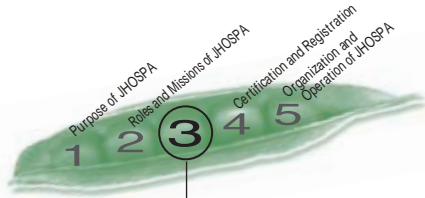


# What Are Voluntary Standards?



Voluntary standards consist of a Positive List (PL) describing raw material that can be used for food utensils, containers and packaging materials and the Standard of Hygienic Testing Methods that establish individual standards for each resin in order to check the quality of products.

< Scheme of voluntary standards >

Voluntary standards	Positive List		Basic polymers	Scope (monomers, quantity), restrictions, etc.
			Additives	Quantity to be added, food restrictions and temperature restrictions, etc.
			Colorants	Food restrictions, etc.
	Standard of Hygienic Testing Methods	Specification for each resin	Specifications of Material	added to Notification No.370
		Specifications of Migration	same as above.	
	Standard of Hygienic Testing Methods for resin	Testing method of materials	Testing method for standards of each resin	
		Testing method of migrations		

The PL Assessment Standard is established, and The Voluntary Standards are appropriately controlled by it.

## Process on Establishment of Voluntary Standards

In November 1974, JHOSPA instituted a preparation manual of voluntary standards (current " PL Assessment Standard ") based on the principle on the use of additives presented by the Ministry of Health and Welfare, and established a " Positive List "


describing starting substances for each of the five resins (PE, PP, PS, AS, and ABS) and

additives that can be used for these resins and the " Standard of Hygienic Testing Methods for each resins " for each resin.

As the thermoplastic resins have been widely used for food utensils, containers and packaging materials the number of " voluntary standards " has increased to 30 as of May 2008.



## Positive List

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- Basic polymer → List of starting monomers, standards for Basic polymer
  - Additives → Additives such as stabilizers, surfactants, and lubricants and colorants

The Positive List defines the starting substances of synthetic resins and additives that can be used for each resin. In case of adding the new resins or new additives on the list, risk assessment based on Standards showed in following concept is required.

It is possible to list the new resins and additives on the positive list by referring to the list of Europe (EU Directive) and the list of U.S.A (FDA), which are based on the same concepts.

## Concept of Listing a New Resin or Additive on the Positive List

In case of adding a new resin or new additive on the positive list, it is evaluated whether a substance migrated into food under the actual condition from food utensils, containers and packaging materials may contaminate the food and affect human health, or whether the use condition under which human health is not affected. If the requirements (quantity of the substance, food type and temperature of using food utensils, containers and packaging materials etc.) under which the safety is confirmed are satisfied, it is allowed the use of the relevant food utensils, containers and packaging materials.

The details of the requirements are showed in following;

Negative in the two kinds of mutagenicity tests.

Estimated daily intake is smaller than acceptable daily intake, or showing the requirements which is satisfied the condition of using (quantity of the substance food type and temperature of using food utensils, containers and packaging materials etc.)

**Acceptable daily intake (ADI) > Estimated daily intake (EDI)**

An additive must be within the limit of technical effect established in The PL Assessment Standard.

(There must be no direct effect on food or biological effect.)

# Standards of Hygienic Testing Methods

Standards of Hygienic Testing Methods define a sanitation standard and a test method for each resin. There are two test methods: Testing method of materials and testing method of migrations.

- **Specification for each resin**
- **Standards of Hygienic Testing Methods**

Standards of Hygienic Testing Methods consist of Testing method of materials to detect residual monomer, additive, heavy metal (cadmium and lead) present in food utensils, containers and packaging materials and testing methods of migrations to determine the quantity of migration of a component present in food utensils, containers and packaging materials into food and define Specifications for each resin and a test methods for each resin.

Basically, the methods conform to the test method defined in the Food Sanitation Law. In addition to the test items defined in the Food Sanitation Law, there are some specific test items corresponding to the characteristics of each resin.

## (1) Material test item

- Cadmium and lead
- Specific test item —————> Items corresponding to each synthetic resin
  - Volatile substance
  - Acrylonitrile and other substances

## (2) Migration test item

- Amount of residuals on extractives heavy metals, and consumption of  $\text{KMnO}_4$
- Specific test item —————> Items corresponding to each synthetic resin
  - Acrylonitrile
  - Formaldehyde and other substances