

The Japanese Positive List System for Agricultural Chemical Residues in Foods and Food Additives

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Summary

On May 29, 2006 the Ministry of Health, Labour and Welfare (MHLW) introduced the positive list system for agricultural chemicals remaining in foods-the system to prohibit the distribution of foods that contain agricultural chemicals above a certain level if maximum residue limits (MRLs) have not been established. The agricultural chemicals include pesticides, feed additives and veterinary drugs. This activity has been based on the Law to Partially Revise the Food Sanitation Law (Law No. 55, 2003). The Law No. 55 has required the MHLW to take the following measures within three years after the publication of the revised Food Sanitation Law (May 30, 2003).

I. Uniform limit (Ministry of Health, Labour and Welfare Notification No. 497)

The Minister of Health, Labour and Welfare has established the level given below, based on the provision of Paragraph 3, Article 11 of the Food Sanitation Law, as the amount unlikely to cause damage to human health that the provision requires the Minister to set; it will take effect on May 29, 2006. Notwithstanding this notification, food products that are manufactured or processed on or before May 28, 2006 may observe the existing regulations, instead of the regulations to be applied from the given date. The amount unlikely to cause damage to human health that the provision of Paragraph 3, Article 11 of the Food Sanitation Law requires the Minister to set is 0.01 ppm.

II. Exempted substances (Ministry of Health, Labour and Welfare Notification No. 499)

The Minister of Health, Labour and Welfare has designated the substances given below, based on the provision of Paragraph 3, Article 11 of the Food Sanitation Law, as substances having no potential to cause damage to human health that the provision requires the Minister to specify; this designation will take effect on May 29, 2006. The substances having no potential to cause damage to human health that the provision requires the Minister to specify are as follows:

1.Zinc, 2.Azadirachtin, 3.Ascorbic acid, 4.Astaxanthin, ······ 65.Wax; 65 substances.

III. Provisional MRLs (Ministry of Health, Labour and Welfare Notification No. 499)

The Minister of Health, Labour and Welfare has partially revised the Specifications and Standards

for Food, Food Additives, Etc. (Ministry of Health and Welfare Notification No. 370, 1959), as given below, based on the provision of Paragraph 1, Article 11 of the Food Sanitation Law; this revision will take effect on May 29, 2006.

Provisional MRLs have been established taking into consideration:

- i. Codex standards,
- ii. Registration withholding limits based on the Agricultural Chemicals Regulation Law, limits of determination for veterinary drugs at the time when they were authorized based on Pharmaceutical Affairs Law (Law No. 145, 1960), or limits of determination for feed additives at the time when they were authorized based on the Law for Safety Assurance and Quality Improvement of Animal Feed (Law No. 35, 1953), and
- iii. Standards established by countries where MRLs are assumed to be established based on toxicity study data equivalent in quality to those used in scientific evaluations by JMPR and JECFA. These countries are Australia, Canada, EU, New Zealand, and United States.

For those chemicals categorized in either of the following two types, ND has been set instead of numerical limits: 1) genotoxic carcinogens and 2) chemicals that have been determined by JMPR or JECFA as those for which the ADI cannot be set. Separately from numerical limits, requirements/restrictions have been imposed on certain types of substances, including antibiotics, antibacterials, substances naturally occurring in foods, and chemicals for which standards are already set for food additive uses, and on applications of MRLs to processed foods.