

Introduction of the Positive List System for Agricultural Chemical Residues in Foods

Department of Food Safety, Ministry of Health, Labour and Welfare May 2005

I. Introduction of the positive list system

The Ministry of Health, Labour and Welfare (MHLW) will introduce a so-called positive list system for agricultural chemicals remaining in foods—a 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, veterinary drugs, and feed additives. This activity is based on the law to partially revise the Food Sanitation Law (Law No. 55, 2003). The system will take effect within three years (May 29, 2006) after the publication of the revised Food Sanitation Law (May 30, 2003).

The Ministry must, by May 2006, take the following three measures toward the implementation of the system.

- i. To establish a certain limit stipulated in Article 11 Paragraph 3 of the revised Food Sanitation Law as a limit that is unlikely to pose adverse health effects (hereinafter referred to as the “uniform limit”)
- ii. To specify substances stipulated in Article 11 Paragraph 3 of the revised Law as those that will not pose adverse health effects (hereinafter referred to as “exempted substances”)
- iii. To establish maximum residue limits stipulated in Article 11 Paragraph 1 of the revised Law, which are provisionally established as compositional specifications for food (hereinafter referred to as “provisional MRLs”)—as maximum levels of chemicals that can remain foods—in order to protect public health and smoothly implement the positive list system.

The Pharmaceutical Affairs and Food Sanitation Council carried out discussions about provisional MRLs in and after June 2003. The MHLW published the first draft of provisional MRLs in October 2003, and the second draft of provisional MRL and the draft uniform level and exempted substances in August 2004, and sought public comments at home and abroad.

II. Discussion by the Food Safety Commission

The final draft has been formulated based on the opinion of the Food Safety Commission (FSC), which was given based on Article 23 Paragraph 1 (5) of the Food Safety Basic Law (Law No. 48, 2003). The FSC carried out discussions twice in April 2005 (the 14th and 21st). On April 28 the Minister received the opinion from the FSC

about six matters that should be kept in mind from the point of view of food safety. These matters include the review of chemicals for which provisional MRLs are to be established and the formulation of a risk assessment program.

The opinion from the FSC (*Japanese*) is available at:

http://www.fsc.go.jp/iinkai/positivelist_170428.pdf

III. Specifics of uniform limit, exempted substances, and provisional MRLs

A. Uniform limit

The level will be applied to agricultural chemicals for which MRLs are not established. Basically, before a chemical is authorized, discussions are conducted on toxicity and other necessary matters. Based on the discussion results, restrictions are set on target crops and use amounts. Also, applications to the target crops and maximum limits that can remain in foods are established. This activity is conducted in the similar manner, regardless of country.

It is appropriate to use a toxicological threshold of 1.5 µg/day as the basis to determine the uniform limit. The threshold is 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. The European Union (EU), which is going to introduce the positive list system, established in January 2005 the uniform level at 0.01 ppm. Considering such circumstances, the limit is reasonable.

Instead of the Uniform Limits, for chemicals for which the ADI by JMPR or JECFA are extremely low, MRLs as ND (not-detected level) are established. For substances for which the limitation of determinations for analytical methods to be used in monitoring tests conducted by the Japanese local governments exceeds 0.01 ppm, LOD of the analytical method are applied.

B. Exempted substances

Exempted substances refer to agricultural chemicals that are determined not to pose adverse health effects, given residue levels and forms, even if these chemicals remain in crops and animal products, including sea foods, to certain levels. These chemicals include those produced by a chemical change from the parent chemicals

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 or territories where MRLs are assumed to be established based on toxicity study data equivalent in quality to those used in scientific evaluations by JECFA.

- i. Chemicals determined as those for which no ADI is needed to be set by risk assessment conducted based on Article 11 of the Food Safety Basic Law,
- ii. Specified agricultural chemicals shown in the Agricultural Chemicals Regulation Law.
- iii. Other substances determined not to pose adverse effects, considering residue levels of applied chemicals. (excepted the above cases)

C. Provisional MRLs

Chemicals for which MRLs are established based on Article 11, Paragraph 1 of the revised Law do not cover all substances including Codex standards and registration withholding limits of substances permitted for use. From the viewpoint of protection of public health and smooth implementation of the system, provisional MRLs are established for chemicals for which MRLs are not established at present. In establishing provisional MRLs, Codex standards and other necessary information are considered.

Provisional MRLs are established taking into consideration:

- i. Codex standards,
- ii. Registration withholding limits based on the Agricultural Chemicals Regulation Law, limit of determination for veterinary drugs at the time when they were authorized based on Pharmaceutical Affairs Law (Law No. 145, 1960), and limitation 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 or areas 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 and areas are United States, EU, Australia, New Zealand, and Canada.

Among those chemicals categorized in either of the following two types, ND will be 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 and determined by the MHLW as those for which ND should be set, as a result of review conducted in response to FSC's opinion. Separately from numerical limits, requirements/restrictions will be imposed on certain types of substances including

Provisional Translation
Original: Japanese

antibiotics, antibacterials, substances naturally occurring in foods, and chemicals for which standards are already set as food additives, and on applications of MRLs to processed foods.

The proposed provisional MRLs will take effect on the date of implementation of the system as compositional standards for food stipulated in Article 11 Paragraph 1 of the Law. Basically, changes will not be made for MRLs already established based on Article 11 Paragraph 1.

<Progress of the activity>

Year 2003

- May: The Law to Partially Revise the Food Sanitation Law was promulgated.
June: The Pharmaceutical Affairs and Food Sanitation Council started discussion on the introduction of the positive list system.
October: The MHLW published the first draft of provisional MRLs and sought public comments (comment period: three months).

Year 2004

- April: The Council started discussion toward formulation of the second draft based on the obtained comments.
August: The MHLW published the second draft of provisional MRLs and draft uniform limit and exempted substances and sought public comments (comment period: three months).

Year 2005

- January: The Council started discussion toward formulation of the final draft based on the obtained comments.
April: The FSC carried out discussion and gave the opinion to the MHLW.

<Future activity>

End of May

The Council and the FSC are separately to conduct discussions.
The MHLW is to seek public comments and to notify the WTO.

August, September

The FSC is to conduct discussion.
The Council is to conduct discussion and to submit the final report to the MHLW.

End of November

The MHLW is to publish the provisional MRLs, uniform limit, and exempted substances (grace period: six months).

Year 2006

End of May

The Positive List System is to be enforced.