The Second Draft of Provisional Maximum Residue Limits (MRLs) for Agricultural Chemicals in Foods

The Ministry of Health, Labour and Welfare revised Food Sanitation Law in May 2003. Based on the revised Food Sanitation Law, the MHLW is going to implement the positive list system. The system is aimed at prohibiting the distribution of foods that contain agricultural chemicals above a certain level unless MRLs for the chemical on the food are established. This system will go into effect within three years after the publication of the revised Food Sanitation Law.

Provisional Translation of the Article 11, Paragraph 3, of the revised Food Sanitation Law (newly established provision)

Any food that contains, as a residue, an active ingredient of an agricultural chemical defined in the Agricultural Chemical Control Law, a feed additive defined in the Feed Additives Safety Control Law, or a veterinary drug defined in the Pharmaceutical Affairs Law (including a substance produced by a chemical change in the active ingredient and excluding any substance specified by the Minister of Health, Labour and Welfare as not posing any adverse health effects) at a level exceeding the amount that is established by the Minister of Health, Labour and Welfare as not posing any adverse health affects after hearing the opinion of the Pharmaceutical Affairs and Food Safety Council, shall not be produced, imported, processed, used, prepared, or stored for the purpose of sale, or sold. However, this provision shall not be applied in the case that the maximum residue limit is established for the chemical on the food, in accordance with the provision of Paragraph 1 in this article.

After the positive list system goes into effect, a food that contains an agricultural chemical without MRLs will be prohibited from being distributed if the chemical residue is over a certain level. The objective of the system is to protect human health. But the introduction of the system in the current situation could result in unnecessary disruption in international food trade, because the number of chemicals with MRLs is small in Japan, compared with that of globally distributed chemicals. Therefore, it is necessary to provisionally establish MRLs before the implementation of the system. These provisional MRLs will be established for chemicals that are domestically authorized under the Agricultural Chemical Control Law, and chemicals for which Codex MRLs or other MRLs are established based on scientific evaluations.

The Subcommittee on Pesticides and Veterinary Drugs under the Food Sanitation Committee have agreed that provisional MRLs should be established according to the following procedure, and that comments on the draft provisional MRLs be invited from various experts.

I. Legal Background

(1) Foods applied the provisional MRLs

The positive list system applies to the foods including processed foods made from them from the production where the agricultural chemicals, veterinary drugs and feed additives may use.

(2) Legal Status of provisional MRLs

The provisional MRLs will be applied as the legal standards based on Article 11 of the Food Sanitation Law, after the positive list system goes into effect (within three years after publication of the revised law, that is, not later than May 2006). The provisional MRLs will be published without distinctions between agricultural chemicals, veterinary drugs, and feed additives.

A grace period of six months will be set after the publication of the finalized MRLs. 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 current established MRLs will remain unchanged and continue to apply. The substances of the current MRLs unchanged at this time are listed in the Note.

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.

- 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.

- 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. The analytical methods and their levels of detection (LOD) will be published in the Official Gazette.

- The residue levels shall not exceed the limits of the agricultural chemicals for primary products such as crops when the MRLs for the substances are established. When metabolites of agricultural chemicals are found in foods, MRLs for the parent substances are applied for the judgment of their compliance. The cases where bothparent substances and their metabolites are subject to the MRLs are excluded.

- Necessary measures will be taken to prevent excessive regulation of substances that can remain in food as agricultural chemical residues when they are naturally occurring in foods and in the natural environment. The requirement on the residue limits will be based on the levels naturally occurring in the foods. naturally.

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

- Individual MRLs will not be established for other processed foods; processed foods can be distributed as long as they are made of ingredients that meet standards under the Food Sanitation Law.

- The substances that are agricultural chemicals already regulated as food additives will not be covered.

- When judging the compliance to the MRL, a test value will 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

The following procedures are applied to draft provisional MRLs.

- Take into account 1) the Codex MRL; 2) the registration withholding limits under the Agricultural Chemicals Law (for veterinary drugs, limits of quantification or determination (LOD) established at authorization under the Pharmaceutical Affairs Law; 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). Australia, Canada, New Zealand, the USA, and European Union have kindly offered their cooperation in response to our request to the foreign delegations at the Food Safety Group meeting on 11 April 2003.

- The procedures below are followed. The decision 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 the subjects of the present Provisional MRLs include many agricultural chemicals based on the introduction of the positive list system, the average level of multiple standards will be adopted since the standards are based upon risk analysis such as reviewing the ADIs and residues in products.

(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 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, 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. Since the same thing has been confirmed for corn at the URL, the same measures will be adopted.

- According to the comments on the first draft, the provisional MRLs are revised when changes in the MRLs in foreign countries are confirmed in the official documents like Code of Federal Register (CFR) in the United States

- If you have any requests for the Provisional MRLs (draft) such as the revision of the levels, and for which toxicity data is available, you can ask the Food Safety Committee for a risk evaluation. Please apply for establishment of MRLs, according to the announcement of the Director of the Food Safety Division, Shoku-An No. 0205001 dated February 5, 2004, "Guidelines on establishing and revising residue standards concerning agricultural chemicals used overseas".

3. Points for consideration in the establishment of provisional MRLs

- 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 show as "Type 7" in Table2. Example: MCPB and MCPB methyl (Herbicide)

- 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) When there is a big difference in MRLs used for one crop, the most appropriate value should be applied, taking the deviation into account. The simple mean value should not be used. However if there is a justifiable rational, it should be considered.

(3) When only EU or one of these four countries sets a numerical value that is the LOD as the MRL, a certain uniform level that does not pose any adverse health effect should be applied in the positive list system.

- Individual limits should be harmonized among crops in the same food category, such as cereal grains and cruciferous vegetables.

- According to the FAO guideline, one significant figure should be used. The figures should be rounded if necessary. In the case that MRL is more than 100 ppm, two significant figures are used.

- , There are two ways of extraction for analysis for tea: hot-water extraction and organic solvents. The provisional MRL for tea is marked with an indication showing that hot-water extraction was used, when the MRLs are based upon a method using the hot-water extraction.

- The post-harvest fungicides are defined as food additives in the Food Sanitation Law. When substances among post-harvested fungicides are registered as food additives in Japan the maximum use levels for the food additives are applied as the provisional MRLs.

- When MRLs for veterinary drugs are established for some organs in the same species, the lowest MRL of the established MRLs for the species is used for the provisional MRLs for the organs for which MRLs are not established. This is based upon the idea that the veterinary drugs are authorized to apply to the species and, for instance in the United States, the residue monitoring is performed on the target organ and the MRLs are not established for all organs in the animal. The cases where MRLs are treated by the above-mentioned way are show as “Type 8” in Table2.

III. Food Categories for MRL setting

(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:

New Food Categories (daily consumption)	Current Category (daily consumption)
Qing-geng-cai (1.37 grams) *(“pak-choi”*-type Chinese cabbage*)*	Other cruciferous vegetables (3.7 grams → 2.3 grams)
Nira (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) In animal origin products the following categories are used. These categories are compiled based upon the Japanese food consumption data so that average food consumptions are more than one gram per day.

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

IV. Review of Provisional MRLs

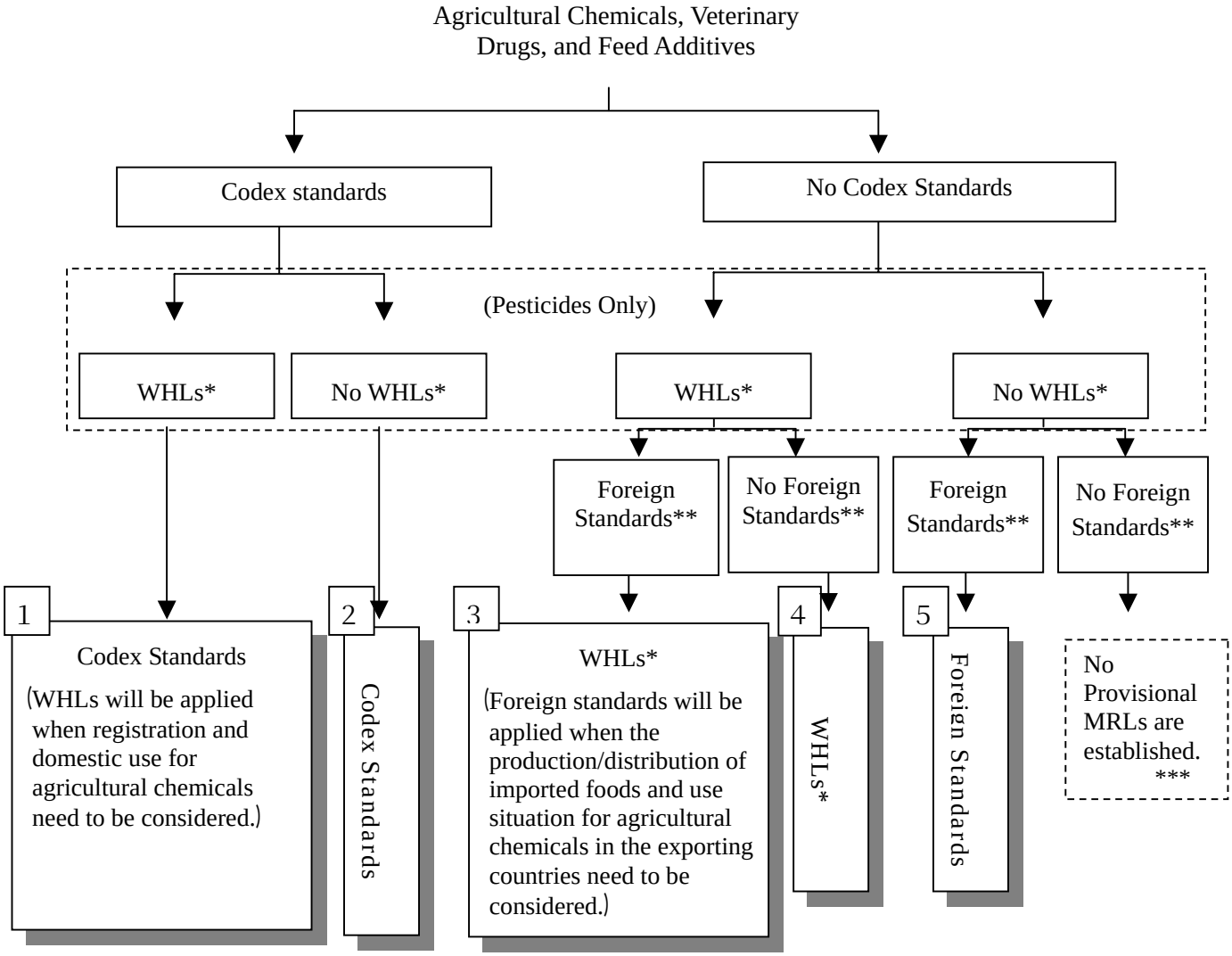
(1) The established provisional MRLs will be reviewed about every five years, according to changes in the reference MRLs used in setting provisional MRLs.

(2) The MRLs will be reviewed based upon the risk assessments obtained from toxicity studies. The reviews will be conducted in the order of priority based upon total diet studies.

(3) The MHLW has developed a system for establishing MRLs on certain crops for agricultural chemicals that are not used at all in Japan or are used only for limited crops, upon request from abroad. In February 2004, the MHLW published a guideline describing procedures for application from abroad.

Figure 1.

Decision Tree on Provisional Maximum Residue Limits (MRLs)



* WHLs: Registration Withholding Limits under the Agricultural Chemicals Control Laws.

** Foreign Standards: Standards in foreign countries that have been based upon scientific toxicity evaluations.

*** When no provisional MRLs are established, a certain level of uniform limit that does not pose adverse health effects is applied.

: Standards that will be applied as Provisional Standards

Type

1. Basically, the codex standard is applied, when both a Codex Standard and an WHL exist
   1-1. The Codex Standard is applied.
   1-2. The WHL is applied when registration and domestic use need to be considered for an agricultural chemical.
2. The Codex Standard is applied, when a Codex Standard exists but no WHL exists.
3. Basically, the WHL is applied, when both an WHL and one or more foreign standards exist.
   3-1. The WHL is applied.
   3-2-1. The foreign standard (or the mean) is applied when the production/distribution of imported foods and use situation for an agricultural chemical in the exporting country need to be considered.
   3-2-2. The appropriate foreign standard is applied with special consideration.
4. The WHL is applied when an WHL exists but no foreign standards exist.
5. The foreign standard (or the mean) is applied when no WHL exists but one or more foreign standards exist.
   5-1. The foreign standard (or the mean) is applied.
   5-2. The appropriate foreign standard is applied with special consideration.
6. Harmonization within the food category is done.
7. Harmonization among substances when the metabolites are relevant is done.
8. The MRLs in other organs of the same species is referred.