

May 31, 2005

**Regarding Establishment of Provisional Maximum Residue Limits (MRLs) in a Positive List System Concerning Agricultural Chemicals Residues in Food etc.
(Final Draft)**

In introducing a positive list system concerning agricultural chemicals residues in food etc., it is essential to establish MRLs (including provisional ones) under the provision of Article 11, Paragraph 1 of the Food Sanitation Law (Law No.233 of 1948), as well as to designate “levels that have no potential to cause damage to human health” and “substances that apparently have no potential to cause damage to human health” stipulated in Article 11, Paragraph 3 of the Food Sanitation Law revised by the law concerning revision of parts of the Food Sanitation Law (Law No.55 of 2003).

The present document describes the policies on establishment of “provisional maximum residue limits”.

Article 11, Paragraph 3 of the revised Food Sanitation Law (Newly Established Provision)

Food⁶ in which residues of any agricultural chemicals¹ (meaning agricultural chemicals stipulated in Article 1-2, Paragraph 1 of the Agricultural Chemicals Regulation Law (Law No.82 of 1948); hereinafter the same applies in the following article), materials added to, mixed in, soaked into or otherwise used in feed (meaning feed specified in Article 2, Paragraph 2 of the Law for Safety Assurance and Quality Improvement of Animal Feed (Law No.35 of 1953))² for any of the purposes specified in the Ministry of Agriculture, Forestry and Fisheries Ordinance issued pursuant to Article 2, Paragraph 3 of the same law, or substances that are ingredients of medical drugs for use in animals³ specified in Article 2, Paragraph 1 of the Pharmaceutical Affairs Law (including substances formed by chemical changes of such substances, and excluding substances to be determined by the Minister of Health, Labour and Welfare as those that apparently have no potential to cause damage to human health⁴) are found at levels above the level to be determined by the Minister of Health, Labour and Welfare, at the Pharmaceutical Affairs and Food Sanitation Council's advice, as that having no potential to cause damage to human health⁵ shall not be produced, imported, processed, used, cooked or stored for sale, or sold; provided, however, that the foregoing shall not apply in cases where the specifications for food ingredients as stipulated in Paragraph 1 have been established with regard to the limits of residual levels of such substances in food of interest⁷.

1-3, substances subject to a positive list system (agricultural chemicals, feed additives, and animal drugs); 4, substances not subject to a positive list system; 5, a uniform limit in a positive list system; 6, the extent of application (Food (including processed food)); 7, MRLs in a positive list system (including provisional ones)

In establishing MRLs for agricultural chemicals, feed additives, and veterinary drugs (referred to as “agricultural chemicals etc.” hereinafter), protection of public health has been the top priority. Also in the introduction of a positive list system, this policy should firmly be maintained. After a positive list system goes into effect, foods containing agricultural chemicals above a certain level with no established MRLs will be prohibited from being distributed. In addition, the current MRLs for agricultural chemicals etc. established based on the Food Sanitation Law does not sufficiently cover internationally approved Codex

standards and the standards for the withholding of agricultural chemicals registration. Taking these facts into consideration, smooth introduction of a positive list system may be inhibited. Thus, provisional MRLs shall be established for those with no established MRLS among agricultural chemicals residues in food etc., referring to Codex standards established based on scientific evaluation from the viewpoint of protection of public health.

I. Legal Background and Application of the provisional MRLs

The provisional MRLs will function as the specifications for food ingredients based on Article 11, Paragraph 1 of the Food Sanitation Law, on the same date of effect of Article 11, Paragraph 3 of the Food Sanitation Law revised by the Law concerning revision of parts of the Food Sanitation Law etc. (date designated by the government ordinance within three years after publication of the Law concerning revision of parts of the Food Sanitation Law etc.). A grace period of six months will be set after the publication. In addition, it is under consideration that the rules will be applied only to the products manufactured after the date of the enforcement.

II. Establishment of the Draft Provisional MRLs

The provisional MRLs will be established by the following procedures.

In introducing the positive list system concerning agricultural chemicals residues in food etc., the current MRLs established as the specifications for food ingredients based on Article 11, Paragraph 1 of the Food Sanitation Law by “Standards for food, additives etc.”(Announcement of the Ministry of Health and Welfare, No.370, 1959, referred to as “the Announcement” hereinafter) will remain unchanged.

1. General Provisions

The general provisions on the following points will be established according to the provision of the Article 11, paragraph 1 of the Food Sanitation Law in introducing the positive list system concerning agricultural chemicals residues in food etc.:

(1) Antibiotics and synthetic antibacterial agents

The current standards for antibiotics and synthetic antibacterials should remain unchanged, but the scope of targeted foods should be harmonized with global standards. The Food Sanitation Law stipulates that foods shall not contain antibiotics and that meat, poultry, eggs, fish, and shellfish shall not contain synthetic antibacterials.

(2) Agricultural chemicals etc. for which ADIs cannot be established

When an ADI cannot be established due to carcinogenecity or other reasons, the provisional MRLs should be established as “Not Detected (ND),” according to the manner that has so far been used.

For substances for which ADIs cannot be established by international institutions (excluding substances for which a request of evaluation of food effects on human health is prioritized by a submission of safety test results to the Food Safety Committee), provisional MRLs shall be “Not Detected (ND)”.

Moreover, for agricultural chemicals etc. for which international institutions established ADIs under 0.03 µg/kg/day (clenbuterol, dexamethasone, trenbolone acetate) or those for which a MRL of “Not Detected (ND)” has already been established, “Not Detected” should be applied to each crop, animal, or aquatic product with no established MRLs.

The analytical methods and their levels of detection will be published in the official gazette.

(3) Agricultural chemicals etc. for which current and provisional MRLs are established

For agricultural chemicals etc. for which current and provisional MRLs are established, the residue levels shall not exceed the limits specified for individual food categories. MRL compliance shall be judged based on compounds included in the list of MRLs with the exception of metabolites that are clearly indicated as regulated in footnotes etc. of the list of provisional MRLs.

(4) Substances intrinsically contained in food

For substances defined as agricultural chemicals etc. that intrinsically exist in the environment and natural food, MRL compliance shall be judged based on the intrinsically contained amounts.

(5) Establishment of standards for processed food

Provisional MRLs for processed foods will be established only when Codex MRLs are established for them.

(6) Handling of processed food

In principle, processed foods with no established provisional MRLs shall be distributable if they are produced or processed from materials complying with MRLs.

In actual monitoring and control of processed foods such as dried ones, effective measures shall be taken. For example, the possibility of violation for materials can be estimated based on values calculated from water content.

(7) Consistency with food additives regulations

For agricultural chemicals etc. that are subject to regulations for food additives, provisional MRLs will not be established.

(8) Judgment of compliance

When judging the compliance to the MRL, a test value will be calculated to one more digit than required and rounded off to the nearest digit and the obtained value will be compared with the corresponding standard limit.

2. Procedures for Drafting Provisional MRLs

Provisional MRLs shall be established based on the following policies, taking into

account 1) the Codex MRLs; 2) the registration withholding limits under the Agricultural Chemicals Regulation Law (for veterinary drugs, limits of quantification (LOQ) or determination established at authorization under the Pharmaceutical Affairs Law and for feed additives, as designated under the Law concerning quality improvement and securing safety of feed; 3) the MRLs in foreign countries that have been based upon scientific toxicity evaluations required by the Joint FAO/WHO Meetings on Pesticide Residues (JMPR) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA), and countries that offered their cooperation in providing these data (USA, Canada, EU, Australia, and New Zealand)(in response to our request to the foreign delegations at the Food Import Promotion meeting on 11 April 2003). The detection tree is shown in Figure 1.

- (1) Since Japan is a member state of the WTO, the Codex standards will be adopted if applicable.
- (2) For substances with no Codex standards, standards established in Japan such as standards for the withholding of agricultural chemicals registration will be adopted. The Ministry of the Environment and the Ministry of Agriculture, Forestry and Fisheries has used these standards in registering agricultural chemicals. They are regarded as being established on a scientific basis according to the results of toxicity tests or residue tests. It is scientifically reasonable to adopt standards based on test results, including toxicity established by the Ministry of the Environment and the Ministry of Agriculture, Forestry, and Fisheries, and this is consistent with the international method of establishing standards.
- (3) For substances with no Codex standards and no domestic standards, foreign countries' standards will be adopted. Based on the fact that every nation applies its own standard not only to domestic products but also to imports, that the standards have been established on a scientific basis according to test results such as those on residues, and that these standards are regarded effective by the WTO, the average level of multiple standards will be adopted.
- (4) Thus, for domestic products when the Codex standards are adopted, and for imports when the Japanese standards are adopted, the respective domestic and foreign standards or standards based on the submitted test results on residues will be adopted as necessary based on the production, distribution and usage conditions of the agricultural chemicals. To be more precise, for grapefruits, lemons, pineapples, wheat, corns, soybeans, etc., which are designated as products with a low self-sufficiency ratio at the URL of the Ministry of Agriculture, Forestry and Fisheries, foreign standards, have been adopted as required.

3. Points for consideration in the establishment of provisional MRLs

- (1) Consistency in standards for individual crops in the same categories

Individual limits should be harmonized among crops in the same food category, such as cereal grains and cruciferous vegetables. The cases for which MRLs are harmonized in the group are shown as "Type 6-1"

(2) Handling of substances remaining in the form of the same metabolites etc.

When chemicals have different active ingredients but remain in food in the form of the same metabolite or decomposed substance, provisional MRLs for these chemicals should be set for the metabolite or decomposed substance. Also, when chemicals have different active ingredients but substances that can be determined for these chemicals are all the same, provisional MRLs should be set for the substance targeted for determination. The cases where MRLs are harmonized among substances when the metabolites are relevant are shown as “Type 6-2”. Example: Acepahte and Methamidophos (Insecticide)

- (3) When MRLs for veterinary drugs are established for some tissues or organs such as muscle and fat etc. in the same species, the lowest MRL of the established MRLs for the species is used for the provisional MRLs for the tissues or organs for which MRLs are not established due to the following reasons; 1) Application of veterinary drugs to species are authorized. If residues can be found in some tissues or organs, they may possibly remain in other tissues or organs more or less; 2) in the US etc., the residue monitoring is performed on the target organ and the MRLs are not established for all organs in the animal. They are shown as “Type 6-3”.
- (4) Based on the current status of analysis methods developed for monitoring and control by local governments, for agricultural chemicals considered difficult to be detected at the level of a uniform standard (0.01 ppm), levels corresponding to LOQs for crops, animal, and aquatic products are employed as alternate of the Uniform Limits. They are shown as “Type 6-4”.
- (5) For agricultural chemicals for which MRLs below a uniform standard (0.01 ppm) are established for some crops etc., the lowest level among those established for the agricultural chemicals etc. in question is employed as provisional MRLs for those other than crops with specific MRLs. They are shown as “Type 6-5” including those indicated in Paragraph 3 of II, 1, (2).
- (6) Those for which MRLs are established based on the test results of crops residues submitted by the Ministry of Agriculture and Fisheries etc., or those for which tissues or organs that is likely to have residues are taken into consideration in applying Type 6-3, are shown as “Type 6-6”.

4. Other points for consideration in the establishment of provisional MRLs

1. Adoption of foreign countries' MRLs

- (1) The mean value should be applied as the provisional MRL when MRLs from multiple countries are used for one crop.

Example:

Food	PR- MRL	Ref.	MRL	WHL	Codex	US	AU	CA	EU	NZ
Orange	3.3 → 3	FC				1		6	3	
Chinese cabbage	0.036 → 0.04	FC				0.02	0.04		0.05	

- (2) Among substances for which LODs are employed as MRLs in foreign countries, for those recognized as specific toxic agents defined by the Poisonous and Deleterious Substances Control Law (Law No.303 of 1950), that are not approved to be applied as agricultural chemicals domestically or abroad, provisional MRLs shall not be established.
- (3) Since emergency application of agricultural chemicals in response to outbreak of pest in the US requires the EPA's approval based on risk evaluations, for those with established MRLs that are approved, provisional MRLs shall be established taking the established MRLs into consideration.

2. Effective Values

According to FAO guidelines, effective values shall be one digit except for Codex standards. For those with the proposed standards above 100 ppm, effective values shall be two digits.

3. For mineral water, since WHO Potable Water Guidelines are employed in Codex standards for mineral water, provisional MRLs should be established based on the standards specified in the Guidelines. In judging compliance of processed food (with the exception of those with individual standards) with provisional MRLs for agricultural chemicals remaining in food etc., standards specified in the Guidelines should be taken into consideration in analyzing agricultural chemicals remained in water used to produce the food in question.
4. Tea extraction methods in Japan are divided into one by hot water and one by organic solutions. In cases of hot water extraction, the same method employed for the reference standard shall be applied for the proposed Provisional MRL, and it shall be noted in the list.
5. For the post-harvest fungicides that are defined as food additives in the Food Sanitation Law, the MRLs in application standards as additives defined by the Food Sanitation Law shall be employed as the provisional MRLs, except for those already with established MRLs.
6. When antibiotics registered as agricultural chemicals are applied as agricultural chemicals, application standards etc. are established based on data at the time of

registration under the Agricultural Chemicals Control Law. They have been applied taking into consideration the standard, “Not Detected” stipulated in the Food Sanitation Law. In order to ensure control of agricultural chemicals etc. to improve protection of public health, the MRLs of specific values shall be established based on LODs employed at the time of registration of agricultural chemicals.

7. Agricultural chemicals etc. with the current MRLs only (those for which provisional MRLs are not proposed) will be listed in the attachment.

III. Food Categories for MRL setting

1. Independent categories shall be established for crops, spices, and herbs with high intake. Since these standards are established with the restructuring of food categories, standards that have been or are expected to be applied in the current categories will be employed as provisional MRLs.

- (1) A food that has currently been categorized as “products other than above-mentioned products” will be separated from that category and newly categorized as a single food category when its consumption is considerably large (above one gram per person per day) and Codex standards are established for that food category. The new food categories will be implemented at the enforcement of the positive list system. The following are examples of separated categories:

<u>New Food Categories (daily consumption)</u>	<u>Current Category (daily consumption)</u>
<i>Qing-geng-cai</i> (1.37 grams) (“pak-choi”-type Chinese cabbage)	Other cruciferous vegetables (3.7 grams → 2.3 grams)
<i>Nira</i> (Chinese chive) (1.74 grams)	Other liliaceous vegetables (2.5 grams → 0.8 grams)
Bamboo shoots (2.05 grams)	Other vegetables (13.3 grams → 11.3 grams)

- (2) Definitions and subjects of “spices” and “herbs” shall be determined based on Codex definitions. For “Condiments”, “Spices” and “Herbs” other than those classified as independent items, new classifications “other spices” and “other herbs” will be established.

2. Categories of animal origin products with daily consumptions as food being below one gram (based upon the Japanese food consumption data) are shown below:

Cattle, muscle	Chicken, muscle
Pig, muscle	Other poultry, muscle
Other terrestrial mammals, muscle	Chicken, fat
Cattle, fat	Other poultry, fat
Pig, fat	Chicken, liver
Other terrestrial mammals, fat	Other poultry, liver
Cattle, liver	Chicken, kidney
Pig, liver	Other poultry, kidney
Other terrestrial mammals, liver	Chicken, edible offal excluding muscle, fat, liver and

	kidney
Cattle, kidney	Other poultry, edible offal excluding muscle, fat, liver and kidney
Pig, Kidney	Other poultry, eggs
Other terrestrial mammals, kidney	Order Salmoniformes
Cattle, edible offal excluding liver and kidney	Order Anguilliformes
Pig, edible offal excluding liver and kidney	Order Perciformes
Other terrestrial mammals, edible offal excluding liver and kidney	Other fish
Milk	Order Decapoda
	Other Crustacea
	Shelled molluscas
	Other aquatic animals
	Other animals
	Honey

IV. Review of Provisional MRLs

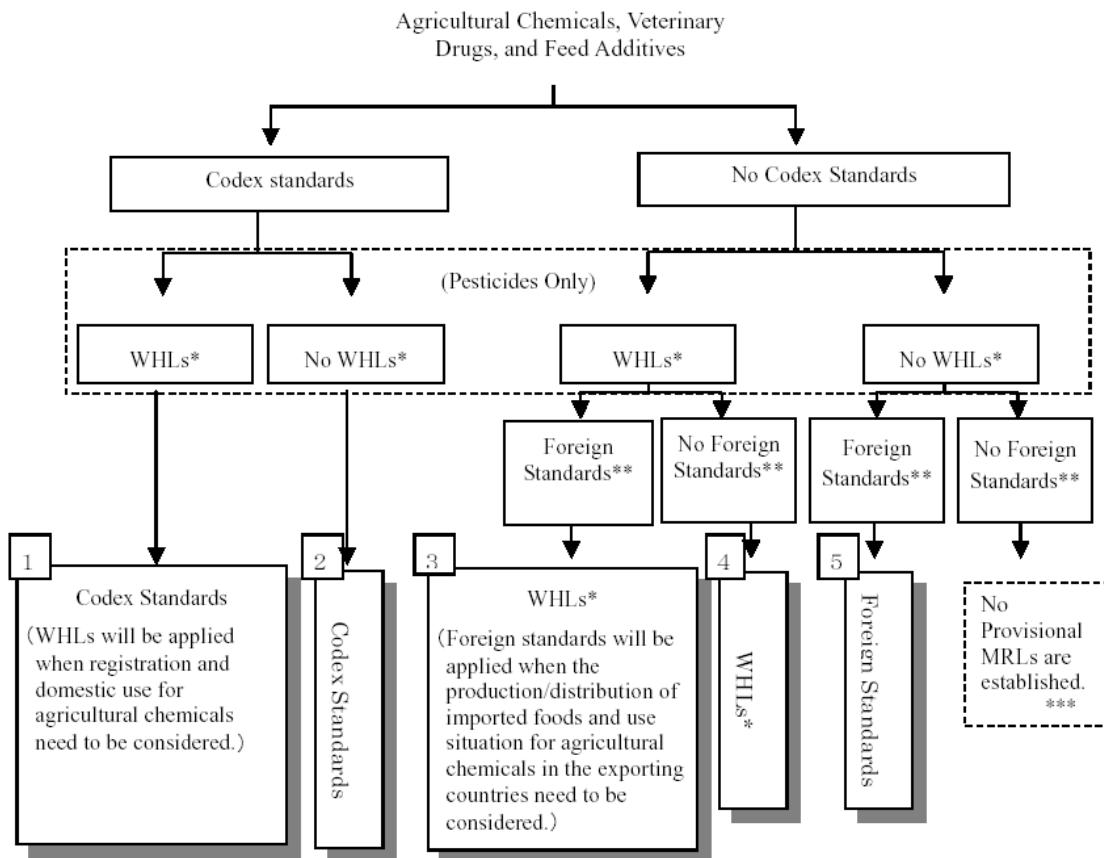
1. The proposed provisional MRLs will be reviewed about every five years after the implementation of the positive list system, according to changes in the reference MRLs used in setting provisional MRLs.
2. The MRLs will be reviewed based upon the risk assessment and Japanese food intake, which is derived from safety test results for substances prioritized according to survey results of agricultural chemicals intake by market basket method etc. Among agricultural chemicals for which provisional MRLs are established, those for which international institutions determined that ADIs cannot be established, or those with newly available national or foreign safety information, the provisional MRLs shall be reviewed based on available data and results of evaluation of food effects on human health requested on a priority basis.
3. According to “Guidelines on establishment and revision of MRLs concerning agricultural chemicals etc. applied abroad” (Announcement, Director of Office of Food Safety, Department of Pharmaceutical and Food, Ministry of Health, Labour and Welfare on February 25, 2004), establishment or revision of MRLs of agricultural chemicals etc. can be requested with submission of data concerning toxicity etc.

V. Others

For analytical methods concerning provisional MRLs, progress of discussion has been published on the website run by the Ministry of Health, Labour and Welfare since August 2004. The following situation will be published as soon as prepared. Discussion will be kept on to improve sensitivity and effectiveness of analytical methods, and the results will be reflected in reviewing provisional MRLs as a whole.

Figure 1.

Decision Tree on Provisional Maximum Residue Limits (MRLs)



* WHLs: Registration Withholding Limits under the Agricultural Chemicals Regulation Law.

** Foreign Standards: Standards in foreign countries (US, EU, Australia, New Zealand and Canada) that have been based upon scientific toxicity evaluations etc. required for scientific evaluations such as JMPR.



: Standards that will be applied as Provisional Standards

In addition to the above decision tree, the other consideration mentioned at the Section 2,(3) would be applied. Those cases are indicated as Type 6-1 to 6-6.

Type

- 1-1. Both the Codex Standard and WHL exist, and the Codex Standard is applied.
- 1-2. Both the Codex Standard and WHL exist, and the WHL is applied.
- 1-3. Both the Codex Standard and WHL exist, and the standard based on crops residues tests is applied.

2. The Codex Standard is applied.
 - 3-1. Both the WHL and one or more foreign standards exist, and the WHL is applied.
 - 3-2. Both the WHL and one or more foreign standards exist, and the foreign standards are applied.
 4. The WHL is applied.
 5. The foreign standards are applied.
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- 6-1. Consistency within the food category is kept.
 - 6-2. Consistency of MRLs between metabolites and relevant substances is kept.
 - 6-3. MRLs of tissues or organs other than relevant tissues or organs of the same species are used as reference.
 - 6-4. Since it was considered difficult to analyze at the level of a uniform standard (0.01 pm), the level corresponding to limits of determination of the analysis method is employed as the provisional MRL.
 - 6-5. Since MRLs below a uniform standard (0.01 ppm) are established for some crops, the lowest value among established MRLs is employed as the provisional MRL.
 - 6-6. Others (e.g. those based on test results, and tissues or organs in which residues are expected are taken into consideration in applying 6-3)