

Concept of the General Provisions

The Ministry of Health, Labour and Welfare plans to establish general provisions concerning the introduction of the “positive list” system for residual agricultural chemicals in foods, based on the provision in Paragraph 2-1 of the “Final Draft of Provisional Maximum Residue Limits for Agricultural Chemicals in Foods, toward the Introduction of the ‘Positive List’ System,” dated 31 May, 2005, in conformity with Section 1, Article 11 of the Food Sanitation Law. The concept outline of these general provisions is as follows:

- Draft on General Provisions

1. Foods shall not contain any antibiotics or synthetic antibacterial substances (which refers to substances obtained by causing chemical reactions to elements and/or compounds through chemical methods, except for decomposition; this applies to hereinafter), except for the following cases:
 - (1) When foods contain food additives determined by the Minister of Health, Labour and Welfare as having no potential to cause damage to human health, under Article 10 of the Food Sanitation Law (Law No. 233 of 1947, hereafter referred to as “the Law”), and foods contain food additives appearing in the List of Existing Food Additives specified in Section 4, Article 2 of the Supplementary Provisions to the Law Concerning Amendments to the Food Sanitation Law and Nutrition Improvement Law (Law No. 101 of 1995).
 - (2) When foods meet the compositional standards given in Paragraph 6 below (excluding cases that fall under section (1) above).
 - (3) When foods have been manufactured or processed using foods that fall under section (2).
2. The substances, including their metabolites, specified in the list below as agricultural chemicals, including pesticides, veterinary drugs, and feed additives (hereinafter referred to as “agricultural chemicals”), shall not be detected in any foods. The residues of the metabolites meet the provision when the metabolites from agricultural chemicals are found in foods and the residue levels of the parent substances meet this provision for the parent substances. Cases where the parent substances and their metabolites are ruled otherwise are excluded.

(See attached Table 1, the list of agricultural chemicals under this provision, in “15 Agricultural Chemicals”)
3. The agricultural chemicals listed in the attached table shall not remain in the corresponding foods (grains, pulse, fruit, vegetables, nuts, tea and hop, meat, bird egg, seafood, honey, and milk) over the limits given in the right column of the table. In the case where the limit is specified as “not detected,” the agricultural chemical shall not be detected in the corresponding food. The residues of the metabolites meet the provision when the metabolites from agricultural chemicals are found in foods and the residue levels of the parent substances meet this provision for the parent substances. Cases where the parent substances and their metabolites are ruled otherwise are excluded.

(See attached Table 2*, the list of maximum residue limits (MRLs) for agricultural chemicals in foods, in “714 Agricultural Chemicals”)

(* The table only lists agricultural chemicals for which provisional MRLs are established)

4. For substances that are not listed in the table given in the previous section and that may remain in foods as environmental contaminants, concentrations in the foods shall not exceed levels that are normally included in the foods.
5. The agricultural chemicals listed in the attached table shall not remain in foods other than those listed in the table (i.e. foods other than grains, pulse, fruit, vegetables, nuts, tea and hop, meat, bird egg, seafood, honey, or milk) over the limits given in the table. In the case where the limit is specified as “not detected,” the agricultural chemical shall not be detected in the corresponding food. The residues of the metabolites meet the provision when the metabolites from agricultural chemicals are found in foods and the residue levels of the parent substances meet this provision for the parent substances. Cases where the parent substances and their metabolites are ruled otherwise are excluded.

(See attached Table 3, the list of maximum residue limits for agricultural chemicals in processed foods, in “61 Agricultural Chemicals”)

6. Foods shall be manufactured or processed using agricultural chemicals that meet the compositional standards specified in the previous sections, 3 through 5, concerning agricultural chemicals for which those sections specify the maximum residue limits in foods. This includes agricultural chemicals that have been manufactured or processed from those meeting the compositional standards as raw materials.
7. The provisions specified in sections 3 through 6 above shall not apply in the case where agricultural chemicals remaining in foods are food additives specified in Article 12 of the Enforcement Regulations of the Food Sanitation Law, or food additives appearing in the List of the Existing Food Additives specified in Section 4, Article 2 of the Supplementary Provisions to the Law Concerning Amendments to the Food Sanitation Law and Nutrition Improvement Law (Law No. 101 of 1995), and where concentrations in the foods are within the levels specified in the Standards for the Use of Food Additives (II-F) under the Law.
8. Judgment for the compliance with the standard limits shall be conducted by calculating a test value to one more digit than required, rounding it off to the nearest digit, and comparing the obtained value with the corresponding standard limit.