula:

[Content in Sample Material (µg/g)] = [Concentration of Test Solution (µg/ml) x 2 (ml) / [Sample Weight (g)]

Tricresyl Phosphate

(1) Qualitative Test

Conduct liquid chromatography analyses using 20 μl each of the test solution and the tricresyl phosphate standard solution under the following operating condition. Then compare the peak detection time in the liquid chromatogram of the test solution with that of the tricresyl phosphate standard solution.

Operation Condition

Column-packing material: Phenylated silica gel
Column tubes: Stainless steel tubes with an inner diameter of 4.6 mm and a length of 250 mm
Column temperature: 50ºC
Detector: Use an ultraviolet absorption detector. Operate the detector at a wavelength of 264 nm.
Mobile phase: Use a mixture of acetonitrile and water (2:1). Adjust the liquid flow rate so that tricresyl phosphate will flow out in about 9 min.

(2) Quantitative Test

In *(1) Qualitative Test*, if the peak detection time in the liquid chromatogram of the test solution and that of the tricresyl phosphate standard solution coincide with each other, conduct the following test.
When measuring the peak area of tricresyl phosphate in the test solution, based on the test results obtained under the operating condition as described in *(1) Qualitative Test*, that peak area must NOT be greater than the peak area of the tricresyl phosphate standard solution.

Dibutyltin Compounds

(1) Qualitative Test

Put 2 ml each of the test solution and the dibutyltin standard solution in a container. To each tube, add 5 ml of acetic acid/sodium acetate buffer solution and 1 ml of sodium tetraethylborate TS. Immediately after that, cap the tubes tightly and shake them up vigorously for 20 min. After leaving the two tubes at room temperature for about 1 hr, collect the separated hexane layer in each tube. Then conduct gas chromatography and mass spectrometry analyses using 1 μl each of these solutions under the following operating condition. Then compare the peak detection time in the gas chromatogram of the test solution with that of the dibutyltin standard solution.

Operating Condition

Columns: Use narrow borosilicate glass tubes with an inner diameter of 0.25 mm and a length of 30 m, coated with 0.25 μm-thick dimethylpolysiloxane containing 0–5 % diphenyl polysiloxane.

Column temperatures: Keep the column at 45ºC for 4 min, and increase the temperature at a rate of 15ºC/min. After it reaches 300ºC, keep that temperature for 10 min.
Inlet temperature of sample solution: 250ºC
Detector: Use a mass spectrometer and detect mass number 263.
Carrier gas: Helium. Adjust the gas flow rate so that dibutyltin derivatives will flow out in about 13 min.

(2) Quantitative Test

In *(1) Qualitative Test*, if the peak detection time in the gas chromatogram of the test solution and that of the dibutyltin standard solution coincide with each other, conduct the following test.
When measuring the peak area of dibutyltin in the test solution, based on the test results obtained under the operating condition as described in *(1) Qualitative Test*, that peak area must NOT be greater than the peak area of the dibutyltin standard solution.

2-Mercaptoimidazoline

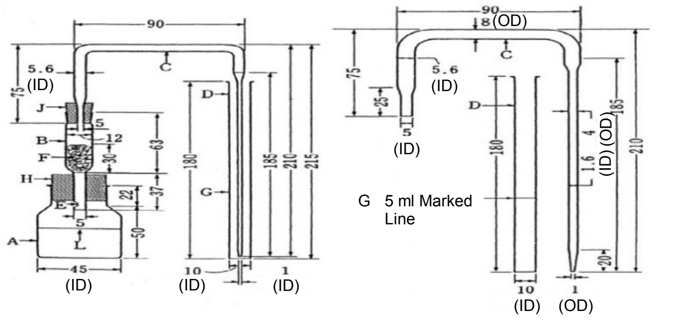
When conducting liquid chromatography analyses using 5 μl each of the test solution and the 2-mercaptoimidazoline standard solution under the following operating condition, the peak of 2-mecaptoimidazoline must NOT be recognized in the liquid chromatogram of the test solution.

Operating Condition

Column-packing material: Octadecyl-silylated silica gel
Column tubes: Stainless steel tubes with an inner diameter of 4.6 mm and a length of 150 mm
Column temperature: 40ºC
Detector: Use an ultraviolet absorption detector. Operate the detector at a wavelength of 238 nm.
Mobile phase: Use a mixture of methanol and water (1:9). Adjust the liquid flow rate so that 2-mercaptoimidazoline will flow out in about 2 min.

7. Arsenic Limit Test

The Arsenic Limit Test is a method to ensure that the amount of arsenic contained in the sample is less than its maximum permissible limit. The amount of arsenic is expressed by an arsenic-trioxide-equivalent amount.
Instrumentation: The following figure shows a schematic view of the instrument.



(Unit: mm)
Figure

A: Gas generation bottle (the volume up to the shoulder is about 70 ml)

B: Exhaust tube

C: Glass tube (ID: 5.6 mm. The area inserted into the absorbing tube is stretched to have an inner diameter of 1 mm.)

D: Absorbing tube (ID: 10 mm)

E: Small hole

F: Glass fiber (about 0.2 g)

G: 5 ml marked line

H and J: Rubber plugs

L: 40 ml marked line

Fill exhaust tube B with glass fiber F up to a height of about 30 mm. Moisten the glass fiber uniformly with a mixture of lead acetate TS and an equal amount of water. Gently vacuum the exhaust tube from the bottom to remove any excessive liquid. Insert the exhaust tube vertically into the center of rubber plug H so that small hole E at the bottom of B will protrude slightly below the bottom face of the rubber plug. Then mount the rubber plug to gas generation bottle A. Attach rubber plug J that holds glass tube C in the vertical position onto the top end of B. The bottom end of glass tube C on the exhaust tube side shall be at the same level as the bottom face of rubber plug J.

Test Procedure

Put the test solution in a gas generation bottle, then add a drop of bromophenol blue TS. Neutralize the solution with ammonia water or ammonia TS. Note that this neutralization process may be omitted in the case where the eluting solution is water. Add 5 ml of hydrochloric acid (1 in 2) and 5 ml of potassium iodide TS to this solution. After leaving the solution for 2 to 3 min, add 5 ml of tin(II) chloride TS and leave it at room temperature for 10 min. Add water to make a 40 ml solution, and then add 2 g of zinc (for arsenic test use). Immediately after that, mount rubber plug H connected to B and C onto the gas generation bottle. Set the edge of the narrow part of glass tube C so that it touches with the bottom of absorbing tube D, into which 5 ml of an arseniureted hydrogen absorbing solution was added in advance. Immerse the gas generation bottle in water at 25ºC up to its shoulder, and keep the bottle in this condition for 1 hr. Remove the absorbing tube, and observe the color of the absorbing solution. If necessary, add pyridine to make a 5 ml solution. This color must NOT be darker than the standard color described below. While analyzing the test solution, prepare a standard color solution as follows. Put the same volume of the eluting solution as the test solution and 2.0 ml of the arsenic standard solution in a gas generation bottle.

Then obtain an absorbing solution using the same method as for the test solution. The color exhibited by this absorbing solution shall be defined as the standard color for this test.

8. Monomer Limit Test

Epichlorohydrin

(1) Qualitative Test

Conduct gas chromatography analyses using 5 μl each of the test solution and the epichlorohydrin standard solution under the following operating condition. Then compare the peak detection time in the gas chromatogram of the test solution with that of the epichlorohydrin standard solution.

Operating Condition

Columns: Use narrow borosilicate glass tubes with an inner diameter of 0.53 mm and a length of 30 m, coated with 1 μm-thick polyethylene glycol.
Column temperatures: Keep the column at 50ºC for 5 min, and increase the temperature at a rate of 10ºC/min to 100ºC.
Inlet temperature of sample solution: 220ºC
Detector: Use a hydrogen flame ionization detector. Operate the detector at around 220ºC. Adjust the amounts of hydrogen and air so that detection sensitivity can be maximized.
Carrier gas: Nitrogen or helium. Adjust the gas flow rate so that epichlorohydrin will flow out in about 7 min.

(2) Quantitative Test

In *(1) Qualitative Test*, if the peak detection time in the gas chromatogram of the test solution and the peak of epichlorohydrin in the gas chromatogram of its standard solution coincide with each other, conduct the following test.
When measuring the peak area of epichlorohydrin contained in the test solution, based on the test results obtained under the operating condition as described in *(1) Qualitative Test*, that peak area must NOT be greater than the peak area of the epichlorohydrin standard solution.

Vinylidene Chloride

(1) Qualitative Test

Add 50 μl of the vinylidene chloride standard solution to a glass bottle with septum cap, into which 2.5 ml of N,N-dimethylacetamide was put in advance. Immediately after that, seal the glass bottle tightly. Heat each of the test solution and the standard solution in a sealed glass bottle for 1 hr. Keep them at a constant temperature of 90ºC, shaking them up occasionally. Then conduct gas chromatography analyses using 0.5 ml each of the gas phase in the two glass bottles under the following operating condition. Compare the peak detection time in the gas chromatogram of the test solution with the peak detection time of vinylidene chloride in the gas chromatogram of its standard solution.

Operating Condition

Columns: Use narrow borosilicate glass tubes with an inner diameter of 0.25 mm and a length of 25m, coated with a 3 μm-thick styrene divinylbenzene-based porous resin.
Column temperatures: Keep the column at 80ºC for 1 min, and increase the temperature at a rate of 10ºC/min. After it reaches 250ºC, keep that temperature for 10 min.
Inlet temperature of sample solution: 200ºC
Detector: Use a hydrogen flame ionization detector. Operate the detector at around 250ºC. Adjust the amounts of hydrogen and air so that detection sensitivity can be maximized.
Carrier gas: Nitrogen or helium. Adjust the gas flow rate so that vinylidene chloride will flow out in about 9 min.

(2) Quantitative Test

In *(1) Qualitative Test*, if the peak detection time in the gas chromatogram of the test solution and the peak detection time of vinylidene chloride in the gas chromatogram of its standard solution coincide with each other, conduct the following test.
When measuring the peak area of vinylidene chloride contained in the test solution, based on the test results obtained under the operating condition as described in *(1) Qualitative Test*, that peak area must NOT be greater than the peak area of the vinylidene chloride standard solution.

Vinyl Chloride

(1) Qualitative Test

Add 50 μl of the vinyl chloride standard solution to a glass bottle with septum cap, into which 2.5 ml of N,N-dimethylacetamide was put in advance. Immediately after that, seal the glass bottle tightly. Heat each of the test solution and the standard solution in a sealed glass bottle for 1 hr. Keep the glass bottles at a constant temperature of 90ºC, shaking them up occasionally. Then conduct gas chromatography analyses using 0.5 ml each of the gas phase in the two glass bottles under the following operating condition. Compare the peak detection time in the gas chromatogram of the test solution with the peak detection time of vinyl chloride in the gas chromatogram of its standard solution. However, when testing metal cans, follow the procedure below. Put 10 ml of the test solution in a glass bottle with septum cap, and seal it immediately. Add 50 μl of the vinyl chloride standard solution into a glass bottle with septum cap, into which 10 ml of ethanol was put in advance. Immediately after that, seal the bottle tightly. Heat each of the test solution and the standard solution in a sealed glass bottle for 30 min, keeping them at a constant temperature of 50ºC, shaking them up occasionally. Using the test solution and the vinyl chloride standard solution, conduct gas chromatography analyses using the same method used for testing when not testing metal cans.

Operating Condition

Columns: Use narrow borosilicate glass tubes with an inner diameter of 0.25 mm and a length of 25 m, coated with a 3 μm-thick styrene divinylbenzene-based porous resin.
Column temperatures: Keep the column at 80ºC for 1 min, and increase the temperature at a rate of 10ºC/min. After it reaches 250ºC, keep that temperature for 10 min.
Inlet temperature of sample solution: 200ºC
Detector: Use a hydrogen flame ionization detector. Operate the detector at around 250ºC. Adjust the amounts of hydrogen and air so that detection sensitivity can be maximized.
Carrier gas: Nitrogen or helium. Adjust the gas flow rate so that vinyl chloride will flow out in about 5 min.

(2) Quantitative Test

In *(1) Qualitative Test*, if the peak detection time in the gas chromatogram of the test solution and the peak detection time of vinyl chloride in the gas chromatogram of its standard solution coincide with each other, conduct the following test.
When measuring the peak area of vinyl chloride contained in the test solution, based on the test results obtained under the operating condition as described in *(1) Qualitative Test*, that peak area must NOT be greater than the peak area of the vinyl chloride standard solution.

Caprolactam

(1) Qualitative Test

Conduct gas chromatography analyses using 1 μl each of the test solution and the caprolactam standard solution under the following operating condition. Then compare the peak detection time in the gas chromatogram of the test solution with the peak detection time of caprolactam in the gas chromatogram of its standard solution.

Operating Condition

Columns: Use narrow borosilicate glass tubes with an inner diameter of 0.32 mm and a length of 30 m, coated with 5 μm-thick dimethylpolysiloxane.
Column temperature: 240ºC
Inlet temperature of sample solution: 240ºC
Detector: Use a hydrogen flame ionization detector. Operate the detector at around 240ºC. Adjust the amounts of hydrogen and air so that detection sensitivity can be maximized.
Carrier gas: Nitrogen or helium. Adjust the gas flow rate so that caprolactam will flow out in about 5 min.

(2) Quantitative Test

In *(1) Qualitative Test,* if the peak detection time in the gas chromatogram of the test solution and the peak detection time of caprolactam in the gas chromatogram of its standard solution coincide with each other, conduct the following test.

When measuring the peak area of caprolactam contained in the test solution, based on the test results obtained under the operating condition as described in *(1) Qualitative Test*, that peak area must NOT be greater than the peak area of the caprolactam standard solution.

Volatile Substances

(1) Preparation of Calibration Curves

Put about 90 ml of tetrahydrofuran in a 100 ml measuring flask. Precisely measure about 50 mg each of styrene, toluene, ethylbenzene, isopropylbenzene, and propylbenzene, and add them into the flask. Then add extra tetrahydrofuran into the flask to make a 100 ml solution. Put 1 ml, 2 ml, 3 ml, 4 ml, and 5 ml each of this solution in a 20 ml measuring flask. Add 1 ml of diethylbenzene TS and then tetrahydrofuran into each flask to make a 20 ml solution. These 5 different solutions will be used as the standard solutions for this test. Conduct gas chromatography analyses using 1 µl each of the standard solutions under the following operating condition. Based on the resulting gas chromatograms, obtain the ratio between the peak area of each of styrene, toluene, ethylbenzene, isopropylbenzene, and propylbenzene, and the peak area of diethylbenzene. Then prepare the calibration curve for each volatile substance.

Operating Condition

Columns: Use narrow borosilicate glass tubes with an inner diameter of 0.25 mm and a length of 30 m, coated with 0.5 µm-thick polyethylene glycol.

Column temperatures: Increase the column temperature at a rate of 4ºC/min from 60ºC to 100ºC. Then increase the temperature further at a rate of 10ºC/min to 150ºC.

Inlet temperature of sample solution: 220ºC

Detector: Use a hydrogen flame ionization detector. Operate the detector at around 220ºC. Adjust the amounts of hydrogen and air so that detection sensitivity can be maximized.

Carrier gas: Nitrogen or helium. Adjust the gas flow rate so that diethylbenzene will flow out in about 11 min.

(2) Test

Conduct a gas chromatography analysis using 1 µl of the test solution under the same operating condition as described in *(1) Preparation of Calibration Curves*. Based on the resulting gas chromatogram, obtain the ratio between the peak area of each of styrene, toluene, ethylbenzene, isopropylbenzene, and propylbenzene, and the peak area of diethylbenzene. Using the calibration curve for each substance,

obtain the concentration of each volatile substance. Then calculate the content of each in the sample from the following formula:
[Content in Sample (μg/g)] = [Concentration of Component (μg/ml)] x 20 (ml) / [Sample Weight (g)]

Diphenyl Carbonate

(1) Preparation of Calibration Curves

Precisely measure about 10 mg of diphenyl carbonate, and put it in a 100 ml measuring flask. Add methanol into the flask to make a 100 ml solution. Put 1 ml, 2 ml, 3 ml, 4 ml, and 5 ml each of this solution in a 20 ml measuring flask, and add water to make a 20 ml solution. These 5 different solutions will be used as the standard solutions for this test (whose concentrations are 5 μg/ml, 10 μg/ml, 15 μg/ml, 20 μg/ml, and 25 μg/ml, respectively). Conduct liquid chromatography analyses using 20 μl each of the standard solutions under the following operating condition. Based on the resulting liquid chromatograms, obtain the respective peak heights/areas of diphenyl carbonate. Then prepare the calibration curve for diphenyl carbonate.

Operating Condition

Column-packing material: Octadecyl-silylated silica gel
Column tubes: Stainless steel tubes with an inner diameter of 4.6 mm and a length of 250 mm
Column temperature: 40ºC
Detector: Use an ultraviolet absorption detector. Operate the detector at a wavelength of 217 nm.
Mobile phase: A: acetonitrile, B: water
Concentration gradient: Change the concentration gradient lineally from A:B (3:7) to (100:0) in 35 min. Then feed acetonitrile for 10 min.

(2) Test

Conduct a liquid chromatography analysis using 20 μl of the test solution under the same operating condition as described in *(1) Preparation of Calibration Curves*. Based on the resulting gas chromatogram, obtain the peak height/area of diphenyl carbonate. Using its calibration curve, obtain the concentration of diphenyl carbonate in the test solution. Calculate the content of diphenyl carbonate in the sample from the following formula:

[Content in Sample (μg/g)] = [Concentration of Sample Solution (μg/ml) x 20 (ml) / [Sample Weight (g)]

Total Lactic Acid

(1) Qualitative Test

Put 1 ml each of the test solution and the lactic acid standard solution in a container, add 100 µl of 0.2 mol/l-sodium hydroxide TS. Tightly seal both tubes. Keep them at a constant temperature of 60ºC for 15 min, shaking them up occasionally. After they cool down, add 100 µl each of 0.2 mol/l-phosphoric acid into the tubes. Conduct liquid chromatography analyses using 100 µl each of these solutions under the following operating condition. Then compare the peak detection time in the liquid chromatogram of the test solution with that of the lactic acid standard solution.

Operating Condition

Column-packing material: Octadecyl-silylated silica gel
Column tubes: Stainless steel tubes with an inner diameter of 4.6 mm and a length of 250 mm
Column temperature: 40ºC
Detector: Use an ultraviolet absorption detector. Operate the detector at a wavelength of 210 nm.
Mobile phase: Use a mixture of phosphoric acid, acetonitrile, and water (0.1:1:99). Adjust the liquid flow rate so that lactic acid will flow out in about 5 min.

(2) Quantitative Test

In *(1) Qualitative Test*, if the peak detection time in the liquid chromatogram of the test solution and that of the lactic acid standard solution coincide with each other, conduct the following test.
When measuring the peak area of lactic acid in the sample solution, based on the test results obtained under the operating condition as described *(1) Qualitative Test*, that peak area must NOT be greater than the peak area of the lactic acid standard solution.

Bisphenol A (including Phenol and p-tert-Butylphenol)

(1) Preparation of Calibration Curves

Precisely measure about 10 mg each of bisphenol A, phenol, and p-tert-butylphenol. Put each of them in a 100 ml measuring flask, and add methanol to make a 100 ml solution. Put 1 ml, 2 ml, 3 ml, 4 ml, and 5 ml each of this solution in a 20 ml measuring flask, and add water to make a 20 ml solution. These 5 different solutions will be used as the standard solutions for this test (whose concentrations are 5 µg/ml, 10 µg/ml, 15 µg/ml, 20 µg/ml, and 25 µg/ml, respectively). Conduct liquid chromatography analyses using 20 µl each of these standard solutions under the following operating condition. Based on the resulting liquid chromatograms, obtain the peak height/area of each of bisphenol A, phenol, and p-tert-butylphenol. Then prepare the calibration curve for each substance.
However, when preparing calibration curves for elution testing, follow the procedure below. Put 2 ml each of the 5 standard solutions above in a 20 ml measuring flask, and add water to make a 20 ml solution

(whose concentrations are 0.5 μg/ml, 1.0 μg/ml, 1.5 μg/ml, 2.0 μg/ml, and 2.5 μg/ml). Using 100 μl each of these solutions, conduct the same liquid chromatography analyses as described above. Then prepare the calibration curve for each of bisphenol A, phenol, and p-tert-butylphenol.

Operating Condition

The operating condition for diphenyl carbonate shall be applied mutatis mutandis.

(2) Test

Conduct a liquid chromatography analysis using 20 μl of the test solution under the same operating condition as described in *(1) Preparation of Calibration Curves*. Based on the resulting liquid chromatogram, obtain the peak height/area of each of bisphenol A, phenol, and p-tert-butylphenol. Then obtain the concentration of each substance contained in the test solution using its calibration curve. Calculate the content of each substance in the sample from the following formula:

[Content in Sample (μg/g)] = [Concentration of Sample Solution (μg/ml) x 20 (ml) / [Sample Weight (g)]

For elution testing, however, perform the following procedure. Using 100 μl of the test solution, conduct the same liquid chromatography analysis as described above. Then obtain the concentration of each of bisphenol A, phenol, and p-tert-butylphenol contained in the test solution from its calibration curve for elution testing.

Phenol

Put 20 ml of the test solution in a container, and add 3 ml of boric acid buffer solution. After shaking up the container well, add 5 ml of 4-amino antipyrene TS and 2.5 ml of potassium hexacyanoferrate(III) TS. Then add water to make a 100 ml solution, shake up the tube well, and leave it at room temperature for 10 min. Separately, put 20 ml of the phenol standard solution in a container, and repeat the same procedure as described above. When measuring absorbance at a wavelength of 510 nm, the absorbance of the test solution must NOT be greater than the absorbance of the phenol standard solution.

Formaldehyde

Put 10 ml of the test solution in a Nessler tube, and add 1 ml of 20 % phosphoric acid. Put 5–10 ml of water in a 200 ml measuring cylinder. Then distill the solution by steam distillation, with the cooler adapter immersed in water. When the volume of the distillate becomes about 190 ml, stop distillation, and then add water to make a 200 ml solution. Put 5 ml of this solution in a test tube with an inner diameter of about 15 mm. Add and mix 5 ml of acetylacetone TS into the solution, and heat the test tube in a boiling water bath for 10 min.

Separately, put 5 ml of water in a test tube with an inner diameter of about 15 mm, and add and mix 5 ml of acetylacetone TS into the solution. Then heat the test tube in a boiling water bath for 10 min, making it the control solution.
When both solutions are observed from the side against a white background, the color exhibited by the test solution must NOT be darker than the color exhibited by the control solution.

Methyl Methacrylate

(1) Qualitative Test

Conduct gas chromatography analyses using 1 µl each of the test solution and the methyl methacrylate standard solution under the following operating condition. Then compare the peak detection time in the gas chromatogram of the test solution with the peak detection time of methyl methacrylate in the gas chromatogram of its standard solution.

Operating Condition

Columns: Use narrow borosilicate glass tubes with an inner diameter of 0.32 mm and a length of 30 m, coated with 5 µm-thick dimethylpolysiloxane.
Column temperatures: After keeping the column at 120ºC for 1 min, increase the temperature at a rate of 5ºC/min to 170ºC.
Inlet temperature of sample solution: 200ºC
Detector: Use a hydrogen flame ionization detector. Operate the detector at around 200ºC. Adjust the amounts of hydrogen and air so that detection sensitivity can be maximized.
Carrier gas: Nitrogen or helium. Adjust the gas flow rate so that methyl methacrylate will flow out in about 4–5 min.

(2) Quantitative Test

In *(1) Qualitative Test*, if the peak detection time in the gas chromatogram of the test solution and the peak detection time of methyl methacrylate in the gas chromatogram of its standard solution coincide with each other, conduct the following test.
When measuring the peak area of methyl methacrylate in the test solution, based on the test results obtained under the operating condition as described in *(1) Qualitative Test,* that peak area must NOT be greater than the peak area of the methyl methacrylate standard solution.

9. Inductively Coupled Plasma Emission Spectrometry

Inductively Coupled Plasma Emission Spectrometry (ICPES) is a method to atomize and excite, with the help of inductively coupled plasma (ICP), the element to be examined (analyte) in a sample, and measure the amount (concentration) of the analyte using the emission intensity of the resulting atomic emission spectrum.

Instrumentation

In general, an inductively coupled plasma spectrometer is made up of the excitation light source, the sample atomizer, the light-emitting unit, the spectroscope unit, the photometer, and the recording unit. The excitation light source consists of a power source, a control system, and a circuit, which supply and control the electric energy required to excite the sample for light emission. The light source also includes auxiliary equipment such as a gas supply source and a cooling system. The sample atomizer consists of a nebulizer and a spray chamber. The light-emitting unit consists of a torch tube and a high-frequency induction coil. The spectroscope unit consists of spectroscope parts such as a light collector and a diffraction grating. The photometer consists of a photodetector and a signal processing system. The recording unit includes displays and recorders. There are three types of ICPES analyses: sequential single-element analyses using a wavelength-scanning spectroscope, sequential multi-element analyses using a wavelength-scanning spectroscope, and simultaneous multi-element analyses using a fixed wavelength polychromator.

Standard Solutions

Unless otherwise specified, use the standard solution recommended for the element to be examined (analyte).

Test Procedure

After checking that the parts always powered on are working as expected, switch ON the excitation light source and the cooling-system. When measuring emission spectral lines in the vacuum ultraviolet region on a vacuum spectroscope, purge the optical axis between the light-emitting unit and the spectroscope unit with argon or nitrogen. Then set the flow rate of argon or nitrogen at a predetermined value. Switch ON the high-frequency power source and then the plasma. Calibrate the spectroscope's wavelength using the emission spectral lines of a mercury-vapor lamp. Inject the test solution prepared by a separately specified method, and measure the emission intensity of an appropriate emission spectral line. The emission intensity of the test solution must NOT be greater than the emission intensity obtained using the standard solution of the element to be examined (analyte) using the same method.

10. Preparation Method of Test Solutions for Elution Tests

Unless otherwise specified, prepare test solutions for elution tests using the following method.
After washing the sample well with water, prepare the test solution using a designated eluting solution in accordance with the following procedure.
Heat 2 ml of the eluting solution per 1 cm^2 of the sample surface area at 60ºC. Keep the solution at 60ºC and leave it for 30 min. When water or 4 % acetic acid is used as the eluting solution for a sample whose service temperature exceeds 100ºC, leave the solution for 30 min at a constant temperature of 95ºC. Likewise, when heptane is used as the eluting solution for such a sample, leave the solution for 1 hr at a constant temperature of 25ºC.

C. Reagents & Testing Solutions (TS): Omitted

D. Specifications by Material Type for Apparatus, Containers, Packaging, or their Materials

1 glass, Ceramic, or Vitreously Enameled Apparatus, Containers, or Packaging

Glass, ceramic, or vitreously enameled apparatus, containers, or packaging must pass the following limit tests.

(1) Samples which have a depth of 2.5 cm or more when filled up with a liquid (excluding vitreously enameled samples with a volume of 3 L or more)

1. Preparation of Test Solutions

Wash the sample well with water. Fill up the sample with 4 % acetic acid, and leave it for 24 hr in a dark place at room temperature. Pour this solution into a beaker for use as the test solution.

2. Elution Tests

a. Cadmium and Lead

1) Preparation of Calibration Curves

Dilute the cadmium standard solution and the lead standard solution appropriately with 4 % acetic acid. Measure the two elements using atomic absorption spectrophotometry or inductively coupled plasma emission spectrometry. Then prepare the calibration curve for each of cadmium and lead.

2) Quantitation Methods

The eluted amount of cadmium and lead in a test solution shall be obtained by atomic absorption spectrometry or inductively coupled plasma emission spectrometry. Depending on the classification of the food utensil, container, or packaging listed in the first column of the following table, the amount of cadmium must NOT exceed the corresponding amount listed in the second column of the table. Likewise, the amount of lead must NOT exceed the corresponding amount listed in the third column of the table.

1st Col.			2nd Col.	3rd Col.
Glass apparatus, containers, or packaging	Cooking apparatus		0.05 µg/ml	0.5 µg/ml
	Other than cooking apparatus	volume < 600 ml	0.5 µg/ml	1.5 µg/ml
		600 ml ≤ volume < 3 L	0.25 µg/ml	0.75 µg/ml
		3 L ≤ volume	0.25 µg/ml	0.5 µg/ml
Ceramic apparatus, containers, or packaging	Cooking apparatus		0.05 µg/ml	0.5 µg/ml
	Other than cooking apparatus	volume < 1.1 L	0.5 µg/ml	2 µg/ml
		1.1 L ≤ volume < 3 L	0.25 µg/ml	1 µg/ml
		3 L ≤ volume	0.25 µg/ml	0.5 µg/ml
Vitreously enameled apparatus, containers, or packaging	Cooking apparatus with a volume of less than 3 L		0.07 µg/ml	0.4 µg/ml
	Other than cooking apparatus with a volume of less than 3 L		0.07 µg/ml	0.8 µg/ml

(2) Samples which cannot be filled up with a liquid, or samples which have a depth of less than 2.5 cm when filled up with a liquid, or vitreously enameled samples with a volume of 3 L or more

1. Preparation of Test Solutions

Wash the sample well with water. (For a vitreously enameled sample with a volume of 3 L or more, make a test piece and use it as the sample for this test.) Fill up the sample with 4 % acetic acid as its eluting solution, and leave it for 24 hr in a dark place at room temperature.

2. Elution Tests

a. Cadmium and Lead

1) Preparation of Calibration Curves

Dilute the cadmium standard solution and the lead standard solution appropriately with 4 % acetic acid. Measure the two elements using atomic absorption spectrophotometry or inductively coupled plasma emission spectrometry. Then prepare the calibration curve for each of cadmium and lead.

2) Quantitation Methods

Analyze the test solution by atomic absorption spectrometry or inductively coupled plasma emission spectrometry, and obtain the concentration of cadmium and lead: C (µg/ml). When the sample's surface area is S (cm^2) and the eluting solution's total volume is V (ml), obtain the eluted amount per unit area of cadmium and lead using the formula below. Depending on the classification of the food utensil, container, or packaging listed in the first column of the following table, the amount of cadmium must NOT exceed the corresponding amount listed in the second column of the table. Likewise, the amount of lead must NOT exceed the corresponding amount listed in the third column of the table.

[Eluted Amount per Unit Area ($\mu g/cm^2$)] = (C x V) /S

1st Col.			2nd Col.	3rd Col.
Glass apparatus, containers, or packaging			0.7 $\mu g/cm^2$	8 $\mu g/cm^2$
Ceramic apparatus, containers, or packaging			0.7 $\mu g/cm^2$	8 $\mu g/cm^2$
Vitreously enameled apparatus, containers, or packaging	Samples which cannot be filled up with a liquid, or samples which have a depth of less than 2.5 cm when filled up with a liquid	Cooking utensils	0.5 $\mu g/cm^2$	1 $\mu g/cm^2$
		Other than cooking utensils	0.7 $\mu g/cm^2$	8 $\mu g/cm^2$
	Samples with a volume of 3 L or more, which have a depth of 2.5 cm or more when filled up with a liquid		0.5 $\mu g/cm^2$	1 $\mu g/cm^2$

2. Synthetic-Resin Apparatus, Containers, or Packaging

(1) General Specifications

Synthetic-resin apparatus, containers, and packaging must pass the following limit tests. (For synthetic-resin samples whose main component is phenol resin, melamine resin, or urea resin, the potassium permanganate consumption limit test described in 2. Elution Tests b. shall be excluded.)

1. Material Tests

a. Cadmium and Lead

Put 1.0 g of the sample on a platinum, quartz, or heat-resistant glass evaporation dish, and add 2 ml of sulfuric acid. Gradually heat the sample until sulfuric acid no longer emits white fumes and most of the sample carbonizes. Then heat and incinerate the sample at about 450ºC in an electric furnace. Moisten the residue on the evaporation dish with sulfuric acid, and heat it again. Repeat this cycle until the sample is completely incinerated. Add 5 ml of hydrochloric acid (1 in 2) to this residue, stir the mixture, and make it evaporate to dryness on a water bath. After cooling, add 20 ml of 0.1 mol/l-nitric acid to dissolve the residue. If there are any insoluble matters, filter them. Use this solution as the test solution for the following test. Analyze this test solution by atomic absorption spectrometry or inductively coupled plasma emission spectrometry for cadmium and lead tests. If it passes these tests, the amount of cadmium and lead contained in the test solution should NOT exceed 5 μg/ ml each, or 100 μg each per gram of the sample.

2. Elution Tests

a. Heavy Metals

The test solution made from 4 % acetic acid as its eluting solution must pass a heavy metal limit test. If it passes the limit test, the amount of heavy metals contained in the test solution should NOT exceed 1 μg/ ml of lead equivalent.

b. Potassium Permanganate Consumption

The test solution made from water as its eluting solution must pass a potassium permanganate consumption limit test. In this case, the consumption of potassium permanganate must NOT exceed 10 μg/ ml.

(2) Individual Specifications

1. Synthetic-Resin Apparatus, Containers, and Packaging whose Main Component is Phenol Resin, Melamine Resin, or Urea Resin

Synthetic-resin apparatus, containers, and packaging whose main component is phenol resin, melamine resin, or urea resin must pass the following limit tests.

a. Elution Tests

1) Phenol
The test solution made from water as its eluting solution must pass a phenol test, one of the monomer limit tests. If it passes the limit test, the amount of phenol contained in the test solution should NOT exceed 5 μg/ ml.

2) Formaldehyde
The test solution made from water as its eluting solution must pass a formaldehyde test, one of the monomer limit tests.

3) Evaporation Residues
In an evaporation residue limit test, the amount of the residue must NOT exceed 30 μg/ ml.

2. Synthetic-Resin Apparatus, Containers, or Packaging Made from Formaldehyde (excluding Synthetic-Resin Utensils, Containers, and Packaging whose Main Component is Phenol Resin, Melamine Resin, or Urea Resin)

Synthetic-resin apparatus, containers, and packaging made from formaldehyde (excluding synthetic-resin apparatus, containers, and packaging whose main component is phenol resin, melamine resin, or urea resin) must pass the following limit tests.

a. Elution Tests

1) Formaldehyde
The test solution made from water as its eluting solution must pass a formaldehyde test, one of the monomer limit tests.

2) Evaporation Residues
In an evaporation residue limit test, the amount of the residue must NOT exceed 30 μg/ ml.

3. Synthetic-Resin Apparatus, Containers, and Packaging whose Main Component is Polyvinyl Chloride

Synthetic-resin apparatus, containers, and packaging whose main component is polyvinyl chloride must pass the following limit tests.

a. Material Tests

1) Dibutyltin Compounds

Shred or pulverize the sample, and put 0.5 g of that sample in a flask with stopper. Add 20 ml of a mixture of acetone and hexane (3:7) and a drop of hydrochloric acid into the flask, and then seal it tightly. Leave the flask overnight at a constant temperature of about 40ºC, shaking it up occasionally. Then filter this solution after cooling. Using a vacuum concentrator, concentrate both the filtrate and washings to about 1 ml at 40ºC or below. Then transfer the concentrated solution into a 25 ml measuring flask using hexane, and add extra hexane into the flask to make a 25.0 ml solution. Centrifuge the solution at 2,500rpm for about 10 min, and take the resulting supernatant liquid as the test solution for the following test. The test solution must pass a dibutyltin compounds test, one of the additives limit tests. If it passes the limit test, the amount of dibutyltin compounds contained in the test solution should NOT exceed 1 μg/ ml of dibutyltin dichloride equivalent, or 50 μg per gram of the sample.

2) Tricresyl Phosphate

Shred or pulverize the sample, and put 0.5 g of that sample in a flask with stopper. Add 15 ml of acetonitrile into the flask, and seal it tightly. Leave the flask overnight at a constant temperature of about

40ºC. Filter this solution, mix the filtrate and washings, and add acetonitrile to make a 25 ml solution. Use this solution as the acetonitrile extract for the following test. Beforehand, inject and flow 5 ml of acetonitrile, and then 5 ml of a mixture of acetonitrile and water (1:1) into a minicolumn packed with octadecyl-silylated silica gel. Mix 5 ml of the acetonitrile extract and 5 ml of water, and inject the solution into the minicolumn. Then elute the analyte using a mixture of acetonitrile and water (2:1), and take 10 ml of the eluate as the test solution for the following test. This test solution must pass a tricresyl phosphate test, one of the additives limit tests. If it passes the limit test, the amount of tricresyl phosphate contained in the test solution should NOT exceed 10 µg/ ml, or 1 mg per gram of the sample.

3) Vinyl Chloride

Shred the sample, and put 0.5 g of that sample in a 20 ml glass bottle with septum cap. Add 2.5 ml of N,N-dimethylacetamide into the bottle, and then seal it up immediately. Use this solution as the test solution for the following test. This test solution must pass a vinyl chloride test, one of the monomer limit tests. If it passes the limit test, the amount of vinyl chloride contained in the sample should NOT exceed 1 µg/g. However, if the sample is difficult to dissolve, leave the sealed glass bottle overnight at room temperature, shaking it up occasionally. Then use it as the test solution.

b. Elution Tests

1) Evaporation Residues

In an evaporation residue limit test, the amount of the residue must NOT exceed 30 µg/ ml. However, when heptane is used as its eluting solution, the amount of the residue must NOT exceed 150 µg/ ml.

4. Synthetic-Resin Apparatus, Containers, and Packaging whose Main Components are Polyethylene and Polypropylene

Synthetic-resin apparatus, containers, and packaging whose main components are polyethylene and polypropylene must pass the following limit tests.

a. Elution Tests

1) Evaporation Residues

In an evaporation residue limit test, the amount of the residue must NOT exceed 30 µg/ ml. However, when the sample operates at a temperature of 100ºC or below, and heptane is used as its eluting solution, the amount of the residue must NOT exceed 150 µg/ ml.

5. Synthetic-Resin Apparatus, Containers, and Packaging whose Main Component is Polystyrene

Synthetic-resin apparatus, containers, and packaging whose main component is polystyrene must pass the following limit tests.

a. Material Tests

1) Volatile Substances

Precisely measure about 0.5 g of the sample, put it in a 20 ml measuring flask, and then add about 15 ml of tetrahydrofuran. After the sample dissolves, add 1 ml of diethylbenzene TS, add tetrahydrofuran to make a 20 ml solution. Use this solution as the test solution for the following test. In a volatile substance test, one of the monomer limit tests, the total amount of styrene, toluene, ethylbenzene, isopropylbenzene, and propylbenzene contained in the test solution must NOT exceed 5 mg/g. As for foamed polystyrene (only for applications exposed to boiling water), the total concentration of these 5 components must NOT exceed 2 mg/g, and the concentration of each of styrene and ethylbenzene must NOT exceed 1 mg/g. However, even after tetrahydrofuran was added to the sample, and after the sample was left overnight, if most of the sample still does not dissolve, perform the following procedure. Precisely measure 0.1 g of the shredded sample, and put it in a 20 ml glass bottle with septum cap. Add 2.0 ml of dichlorobenzene TS into the glass bottle, and seal it up immediately. Use this solution as its test solution. In a volatile substance test, the total amount of styrene, toluene, ethylbenzene, isopropylbenzene, and propylbenzene contained in the test solution must NOT exceed 5 mg/g.

i. Preparation of Calibration Curves

Put about 80 ml of dichlorobenzene TS in a 100 ml measuring flask. Precisely measure about 100 mg each of styrene, toluene, ethylbenzene, isopropylbenzene, and propylbenzene, and add them into the measuring flask. Add extra dichlorobenzene TS to make a 100 ml solution. Take 1 ml, 2 ml, 3 ml, 4 ml, and 5 ml each of this solution, and add dichlorobenzene TS to make a 20 ml solution. Put 2.0 ml each of this solution in a 20 ml glass bottle with septum cap, and seal up the bottle immediately. Use these 5 solutions as the standard solutions to prepare calibration curves. Then heat these sealed glass bottles at 140ºC for 1 hr, shaking them up occasionally. Conduct gas chromatography analyses using 1 ml each of the gas phase in the glass bottle under the following operating condition. Based on the resulting gas chromatograms, obtain the ratio between the peak area of each of styrene, toluene, ethylbenzene, isopropylbenzene, and propylbenzene, and the peak area of trimethylbenzene. Then prepare the calibration curve for each volatile substance.

Operating Condition

Columns: Use narrow borosilicate glass tubes with an inner diameter of 0.25 mm and a length of 30 m, coated with 0.5 μm-thick polyethylene glycol.

Column temperatures: Keep the column at 60ºC for 1 min, and increase the temperature at a rate of 6ºC/ min to 150ºC. Increase the temperature further at a rate of 30ºC/ min to 180ºC.
Inlet temperature of sample solution: 220ºC
Detector: Use a hydrogen flame ionization detector. Operate the detector at around 220ºC. Adjust the amounts of hydrogen and air so that detection sensitivity can be maximized.
Carrier gas: Nitrogen or helium. Adjust the gas flow rate so that trimethylbenzene will flow out in about 9 min.

ii. Test

Conduct a gas chromatography analysis using the test solution under the same operating condition as described in *i. Preparation of Calibration Curves* above. Based on the resulting gas chromatogram, obtain the ratio between the peak area of each of the 5 volatile substances and the peak area of trimethylbenzene. From their respective calibration curves, obtain the concentration of each of styrene, toluene, ethylbenzene, isopropylbenzene, and propylbenzene. Then calculate the content of each component from the following formula:
[Content (µg/g)] = [Concentration of Test Solution (µg/ml)] x (2 ml) / [Sample Weight (g)]

b. Elution Tests

1) Evaporation Residues

In an evaporation residue limit test, the amount of the residue must NOT exceed 30 µg/ml. However, when heptane is used as the eluting solution, the amount of the residue must NOT exceed 240 µg/ml.

6. Synthetic-Resin Apparatus, Containers, and Packaging whose Main Component is Polyvinylidene Chloride

Synthetic-resin apparatus, containers, and packaging whose main component is polyvinylidene chloride must pass the following limit tests.

a. Material Tests

1) Barium

Put 0.5 g of the sample on a platinum, quartz, or heat-resistant glass evaporation dish. After gradually carbonizing the sample at about 300ºC over direct fire, heat it further at about 450ºC for incineration. Add 50 ml of 0.1 mol/l-nitric acid to this residue and dissolve it. Use this solution as the test solution for the following test. The test solution must pass a barium test using atomic absorption spectrometry or inductively coupled plasma emission spectrometry. If it passes the limit test, the amount of barium contained in the test solution should NOT exceed 1 µg/ ml, or 100µg per gram of the sample.

2) Vinylidene Chloride

Shred the sample, and put 0.5 g of that sample in a 20 ml glass bottle with septum cap. Then add 2.5 ml of N,N-dimethylacetamide into the bottle and seal it up immediately. Use this solution as the test solution for the following test. This test solution must pass a vinylidene chloride test, one of the monomer limit tests. If it passes the limit test, the amount of vinylidene chloride contained in the sample should NOT exceed 6μg/g.

b. Elution Tests

1) Evaporation Residues

In an evaporation residue limit test, the amount of the residue must NOT exceed 30 μg/ml.

7. Synthetic-Resin Apparatus, Containers, and Packaging whose Main Component is Polyethylene Terephthalate

Synthetic-resin apparatus, containers, and packaging whose main component is polyethylene terephthalate must pass the following limit tests.

a. Elution Tests

1) Antimony

The test solution made from 4 % acetic acid as its eluting solution must pass an antimony test using atomic absorption spectrometry or inductively coupled plasma emission spectrometry. If it passes the limit test, the amount of antimony contained in the test solution should NOT exceed 0.05 μg/ml.

2) Germanium

The test solution made from 4 % acetic acid as its eluting solution must pass a germanium test using atomic absorption spectrometry or inductively coupled plasma emission spectrometry. If it passes the limit test, the amount of germanium contained in the test solution should NOT exceed 0.1μg/ml.

3) Evaporation Residues

In an evaporation residue limit test, the amount of the residue must NOT exceed 30 μg/ml.

8. Synthetic-Resin Apparatus, Containers, and Packaging whose Main Component is Polymethyl Methacrylate

Synthetic-resin apparatus, containers, and packaging whose main component is polymethyl methacrylate must pass the following limit tests.

a. Elution Tests

1) Methyl Methacrylate

The test solution made from 20 % ethanol as its eluting solution must pass a methyl methacrylate test, one of the monomer limit tests. If it passes the limit test, the amount of methyl methacrylate contained in the test solution should NOT exceed 15μg/ml.

2) Evaporation Residues

In an evaporation residue limit test, the amount of the residue must NOT exceed 30 μg/ml.

9. Synthetic-Resin Apparatus, Containers, and Packaging whose Main Component is Nylon

Synthetic-resin apparatus, containers, and packaging whose main component is nylon must pass the following limit tests.

a. Elution Tests

1) Caprolactam

The test solution made from 20 % ethanol as its eluting solution must pass a caprolactam test, one of the monomer limit tests. If it passes the limit test, the amount of caprolactam contained in the test solution should NOT exceed 15μg/ml.

2) Evaporation Residues

In an evaporation residue limit test, the amount of the residue must NOT exceed 30 μg/ml.

10. Synthetic-Resin Apparatus, Containers, and Packaging whose Main Component is Polymethylpentene

Synthetic-resin apparatus, containers, and packaging whose main component is polymethylpentene must pass the following limit tests.

a. Elution Tests

1) Evaporation Residues

In an evaporation residue limit test, the amount of the residue must NOT exceed 30 μg/ml. However, when heptane is used as its eluting solution, the amount of the residue must NOT exceed 120 μg/ml.

11. Synthetic-Resin Apparatus, Containers, and Packaging whose Main Component is Polycarbonate

a. Material Tests

1) Bisphenol A (including Phenol and p-tert-Butylphenol)

Put 1.0 g of the sample in a 200 ml conical flask, and add 20 ml of dichloromethane. After the sample dissolves, add 100 ml of acetone dropwise, stirring the solution well. Centrifuge the solution at 3,000rpm for about 10 min, and concentrate the resulting supernatant liquid to about 2 ml using a vacuum concentrator. Add 10 ml of acetonitrile, and make a 20 ml solution by adding water. Take 1 ml of the solution, and filter it through a membrane filter with a pore diameter of 0.5 μm or smaller. Use this solution as the test solution for the following test. In a bisphenol A test (including phenol and p-tert-butylphenol), one of the monomer limit tests, the total amount of bisphenol A, phenol, and p-tert-butylphenol contained in the test solution must NOT exceed 500 μg/g.

2) Diphenyl Carbonate

Use the test solution obtained using the same method as described in *1) Bisphenol A (including Phenol and p-tert-Butylphenol).* In a diphenyl carbonate test, one of the monomer limit tests, the amount of diphenyl carbonate contained in the test solution must NOT exceed 500 μg/g.

3) Amines

Put 1.0 g of the sample in a 200 ml conical flask, and add 20 ml of dichloromethane. After the sample dissolves, add 100 ml of acetone dropwise, and centrifuge the solution at 3,000rpm for about 10 min. After concentrating the resulting supernatant liquid to about 1 ml using a vacuum concentrator, add dichloromethane to make a 2 ml solution. Use this solution as the test solution for the following test. In an amines test (only for triethylamine and tributylamine), one of the additives limit tests, the total amount of triethylamine and tributylamine contained in the test solution must NOT exceed 1 μg/g.

b. Elution Tests

1) Bisphenol A (including Phenol and p-tert-Butylphenol)

i. Apparatus, Containers, or Packaging Used for Oil & Fat and High-Fat Food Products

Wash the sample well with water. Fill up the sample with an eluting solution prepared using 2 ml of heptane per 1 cm^2 of sample surface area. Keep the sample at 25ºC for 1 hr. Transfer 25 ml of this solution onto a separatory funnel and add 10 ml of acetonitrile. After shaking it up for 5 min, leave it to rest. Then transfer the acetonitrile layer into a 25 ml measuring flask. Add 10 ml of acetonitrile to the heptane layer, and repeat the same procedure as above. Then add the acetonitrile layer to the above-mentioned measuring flask. Then add acetonitrile to make a 25 ml solution. Use this solution as the test solution for the following test. In a bisphenol A test (including phenol and p-tert-butylphenol), the total amount of bisphenol A, phenol, and p-tert-butylphenol contained in the test solution must NOT exceed 2.5 μg/ml.

ii. Apparatus, Containers, or Packaging Used for Foods Other than Oil & Fat and High-Fat Food Products

For apparatus, containers, or packaging used for the food listed in the first column of the following table, the test solution shall be prepared using the corresponding solvent listed in the second column as its eluting solution. In a bisphenol A test (including phenol and p-tert-butylphenol), one of the monomer limit tests, the total amount of bisphenol A, phenol, and p-tert-butylphenol contained in the test solution must NOT exceed 2.5 μg/ml.

1st Col.		2nd Col.
Alcoholic beverages		20 % ethanol
Foods other than oil & fat, high-fat food products and alcoholic beverages	above pH 5	Water
	pH 5 or below	4 % acetic acid

2) Evaporation Residues

In an evaporation residue limit test, the amount of the residue must NOT exceed 30 μg/ml.

12. Synthetic-Resin Apparatus, Containers, and Packaging whose Main Component is Polyvinyl Alcohol

Synthetic-resin apparatus, containers, and packaging whose main component is polyvinyl alcohol must pass the following limit tests.

a. Elution Tests

1) Evaporation Residues

In an evaporation residue limit test, the amount of the residue must NOT exceed 30 µg/ml.

13. Synthetic-Resin Apparatus, Containers, and Packaging whose Main Component is Polylactic Acid

Synthetic-resin apparatus, containers, and packaging whose main component is polylactic acid must pass the following limit tests.

a. Elution Tests

1) Total Lactic Acid

The test solution made from water as its eluting solution must pass a total lactic acid test, one of the monomer limit tests. If it passes the limit test, the amount of total lactic acid contained in the test solution should NOT exceed 30 µg/ml.

2) Evaporation Residues

In an evaporation residue limit test, the amount of the residue must NOT exceed 30 µg/ml.

14. Synthetic-Resin Apparatus, Containers, and Packaging whose Main Component is Polyethylene naphthalate

Synthetic-resin apparatus, containers, and packaging whose main component is polyethylene naphthalate must pass the following limit tests.

a. Elution Tests

1) Germanium

The test solution made from 4 % acetic acid as its eluting solution must pass a germanium test using atomic absorption spectrometry or inductively coupled plasma emission spectrometry. If it passes the limit test, the amount of germanium contained in the test solution should NOT exceed 0.1µg/ml.

2) Evaporation Residues

In an evaporation residue limit test, the amount of the residue must NOT exceed 30 µg/ml.

3. Rubber Apparatus, Containers, or Packaging

(1) Rubber Apparatus (excluding Baby Utensils), Containers, or Packaging

Rubber apparatus (excluding baby utensils), containers, or packaging must pass the following limit tests (excluding the 2-mercaptoimidazoline test described in *1. Material Tests b.* for rubber products not containing chlorine).

1. Material Tests

a. Cadmium and Lead

For samples other than silicone rubber products, put 1.0 g of the sample on a platinum, quartz, or heat-resistant glass evaporation dish. Add 2 ml of sulfuric acid to the sample and heat it gradually. Continue heating it until sulfuric acid no longer emits white fumes and most of the sample carbonizes. Then heat and incinerate the sample at about 450ºC in an electric furnace. Moisten the sample on the evaporation dish with sulfuric acid, and heat it again. Repeat this cycle until it is completely incinerated. Add 5 ml of hydrochloric acid (1 in 2) to this residue, stir the mixture, and make it evaporate to dryness on a water bath. After cooling, add 20 ml of 0.1 mol/l-nitric acid to dissolve the residue. If there are any insoluble matters, filter them. Use this solution as the test solution.

For silicone rubber samples, shred the sample, measure 0.5 g of that sample and put it into a platinum or nickel crucible. Add 5 g of sodium hydroxide and 2 g of boric acid into the crucible, and stir the content well. Gently heat the crucible over a gas burner to a temperature at which the content will dissolve. Stop heating as soon as the sample completely dissolves, and allow it to cool at room temperature. Put about 75 ml of hot water and the crucible into a beaker. While heating the beaker on an as-needed basis, shake up the crucible to dissolve the solid material attached inside. Remove the crucible from the solution, washing it with a small amount of water. While stirring it, pour the solution in small portions into a flask with stopper, which contains 15 ml of nitric acid. After leaving it overnight at room temperature, add 5 mol/l-ammonium acetate TS to the solution to adjust the pH to 3.5. Inject the pH-adjusted solution into a chelating resin-packed minicolumn (500 mg), into which 5 ml of methanol, 5 ml of 0.1 mol/l-nitric acid, and 10 ml of water were separately injected and flowed in advance. In addition, inject 1 mol/l-ammonium acetate TS and 10 ml of water into the minicolumn. Then elute the analyte with 0.1 mol/l-nitric acid, and obtain 10 ml of the eluate. Use this eluate as the test solution for the following test.

This test solution must pass cadmium and lead tests using atomic absorption spectrometry or inductively coupled plasma emission spectrometry. If it passes the limit test, the amount of cadmium and lead contained in the test solution should NOT exceed 5 μg/ml each, or 100 μg each per gram of the sample.

b. 2-Mercaptoimidazoline

Shred the sample, measure 1.0 g of this sample and put it in a flask with stopper. Add 50 ml of methanol, and seal up the flask. Then leave the flask overnight at a constant temperature of about 40ºC, shaking it up occasionally. Filter this solution after cooling. Using a vacuum concentrator, concentrate both the filtrate and washings to about 5 ml at 40ºC or below. Then add water to make a 10 ml solution. Take 1 ml of the solution, and filter it through a membrane filter with a pore diameter of 0.5 μm or smaller. Use this solution as the test solution for the following test. This test solution must pass a 2-mercaptoimidazoline test, one of the additives limit tests.

2. Elution Tests

a. Phenol

The test solution made from water as its eluting solution must pass a phenol test, one of the monomer limit tests. If it passes the limit test, the amount of phenol contained in the test solution should NOT exceed 5 μg/ml.

b. Formaldehyde

The test solution made from water as its eluting solution must pass a formaldehyde test, one of the monomer limit tests.

c. Zinc

Take 1 ml of the test solution made from 4 % acetic acid as its eluting solution, and add 4 % acetic acid to make a 15 ml solution. The test solution must pass a zinc limit test using atomic absorption spectrometry or inductively coupled plasma emission spectrometry. If it passes the limit test, the amount of zinc contained in the test solution should NOT exceed 15 μg/ml.

d. Heavy Metals

The test solution made from 4 % acetic acid as its eluting solution must pass a heavy metal limit test. If it passes the limit test, the amount of heavy metals contained in the test solution should NOT exceed 1 μg/ml of lead equivalent. In the case where the addition of sodium sulfide TS produces white turbidity and affects the test result, perform the following procedure. Neutralize the test solution with ammonia water, making the pH 7 or higher. Add potassium cyanide TS to this solution, and then conduct the heavy metal limit test.

e. Evaporation Residues

In an evaporation residue limit test, the amount of the residue must NOT exceed 60 μg/ml. For rubber apparatus, test solutions must be prepared using water as their eluting solution. On the other hand, for rubber containers and packaging used for oil & fat and high-fat food products, test solutions must be prepared using 20 % ethanol.

(2) Rubber Baby Utensils

Rubber baby utensils must pass the following limit tests.

1. Material Tests

a. Cadmium and Lead

Rubber baby utensils must pass tests in accordance with *(1) Rubber Apparatus (excluding Baby Utensils), Containers, or Packaging, 1. Material Tests, a. Cadmium and Lead*. In this case, use the following solutions as the standard solutions: add 0.1 mol/l-nitric acid to 10 ml each of the cadmium standard solution and the lead standard solution to make a 100 ml solution. If it passes the limit test, the amount of each of cadmium and lead contained in the test solution should NOT exceed 0.5 µg/ml, or 10 µg per gram of the sample.

2. Elution Tests

a. Preparation of Test Solutions

Wash the sample well with water, and put it in 20 ml of a designated eluting solution per gram of the sample. Leave the solution for 24 hr at a constant temperature of 40ºC. Use this solution as the test solution for the following test.

b. Test

1) Phenol

(1) *Rubber Apparatus (excluding Baby Utensils), Containers, or Packaging, 2. Elution Tests, a. Phenol,* shall be applied mutatis mutandis.

2) Formaldehyde

(1) *Rubber Apparatus (excluding Baby Utensils), Containers, or Packaging, 2. Elution Tests, b. Formaldehyde*, shall be applied mutatis mutandis.

3) Zinc

Take 20 ml of the test solution prepared using water as its eluting solution, and add 5 drops of acetic acid. This solution must pass a zinc limit test using atomic absorption spectrometry or inductively coupled plasma emission spectrometry. If it passes the limit test, the amount of zinc contained in the test solution should NOT exceed 1 μg/ml.

4) Heavy Metals

(1) *Rubber Apparatus (excluding Baby Utensils), Containers, or Packaging, 2. Elution Tests, d. Heavy Metals*, shall be applied mutatis mutandis.

5) Evaporation Residues

In an evaporation residue limit test, the amount of the residue must NOT exceed 40 μg/ml. In this test, use water as the eluting solution.

4. Metal Cans (excluding those containing dried foods (except oil & fat and high-fat food products); this applies to all the metal cans described in this section.)

Metal cans must pass the following limit tests. (If the part of a metal can that directly touches food is not coated with a synthetic resin, the test items described in *(2) Test, 2. through 6.* shall be excluded.)

(1) Preparation of Test Solutions

Unless otherwise specified, prepare the test solution as follows.
After washing the sample well with water, prepare the test solution using the following procedure, using the eluting solution specified by each limit test.
If the sample has a structure that can be filled with a liquid, fill up the sample with the eluting solution heated to 60ºC. Then cover the sample with a watch glass, and leave it for 30 min at a constant temperature of 60ºC.
If the sample does not have a structure that can be filled with a liquid, heat 2 ml of the eluting solution per 1 cm^2 of the sample's surface area. Immerse the sample in the eluting solution. Then leave it for 30 min at a constant temperature of 60ºC.
In this case, if the sample is used at a service temperature exceeding 100ºC, and if water is used as the eluting solution, leave it for 30 min at a constant temperature of 95ºC. Likewise, if heptane or pentane is used as the eluting solution, leave it for 1 hr at a constant temperature of 25ºC.

(2) Test

1. Arsenic, Cadmium, and Lead

For containers or packaging used for the food listed in the first column of the following table, prepare a test solution using the corresponding solvent listed in the second column as its eluting solution for the following limit tests.

1st Col.	2nd Col.
Food with a pH above 5	Water
Food with a pH of 5 or below	0.5 % citric acid solution

a. Arsenic

Conduct an arsenic limit test using 10 ml of the test solution. If it passes the limit test, the amount of arsenic contained in the test solution should NOT exceed 0.2 µg/ml of diarsenic trioxide equivalent.

b. Cadmium and Lead

The test solution must pass cadmium and lead limit tests using atomic absorption spectrometry or inductively coupled plasma emission spectrometry. In this case, test solutions made using water must contain 5 drops of nitric acid per 100 ml. The cadmium standard solution must be the solution for metal can test use, and the lead standard solution must be the solution for metal can test use. If it passes the limit test, the amount of cadmium and lead contained in the test solution should NOT exceed 0.1 µg/ml and 0.4 µg/ml, respectively.

2. Phenol

The test solution made from water as its eluting solution must pass a phenol test, one of the monomer limit tests. If it passes the limit test, the amount of phenol contained in the test solution should NOT exceed 5 µg/ml.

3. Formaldehyde

The test solution made from water as its eluting solution must pass a formaldehyde test, one of the monomer limit tests.

4. Evaporation Residues

In an evaporation residue limit test for which the test solution is prepared using the eluting solution specified in that test procedure, the amount of evaporation residue must NOT exceed 30 µg/ml. However, if the sample is taken from a metal can that is coated inside with a coating material whose main raw materials are natural oil and fat, and that contains more than 3 % of zinc oxide in the coating film, and if heptane is used as its eluting solution, the amount of evaporation residue must NOT exceed 90 µg/ml. In this case, if the amount of evaporation residue exceeds 30 µg/ml when water is used as its eluting solution, the test solution must also pass the following test.

Add 30 ml of chloroform to the evaporation residue, which was obtained using water as the eluting solution for the test solution. Warm the solution, filter it, and put the filtrate on a platinum, quartz, or heat-resistant glass evaporation dish, whose weight is known. Further wash the evaporation residue twice with 10 ml of chloroform each time. Warm the solution, filter it, and add the filtrate to the evaporation dish. Then evaporate and dry the solution on a water bath. After cooling, weigh the evaporation dish to obtain the difference in weight a (mg) before and after the washing with chloroform. The amount of chloroform-soluble materials calculated from the following formula must NOT exceed 30 µg/ml.

[Amount of Chloroform-Soluble Materials (µg/ml)] = [(a – b) x 1,000] / [Amount of Initial Test Solution (ml)]

where b: the blank value obtained using the same volume of the eluting solution as the test solution (mg)

5. Epichlorohydrin

The test solution prepared using pentane as its eluting solution must pass an epichlorohydrin test, one of the monomer limit tests. If it passes the limit test, the amount of epichlorohydrin contained in the test solution should NOT exceed 0.5 µg/ml.

6. Vinyl Chloride

If the sample has a structure that can be filled with a liquid, fill up the sample with ethanol cooled to 5ºC or below. Then seal the sample tightly, and leave it for 24 hr at 5ºC or below.
If the sample does not have a structure that can be filled with a liquid, immerse the sample in ethanol cooled to 5ºC or below, whose volume is 2 ml per 1 cm^2 of the sample's surface area. Leave it in a sealed container for 24 hr at 5ºC or below.
Put 10 ml of the obtained solution in a glass bottle with septum cap, and seal it up immediately. Use this solution as the test solution for the following test. This test solution must pass a vinyl chloride test, one of the monomer limit tests. If it passes the limit test, the amount of vinyl chloride contained in the test solution should NOT exceed 0.05 µg/ml.

E. Specifications for Apparatus, Containers, or Packaging by Application

1. Containers/Packaging Used for Retort Pouch Foods (excluding canned foods or bottled foods; this applies to all the retort pouch foods described in this section.)

Containers/packaging used for retort pouch foods must satisfy all the following requirements. (Only requirement (4) shall not apply to those containers/packaging that will be sealed by seaming.)

(1) These containers/packaging must be light-blocking and gas-impermeable. This shall not apply to those containers/packaging whose content is unlikely to deteriorate in quality due to rancid oil and fat.
(2) When filled up with water, sealed up, and pressurized and heated in the same way as in the manufacturing process, these containers/packaging must NOT break, deform, color, or discolor.
(3) These containers/packaging must NOT allow the content or water to leak in a compression test, one of the strength limit tests.
(4) These containers/packaging must represent a measurement value of 23N or greater in a heat-seal strength test, one of the strength limit tests. This shall not apply to the box-shaped containers/packaging whose maximum bursting pressure is 20 kPa or higher in an internal pressure test, one of the strength limit tests.
(5) These containers/packaging must NOT allow the content or water to leak in a drop test, one of the strength limit tests. If they are wrapped in extra packaging for retailing, the containers/packaging must receive this drop test in that form.

2. Containers/Packaging Used for Soft Drinks (excluding fruit juices as raw materials; this applies to all the soft drinks described in this section.)

Containers/packaging used for soft drinks refer to the following containers/packaging: glass containers/packaging, metal containers/packaging (including metal containers/packaging that use a non-metal material to seal the opening; this applies to all the metal containers/packaging described in this section), synthetic-resin containers/packaging, synthetic-resin-laminated paper containers/packaging, synthetic-resin-laminated aluminum foil containers/packaging, or combined containers/packaging (which use two or more of metal, synthetic-resin, synthetic-resin-laminated paper, and synthetic-resin-laminated aluminum foil; this applies to all the combined containers/packaging described in this section). These containers/packaging must satisfy all the requirements listed in (1) through (4) below.

(1) Glass Containers/Packaging Used for Soft Drinks

1. If collected and used repeatedly, glass containers/packaging used for soft drinks must be transparent.

2. Glass containers/packaging used for soft drinks must pass the following tests. This shall not apply to those containers/packaging that will be sealed with a paper lid.

a. The glass containers/packaging that will be filled with a carbonated soft drink must NOT allow gas to leak in a continuous pressure test, one of the strength limit tests.
b. The glass containers/packaging that will be hot filled with a soft drink must NOT allow air to leak in a depressurization test, one of the strength limit tests.
c. The glass containers/packaging that will be filled with a non-carbonated soft drink by a method other than hot filling must NOT allow the content to leak in a water leak test, one of the strength limit tests.

(2) Metal Containers/Packaging Used for Soft Drinks

1. Metal containers/packaging used for soft drinks must pass the following limit tests.

a. The metal containers/packaging used for soft drinks whose internal pressure exceeds atmospheric pressure at room temperature must NOT allow air to leak in a pressure test, one of the strength limit tests.
b. The metal containers/packaging used for soft drinks whose internal pressure does not exceed atmospheric pressure at room temperature must NOT allow air to leak in a depressurization test, one of the strength limit tests.

2. The metal containers/packaging used for soft drinks that use a non-metal material to seal the opening must pass the following limit tests.

a. Pinholes must NOT be found in a pinhole test, one of the strength limit tests. In this case, test the metal container/packaging, with its opening facing downward.
b. The non-metal material used for sealing must represent a measurement value of 490 kPa or greater in a burst strength test, one of the strength limit tests.
c. The non-metal material used for sealing must represent a measurement value of 15N or greater in a sticking strength test, one of the strength limit tests.

(3) Synthetic-Resin Containers/Packaging, Synthetic-Resin-Laminated Paper Containers/Packaging, and Synthetic-Resin-Laminated Aluminum Foil Containers/Packaging Used for Soft Drinks

1. Synthetic resins used for the parts that directly touch the content shall be specified by the individual specifications described in *Chapter III. Apparatus, Containers and Packaging, D. Specifications by Material for Apparatus, Containers, Packaging, or their Materials, 2. Synthetic Resin Utensils, Containers, or Packaging, (2) Individual Specifications*. This shall not apply to the synthetic-resin-laminated aluminum foil used for sealing.

2. These containers/packaging used for soft drinks must pass the following limit tests.

a. These containers/packaging used for soft drinks must NOT allow the content or water to leak in a drop test, one of the strength limit tests.
b. Any pinhole must NOT be found in a pinhole test, one of the strength limit tests.
c. The synthetic-resin-laminated paper containers/packaging for soft drinks that will be heat sealed must NOT allow air to leak in a seal test, one of the strength limit tests.
d. The synthetic-resin containers/packaging and the synthetic-resin-laminated aluminum foil containers/packaging for soft drinks that will be heat-sealed must NOT allow the content or water to leak in a compression test, one of the strength limit tests.
e. The part of these containers/packaging that will be filled with a carbonated soft drink and sealed with a crown cap or the like must NOT allow gas to leak in a continuous pressure test, one of the strength limit tests.
f. The part of these containers/packaging that will be hot filled with a soft drink and sealed with a crown cap or the like must NOT exhibit the color of methylene blue in a continuous depressurization test, one of the strength limit tests.
g. The part of these containers/packaging that will be filled with a non-carbonated soft drink by a method other than hot filling and sealed with a crown cap or the like must NOT allow the content to leak in a water leak test, one of the strength limit tests.

(4) Combined Containers/Packaging for Soft Drinks

1. Metal materials used for these combined containers/packaging must satisfy the specifications described in Chapter III. Apparatus, Containers and Packaging, D. Specifications by Material for Apparatus, Containers, Packaging, or their Materials, 4. Metal Cans (excluding those containing

dried foods (except oil & fat and high-fat food products), which applies to all the metal cans described in this section.). At the same time, synthetic resin, synthetic-resin-laminated paper, and synthetic-resin-laminated aluminum foil used for these combined containers/packaging must satisfy the requirements stipulated in (3) Synthetic-Resin Containers/Packaging, Synthetic-Resin-Laminated Paper Containers/Packaging, and Synthetic-Resin-Laminated Aluminum Foil Containers/Packaging, 1.

2. Combined containers/packaging used for soft drinks must pass the following tests.

a. Combined containers/packaging used for soft drinks must NOT allow the content or water to leak in a drop test, one of the strength limit tests.
b. Pinholes must NOT be found in a pinhole test, one of the strength limit tests.
c. The combined containers/packaging for soft drinks that will be heat-sealed must NOT allow air to leak in a seal test, one of the strength limit tests.
d. The combined containers/packaging that will be hot filled with a soft drink must NOT allow air to leak in a depressurization test, one of the strength limit tests.
e. The combined containers/packaging that will be filled with a soft drink by a method other than hot filling, and that will be sealed by a method other than heat-sealing, must NOT allow the content to leak in a water leak test, one of the strength limit tests.

3. Apparatus Used for Manufacturing Frozen confections

(1) Apparatus which are used for manufacturing frozen confections must have a structure that is easy to clean. The inner surface and the surface that touches food must be finished smoothly. They must be made of raw materials which will not rust, or must be fabricated to prevent rusting.
(2) Dispensing machines and capping machines which are used for manufacturing frozen confections must be easy to clean and sterilize. These machines must also be capable of preventing dirt and other contaminations.
(3) Containers which are used for storing or carrying frozen confections must have dust and insect proofing devices. These containers must have a structure that can prevent thawed water from touching frozen confections directly.

4. Automatic Food Vending Machines (limited to those vending machines in which the food touches the machine parts directly), and the containers used to sell the food through these vending machines, must satisfy all the requirements listed in (1) through (3) below.

(1) Main Unit of Automatic Food Vending Machine

1. Materials

The parts that directly touch food must be made of materials like stainless steel, from which toxic and noxious substances are unlikely to be eluted, and which are also acid-resistant, heat-resistant, water-resistant, and impermeable. The parts that filter the food shall not be required to use an impermeable material.

2. Structure and Function

a. These vending machines must have a structure that can clean and sterilize the parts that directly touch food.
b. These vending machines must have a structure that does not allow easy access from the outside to the food or the parts that directly touch the food.
c. To protect the food-storing part from heat/steam generated in the other parts, these vending machines must have an exhaust system, or a partition wall between the food-storing part and the other parts.
d. The food-storing part, or the food-cooking part, must have a structure that can prevent rodents and insects from entering, and that can keep itself from dust and other contaminations.
e. The food outlet must have a structure that insulates itself from outside air except during the time when the food is being sold.
f. The part that stores apparatus and seasonings, such as chopsticks and cups which are served with the food, must have a structure that can prevent dust and other contaminations. This shall not apply to the case where these apparatus and seasonings are put in a separate container/packaging or packaging so that they will not be contaminated by dust and other impurities, or the case where they are served with the food wrapped together.
g. The door of a vending machine into which the food is fed must be lockable.
h. Vending machines that cook food must have a structure that automatically starts cooking each time the food is sold. However, the vending machines that extract coffee and satisfy all the requirements listed in 1) through 4) below shall not be required to extract coffee each time the food is sold.

1) When the temperature of hot water used to extract coffee is lower than 85ºC, the vending machine automatically stops selling the food.
2) The vending machine must be equipped with a heating system capable enough to keep extracted coffee at 63ºC or above. At the same time, when it can no longer keep that temperature, the vending machine automatically stops selling the food and will not automatically start selling the food again.
3) When extracted coffee is stored for more than 22 hr before being sold, the vending machine must automatically stop selling the food.
4) The vending machine must be equipped with a device that can dry the part in which extracted coffee is stored (limited to the part that touches directly with the coffee) at 63ºC or above for more than 2 hr once every day.

i. Vending machines that cook food using hot water must supply hot water with a temperature of 85ºC or above each time the food is sold. At the same time, these vending machines must automatically stop selling the food when the temperature of hot water is lower than 85ºC. This shall not apply to the vending machines that cook powdered soft drinks. This also shall not apply to the vending machines that have a container filled with raw materials for cooking in advance, which satisfy all the requirements listed in 1) and 2) below. These vending machines cook such raw materials in the container, supply hot water with a temperature of 75ºC or above each time the food is sold, and automatically stop selling the food when the temperature of hot water is lower than 75ºC.

1) These raw materials must be dried powder or shredded materials.
2) The bacterial counts (viable aerobic counts) of these raw materials must NOT exceed 3,000 per gram of a specimen. At the same time, these raw materials must be negative for coliform bacteria. In this case, bacterial counts (viable aerobic counts) measurements and coliform bacteria limit tests shall be conducted in accordance with *Chapter I. Food, D. Respective Articles: Powdered Drink Beverages, 1. Ingredient Standards for Powdered Soft Drinks, (3) 1., 2., and 3*.

j. Vending machines that freeze, refrigerate, or warm food (excluding carbonated soft drinks and retort pouch foods) must be equipped with a temperature control device that can adjust food storage temperatures, and a temperature gauge that indicates food storage temperatures. This shall not apply to those automatic vending machines that sell soft drinks in cups, whose piping and all other parts have a closed structure, and which use a carrying apparatus tightly capped, sealed, or equally protected by other methods.

k. Vending machines that freeze, refrigerate, or warm food (excluding carbonated soft drinks and retort pouch foods) must be equipped with a cooling system or heating system capable enough to keep the food at the following temperatures. At the same time, these vending machines must stop selling the food and will not automatically start selling the food again when it can no longer keep the temperature. This shall not apply to those automatic vending machines that sell soft drinks in cups, whose piping and all other parts have a closed structure, and which use a carrying apparatus tightly capped, sealed, or equally protected by other methods.

1) –15ºC or below for vending machines that freeze food
2) 10ºC or below for vending machines that refrigerate food
3) 63ºC or above for vending machines that warm food

l. Vending machines that use water supplied from a water service under the Water Supply Law must have a structure that automatically feeds water from the faucet and does not allow water to flow backward. This shall not apply to those vending machines that supply water from a cartridge feed-water tank (a detachable container mounted on an automatic vending machine for water supply: this applies to all the cartridge feed-water tanks described in this section).

m. Vending machines that use water other than that supplied from a water service under the Water Supply Law, or water from a cartridge feed-water tank, must be equipped with a heat sterilizing apparatus that can boil the water before use for more than 5 min, a sterilizing apparatus with equivalent or higher capability, or a bacterial filter apparatus.

(2) Cartridge Feed-Water Tanks

1. Materials

The parts that directly touch water must be made of materials like stainless steel, from which toxic and noxious substances are unlikely to be eluted, and which are also acid-resistant, water-resistant, and impermeable.

2. Structure

The openings such as a feed-water inlet must be sealed up with a screw-in plug or cap. At the same time, they must not be exposed directly to outside air during transportation.

(3) Containers

1. Containers used for selling food (excluding soft drinks) must be cleaned and sterilized. This shall not apply to unused paper, synthetic-resin, synthetic-resin-laminated paper, and aluminum foil containers or combined containers (which refer to those containers that use two or more of paper, synthetic resin, synthetic-resin-laminated paper or metal: this applies to all the combined containers described in this section), which are sterilized, or manufactured by a method that has an antiseptic effect, and handled so carefully that they would not be contaminated before use.

2. Containers used for selling soft drinks must be unused paper, synthetic-resin, synthetic-resin-laminated paper, and aluminum foil containers or combined containers, which are sterilized, or manufactured by a method that has an antiseptic effect, and handled so carefully that they would not be contaminated before use.

5. Carrying Apparatus or Containers/Packaging for Soft Drink Concentrates Stored in Automatic Vending Machines to Sell Food in Cups, or Full Automatic Soft Drink Cooking Machines

(1) Metallic carrying apparatus or containers/packaging must have a screw-in plug or cap. They must have a structure that is easy to clean, and the inner surface must be finished smoothly. They must be made of materials which will not rust, or must be fabricated to prevent rusting.

(2) The following specifications shall be applied mutatis mutandis to synthetic-resin carrying apparatus or containers/packaging: *Chapter III. Apparatus, Containers and Packaging, E. Specifications for Apparatus, Containers, or Packaging by Application, 2. Containers/Packaging Used for Soft Drinks (excluding fruit juice concentrates; this applies to all the soft drinks described in this section.), (3) Synthetic-Resin Containers/Packaging, Synthetic-Resin-Laminated Paper Containers/Packaging, and Synthetic-Resin-Laminated Aluminum Foil Containers/Packaging*.

F. Product Standards for Apparatus, Containers, and Packaging

1. The parts of apparatus, containers, and packaging made of copper or copper alloys that touch food must be plated with tin or silver, or treated in a way that would not cause sanitary hazards. This shall not apply to those apparatus, containers, and packaging made of copper or copper alloys that have an inherent luster and will not rust.

2. If chemically synthesized colorants are used for production of apparatus, containers, or packaging, any colorant other than those listed in Appended Table 1, the Ordinance for Enforcement of the Food Sanitation Act, must NOT be used. This shall not apply to the case where such colorant is blended with glaze, glass, or vitreous enamel, and where such colorant is blended by other methods that would not allow it to dissolve into the food.

3. Paper, kyogi (paper-thin sheets of wood), or metal foil containers/packaging which are used for frozen confections must be sterilized after being manufactured.

4. When producing apparatus, containers, or packaging, the vertebral columns of certain cattle must NOT be used as raw materials. This shall not apply to the case where any one of the following items is used as a raw material.

(1) Oil and fat derived from the vertebral columns of certain cattle, which are hydrolyzed, saponified, or transesterified under high temperature and pressure.
(2) The vertebral columns of certain cattle aged 30 months or below, which are defatted, acid decalcified, acid or alkaline treated, filtered, and sterilized at 138ºC or above for at least 4 sec, or those vertebral columns that receive equivalent or higher levels of treatments to reduce infectivity.

5. When producing apparatus, containers, or packaging whose service temperatures exceed 40ºC, polylactic acid that contains more than 6 % of D-lactic acid must NOT be used. This shall not apply to those apparatus, containers, or packaging that are used at 100ºC or below up to 30 min or at 66ºC or below up to 2 hr.

Chapter IV. Toys

A. Specifications for Toys and their Raw Materials

1. Transfer pictures must pass the following limit tests. The water used for these tests shall be distilled water.

(1) Preparation of Test Solutions

Cut out the colored part of the transfer picture as a sample, and immerse it in 2 ml of 40ºC water per 1 cm^2 of the surface area. Cover the sample with a watch glass, and leave it for 30 min at 40ºC, shaking it up occasionally.

(2) Test

1. Heavy Metals

20 ml of the test solution must pass the limit tests described in *Chapter III. Apparatus, Containers, and Packaging, B. General Test Methods for Apparatus, Containers, or Packaging, 4. Heavy Metals Limit Tests*. If it passes the limit test, the amount of heavy metals contained in the test solution should NOT exceed 1 μg/ml of lead equivalent.

2. Arsenic

20 ml of the test solution must pass the limit tests described in *Chapter III. Apparatus, Containers, and Packaging, B. General Test Methods for Apparatus, Containers, or Packaging, 7. Arsenic Limit Tests*. If it passes the limit test, the amount of arsenic contained in the test solution should NOT exceed 0.1 μg/ml of diarsenic trioxide equivalent.

2. Origami papers must pass the following limit tests.
The water used for these tests shall be distilled water.

(1) Preparation of Test Solutions

Immerse the sample in 2 ml of 40ºC water per 1 cm^2 of the surface area. Cover the sample with a watch glass, and leave it for 30 min at 40ºC, shaking it up occasionally.

(2) Test

1. Heavy Metals

Chapter IV. Toys, A. Specifications for Toys and their Raw Materials, 1. (2) Test, 1. Heavy Metals, shall be applied mutatis mutandis.

2. Arsenic

Chapter IV. Toys, A. Specifications for Toys and their Raw Materials, 1. (2) Test, 2. Arsenic, shall be applied mutatis mutandis.

3. Rubber pacifiers must pass the limit tests described in Chapter III. Apparatus, Containers, and Packaging, D. Specifications by Material for Apparatus, Containers, Packaging, or their Materials, 3. Rubber Apparatus, Containers, or Packaging, (2) Rubber Baby Utensils.

4. Coatings on toys must pass the following limit tests.

(1) Preparation of Test Solutions

Prepare a sample by scraping the coatings off the toy and then pulverizing it to 0.5 mm mesh or lower. For elastic coatings difficult to pulverize such as resins, prepare a sample by making it as fine as possible. Precisely measure about 100 mg or more of the sample, add 50 times as much 0.07 mol/l-hydrochloric acid, and shake it for 1 hr at 37ºC, light shielded. After leaving it for 1 hr at a constant temperature of 37ºC, filter the solution. If the amount of the sample is 10 mg or more and less than 100 mg, add 5 ml of 0.07 mol/l-hydrochloric acid before testing. If the amount of the sample is less than 10 mg, do not test the sample.
0.07 mol/l-hydrochloric acid shall be prepared by adding distilled water to 6.3 ml of hydrochloric acid / HCl [JIS K 8180; special grade] to make a 1,000 ml solution.

(2) Test

1. Cadmium, Lead, and Arsenic

Put 0.1 ml of the cadmium standard stock solution, 0.1 ml of the lead standard stock solution, and 1.3 ml of the arsenic standard stock solution in a container, and add 0.07 mol/l-hydrochloric acid to make a 100 ml solution. 1 ml of this solution contains 1μg each of cadmium, lead, and arsenic. Dilute this solution with 0.07 mol/l-hydrochloric acid appropriately. Measure the concentration of each element using the same method as for the test solution, and prepare the calibration curve for each of cadmium, lead, and arsenic. The cadmium standard stock solution, the lead standard stock solution, and the arsenic standard stock solution must be those specified in *Chapter III. Apparatus, Containers, and Packaging, C. Reagents & Testing Solutions (TS), 4. Standard Solutions, Standard Stock Solutions*.
The concentration of each of cadmium, lead, and arsenic in the test solution shall be obtained using the methods described in *Chapter III. Apparatus, Containers, and Packaging, B. General Test Methods for Apparatus, Containers, or Packaging, 3. Atomic Absorption Spectrometry, or 9. Inductively Coupled Plasma Emission Spectrometry*. The elution amount of each of cadmium, lead, and arsenic per gram of the test sample calculated from the following formula must NOT exceed 75 μg/g, 90 μg/g, and 25 μg/g, respectively. In this case, the amount of arsenic shall be measured by atomic absorption spectrometry at a wavelength of 193.7 nm.

[Elution Amount (μg/g)] = [Concentration of Test Solution (μg/ml)] x [Volume of Test Solution (ml)] / [Sample Weight (g)] x [(100 – Correction Value) / 100]
where correlation values are 30 for cadmium and lead, and 60 for arsenic.

5. Coatings using polyvinyl chloride must pass the limit tests described in *Chapter IV. Toys, A. Specifications for Toys and their Raw Materials, 4. Limit Tests*, and the following limit tests as well. The water used for these tests shall be distilled water.

(1) Preparation of Test Solutions

Cut out a sample from a coated toy or prepare its specimen. After immersing the sample in 2 ml of 40ºC water per 1 cm^2 of the surface area, cover the sample with a watch glass, and leave it for 30 min at 40ºC, shaking it up occasionally.

(2) Test

1. Potassium Permanganate Consumption

Add water to 50 ml of the test solution to make a 100 ml solution. In a test using the solution using the method described in *Chapter III. Apparatus, Containers, and Packaging, B. General Test Methods for Apparatus, Containers, or Packaging, 1. Potassium Permanganate Consumption Limit Test*, the potassium permanganate consumption obtained from the following formula must NOT exceed 50 μg/ml.

[Potassium Permanganate Consumption (μg/ml)] = [(a – b) x 0.316 x f x 1,000] / 50
where
a: the volume of 0.002 mol/l-potassium permanganate solution consumed in the main test (ml)
b: the volume of 0.002 mol/l-potassium permanganate solution consumed in the blank test (ml)
f: the factor of 0.002 mol/l-potassium permanganate solution

2. Evaporation Residues

In a test using 200–300 ml of the test solution using the method described in *Chapter III. Apparatus, Containers, and Packaging, B. General Test Methods for Apparatus, Containers, or Packaging, 5. Evaporation Residue Limit Tests*, the amount of evaporation residues must NOT exceed 50 μg/ml.

6. The part of a toy (excluding coatings) made using materials whose main component is polyvinyl chloride must pass the following limit tests. The water used for these tests shall be distilled water.

(1) Preparation of Test Solutions

Cut out a sample from a toy or prepare its specimen. After immersing the sample in 2 ml of 40ºC water per 1 cm^2 of the surface area, cover the sample with a watch glass, and leave it for 30 min at 40ºC, shaking it up occasionally.

(2) Test

1. Potassium Permanganate Consumption

Chapter IV. Toys, A. Specifications for Toys and their Raw Materials, 5. (2) Test, 1. Potassium Permanganate Consumption, shall be applied mutatis mutandis.

2. Heavy Metals

Chapter IV. Toys, A. Specifications for Toys and their Raw Materials, 1. (2) Test, 1. Heavy Metals, shall be applied mutatis mutandis.

3. Cadmium

Add 5 drops of nitric acid to 100 ml of the test solution. This solution must pass a cadmium test using the method described in *Chapter III. Apparatus, Containers, and Packaging, B. General Test Methods for Apparatus, Containers, or Packaging, 3. Atomic Absorption Spectrometry, or 9. Inductively Coupled Plasma Emission Spectrometry*. In this case, use the cadmium standard solution prepared using the following procedure: to make a 100 ml solution, add water to 10 ml of the cadmium standard solution, which is described in *Chapter III. Apparatus, Containers, and Packaging, C. Reagents & Testing Solutions (TS), 4. Standard Solutions, Standard Stock Solutions*. Then add 5 drops of nitric acid in the solution. If it passes the limit test, the amount of cadmium contained in the test solution should NOT exceed 0.5 μg/ml.

4. Evaporation Residues

Chapter IV. Toys, A. Specifications for Toys and their Raw Materials, 5. (2) Test, 2. Evaporation Residues, shall be applied mutatis mutandis.

5. Arsenic

Chapter IV. Toys, A. Specifications for Toys and their Raw Materials, 1. (2) Test, 2. Arsenic, shall be applied mutatis mutandis.

7. The part of a toy made from plasticized materials must NOT contain more than 0.1 % of dibutyl phthalate, bis(2-ethylhexyl) phthalate, or benzyl butyl phthalate.

8. For the toys stipulated in the Ordinance for Enforcement of the Food Sanitation Act, Article 78, 1 (excluding those covered by Item 9 below), synthetic resins whose main component is polyvinyl chloride using di-isononyl phthalate as a raw material must NOT be used as its raw material.

9. For the toys stipulated in the Ordinance for Enforcement of the Food Sanitation Act, Article 78, 1, the part of a toy made of plasticized materials intended to directly touch the mouths of babies must NOT contain more than 0.1 % of di-isodecyl phthalate, di-isononyl phthalate, or di-n-octyl phthalate.

10. The part (excluding coatings) made using materials whose main component is polyethylene must pass the following limit tests. The water used for these tests shall be distilled water.

(1) Preparation of Test Solutions

Cut out a sample from a toy or prepare its specimen. After immersing the sample in 2 ml of 40ºC water per

1 cm^2 of the surface area, cover the sample with a watch glass, and leave it for 30 min at 40ºC, shaking it up occasionally.

(2) Test

1. Potassium Permanganate Consumption

In a test to which *Chapter IV. Toys, A. Specifications for Toys and their Raw Materials, 5. (2) Test, 1. Potassium Permanganate Consumption*, is applied mutatis mutandis, the potassium permanganate consumption must NOT exceed 10 μg/ml.

2. Heavy Metals

Chapter IV. Toys, A. Specifications for Toys and their Raw Materials, 1. (2) Test, 1. Heavy Metals, shall be applied mutatis mutandis.

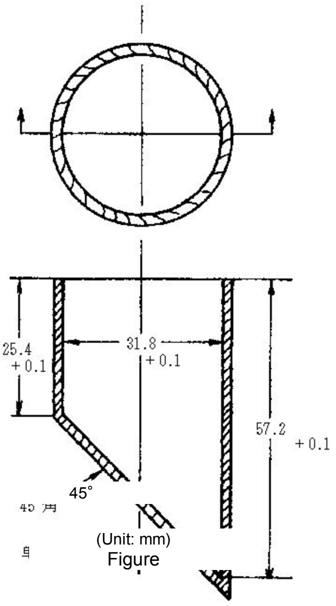
3. Evaporation Residues

In a test to *which Chapter IV. Toys, A. Specifications for Toys and their Raw Materials, 5. (2) Test, 2. Evaporation Residues*, is applied mutatis mutandis, the amount of evaporation residues must NOT exceed 30 μg/ml.

4. Arsenic

Chapter IV. Toys, A. Specifications for Toys and their Raw Materials, 1. (2) Test, 2. Arsenic, shall be applied mutatis mutandis.

11. The metallic toy accessories that babies might swallow must pass the following limit tests. The definition of these toys is as follows: when put in a container with the dimensions as shown in the following figure, the toy fits inside the container without being compressed.



(Unit: mm)
Figure

(1) Preparation of Test Solutions

Put the sample in a beaker with a diameter of about 40 mm, and add 0.07 mol/l-hydrochloric acid with a temperature of 37ºC until the sample is completely immersed. After leaving it for 2 hr at 37ºC, light shielded, filter the solution. Then, 0.07 mol/l-hydrochloric acid shall be prepared by adding distilled water to 6.3 ml of hydrochloric acid / HCl [JIS K 8180; special grade] to make a 1,000 ml solution.

(2) Lead

Put 0.1 ml of the lead standard stock solution in a container, and add 0.07 mol/l-hydrochloric acid to make a 100 ml solution. 1 ml of this solution contains 1 μg of lead. Dilute this solution with 0.07 mol/l-hydrochloric acid appropriately, and measure the amount of lead contained in each solution using the same method as for the test solution. Then prepare the calibration curve for lead. The lead standard stock solution must be the one specified in *Chapter III. Apparatus, Containers, and Packaging, C. Reagents & Testing Solutions (TS), 4. Standard Solutions, Standard Stock Solutions*.
The concentration of lead in the test solution shall be measured using the method described in *Chapter III. Apparatus, Containers, and Packaging, B. General Test Methods for Apparatus, Containers, or Packaging, 3. Atomic Absorption Spectrometry, or 9. Inductively Coupled Plasma Emission Spectrometry*. The elution amount of lead per gram of the sample obtained from the following formula must NOT exceed 90 μg/g.
[Elution Amount (μg/g)] = [Concentration of Test Solution (μg/ml)] x [Volume of Test Solution (ml)] / [Sample Weight (g)] x [(100 – Correction Value) / 100]
where the correction value of lead is set at 30.

12. If there are alternative methods to the specified methods listed in items 1 through 6, 10, and 11, and if such alternative methods provide higher accuracy than the specified methods, these alternative test methods may be used. Note that if the test results using the alternative methods are questionable, the final determination shall be made using the specified test methods.

B. Product Standards for Toys

1. If chemically synthesized colorants are used when manufacturing toys, any colorant other than those listed in Appended Table 1, the Ordinance for Enforcement of the Food Sanitation Act, must NOT be used. This shall not apply to those colorants that pass the following test.
   Cut out the colored part of the sample, and immerse it in 2 ml of 40ºC water per 1 cm^2 of the surface area. Cover the sample with a watch glass, and leave it for 10 min at 40ºC, shaking it up occasionally. Use this solution as the test solution. Put 50 ml of the test solution in a Nessler tube with an inner diameter of 20 mm, an outer diameter of 24 mm, the distance between the bottom of the tube and the bottom end of the plug of 20 cm, and lines marked at intervals of 5 ml up to 50 ml. Observe the Nessler tube from above and the side against a white background. The elution of the colorant must NOT be seen.