Provisional Translation
Original: *Japanese*

Responses to Major Comments on the Provisional MRLs (First Draft) (except for comments on specific standard levels)

1. General comments

1-1. "Public Health Protection" should be clearly stated as a major premise in developing the Provisional MRLs (Japanese Consumers' Co-operative Union).

[Response]

Revisions will be made according to the comment.

1-2. (1) Not only directly edible food, but also ingredients should be covered as the subjects of control from the viewpoint of food safety (Japan Oilseeds Processors Association, Morio Hamashima). (2) Agricultural chemicals are unlikely to remain in processed "cornmeal" compared with "fresh corn". Since it is unreasonable to establish a uniform "national standard", the development of Provisional MRLs according to usage is strongly demanded (Japan Feed Trade Association).

Note: Oil materials such as cottonseed, flax seed, and rapeseed

[Response]

For products such as cottonseed and corn, since standards not according to usage but according to product have been developed both in the domestic standards and the Codex standards, it would be reasonable to also follow this method in developing the Provisional MRLs.

For processed food, as stated in II-4 of the "Guidelines for comments on the proposed Provisional MRLs (first draft) for agricultural chemical residues (referred to as the 'briefing paper' hereinafter)", Provisional MRLs have been developed only for processed foods with established international standards, since residue levels depend on the raw materials, their proportion, processing methods and so on. Basically, agricultural chemical residues should be controlled at the stage of the raw materials.

1-3. Agricultural chemicals are used for various farm products, including many minor ones. In the development of agricultural chemicals, it is typical to register them for major products first, and then expand registration to other and minor ones. Group Tolerance or the Group MRL system (by product group) that has been implemented in the US and EU should be introduced (Japan Crop Protection Association).

[Response]

Provisional MRLs have been developed based on the relevant products and their standards in the US and EU, which have adopted the above-mentioned system in addition to registration according to the Agricultural Chemicals Control Law in Japan. Therefore, the range of the relevant products is consistent with that in the US and Europe.

1-4. Although the intake of fenitrothion has already reached its ADI (Acceptable Daily Intake), no measures have been taken to deal with this matter. How will it be dealt with (Forum for Genetic Toxicity)

[Response]

'Has reached its ADI' can be interpreted as that fenitrothion, etc., has reached its limit for the estimated theoretical maximum daily intake (TMDI). However, the actual intake of fenitrothion investigated using the market basket method, 0.3-2.9% of the ADI in 1991-2000, was much lower than the value estimated by the TMDI method. Based on this fact, there is no necessity to pay special attention to fenitrothion, etc.

The Provisional MRLs have been developed based on the Codex and foreign standards. The official standards will be established based on the tentative ones according to the priority evaluated through research results, such as those on actual daily intake.

1-5. Revision of the Provisional MRLs
(1) The Provisional MRLs should be revised not every five years, but as necessary (Japan Frozen Food Association).
(2) The Provisional MRLs should be reviewed more frequently (e.g. every few years), taking the current situation, such as the accelerated development of drugs, into consideration (Japan Biscuit Association, All Nippon Kashi Association, Chocolate & Cocoa Association of Japan, Nissin Cisco Co., Ltd., Nichirei Corporation Bourbon Corporation, Maruha Corporation, and Morinaga & Co., Ltd.).
(3) Will the Provisional MRLs become official standards after a review (Toshihiro Nagayama)?
(4) The Provisional MRLs should be reviewed based on precise exposure evaluation using actual intake in Japan (Japan Food Information Center (JFIC), Nisshin Seifun Group Inc., and Nisshin Flour Milling Inc.).

[Response]

Review of the Provisional MRLs every five years is reasonable since the standards need to be reviewed in conjunction with the Agricultural Chemicals Control Law domestically, and the system for establishing or revising standards upon application from exporting countries has been established.

The Provisional MRLs will be reviewed based on risk evaluation and food intake in Japan according to the priority evaluated through research results, such as those on daily intake. The Provisional MRLs will become the official standards after the review process.

1-6. In developing the Provisional MRLs, the evaluation method for antimicrobials, for example, differ between the JECFA, the EC Scientific Committee on Food (SCF) and the FDA. The former two organizations use different formulas in calculating the ADI based on the MIC (minimum inhibitory concentration), and the FDA does not use the MIC. In addition, the conclusion for a Bovine Somatotropin (BST) differs between the JECFA and ECSCF. Thus, in any future review of the Provisional MRLs, sufficient investigation should be conducted in response to the fact that foreign countries have not always established standards based on data that the JMPR and JECFA have adopted (Japanese Consumers' Co-operative Union).

[Response]

The comment will be taken into consideration in reviewing the Provisional MRLs based on risk evaluation from comprehensive viewpoints.

1-7.

(1) Not only 650 types, but all existing agricultural chemicals in the world should be controlled. Standards should be established based on total intake (Toshiko Matsuda).
(2) Since it is difficult to determine all agricultural chemicals, the evaluation method for standards for extracts using organisms such as microbes should be considered (Environmental Bureau, City of Kitakyusyu).
(3) A total standard level for agricultural chemicals should be established to reduce the total intake (Anti-agricultural chemical Tokyo group).

[Response]

The present so-called positive list system (referred to as the "positive list system" hereinafter) regulates all agricultural chemicals. To be more precise, with a few exceptions, established residue standards, including tentative ones, are applied as applicable, and uniform standards are applied to those without established standards. In developing Provisional MRLs, evaluation has been conducted based on scientific data, and residue standards declared by nations or regions have been referred to after being verified.

In reviewing the Provisional MRLs based on risk evaluation, they will be re-considered based on food intake in Japan.

No test methods using organisms are available at present.

Since substances have different levels of toxicity and properties, standards have been developed for individual agricultural chemicals domestically and internationally.

1-8. As in the positive list system for food additives, the distribution of food that is found to contain agricultural chemicals without an established standard should be banned (Anti-agricultural chemical Tokyo group).

[Response]

The Food Sanitation Law controls residues, including agricultural chemicals. The positive list system will prohibit the distribution of food containing residues leading to the assurance of public health protection.

Since the usage of agricultural chemicals is outside the scope of the Food Sanitation Law, it is impossible to control them under the Law.

1-9. The definition of the relevant residues should be clarified. Even if used in the same fashion, MRLs differ according to the parent compounds and metabolites. The definition of residues is sometimes different between agricultural chemicals and veterinary medicines, even if they are identical (Australian government, Japanese Consumers' Co-operation Union).

[Response]

Efforts have been made to clarify the range of subjects of the Provisional MRLs, including agricultural chemicals, by various means such as listing product names and footnotes.

In the future, the publication of test methods (draft) will make the details of the regulations clearer.

1-10. Since more than 60% of foods are imported, worldwide agreement should be reached on the proposed Provisional MRLs for individual farm and animal products. For agricultural chemicals whose efficiency depends on geographic or climatic conditions, specific responses are required (Aohata Corporation).

[Response]

The first draft of the proposed Provisional MRLs has been provided to the Conference for the Promotion of Food Import Facilitation (Food Safety Group, FSG), comprised of embassies, for their comments. Comments will be broadly sought domestically and internationally through the WTO, etc. Please see response 4-1 for the latter part.

1-11.

(1) At least a one-year moratorium should be provided before the implementation of the Provisional MRLs, taking production plans into consideration (Japan Food Industry Center, Ajinomoto Co., Inc.).

(2) A sufficient period for should be provided before the implementation of the system to allow for the proper dissemination of information on the analysis methods (Japan Food Industry Center).

[Response]

The Provisional MRLs will be implemented over a 6-month period from the announcement following confirmation of the Food Sanitation Group after completion of the procedures, including public comment on the final draft, and notification to the WTO. Details of the analysis methods will be disclosed one by one, and the full details will be provided no later than the announcement.

1-12. Since some processed foods have a shelf life of more than 2 years, the positive list system should be applied to products made after the implementation. Minor deviations from the standards with no effect on human health should be exempted from its application (Japan Food Industry Center, Yuriko Takemura, Hiroo Mizuno, Takashi Miyashita).

[Response]

The Provisional MRLs will probably be applied to products made after the implementation. Since residue standards are established as being levels at which there are no adverse effects on human health based on scientific data, even minor deviations will be recognized as noncompliance under the Food Sanitation Law. See the announcement of the Director, Office of Information, Food Safety Division, Shoku-An-Ki No.0204001 dated February 4, 2004, “Questions on the interpretation of Article 7, Section 2 of the Food Sanitation Law” for details.

1-13. Is it due to the high intake that reindeer are categorized separately among the land mammals, and pheasant and partridge are among the poultry? They should be included in ‘others’ (Toshihiro Nagayama).

[Response]

According to the comment, a daily intake of sheep, horse, deer, goat, rabbit, and reindeer meat of less than 1 g in a national nutrition survey will determine their inclusion under other land mammals, and duck, turkey, quail, goose, pheasant and partridge will be included under other poultry. In addition, the classification of fish will be re-organized.

2. Proposed general regulations (Regulations of the proposed Provisional MRLs (first draft) related to the introduction of the positive list system) (draft)

2-1.

(1) Under the positive list system, substances with no established residue standards should not be detected. Therefore, substances with no toxicity data should not be detected as a general rule, and the acceptable detection level should be the detection limit (Michiko Kamiyama).

(2) It is assumed that food containing substances such as agricultural chemicals over a certain level with no established standards should not be distributed as a general rule. What does the term "as a general rule" mean operationally? If it means "not detectable (ND)", the distribution of products containing agricultural chemicals used in the past could also be prohibited if their standards have not been established based on the shelf life. Agricultural chemicals with a long shelf life could be detected even in domestic products (Kokusan Shoyaku Co. Ltd.).

[Response]

It has just been decided that a certain standard (uniform standard) will be established for agricultural chemicals without established standards as "levels with no adverse effects on human health", taking foreign cases into consideration, since non-intentional residues can be expected to occur through the environment, etc., for agricultural chemicals, unlike for food additives.

It is recognized that nations such as New Zealand, Germany and the US, having adopted the positive list system to control agricultural chemical residues, have a standard of 0.1 ppm, 0.01 ppm, and 0.01-0.1 ppm as their unofficial operational target range, respectively.

The EU has proposed 0.01 ppm as the standard.

Control not by uniform standards but by detection limits in implementing the positive list system was not adopted in the revised law of May 2003, since detection limits could change due to scientific advances, and detection limits not related to a threat to human health could be too strict.

2-2.

(1) It is unreasonable that the positive list system is applied equally to agricultural chemicals and antibiotics, whose characteristics are totally different, while they should not be detected as before. In particular, traditionally, antibiotics should not be detected as veterinary drugs, while some antibiotics (e.g. streptomycin) are regarded as agricultural chemicals (pesticides) under the Agricultural Chemicals Control Law. Individual or uniform standards will be applied to them when they are detected in farm products. The methods and detection limits should be clarified as to when they should not be detected (Nichirei Corporation).

(2) Although it is stipulated that "antibiotics should not be detected in food", the same standards should be established for antibiotics as for agricultural chemicals (Japan Food Industry Center).

[Response]

It has been conventionally stipulated that antibiotics should not be detected not only as veterinary drugs, but also as agricultural chemicals, with the exception of those with established standards. This requirement should be maintained even after the implementation of the positive list system. Therefore, uniform standards will not be applied to antibiotics. In other words, while relevant standards would be applied to them as applicable, those with no standards should not be detected.

For antibiotics with national standards, the Codex standards, or the US standards, Provisional MRLs have been developed as for other agricultural chemicals.

2-3.

(1) What is the definition of "contamination in the natural environment"? What is the typical level in food (Australian government)?
(2) How will classical agricultural chemicals such as copper, lead, sulfur be dealt with (Japan Tea Association)?

[Response]

Some agricultural chemical residues cannot be distinguished from the original components. In this case, standards have been established as required (e.g. arsenic) to ensure public health protection. On the other hand, since uniform standards are not suitable for original components, Section 4 of the proposed regulations was developed. The levels of these chemicals depend on the individual substances or types of food, and cannot be determined uniformly. We will propose a means of dealing with the above-mentioned substances as soon as the discussions are completed.

2-4.

(1) Since it is difficult to determine values to the next significant digit for some agricultural chemicals using a mass spectrometer, which is the most precise measure, "the concentration will be determined up to a level that is sufficient for comparison with standards in practical examinations" (Nara Prefectural Institute for Hygiene and Environment).
(2) Any additional significant digit of value determined for analysis should be compared as it is without being rounded (Nara Prefectural Institute for Hygiene and Environment).
(3) The proposed Regulation 8 states that rounded experimental values determined within one significant digit up from the standards should be compared with the standards. Is this method consistent with the measurement uncertainty discussed in CCPR? It seems not to comply with the principles of analytical chemistry (Australian government, EU).

Note: Measurement uncertainty that has been discussed by CCPR and CCMAS means that the uncertainty due to the determination methods should be considered for analytical values.

[Response]

Rounding of the analytical values up to the next significant digit has been the general rule,

and has been adopted in the Japanese Pharmacopoeia and US Pharmacopoeia.

An additional digit is necessary when the standard and the determination are close (e.g. when the standard is 0.5 ppm and the determination is 0.5 ppm), and it is not always required.

The method is not contradictory to the degree of measurement uncertainty proposed by the CCPR, and that is widely used in foreign countries.

2-5. There is no description regarding biological pesticides. Is it reasonable to understand that they are "excluded from the substances designated by the Minister of Health, Labour and Welfare: Positive list system"? In addition, organic pesticides mainly used for organic vegetables such as Matrine (an extract from sophora roots) should be discussed (Japan Tea Association, Nippon Suisan Kaisya Ltd., Mitsui & Co., Ltd.).

[Response]

Regarding agricultural chemicals excluded from the positive list system please refer to the document entitled "Regarding Establishment of the substance to be determined by the Minister of Health, Labour and Welfare as those that apparently have no potential to cause damage to human health as Specified in Article 11, paragraph 3 of the Food Sanitation Law (Draft)".

If you have any further comments, please attach a copy of official documents issued by foreign governments such as the US Federal Register explaining the background for not establishing standards in the relevant country, the ADI, residual properties, etc.

Risk evaluations should be available for submitted data on toxicity. Please apply according to the announcement of the Director of the Food Safety Division, Syoku-An No. 0205001, dated February 5, 2004, "Guidelines on establishing and revising residue standards concerning agricultural chemicals used overseas".

3. Substances that should be not detectable

3-1.

(1) Substances with an established ADI and standards for withholding registration or residue standards that were subsequently found to be carcinogenic (e.g. DDVP), and that were confirmed to be endocrine disrupters in animal experiments (vinclozolin), or that have been used both for humans and animals with most frequent drug-resistant organisms issues leading to a ban due to a revision of the current standards (oxytetracycline), should be not detectable. In addition, substances identified as examples of suspected environmental hormones by the Ministry of the Environment (e.g. DDT) should be not detectable or their Provisional MRLs should be their detection limits as a general rule. Priority substances for risk evaluation by the Ministry of the Environment should also be not detectable (Michiko Kamiyama).

(2) Substances judged as included under suspected Type I specific chemicals or as hazardous substances under the Law Concerning the Examination and Regulation of the Manufacture and Handling of Chemical Substances, whose standards for withholding registration expired with the expiration of agricultural chemicals registration, should be not detectable, or their Provisional MRLs should be their detection limits (e.g. chlordane and vinclozolin) (Michiko Kamiyama).

[Response]

ADIs for agricultural chemicals should be reviewed based on current scientific findings as required. However, it is reasonable for the above-mentioned substances to not be included among substances that should be not detectable domestically and internationally. The issue of drug-resistant organisms will be discussed by the Food Safety Committee.

3-2.

(1) "Not detectable" substances in food, including imports, should be determined based on detection values equivalent to the "minimum requirement performance limit" established by the EU (Japan Consumers' Co-operation Union).

(2) Analysis sensitivity for the relevant substances varies according to the country. The EU has been adopting minimum requirement performance limits for some of these substances (EU).

Note: The minimum requirement performance limit (MRPL) is defined in the EU Directive 2002/657/EC as below:

Minimum required performance limit (MRPL) means minimum content of an analyte in a sample, which at least has to be detected and confirmed. It is intended to harmonize the analytical performance of methods for substances for which no permitted limited has been established.

[Response]

For "not detectable" substances, official test methods will be announced, and detection limits will be defined. They will be determined based on their current status in foreign countries to ensure their sensitivity and feasibility.

3-3. Agricultural chemicals for which carcinogenicity, teratogenicity, or reproductive toxicity have been detected in animal experiments should be evaluated with regard to safety, and their residue standards should be not detectable (ND) as a general rule (Anti-agricultural chemical Tokyo group).

[Response]

A substance for which a threshold level cannot be established such as one with carcinogenicity and reproductive toxicity should be not detectable.

These requirements are stated in Section 2 of the proposed regulations with Table 1 indicating the relevant agricultural chemicals.

Reference: Proposed regulations, Table 1 List of "Not Detectable" agricultural chemicals in foods

Product Name	English Name	Principle Uses
2,4,5-T	2,4,5-T	agricultural chemical, herbicide
Amitrole	Amitrole	agricultural chemical, herbicide
Captafol	Captafol	agricultural chemical, antimicrobial agent
Carbadox including quinoxaline-2-carbonic	Carbadox including QCA	veterinary drug, antibiotics
Chloramphenicol	Chloramphenicol	veterinary drug, antibiotics
Chlorpromazine	Chlorpromazine	veterinary drug, tranquilizer
Cyhexatin, Azobyclotin	Cyhexatin, Azocyclotin	agricultural chemical, fungicide
Dimetridazole	Dimetridazole	veterinary drug, antiparasitic drug
Daminozide	Daminozide	agricultural chemical, growth promoter
Nitrofurans	Nitrofurans	veterinary drug, antimicrobial agent
Metronidazole	Metronidazole	veterinary drug, antiparasitic drug
Ronidazole	Ronidazole	veterinary drug, antiparasitic drug

* Flumekin for which the ADI was canceled in JECFA in February 2003, was included in Table 1 in the first proposal published in October 2003. However, since the ADI was re-established in JECFA in February 2004, it is excluded from Table 1.

4. How to establish the Provisional MRLs

4-1.

(1) Among the 1) Codex standards, 2) standards for withholding registration, and 3) foreign standards, the lowest level should be adopted as the tentative standard (Anti-agricultural chemical Tokyo group, Nobuko Kawamichimae).

(2) It should be stated that the lowest level should be adopted among the current standards, standards for withholding registration, international standards and foreign standards according to the concept of the Food Sanitary Investigation Committee in 1972 (Michiko Kamiyama).

(3) For substances with no domestic standards, the lowest among the foreign standards should be adopted (Japanese Consumers' Co-operation Union).

(4) When an average level of reference foreign standards is adopted, products containing substances at levels above the Provisional MRLs can be imported. To ensure safety and smooth distribution, the highest of all foreign standards should be adopted (Australian government, EU, Flour Millers Association, Methyl Bromide Industry, U.S. Wheat Associates, Nisshin Seifun Group Inc., Nisshin Flour Milling Inc., Nippon Flour Mills Co., Ltd.).

(5) When foreign standards are adopted, these should not consider a simple average, but the feasible level for the food industry. For a farm product that is imported mainly from a country with the highest standard level, for example, sufficient attention should be paid in order to avoid adverse effects on the supply as a result of applying the tentative standard. The standards of the main exporters should be adopted (Japan Food Industry Center, Japan Food Information Center (JFIC), Bayer CropScience Japan, Syunsuke Horiike).

(6) For substances with no Codex standards that have no standards for withholding registration, or for which foreign standards are higher than standards for withholding registration, foreign standards should be referred to. The reason why the Japanese government decided to adopt the average level should be explained clearly (US Embassy).

(7) In adopting foreign standards as the Provisional MRLs, attention should be paid to the supply-demand balance. In particular, for agricultural chemicals whose standards are not Codex standards and are lower than those of the US, which is the main exporter, the matter should be carefully discussed with interested parties, taking their importance into consideration (US Grain Council).

(8) When there are significant differences between the foreign standards, GAPs, the basis for the established standards, should be considered. In addition, when it is statistically clear that the relevant product has been imported mainly from the relevant nation, not the average but the level for that nation should be adopted if it is the highest (Japan Crop Protection Association).

(9) Standards for veterinary drugs have been established based on detection limits since they have been traditionally not detectable as a general rule. However, since detection limits depend on the type of assay, the Provisional MRLs should be established based on foreign standards, if applicable (Dainippon Pharmaceutical Co., Ltd.).

(10) For corn, foreign standards should be adopted, since the rate of dependence on imports is higher than that for wheat for which foreign standards were adopted (Japan Feed Trade Association).

[Response]

The Provisional MRLs (draft) have been developed based on foreign standards established in a scientific way equivalent to that for the Codex standards, standards for withholding registration, JMPR, etc., to ensure public health protection and to avoid unnecessary trade barriers.

Since Japan is a member state of the WTO, the Codex standards would be adopted if applicable.

For substances with no Codex standards, standards established in Japan such as standards for the withholding of agricultural chemicals registration would be adopted. These standards have been used in registering agricultural chemicals by the Ministry of the Environment and the Ministry of Agriculture, Forestry and Fisheries. 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.

For substances with no Codex standards and no domestic standards, foreign standards would 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 would be adopted since it is difficult to conduct risk analysis such as reviewing the ADIs, residues in products and intake levels for individual agricultural chemicals. However, when there are “reasonable reasons” as specified in Note 6 of the briefing paper, not the average but an appropriate value would be adopted taking the differences into consideration, as stated in response 4-13.

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 would 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. that 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.

Veterinary drugs have been dealt with in a similar fashion. In addition, it is desirable to use values notified by the Ministry of Agriculture, Forestry and Fisheries based on domestic test results, such as those for residues, to ensure consistency with the Ministry.

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 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”.

4-2. For substances for which there are foreign standards that are far from those established not based on detection limits, standards that are equivalent to the detection limits should not be used in calculating the average (Bayer CropScience Japan).

[Response]

Even in this case, since the standards are used as a basis for regulation in the relevant country or region, it is reasonable to use them in calculating the average.

4-3.

(1) Even for nations other than the five reference nations, when standards are established based on test results implemented in the relevant nation, these standards can be adopted as the Provisional MRLs. For products expected to be imported from nations other than the five, the standards of the exporters should be adopted. The standards of nations with an export record, or major exporters such as China, Taiwan and Thailand, should also be adopted (Japan Fresh Produce Import and Safety Association, Japan Frozen Food Association, Japan Tea Association, Japan Crop Protection Association, Edible Oil Trade Association, Syngenta Japan K. K., Nichirei Corporation, Mitsui & Co., Ltd., Takashi Miyashita).

(2) To avoid any adverse impact on farm products exported from Korea, for substances with Korean standards, the establishment of standards for those with no established standards in Japan, and upward adjustment for those with the lower standards is requested (Korean Embassy).

(3) Since Germany is a major hop exporter, the German standards should be adopted (Joh. Barth & Sohn GmbH & Co. KG, S. H. Steiner, Hopfen, GmbH, TOP HOP Ltd.).

[Response]

Foreign standards used as a reference in developing the Provisional MRLs should be scientifically strict. Therefore, during the one-month period after the Conference for the Promotion of Food Import Facilitation held on April 11, 2003, we accepted proposals through embassies in Japan and adopted foreign standards based on scientific data equivalent to that of the JMPR and JECFA. This scientific data is used as a reference with due evaluation of available residual standards established in nations on regions.

Since most hops are imported, the adoption of foreign standards will be considered as noted in Figure 3 in the briefing paper. If you request the establishment of new standards or the revision of the Japanese standards (including the tentative ones) for agricultural chemicals used overseas, please submit an application according to the request system (see response 4-1).

4-4. Although all of the US standards should be taken into consideration, many are missing. Please indicate which documents are being referred to. The current standards should be strictly adhered to (US Embassy).

[Response]

For the US standards, URL of the EPA and FDA were referred to at the time of the development of the Provisional MRLs. If you find any errors, please send us the details.

4-5. There are many Codex standards with restrictions. For example, standards for cyromazine are sometimes accompanied by a note "The MRL accommodates external treatment". To prevent unreasonable usage, such restrictions should be clearly stated, as necessary (Japan Consumers' Co-operation Union).

[Response]

Since the usage of agricultural chemicals in the process of production is outside the scope of the Food Sanitation Law, it is difficult to control this under the Law.

4-6.

(1) Since no toxicity data, the basis for established ADI levels, is published, the appropriateness of proposed standards cannot be evaluated. Data on toxicity tests and residue tests submitted at the time of registration should be published when establishing the final proposed standards (Anti-agricultural chemical Tokyo group).

(2) Since the current Provisional MRLs are to be finalized within 3 years due to the scheduled revision of the laws, there is no alternative to proceeding without frequent exchanges of information and opinions with the Food Safety Committee. However, the Provisional MRLs should be reviewed based on risk evaluations conducted by the Food Safety Committee according to the principles of risk analysis, and details of the action plan should be published (Japanese Consumers' Co-operative Union).

[Response]

Since the Provisional MRLs have been developed based on standards for withholding registration under the Agricultural Chemicals Control Law and international standards in preparation for the introduction of the positive list system by May 2006, it will be difficult to accept the request (1).

The Provisional MRLs will be reviewed according to the priority determined based on results of scheduled daily intake surveys. At that time, the required data including toxicity test results, will be compiled and sent to the Food Safety Committee for risk evaluation.

4-7. Standards have also been established for agricultural chemicals that have not been listed on the Agricultural Chemicals Control Law or standards for withholding registration, assuming that the products are imported. However, the list of veterinary drugs used for marine products does not include those approved in foreign countries. They should be harmonized with foreign standards (Nippon Suisan Kaisha, Ltd.).

[Response]

As mentioned in response 4-3, the Provisional MRLs (first proposal) have been developed based on foreign standards, including the US standards, in addition to the Codex standards,

not only for agricultural chemicals but also for veterinary drugs and feed additives.

4-8. Standards should be established taking the effects on pregnant women and children into consideration (Anti-agricultural chemical Tokyo group).

[Response]

In Japan and other reference nations, in developing the proposed standards, standards have been established based on levels with no adverse effects and safety factors according to the results of various animal studies including reproductive toxicity tests and teratogenicity tests to identify effects on pregnant women, fetuses, and children.

4-9.

(1) In many countries, residues in organs and tissues representing internal residue properties most precisely are used as indicators among the results of residue tests using markers. In the movement towards establishing international standards to control veterinary drug residues, Japan should also establish standards based on the same policy. Since this method can guarantee low residues in other tissues by confirming residue properties in the target tissue without establishing standards for minor organs, it will be more practical (Animal and Marine Products Residue Safety Committee, Eli Lilly Japan K. K.).

(2) In foreign countries, according to the so-called food basket concept, acceptable residue levels are assigned to edible tissues such as eggs, milk and meat and farm products, based on public intake of various products for which the substance is approved. Japan should also adopt the food basket concept instead of a simple average in establishing standards (Animal and Marine Products Residue Safety Committee, Japan Scientific Feeds Association, Japan Veterinary Products Association, Takeda Schering-Plough Animal Health K.K., Eli Lilly Japan K. K.).

(3) It is reported that a uniform standard (might be 0.01 ppm) will be applied to animals, organs and tissues with no established standards. However, Provisional MRLs should be developed for animals, organs and tissues with no established standards based on a comparison of the Japanese standard for the intake of organs and tissues between the animals, organs and tissues with established standards and other relevant animals (Japan Veterinary Products Association).

[Response]

In the US, tests on target organs are conducted in slaughter houses to ensure safety. However, since it is relatively difficult to control imports dominating over 50% of the supply on a calorific basis using target organs, it will be impossible to adopt only the above-mentioned method in Japan.

Since Codex standards and foreign standards have been adopted in developing the present Provisional MRLs without reviewing ADI levels, it will be difficult to adopt a method of assigning acceptable residues to each product according to the intake based on the ADI.

On the other hand, if standards have been established for some tissues and organs, such as muscle or fat, the lowest level among the standards for tissues and organs of the relevant

animal with established standards will be adopted as the standards for other tissues and organs since the substance is approved for the relevant animal, and standards have not been established for all organs and tissues based on the test system using target organs.

4-10. It is not appropriate that the “detection limits will not be adopted as a reference, but a uniform standard will be adopted”. When a detection limit higher than a proposed uniform standard has been established based on the registration conditions of the relevant product or detection limits of the product by area, the detection limit should be adopted as the reference (Bayer CropScience Japan).

[Response]

In relation to Note 6-(3) in the briefing paper, since it is exceptional in countries not adopting the positive list system, detection limits adopted as standards for substances approved for the above-mentioned products can be adopted in establishing the Provisional MRLs. In this case, please submit copies of official documents issued by the relevant government such as the US Federal Register.

4-11. Proposals on the residue properties of products by the Ministry of Health, Labour and Welfare provides uniform standards for each similar food classification. This concept can be applied to animals. Since the consumption levels of the muscle of cattle, pigs, chicken, and sheep is close, the MRL for cattle can be used as the tentative MRL for pigs (Eli Lilly Japan K. K., Dainihon Jochugiku Corporation).

[Response]

Since veterinary drugs are approved for each animal, and residue standards should be determined based on the amount of residue for the appropriate usage, it will be difficult to use the MRL of cattle for pigs.

Note 7 in the briefing paper should be applied in a quite limited way.

4-12. The meaning of “considering the consistency of standards by product” in Note 7 of the briefing paper should be clarified (EU).

[Response]

The example of this article has been shown as Type 6. However, its application is quite limited. For example, a uniform standard has been established for almost all animal products, and the value is sometimes applied to the remaining animals.

4-13.

(1) It is stipulated that “an appropriate value would be adopted when totally different standards have been established for a single farm product”. The details of this exceptional regulation should be indicated (US Embassy).
(2) For substances with no Codex standards and with foreign standards, three patterns are shown. Please show the conditions for adopting Type 3-2-1 and 3-2-2 for which foreign standards are adopted even though domestic registration exists (Flour Millers Association, Dainippon Pharmaceutical Co., Ltd.).
(3) In the description, “appropriate values should be adopted when there are major differences among foreign standards, but reasonable causes should be taken into consideration”, the reasonable causes should be clarified (EU).

[Response]

(1) is related to Note 6-(2) in the briefing paper, and is represented as Type 3-2-2 and 5-2 in the Figure. In the present first draft, no example for 3-2-2 exists, and standards for chlorothalonil for huckleberries and nicarbazin for duck are exemplified for Type 5-2. Since an EU standard for chlorothalonil for huckleberries is considered far from those for strawberries, and an Australian standard for nicarbazin is significantly different from those for other meat, the average of foreign standards was calculated with the exception of these values.

Please see response 4-1 for Type 3-2-1 indicated in (2).

Reasonable causes stated in (3) include that the usage or volume of the relevant agricultural chemicals is appropriate for the climate and agricultural practices in the relevant region and that the average values adopted as proposed residue standards are not appropriate based on the results of residue tests under the conditions.

4-14. For sulfa products among veterinary drugs, a standard for the individual substance has been established as 0.1 ppm in the present proposal, which is not equivalent to an acceptable residue standard in Korea (draft proposal, 0.1 ppm for total sulfa products) or the EU standard (0.1 ppm for total sulfa products). When standards are applied to individual substances, it is appropriate to adopt a standard for the total of sulfa products as in Korea than to establish individual standards, to avoid toxicological issues such as the difficulty in applying individual standards to total residues in mixed uses. In addition, sulfa products are similar as to the mode of internal metabolism and the level for the development of toxicity. On the other hand, a total standard is applied to streptomycin or tetracycline. The means of applying standards is sometimes inconsistent (Korean Embassy).

[Response]

Sulfa products and streptomycin have been dealt with according to the concept of the Codex standards. In the Codex standards, an individual standard has been established only for sulfadimidine, and the above-mentioned method has not been adopted. For streptomycin, etc., the Codex standards have been established in the same way as ours.

4-15.

(1) Is it correct to understand that MRLs need not be established (uniform standards are not applied) for BST and estradiol 17β natural hormones (Eli Lilly Japan K. K.)?

(2) Some products such as growth hormones, including BST and estradiol 17β, are not mentioned even though their effects on public health are important. The reasons why growth hormones were not mentioned in the document should be described (Japan Consumers' Co-operation Union).

[Response]

Since residue levels for BST and estradiol 17β are judged unnecessary in the Codex or JECFA, they are not included in the proposed Provisional MRLs (first proposal). It is considered that they should not be over the amounts naturally existing as stipulated in Regulation 4.

4-16. Codex MRLs, the basis for a tentative standard for cottonseed oil, mixes up standards for crude oils and edible oils. An MRL for crude oils applied to edible oils would be too lenient, and an MRL for edible oils applied to crude oils would be too strict. The scope of the standard should be clarified, whether referring to crude oils or edible oils (National Institute of Health Sciences, Edible Oil Trade Association).

[Response]

They will be divided into crude oils and edible oils according to the Codex standards.

4-17. No standards for egg yolk have been established for the eggs of chickens, turkeys and other poultry. Since agricultural chemicals remain mainly in the egg yolk, it is inappropriate to apply uniform standards to the whole egg and the egg yolk. Standards for egg yolk should be three to four times those for the whole egg, or egg yolk should be deleted (Tomoka Watanuki).

[Response]

Standards for eggs have traditionally been established for the whole egg both in the Japanese standards and the Codex standard. Also in the future, these will be established for the whole egg, and egg yolk will be deleted. When reference standards are established for egg yolk only, a standard should be established for egg yolk itself. In this case, however, a uniform standard will not be applied to the whole egg.

For milk and milk fat, when there is a residue level for one, a uniform level will not be applied to the other.

5. Processed foods

5-1.

(1) The guidelines on residue standards for processed foods, "processed food manufactured or processed using materials conforming with residue standards are regarded as conforming with the residue standards" should be clearly stated to ensure the smooth distribution of processed food (It will be impossible to establish individual residue standards for all processed food. However, the following recognition should be shared among interested parties in the distribution process: There are 1) products for which residue level certificates of the raw materials serve as the certificates of the products themselves, and 2) products for which individual standards have been established) (Hiroo Mizuno, Japan Food Industry Center).

(2) Standards for concentrated products should be clearly stated (e.g. vegetable juice, dried fruits, dried vegetables) (Japan Oilseeds Processors Association, Yomeisyu Seizo Co., Ltd., Kunihiko Ogawa).

[Response]

Processed foods manufactured or processed using raw materials that meet the residue standards can be legally distributed (Article 6 in the proposed regulation). First of all, a uniform standard is applied to them. Then, if the detection level is higher than the uniform standard, it will be evaluated based on individual standards established for farm, animal or marine products used as the raw materials. For diluted products, this will be evaluated based on the proportion of farm, animal or marine products used as the raw materials and values calculated from their residue standards. For concentrated products, this will first be evaluated based on values calculated from the level of water content. If this is not sufficient, the raw materials will be checked.

For processed foods with established Codex standards, the Provisional MRLs have been developed for individual products based on the Codex standards.

5-2.

(1) For processed products whose safety can be guaranteed, standards for the raw materials should be deleted (Morio Hamashima).

(2) For a product made of processed materials, the analyzed agricultural chemicals cannot be evaluated without their standards. A uniform tentative standard should be applied to all phases from the primary farm products to the final products (Nisshin Cisco Co., Ltd.).

(3) For processed food with no established Codex standards, standards should be established (Ajinomoto Co., Inc.).

(4) For processed products, not the raw materials, but the final products or all stages leading to the final products should be controlled (Japan Biscuit Association, Bourbon Corporation, Kazuyuki Tsuchiya).

[Response]

As stated in response 1-2, standards for processed products have been established for their raw materials. Since residue levels depend on the types of raw materials, their proportion,

and processing methods, only processed products with established Codex standards are included as subjects of the Provisional MRLs, and agrichemical residues are controlled at the stage of raw materials as a general rule. This method is also adopted in those countries adopting the positive list system, such as the US.

5-3. How should processed products using raw materials with no established pesticide residue levels be dealt with (Japan Tea Association)?

[Response]

The positive list system covers all food including processed products. Therefore, raw materials with no established residue levels are controlled by a uniform standard.

5-4. The final products and raw materials of nutritional supplements contain many herbal medicines and plant extracts for which standards on pesticide residue levels are necessary. For some herbal medicines and plant extracts that have been distributed as pharmaceutical products in Europe, standards have been established based on the European Pharmacopoeia 4th Edition. They can be used as references (Indena Japan Co., Ltd.).

[Response]

As mentioned before, reference nations or regions for the present proposal have established standards through evaluations based on scientific data equivalent to those of the JMPR and JECFA. These standards have been used as references based on available data provided by them.

It is not necessarily appropriate to apply the European Pharmacopoeia, an official compendium for medicines, to food.

5-5. For a processed product made from a single ingredient, a standard can be established based on the level of water content taking its residue standard into consideration. In this context, the definition of “regarded as processed/not processed” should be clarified. Even if residues in the raw materials used for the relevant product are below the detection limit, concentrated residues can be detected in dried food (such as freeze-dried food) and concentrated extracts (such as extract products). Therefore, the definition of “processed” should be clarified. Especially for antibiotics and synthesized antimicrobials, “Specification of Ingredients” in the “Standards for Food and Additives” states that “antibiotics and antimicrobials should not be detected”. Please clarify whether it is appropriate to understand that residues in concentrates made from raw materials with acceptable residues below the detection limits are covered by the regulations (Japan Frozen Food Association, Maruha Corpoartion).

[Response]

Under the positive list system, substances should not be detected above a uniform standard level with the exception of those with individual established standards (including processed

products). When substances, such as agricultural chemicals, are detected at levels above a uniform standard level, the relevant food is evaluated for the conformity of the raw materials. Thus, the evaluation is not based on “regarded as processed product/not processed”, but based on the food category adopted in developing the standards.

Proposed regulations 1 and 2 are applied to the product itself even if it is concentrated or dried.

5-6. It is impossible for a bakery to control agricultural chemicals remaining in bread. Standards should be established at the stage where residues can be controlled. The Provisional MRLs for bread should be established at the stage of wheat and flour (Japan Baking Industry Association).

[Response]

For processed products, Provisional MRLs have been developed for those with established Codex standards.

As stated in the Food Safety Basic Law (Law No. 48 in 2003), the food industry, including bakeries, should recognize its primary responsibility for ensuring food safety, and take the necessary measures.

6. Specific comments on standard levels

6-1. Standards for agrichemical metabolites
On the assumption that an agricultural chemical A is metabolized to an agricultural chemical B, and that Provisional MRLs have been developed for both A and B, for a farm product X, individual standard levels should be developed not only for A but also for its metabolite B. e.g.: triadimefon/triadimenol, carbosulfon/benfracarb/furathiocarb /carbofuran (Ishihara Sangyo Kaisha, Ltd., Suntory Limited).

[Response]

When both agricultural chemicals A and B are detected in product X in this case, a uniform standard would not be applied to B. Depending on the toxicity and residue properties of A and B, and the conditions of metabolism of A to B, standards will be established to avoid inconsistency between A and B.

6-2. Pesticide levels for photoisomers
(1) On the assumption that Provisional MRLs have been developed for agricultural chemicals C and D that are photoisomers, different standards for C and D for farm product X results in inconsistency, and analysis is technically difficult. A uniform standard for C and D should be established based on statistics.
(2) The Provisional MRLs for agricultural chemicals C and D should be identical, when C is one of the isomers of D. e.g. esfenvalerate/fenvalerate (Sumitomo Chemical Co., Ltd., Nichirei Corporation).

[Response]

Since toxicity depends on the types of isomers, and standards can also be different among them, it is not appropriate to establish a uniform standard based on statistics. Standards should be individually discussed.

Efforts will be made to make it consistent for case (2).

6-3. Residue standards for tetracycline antibiotics for marine products are limited to oxytetracycline. This should be a total value combined with chlortetracycline and tetracycline, as for animal products. If the current standard remains, residue standards for chlortetracyclines and tetracyclines should be established. An ADI level established by the Codex is 30 μg/kg bw/day for oxytetracycline, chlortetracycline, and tetracycline as an individual or total value (Japan Food Industry Center, Japan Frozen Food Association, Hanwa Co., Ltd., K.K Hyoshoku, Maruha Corporation, Tokushige Amano, Akio Kato, Yukihito Harada).

[Response]

The residue standard for oxytetracycline for marine products is the current standard. As stated in Note 1 in the briefing paper, since the current standards are not covered by the present proposal, it will not be changed to a total value combined with chlortetracyclines and

tetracyclines according to the Provisional MRLs. In addition, it has been traditionally assumed that antibiotics with no individual residue standards should not be detected. This applies to chlortetracyclines and tetracyclines for marine products.

While the JECFA has established 30 μg/kg bw/day as an ADI level for oxytetracycline, chlortetracycline, and tetracycline as an individual or total value, the Codex standards provide only a standard for oxytetracycline for marine products.

If you have a request to revise the current standards, please apply according to the announcement of the Director, Food Safety Division, Shoku-An No. 0205001 (February 5, 2004) “Guidelines on establishing and revising residue standards concerning agricultural chemicals used overseas” .

7. Out of the scope

(1) Handling of the current standards

1) Harmonization with international standards is insufficient due to the historical process. As for the current residue standards established before the establishment or revision of foreign standards, some of these foreign standards are not reflected in the Provisional MRLs. Provisional MRLs should also be developed for products with established residue standards, as required. The current standards should be reviewed (Flour Millers Association, Syngenta Japan K.K., Nichirei Corporation).

2) While some agricultural chemicals are designated as food additives in Japan (e.g. OPP used for post-harvest processing), they are designated as agricultural chemicals in the Codex standards. These substances should be reclassified as agricultural chemicals, and included in the present proposal (Japanese Consumers' Co-operative Union).

3) Some current standards should also be revised due to problems such as establishing the ADI level, the use of post-harvest agricultural chemicals, and environmental hormones (Michiko Kamiyama).

(2) Uniform standards

1) It is assumed that substances above the uniform standards are controlled. The policy under which uniform standards are established, including the underlying scientific basis, should be clarified (US Embassy, Mitsui & Co., Ltd.).

2) Foreign uniform standards range from 0.01 ppm to 0.1 ppm. The standard should be 0.01 ppm as long as validation by analysis is possible in order to ensure public health protection (Japan Consumers' Co-operation Union).

3) Residue standards should originally be established for individual chemicals based on an evaluation of their safety in a scientific way. The establishment of strict uniform standards for residues irrespective of their safety is scientifically untenable. Establishment of standards without a scientific basis will not contribute to restoring public confidence in food safety (Nichirei Corporation).

4) Uniform standards should be established for individual substances (Boehringer Ingelheim Shionogi Vetmedica Co, Ltd.).

5) Uniform standards should not be applied to all products, but established for individual products, based on differences in national intake levels according to dietary patterns, rates of dependence on imports, and ensuring wide distribution (Japan Feed Trade Association).

6) Uniform standards should depend on the existence of safety evaluations, the type of animals, type of organs, etc. For example, while 0.1 ppm is adopted for substances for which a safety evaluation was conducted in the five reference nations, 0.01 ppm is adopted for others (Japan Crop Protection Association,

Takeda Schering-Plough Animal Health K.K.).

7) It is assumed that uniform standards are applied to substances with no Codex standards or foreign standards. However, residues of antibiotics such as oxytetracycline and streptomycin are evaluated based on their status of being "not detectable" or otherwise. Uniform standards below the detection limits would therefore not make sense. It is expected that residues should be detectable for substances used according to the Agricultural Chemicals Control Law, resulting in confusion among users. Thus, a uniform standard for products should be 0.05 ppm, which is the detection limit (Pfizer Japan Inc.).

8) Attention should be paid to avoiding problems such as determination errors caused by uniform standards close to the detection limits (Kikkoman Corporation).

(3) Methods of analysis

1) In order to improve the inspection system, various measures such as funding schemes for the improvement of equipment such as GC/MS and LC/MS, the establishment of leasing schemes, improving the availability of mixed standards conforming with uniform analysis methods, and training in advanced analytical techniques should be implemented (Himeji City Institute of Environment and Health, Environmental Bureau, City of Kitakyushu).

2) Reference materials for all substances related to the standards (including metabolites) should be easily available. The circumstances should be improved for private facilities to obtain unrestricted access to reference materials whenever they require examination, as with public or semi-private institutes (Kikkoman Corporation, Snow Brand Milk Products Co., Ltd., Takashi Miyashita).

3) It can be expected that individual analysis methods will be required for many agricultural chemicals for which a uniform analysis is unavailable. Although it is difficult to investigate all agricultural chemicals, consumers will not be satisfied with the situation. Countermeasures should be suggested (Environmental Bureau, City of Kitakyushu).

4) Not only a single method, but other methods equivalent to or more precise than the designated one should be acceptable, with clarification of the detection limits and the means of evaluating the level of precision for each method (Since no detection limits are provided for the monitoring test methods for imported food, the definition of "not detectable" is unclear). In addition, for substances not listed in the present proposal (excluding specific agricultural chemicals), test methods should be established if uniform standards are applied to them (Nichirei Corporation).

5) For test methods, appropriate evaluation methods should be discussed to improve their availability in many facilities, their simplicity and precision, and any variation between examiners (Morio Hamashima).

6) A sufficient period is necessary before the implementation of analysis methods

after their announcement (Ajinomoto Co., Inc., Kikkoman Corporation, Nisshin Seifun Group Inc., Nisshin Flour Milling Inc.).

7) The current status of the development of analysis methods should be disclosed as far as possible. Presentation meetings are desirable (Japan Soft Drink Association).

8) For standards established for multiple agrichemical ingredients of an identical analyte, the names of the original ingredients should be clarified. In addition, details of the methods of analysis for specifying the original ingredients should be announced (Himeji City Institute of Environment and Health).

9) Sufficient analytical capacity should be established to avoid a shortage of analysis facilities (Japan Soft Drink Association).

10) Measures should be taken to avoid confusion caused by different analysis methods or detection limits led by advanced analysis techniques (Flour Millers Association, Morio Hamashima).

11) Examination methods for processed foods should be developed (Japan Dairy Industry Association).

12) No markers to be tested are provided for substances with the exception of tetracyclines and febantel (EU).

(4) How to establish residue levels in general

1) Measures should be taken to reduce the usage of agricultural chemicals. An increase in the number of controlled agricultural chemicals and stricter residue standards will not lead to safer food (Anti-agricultural chemical Tokyo group).

2) Sufficient attention should be paid to intake from water and the air (especially, air pollution surrounding farm areas, indoor pollution, downtown pollution, drinking water pollution caused by agricultural chemicals) (Anti-agricultural chemical Tokyo group).

3) Since the ADI levels used as a basis for the calculations have been established for individual substances, and no evaluation has been conducted for combined intake, the current residue levels are not scientifically reliable (Anti-agricultural Chemicals Tokyo Group, Nobuko Kawamichimae).

4) The results of work of the Endocrine Disrupter Committee should be taken into consideration (Nobuko Kawamichimae).

(5) Monitoring and Guidance

1) It is not feasible to test all agricultural chemicals and veterinary drugs. No description of a future inspection system through market monitoring and inspection facilities is provided by the Ministry of Health, Labour, and Welfare. Inspection systems for domestic products should also be clarified (Kikkoman

Corporation, Nichirei Corporation, Takashi Miyashita).

2) The importation of foreign farm products that deviate from the standards should be prevented by strengthening the inspection system (Japan Biscuit Association, All Nippon Kashi Association, All Nippon Kashi Industry Association, Chocolate & Cocoa Association of Japan, Nisshin Cisco Co., Ltd., Bourbon Corporation, Morinaga & Co., Ltd.).