

**The Second Draft on
the General Provisions to Enforce the Positive List System**

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The following provisions will be established in the publication under the provision in Article 11, Paragraph 1 of the Food Sanitation Law in order to implement the Positive List System for agricultural chemicals in foods. Please note that wording in these provisions may be subject to change from the legal viewpoint.

Draft on General Provisions

1. Foods shall not contain any antibiotics or synthetic antibiotic substances, except for the following cases.
 - (1) When foods contain food additives authorized under Article 6, and foods contain food additives appearing in the List of Existing Food Additives specified in the Supplementary Provisions to the Law Concerning Amendments to the Food Sanitation Law and Nutrition Improvement Law, No. 101, 1995.
 - (2) When foods meet the compositional standards given in Paragraphs 3 through 5 below (excluding cases falling into section (1) above).
 - (3) When foods have been manufactured or processed, using foods falling into 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. 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, it is considered that the residues of the metabolites meet this provision. The 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)

3. The agricultural chemicals listed in the attached table shall not remain in the corresponding foods over the limits given in the table. In the case that the limit is specified as “not detected,” the agricultural chemical shall not be detected in the corresponding food. 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, it is considered that the residues of the metabolites meet this provision. The cases where the parent substances and their metabolites are ruled otherwise are excluded.
(See attached Table 2, only the First Draft of Provisional Maximum Residue Limits (MRLs))

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 over the limits given in the table. In the case that the limit is specified as “not detected,” the agricultural chemical shall not be detected in the corresponding food. 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, it is considered that the residues of the metabolites meet this provision. The cases where the parent substances and their metabolites are ruled otherwise are excluded.
(See attached Table 3)
6. Any food shall be manufactured or processed, using those that meet the compositional standards specified in the previous sections, 3 through 5.
7. The provisions specified in sections 3 through 6 above shall not apply in the case that agricultural chemicals remaining in foods are food additives specified in Article 3 of the Enforcement Regulations of the Food Sanitation Law or food additives appearing in the List of the Existing Food Additives and that concentrations in the foods are within the levels specified in the Standards for the Use of Food Additives 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 and rounding it off to the nearest digit and by comparing the obtained value with the corresponding standard limit.