

Introduction of Good Manufacturing Practice (GMP) Concerning Foods Containing Ingredients or Substances That Require Specific Cautions

The Act Partially Amending the Food Sanitation Act etc. (the “Amendment Act”) was promulgated on June 13, 2018. Based on the Amendment Act, the Minister of Health, Labour and Welfare shall designate ingredients or substances* (“ingredients etc.”) that require specific cautions from the viewpoint of preventing the occurrence of health hazards. The Ministry of Health, Labour and Welfare will introduce GMP for the foods containing the designated ingredients etc. to prevent the occurrence of health hazards.

* *“Ingredients” means components of a substance.*

“Substances” includes the whole and part of a substance. For plants, for example, the whole plant and parts of a plant, such as roots and flowers.

1. Good Manufacturing Practice (GMP)

The following items shall be observed as standards for the manufacturing or processing for the foods.

- Appointment of a managing supervisor
- Preparation of master formulae
- Preparation of standard operating procedures (SOPs)
- Production and quality controls of the raw materials
- Production and quality controls of the products
- Shipment control
- Validation for production and quality controls
- Management of changes in SOPs
- Management of deviations in SOPs
- Information management on quality and handling of defective products
- Self-inspection
- Management of documents and records

2. Enforcement date of GMP

GMP is scheduled to be implemented on the enforcement date of the Amendment Act (June 1, 2020).