

**Syoku-An No.1129001**  
**November 29, 2005 <sup>\*1</sup>**

**Director Notice <sup>\*2</sup>**

**Department of Food Safety**  
**Pharmaceutical and Food Safety Bureau**  
**Ministry of Health, Labour and Welfare**

**Establishment of Applicable Laws and Ordinances in Response to the Implementation of Paragraph 3, Article 11, Which Has Been Newly Added to the Food Sanitation Law, Based on the Law to Partially Amend the Food Sanitation Law**

On November 29, 2005 the Ministry of Health, Labour and Welfare published four notifications and two ministerial ordinances pursuant to Paragraph 3, Article 11, which was newly added to the Food Sanitation Law based on the Law to Partially Amend the Food Sanitation Law (Law No. 55, 2003):

- Notification to specify uniform limit (Ministry of Health, Labour and Welfare Notification No. 497, 2005)
- Notification to designate exempted substances (Ministry of Health, Labour and Welfare Notification No. 498, 2005)
- Notification to partially revise the Specifications and Standards for Food, Food Additives, Etc. (Ministry of Health, Labour and Welfare Notification No. 499, 2005)
- Notification to partially revise the Guidelines for the Implementation of Monitoring and Guidance Concerning Food Sanitation (Ministry of Health, Labour and Welfare Notification No. 495, 2005)
- Ordinance to partially revise the Enforcement Regulations under the Food Sanitation Law (Ministry of Health, Labour and Welfare Ordinance No. 166, 2005)
- Ordinance to partially revise the Ministerial Ordinance Concerning Compositional Standards, Etc. for Milk and Milk Products (Ministry of Health, Labour and Welfare Ordinance No.167, 2005)

Notification No. 497 specifies a level as the amount unlikely to cause damage to human health that Paragraph 3, Article 11 of the Food Sanitation Law requires the Minister to set. Hereinafter the level is referred to as “uniform limit.” Notification No. 498 specifies substances as having no potential to cause damage to human health that Paragraph 3, Article 11 of the Food Sanitation Law requires the Minister to designate. Hereinafter these substances are referred to as “exempted substances.” Notification No. 499 stipulates the partial revision of the Specifications and Standards for Food, Food Additives, Etc., based on Paragraph 1, Article 11 of the Food Sanitation Law. This revision includes newly established residue standards. The provision of Paragraph 3, Article 11 will take effect in May 29, 2006 with the uniform limit, the application of exempted substances, and maximum residue limits.

The following shows a background and summary of the revision of the Food Sanitation Law.

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<sup>\*1</sup> The Director Notice (Syoku-An No.1129001) was updated twice: Syoku-An No. 0315002, March 15, 2006; Syoku-An No. 0526004, May 26, 2006. This document reflects the revisions.

<sup>\*2</sup> This document is rearranged from the original Director Notice (Syoku-An No.1129001, November 29, 2005). This rearrangement aims to help English readers understand the operation of the positive list system for agricultural chemicals.

## **Section 1. Background of the Revision of the Food Sanitation Law**

Based on the law concerning amendment, the provision of Paragraph 3, Article 11 has been newly added to the Food Sanitation Law (Law No. 233, 1947, hereinafter referred to as “the Law”). Under the so-called “Positive List System” introduced based on this provision, it shall be prohibited to manufacture, import, process, use, cook, or store for sales or sell food containing ingredients of agricultural chemicals, feed additives, or veterinary drugs (including substances produced through chemical changes of the parent substances; excluding exempted substances) over the amount unlikely to cause damage to human health that the Minister sets after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

However, if food compositional standards are specified based on Paragraph 1, Article 11 of the Law, these standards shall supersede the above-mentioned amount.

## **Section 2. Summary of the Revision of the Food Sanitation Law**

### **1 Uniform Limit**

The Minister of Health, Labour and Welfare has established the level 0.01 ppm, based on the provision of Paragraph 3, Article 11 of the Law, as the level (uniform limit) unlikely to cause damage to human health that the provision requires the Minister to set after hearing the opinion of the Pharmaceutical Affairs and Food Sanitation Council.

Basically, agricultural chemicals (in this document, “agricultural chemicals” refers to agricultural chemicals, feed additives, and veterinary drugs) which are used in and outside Japan are evaluated from various aspects, including toxicity, prior to the authorization of their use. Based on these evaluations, restrictions are set on use amounts and target crops on which they are permitted for use. Also, ways of use and residue standards for foods are established. The uniform limit is applied to agricultural chemicals for which residue standards are not established.

It is appropriate to use a toxicological threshold of 1.5 µg/day as a reference permissible intake of individual agricultural chemicals to which the uniform limit is applied. The threshold is estimated based on the acceptable exposures, which are used in evaluations of flavoring agents by JECFA (Joint FAO/WHO Expert Committee on Food Additives) and in evaluations of indirect additives by the US FDA (Food and Drug Administration), and on the ADIs (Acceptable Daily Intakes) of chemicals that had been already evaluated by JMPR (Joint FAO/WHO Expert Meeting on Pesticide Residues) or JECFA or in Japan.

The uniform limit is set at 0.01 ppm so that the estimated intake of agricultural chemicals to which the limit is applied does not exceed 1.5 µg/day when calculated based on the food consumption of Japanese population.

### **2 Exempted Substances**

The Minister of Health, Labour and Welfare has designated the substances (exempted substances) based on the provision of Paragraph 3, Article 11 of the Law, as substances having no potential to cause damage to human health that the provision requires the Minister to specify.

“Exempted substance” refers to any agricultural chemical that is determined not to pose adverse health effects, judging from the nature of residue, such as residue pattern, even if the chemical remains in crops and

animal and fishery products to a certain level. Exempted substances include those produced by chemical changes from the parent chemicals (decomposition products).

Exempted substances are those that meet conditions given in i through iii below. In specifying those, the MHLW took into account evaluations in Japan, evaluations by JECFA and JMPR, evaluations based on the Agricultural Chemicals Regulation Law (Law No. 82, 1948), also evaluations in countries where MRLs are assumed to be established based on toxicity study data equivalent in quality to those used in scientific evaluations by JECFA.

- i. Agricultural chemicals and their decomposition products which are determined not to pose adverse health effects, judging from the nature of residue, such as residue pattern, even if these chemicals remain in crops and animal and fishery products to certain levels.
- ii. Specified agricultural chemicals shown in the Agricultural Chemicals Regulation Law, and chemicals for which registration withholding limits are not established and which are determined not to pose adverse health effects even if crops exposed to these chemicals are consumed.
- iii. Agricultural chemicals which are determined not to require any ADI in foreign countries and whose uses are not restricted.

### **3 Residue Standards**

The general compositional standards for food (hereinafter referred to as “General Requirements”)—specified in Section A, Part 1 *Food in Specifications and Standards for Food, Food Additives, Etc.*, (Ministry of Health and Welfare Notification, No.370, 1959, hereinafter referred to as “Notification No. 370”)—have been revised to add food standards established based on Paragraph 1, Article 11 of the Law.

The uniform limit is not applied to substances, including decomposition products, for which food standards (maximum residue limits: MRLs) are established based on Paragraph 1, Article 11 of the Law.

The following is the overview of the revision of the General Requirements.

#### **(1) Item 1**

Item 1 has been combined and revised from the provisions of items 1 and 2 of the current General Requirements. The revised provision stipulates that any food shall not contain antibiotics or chemically synthesized antibacterials (hereinafter referred to as “antibacterials”). In addition, Item 1 reflects other provisions established based on Notification No. 499.

The current General Requirements ban the existence of antibiotics in any food unless otherwise specified but does not restrict the existence of antibacterials in food products other than meat, eggs, and finfish and shellfish. The revised General Requirements ban the existence of antibiotics and antibacterials in any food unless otherwise specified. Since Paragraph 3, Article 11 of the Law applies to all food products, the revised General Requirements also target all food products for the restriction of antibiotics and antibacterials.

#### **(2) Items 2 to 4**

Items 3 to 5 of the current General Requirements have been shifted to the Items 2 to 4 of the revised Requirements.

(3) Item 5

Item 5 shows a list of the ingredients of agricultural chemicals that are prohibited from remaining in food (table in Item 5(1) of the revised General Requirements) unless otherwise specified, as well as analytical methods to verify that prohibited agricultural chemical ingredients do not remain in food (Items 5(3)–(15)) and sample materials used for tests (table in Item 5(2) of the revised General Requirements).

Prohibited ingredients shall not be detected when testing is conducted using the analytical methods specified in this item. Standards for these ingredients are specified as ND (not detected).

If a food is found to contain a prohibited ingredient, for which ND is set, the food will be treated as a violation of food standards stipulated in Paragraph 1, Article 11 of the Law.

(4) Item 6

This item specifies MRLs for individual foods, mainly on non-processed primary foods. The MRLs are shown by agricultural chemical. The item follows Item 6 of the current General Requirements.

Revisions are summarized below:

A. Food classification has been modified as necessary.

- Three individual food categories have been created for vegetables: qing-geng-cai, *nira* (garlic chive), and bamboo shoots. In the current General Requirements, qing-geng-cai is classified in the “other cruciferous vegetables” category, *nira* in the “other liliaceae plants” category, and bamboo shoots in the “other vegetables” category.

The current MRLs for “other cruciferous vegetables,” “other liliaceous plants,” and “other vegetables,” are applied to these three vegetables, respectively.

- For spices and herbs, new food categories have been created for “other spices” and “other herbs,” to harmonize with the international standards (Codex standards) since Codex standards have been newly set for these food categories.

For the definitions of spices and herbs, see Attachment 1. The definitions apply in common in Notification No. 370.

B. For some of agricultural chemicals, revisions have been made to ensure consistency with MRLs that were newly established based on Notification No. 499.

Specifically, MRLs have been newly established for the “dichlorvos and naled” group and the “deltamethrin and tralomethrin” group, and unnecessary MRLs have been deleted.

C. Necessary revisions, such as organizing agricultural chemical names, have been made.

(5) Item 7

This item has been newly established to contain MRLs that were specified in Notification No. 499. The item mainly targets individual non-processed primary foods. The standards are shown by agricultural chemical. Basically, it has the same significance as Item 6 and applies accordingly.

Points to note about the implementation of Items 6 and 7 are given in Attachment 2.

(6) Item 8

When agricultural chemical ingredients are identical to substances originally occurring in food, it is difficult to determine whether ingredients in a food have derived from use of agricultural chemicals or whether they originally occur in the food. Based on the provision of Item 8, the uniform limit is not applicable to agricultural chemical ingredients that are identical to originally occurring substances in food and that remain at quantities equivalent to naturally occurring levels.

Item 8 applies to cases in which no specific residue standards are established for agricultural chemicals. Since it is impossible to fully list target substances, whether or not it is applicable is judged individually.

(7) Item 9

This item specifies MRLs mainly for processed foods. These limits are shown for individual foods by agricultural chemical. It is implemented the same as Items 6 and 7.

For handling conditions of processed foods, see Item 10.

(8) Item 10

Based on of Paragraph 3, Article 11 of the Law, the uniform limit targets all foods. As a rule, this standard also applies to processed foods without MRLs based on Paragraph 1, Article 11 of the Law. However, processed foods will be deemed to comply with the existing MRLs, regardless of levels of agricultural chemicals remaining in these foods, if the food ingredients used in the production of the processed foods have met the corresponding MRLs, and these processed foods are exempted from the application of the uniform limit.

The processed foods appearing in Item 9 have already been reviewed, and MRLs are given. The MHLW is going to add standards in Item 9, as necessary.

#### **4 Enforcement Regulations of the Food Sanitation Law**

In the wake of the establishment of Paragraph 3, Article 11, the Enforcement Regulations of the Food Sanitation (Ministry of Health and Welfare Ordinance No. 23, 1948, hereinafter referred to as “Enforcement Regulations”) have been amended as below:

- (1) Cases not conforming to the provision of Paragraph 3, Article 11 have been added to exemptions from the application of the so-called Planned Import System stipulated in Paragraphs 4–6, Article 32 of the Enforcement Regulations.
- (2) Substances with potential health risks listed in Table 2 based on the Enforcement Regulations have been reorganized.
- (3) For antibiotics and antibacterials, terms and expressions are revised in accordance with other relevant laws and ordinances. Target substances remain unchanged.

#### **5 Ministerial Ordinance Concerning Compositional Standards, Etc. for Milk and Milk Products**

In the wake of the establishment of Paragraph 3, Article 11, the Ministerial Ordinance concerning Compositional Standards, Etc. for Milk and Milk Products (Ministry of Health and Welfare Ordinance No. 52, 1951, hereinafter referred to as “Ministerial Ordinance concerning Milk”) has been revised as below.

- (1) General compositional standards for milk, etc. (milk, milk products, and other food products made mostly of foods classified in the first two food categories) listed in the table based on the Ministerial Ordinance concerning Milk have been revised, as necessary.
- (2) For antibiotics and antibacterials, terms and expressions are revised in accordance with other relevant laws and ordinances. Target substances remain unchanged.
- (3) Table 2 has been deleted since currently residue standards for milk, etc are established only for the veterinary drugs appearing in the table but Paragraph 3, Article 11 of the Law applies to all veterinary drugs.

## **6 Guidelines for the Implementation of Monitoring and Guidance Concerning Food Sanitation**

The implementation provision of monitoring and guidance based on Paragraph 3, Article 11 of the Law has been added to the guidelines for monitoring and guidance. The guidelines encourage the prefectural governments to stipulate necessary matters based on Paragraph 3, Article 11 in the monitoring and guidance plan developed by prefectures based on Article 24.

## **Section 3. Dates of Implementation and Application**

### **1 Ministerial Ordinances**

The above mentioned Ministerial Ordinances will become effective on May 29, 2006.

### **2 Notifications**

Notifications 497, 498, and 499 and other relevant notifications will become effective on May 29, 2006.

#### Transitional measure

For application of the uniform limit (Notification 497) and MRLs (Notification 499), the transitional measure will be taken. Food products that are manufactured or processed on or before May 28, 2005 may observe the existing regulations, instead of the regulations to be applied from the given date. This stipulation means that if food products that are manufactured or processed on or before May 28 are placed on the market on or after May 29, the new regulations will not apply during the period between the time of manufacturing or processing and the time of distribution (placing on the market). This period includes the transportation period of imported products.

“Food manufactured or processed” means any food which is made through a series of processes, from ingredients to final products. Unprocessed primary food products, such as crops, are not included. A series of processes includes packaging or wrapping.

Applicability of the transitional measure is based on the judgment whether the time of manufacturing or processing is on or before May 29, 2006. “The time of manufacturing or processing” means the time at which a product is ready for sale, basically, the time when it is packaged as a finished product. Imported foods are treated equally to domestically produced products, regardless of the time of import.

Applicability of the transitional measure is summarized

- Unprocessed primary foods: The transitional measure is not applicable to unprocessed primary foods, which basically do not require additional manufacturing or processing processes for sale. The uniform limit and residue standards apply to all unprocessed primary foods which are on the market on and after May 29, 2006.
- Processed foods: Whether foods are produced at home or abroad, applicability of the transitional measure is judged based on the time of the completion of manufacturing or processing (when the products are ready for sale to end users). When foods are manufactured or processed using processed foods, applicability is judged based on when they are ready for sales to consumers after manufacturing or processing processes are completed, regardless of when the processed foods used as ingredients are manufacture or processed.

## **Section 4      Other Points to Note**

### **1      Food Safety Assessment after the Implementation of Paragraph 3, Article 11 of the Law**

The uniform limit and exempted substances are based on foreign standards and assessments by international organizations, such as Joint FAO/WHO Expert Committee on Food Additives. However, prior to the standard setting, safety assessment by the Food Safety Commission had not taken place. The Food Safety Basic Law (Law No. 48, 2003) requires the commission in the Cabinet Office to conduct safety assessment before the government formulates policies on food safety. In this case, the formulation of policies refers to the establishment of food standards. The Ministry of Health, Labour and Welfare is going to request the commission to conduct safety assessment of target agricultural chemicals.

Also, the ministry will systematically ask the commission to conduct safety assessments of substances for which MRLs have been established. Currently, the MRLs appearing in the table in Item 7 (1) are so-called provisional MRLs. After required safety assessments are completed, these MRLs will be delisted and revised limits will be placed in the table in Item 6 (1).

### **2      Scope of the Application of Paragraph 3, Article 11 of the Law**

#### **(1) Agricultural chemicals**

Paragraph 3, Article 11 regulates the residue of agricultural chemicals in food. Basically, this provision will not apply to a food even if the food contains ingredients of an agricultural chemical if it is clear that the chemical has been used for a purpose other than agricultural production.

However, in the process of manufacturing or processing a food, if an agricultural chemical whose ingredients have food standards based on Paragraph 1, Article 11 of was used for other purposes than agricultural production and if its use has resulted in residue of the ingredients in the food (e.g., A substance was used for sterilizing an equipment in the production facility of a food, and the use has resulted in a residue in the food due to contact with equipment.), the food may be subject to Paragraph 3, Article 11, since it is very difficult to determine whether the chemical was used for an agricultural production or non-agricultural production purpose.

Whether or not substances remaining in food were used for agricultural production is judged based on relevant national regulations, such as Agricultural Chemicals Regulation Law, and normal uses of these substances.

(2) Products resulting from chemical changes

Paragraph 3, Article 11 applies to substances produced from agricultural chemical ingredients through chemical changes (decomposition products) as well as the parent ingredients. However, basically, this provision does not apply to decomposition products that are deemed not to be harmful, judging from similarity or identity in the characteristic and severity of toxicity to parent chemical ingredients.

### **3 Analytical Methods Stipulated in Notification No. 499**

Attachment table 3 contains the detection limits of the analytical methods stipulated in Items 5, 6, and 7 of the General Requirements.

Other analytical methods for agricultural chemicals for which residue standards have been established this time will be stipulated in Director Notice as necessary.

## **Section 5 Abolishment of Existing Notices**

The following notices will be abolished on May 29, 2006:

- (1) Kan-Shoku-Ka No.53, July 21, 1970, "Agricultural Chemical Residues in Cucumber"
- (2) Kan-Shoku-Ka No.79, October 1, 1970, "Agricultural Chemical Residues in Potatoes"
- (3) Kan-Nyu No.60, June 15, 1971, "Transitional Acceptable Limits for Organochlorine Agricultural Chemicals Residues in Milk"
- (4) Kan-Nyu No.58, October 30, 1980, "Handling of Sea Mussels Captured in the Seto Inland Sea"
- (5) Kan-Nyu No.59, October 30, 1980, "Handling of Sea Mussels"
- (6) Ei-Shoku No.12, January 21, 1985, "Regulation on Residue of EDB (Ethylene Dibromide) for Imported Wheat Flour"
- (7) Ei-Syoku No.79 and Ei-Ka No.30, May 20, 1987, "Revision of the Transitional Residue Limit for EDB Fumigation"
- (8) Ei-Nyu No.42, August 27, 1987, "Prevention of Distribution of Imported Meat Containing DDT, Etc."
- (9) Ei-Syoku No.15 and Ei-Ka No.5, January 27, 1988, "Revision of the Transitional Residue Limit for EDB Fumigation"
- (10) Ei-Syoku No.185 and Ei-Ka No.67, September 30, 1988, "Revision of the Transitional Residue Limit for EDB Fumigation"