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Major Comments on the Provisional MRLs (Second Draft) (Except for the Comments on Specific Standard Levels)

No.	Classification	Comments	Submitted by	Document No.	Proposed response
1	1	The positive list system requires more than just sampling and analyzing final products to ensure consumer protection. Consistent management of food chain including preventive approaches should be stipulated in the preamble.	Japanese Consumers' Co-operative Union	144	Understanding the importance of consistent management throughout manufacturing and distribution processes in the positive list system will be deepened by measures such as risk communication.
2	1	In cooperation with the relevant agencies including the Ministry of Agriculture, Forestry, and Fisheries, Ministry of Economy, Trade and Industry, and Fair Trade Commission, monitoring and controlling should be implemented to prevent operators at the "superior positions", such as distributors, retailers, and food manufacturers producing highly processed products from raw materials, from being engaged in irregularities. These irregularities include submission of certificates of unnecessary analyses of agricultural chemicals including those that are not actually applied (e.g. analyses of approximately 700 kinds of substances in total). (Many similar comments submitted)	Japan Food Industry Center, All Nippon Kashi Industry Association, Japan Biscuit Association, Japan Extract Flavor Association, Japan Aquatic Food Sanitary Committee, and Japan Oilseeds Processors Association	71, 75, 83, 99, 113, 128, etc.	Agricultural chemicals with no current standards shall be regulated by the positive list system. Therefore, there are no examinations required for all agricultural chemicals with established standards. Appropriate control at every stage of distributions and communications is essential. It is considered reasonable to conduct tests based on available information on agricultural chemicals. For example, applied agricultural chemicals that have past records should be examined. Relevant agricultural chemicals should be examined for products with established control standards or records. Details will be shown in the announcement of the system. In addition, the Ministry of Health, Labour and Welfare will make more effort to ensure risk communication.
3	1	In order to reduce importers" burden, such as provision of residues" test results of all substances including unapplied agricultural chemicals, provision of information and instructions to distributors and retailers, and of information and food education to consumers should be promoted. (Two similar comments submitted)	Nippon Suisan Kaisya Ltd., Snow Brand Milk Products Co., Ltd.	19, 31	
4	1	Regarding the application of provisional MRLs to imported processed products, it is unclear whether imported products subject to the positive list system are judged based on the date of import (date of entry) or the date of production. Since it is stated that the application of the provisional MRLs will be preferably limited to those produced after the implementation date for domestic products, imports should also be judged based on the production date. (Many similar comments submitted)	Nippon Suisan Kaisya Ltd., Snow Brand Milk Products Co., Ltd., Japan Imported Food Safety Promotion Association, Kikkoman Corporation, Japan Food Industry Center, Japan Aquatic Food Sanitary Committee	19, 31, 49, 69, 71, 113, etc.	According to the law, domestic distribution of imported products shall commence on the date of import (entry). Therefore, application of the provisional MRLs shall commence on the import date. For processed food, since some have extended the period of distribution after production, application of the provisional MRLs will be preferably limited to those produced after the implementation date. In addition, the revised Food Sanitation Law in May 2003 stipulates that the positive list system be effective no later than May 2006.
5	1	Crops require a certain period from cultivation to harvest, and vary according to season. Since 6 months is considered too short for dissemination of information in many cases, a certain transitional period should be provided. (Two similar comments submitted)	Mitsui& Co., Ltd., Japan Frozen Food Association	37, 42	For the positive list system, the dissemination period as those of previous residue standards is considered reasonable since provisional MRLs are established according to residue standards such as Codex standards. These establishments are based on internal or external registrations and appropriate application of agricultural chemicals. The whole picture has taken a long time with the publishing of the first and second drafts. In addition, the revised Food Sanitation Law in May 2003 stipulates that the positive list system shall become effective no later than May 2006.

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6	1	For newly added test items, preparation period such as for analysis should be allowed. The implementation date should vary according to the situation specific to each area. (Original in English)	Chinese Government	134	Six months will be provided for dissemination of information before the implementation. Information on the review processes of the analysis methods has been provided, which the interested parties should refer to. In addition, the revised Food Sanitation Law in May 2003 stipulates that the positive list system shall become effective no later than May 2006.
7	1	A period of more than the proposed 6 months between the announcement and the implementation should be provided to prepare for the establishment of frameworks, such as alteration of veterinary drug holidays (or confirmation of the appropriate conventional holidays under the new standards). It is also necessary to familiarize the analysts with the analysis methods.	Animal and Aquatic Products Residue Safety Committee	33	Six months will be provided to allow interested parties to prepare before the implementation. The second draft was already published, and parties who are interested should take it into consideration. In addition, the revised Food Sanitation Law in May 2003 stipulates that the positive list system shall become effective no later than May 2006.
8	1	Substances should be classified into those applied domestically and abroad. In addition, information including the timing of application should be clarified for each substance. (Two similar comments submitted)	Snow Brand Milk Products Co., Ltd., Japan Dairy Industry Association	31, 84	Since the positive list will be applied to all substances domestic and overseas, classification is not required. It is considered difficult to provide information on the timing of application of agricultural chemicals, since they are used as necessary. The existence of national or foreign standards, c.f. the necessity of approval described in the second draft should be used as reference.
9	1	Residue standards for some agricultural chemicals may be established in reference to foreign countries or areas before the final announcement. It should be clearly stated that these standards shall be adopted as the provisional MRLs as much as possible before the final announcement. (Two similar comments submitted)	Northwest Horticultural Council, Nisshin Seifun Group, Nisshin Seifun Co., and Nisshin Foods Inc.	15, 46	Residue standards of agricultural chemicals established no later than the submission date of comments announced by the WTO will be incorporated into the provisional MRLs as far as information, such as copies of official journals, are provided.
10	1	What is the latest date of newly registered or revised US MRLs incorporated in the standards? (Original in English)	The United States Government	142	See No.9
11	1	The provisional MRLs should be reviewed according to the availability of toxicological data and Japanese food intake for products with high priority based on the results of the comprehensive discussion of the intake survey. The survey includes topics of agricultural chemicals and veterinary drugs, and the current status of discussion in international institutions.	Japanese Consumers' Co-operative Union	144	The provisional MRLs will be reviewed according to risk evaluations derived from safety test results and food intake for products with high priority based on survey results of agricultural chemical intake through market basket method.
12	1	1) Different classifications of product groups among standards for the withholding of agricultural chemicals registration specified in the Agricultural Chemicals Regulation Law, minor products, and residue standards specified in the Food Sanitation Law should be uniform. 2) The standards for the withholding of agricultural chemicals registration for fruits shall not be applied to nuts and seeds. The provisional MRLs should not be established for nuts and seeds with no applicable domestic standards.	Anti-agricultural Chemicals Tokyo Group	115	The standards for the withholding of agricultural chemicals registration under the Agricultural Chemicals Regulation Law are established by crop group, after confirming that the results of exposure evaluations based on intake of each crop group are within the range of ADIs. The "minor products" transitional measure for is based on the standards of agricultural chemical registration withholding in each crop group. Thus, the provisional MRLs are established for crop food with standards for the withholding of agricultural chemical registration.
13	1	It is desirable that flavors with 2 major classifications of spices and herbs are included in the list of crops in the second draft of provisional MRLs. Specifically, independent major items, "other spices" and "other herbs" (e.g. 27 items as below (skipped)) should be added.	All Nippon Spice Association	110	For spices and herbs, those items not considered to be independent major items will be classified into "other spices" and "other herbs".

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14	1	Dried fruit peel has been used as ingredients of soft drinks (e.g. dried peel of an orange “Citrus Unshiu Peel”). The standards for dried fruit peel should be clarified. (Two similar comments submitted)	Japan Soft Drinks Association, Suntory Ltd.,	36, 39	Orange peel will be classified into spices or herbs, and provisional MRLs will be established.
15	1	1) Is salt subject to the positive list? 2) If so, are standards for ways of production, process, application and storage established? 3) What is the frequency of agricultural chemicals analyzed and the judging method? (Four similar comments submitted)	Salt Industry Center of Japan, Naruto Salt Mfg. Co., Ltd., Japan Salt Industry Association, Co-operative Association of Processing and Packaging of Imported Salt	40, 62, 106,107	Salt is covered by the provisional MRLs since it is food. Since agricultural chemicals are applied to crops, agricultural chemical residues are considered unnecessary for salt. Frequency of analysis will be determined based on the possibility of residues.
16	1	The range of “other vegetables” and “other fruits” is not clear. Into what groups are spearmint and olive classified? (Original in English)	The United States Government	142	“Other vegetables” include vegetables other than the ones listed. To clarify, major examples will be informed through the announcement as much as possible.
17	1	A list of compounds on the margin should be developed. The range of “other vegetables” and “other fruits” should be clarified. (Original in English)	Australian Government	113	See No.16
18	1	Various grasses and barks of trees (Attachment 1 skipped) are used as flavor in producing alcohol such as gin. Into what groups are they classified into according to the Food Sanitation Law?	Suntory Ltd.	39	See No.16
19	1	A list of correlations between parent compounds and their metabolites should be developed.	Japanese Consumers’ Co-operative Union	144	A list of correlations between compounds and metabolites described such as in the footnotes will be developed.
20	2	It is stated that in general, antibiotics and other synthetic antibacterial chemicals “should not be contained”, and that 12 agricultural chemicals, etc. should be “not detected”. The difference between the two should be clarified. In addition, for those that “should not be contained”, analysis methods and LODs should be clarified to prevent unnecessary confusion among crop producers and aquatic and animal products, food manufacturers, and consumers. (Many similar comments submitted)	The American Chamber of Commerce in Japan/European Business Community, Quality and Safety Committee of Imported Frozen Vegetables, Maruha Co., Ltd., Ajinomoto Co., Inc., Animal and Aquatic Products Residue Safety Committee, etc.	16, 33, 96, 100, 107, etc.	Substances for which ADIs can”t be established due to carcinogenicity with genetic toxicity, residues in food are not allowed, and they should be “not detected” by the established analysis methods. For antibiotics with the exception of those with specific residue standards, the current standard of “should not be contained” is applied. For animal and aquatic products, antibiotics “should not be contained” by the announced test methods. The test methods will be developed for crops.
21	2	Established NOELs are inconsistent with the standard “should not be contained” for antibiotics which ADIs were evaluated. Therefore, antibiotics with established MRLs based on ADI evaluation in foreign countries, or with residue control by other standards should not be subject to the standard, “should not be contained”. For example, for antibiotics with established MRLs or other standards for at least one species, “should not be contained” is inappropriate. Standards based on other regulations such as appropriate LODs by appropriate test methods should be applied to other species or other tissues or organs with no established MRLs.	Eli Lilly Japan K.K.	122	See No.20
22	2	Registration of agricultural chemicals containing antibacterial substances has already been approved by the Ministry of Agriculture, Forestry and Fisheries based on Agricultural Chemicals Regulation Law. The applications (including re-registration) include toxicological test results and domestic residue test results for each crop. Therefore, for internally registered products, the provisional MRLs should be LODs employed registration (0.05 ppm), not “should not be contained”.	Pfizer Japan Inc.	20	For residue control of antibiotics, standards for agricultural chemicals with internal registration are established based on data at the time of registration. They are considered in compliance with the provision “should not be contained” in the Food Sanitation Law. To make clear, refer to the data in establishing the provisional MRLs.

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23	2	A list of naturally occurring substances for which MRLs are not required should be published. (Original in English) (Seven similar comments submitted)	California Farm Bureau Federation, National Potato Council, Cranberry Marketing Committee, International Federation for Animal Health (IFAH), Animal Health Institute, U.S. Hop Industry Plant Protection Committee, The California Cherry Advisory Board, National Potato Council	2, 4, 6, 10, 12, 86	Examples will be shown in the announcements for operation of general regulations 4 (“the amount of substances intrinsically contained in foods should not exceed the general content”). The results of continued investigation on the content will be published. The range of exempted substances for which “residue standards are not established if they apparently have no potential to cause damage to human health based on the condition and degree of residues” in foods with agricultural chemicals, etc. shall be published in the announcement.
24	2	Substances determined as having no potential of causing damage to human health in normal concentrations including those naturally-occurring are exempted from the list of standards. In contrast, all substances that have no potential in causing damage to human health are not necessarily included in “exempted substances”. For example, natural types of breeding hormones are not included in such lists. In order to avoid confusion, these substances should be included in a list of exempted substances.	Eli Lilly Japan K.K.	122	See No.23
25	2	Data concerning the amounts of substances intrinsically contained are required to determine if the amount contained in food doesn”t exceed. Specifically, investigation of substances with no domestically accumulated data such as hormones should be prioritized.	Japanese Consumers’ Co-operative Union	144	See No.23
26	2	The effective digit of standards is proposed as one. However, not the rounded figures, but the figures as they are should be employed if not averaged.	Japanese Consumers’ Co-operative Union	144	The effective digit of standards is determined according to the international practices (FAO guidelines).
27	3	Bases for “Not Detected” are not scientifically clear, especially for those for which both of “Not Detected” and actual values are established. Test methods by which substances should be “Not Detected” should be clarified. (Original in English)	Chinese Government	134	For substances for which ADIs can”t be established due to carcinogenicity with genetic toxicity, residues in food are not allowed, and they should be “Not Detected” by the established analysis methods. For agricultural chemicals, etc. that should be “Not Detected” in some products, provisional MRLs are established based on Codex standards, if applicable, for products with no established standards.
28	4	The lowest standards among established provisional MRLs for the relevant animals shall be applied to other tissues or organs for animals which standards are established. However, since residues are often the lowest in muscles where the standards are established, residues in other tissues or organs may not comply with the regulations even with appropriate drug holidays if the lowest MRLs are applied. Therefore, internationally consistent regulation systems, including employment of no standard or the highest MRLs based on a market basket method, should be introduced for organs with no established MRLs. (Many similar comments submitted)	Animal Health Institute, The American Chamber of Commerce in Japan/European Business Community, Animal and Aquatic Products Residue Safety Committee, Eli Lilly Japan K.K., etc.	6, 16, 33, 122, etc.	The degree of residues generally differs between muscle, fat (referred to as muscle, etc. hereinafter), liver, kidney, and other organs (referred to as liver, etc. hereinafter). Therefore, the lowest standards among those for each classification (muscles, etc. or liver, etc.) shall be applied to others in each classification for animals with established standards.
29	4	In foreign countries, the definition of minor animal species, residues control, handling of drug holidays, and responses following non-indicated use of veterinary drugs to these animals, are specified to a certain degree. The establishment of standards consistent with major species and introduction of appropriate ways of residue control should be discussed in order to avoid overregulation and excessive limitation of available drugs for animal products derived from minor species with significantly lower intake compared to the major ones. (Many similar comments submitted)	Animal Health Institute, Canadian Animal Health Institute, The American Chamber of Commerce in Japan/European Business Community, Animal and Aquatic Products Residue Safety Committee, Eli Lilly Japan K.K., etc.	6, 7, 16, 33, 122, etc.	It is difficult to employ data of different species for cases where no residue test data are available.

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30	4	Standards of domestic veterinary drugs and additives are based on LODs of residue tests indicated in the applications for approval. However, these values depend on the approval time, and lower levels are required according to the improved detection methods. On the contrary, the values specified in the second draft, mainly 50 ppb (or lower) for veterinary drugs, are not necessarily consistent with LODs at the time of approval or designation, raising a question to the description where domestic standards in the second draft "are established in a scientific fashion". It is important to not simply apply the standard 50 ppb (or domestic LODs), but to establish the scientifically sound MRLs or appropriate limits of analysis based on ADIs and validated LOQs (or LODs) in foreign countries if possible.	Animal and Aquatic Products Residue Safety Committee	33	Residue standards are established based on the values specified by the Pharmaceutical Affairs Law for cases with no Codex standards.
31	4	Even in reference nations, standards are not established for all approved substances. MRLs are not established when residues with no drug holidays are below the LODs or ADIs. In some cases such as feed additives in EU, it is not MRLs but drug holidays that are established based on ADIs and validated data including analysis results. Therefore, a uniform standard of 10 ppb should not be employed simply due to nonestablished MRLs in foreign countries. LOQs of the analysis methods should also be taken into consideration.	Animal and Aquatic Products Residue Safety Committee	33	If LODs are employed as standards for substances that are approved for animals in the reference nations, the LODs shall be adopted as the provisional MRLs.
32	4	The same standards are employed for tissues and organs for residues in aquatic species. However, similar to mammals, residues vary depending on fish tissues. In addition, residues have been reviewed only for limited tissues consisting mainly edible parts in Japan. Establishment of consistent standards for specific organs based on the current residue control and introduction of scientifically appropriate control measures are desirable.	Animal and Aquatic Products Residue Safety Committee	33	Taking into consideration that residue standards are established mainly for edible parts, parts taken for tests are specified as "parts generally for human consumption". It will be stated in the announcements of analysis methods.
33	4	Provisional MRLs based on emergency clause (clause 18) should be adopted. (Original in English) (Seven similar comments submitted)	The United States Government, The California Cherry Advisory Board, National Potato Council, California Table Grape Commission, California Strawberry Commission, U.S. Hop Industry Plant Protection Committee, and California Farm Bureau Federation	2, 3, 5, 9, 10, 12, 142	Emergency use of agricultural chemicals in response to the outbreak of pests in the US requires approval from the US EPA for reasons of risk evaluation. Thus, provisional MRIs shall be established based on such standards for the approved agricultural chemicals.
34	4	Some agricultural chemicals approved in the US (with established standards) are not included in the second draft (e.g. EPTC, Ferbarn, Maneb, zineb, Ziram, Streptmycin etc.) Agricultural chemicals approved in the US and/or EU not included in the current draft should be added after screening.	Japan Fruit Juice Association	112	See No.19
35	4	Standards in Step 6 or above in the Codex evaluation should be taken into consideration with foreign standards in establishing provisional MRLs.	Animal Health Institute, Canadian Animal Health Institute, Animal and Aquatic Products Residue Safety Committee	6, 7, 33	Since Codex residue standards (MRLs) are adopted in Step 8, it is difficult to refer to residue standards in Step 6 for possibility of revision.
36	4	The current situation of the establishment of Codex interim MRLs should be reflected.	Japanese Consumers' Co-operative Union	144	It is recognized that the Codex Residue Agricultural Chemical Committee has been discussing on topics including the establishment methods of interim MRLs. Therefore, it is difficult to refer to it.
37	4	The average should not be easily employed, and foundations of their establishment should be investigated for substances for which significant differences are found among foreign standards.	Japanese Consumers' Co-operative Union	144	Reference foreign standards are established in scientific ways based on residue tests. For substances with multiple reference foreign standards, therefore, the averages can be reasonably employed.

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38	4	It is not clear what cases domestic standards (standards for the withholding of agricultural chemicals registration), and not Codex standards are adopted. The details of "based on production, distribution and actual status of usage of agricultural chemicals" should be clarified. Although examples of MRLs foreign standard low self-sufficiency rate products, such as grapefruit, lemon, pineapple, wheat, corn, and soybean are shown on the site of Ministry of Agriculture, Forestry and Fisheries, examples of MRLs domestic standards (standards for the withholding of agricultural chemicals registration) and their reasons are not published. In fact, only "paraquat for rice" can be found as an example of standards that are not Codex but domestic (standards for the withholding of agricultural chemicals registration) (Type 1-2).	Nichirei Corporation	30	Adoption standards for the withholding of agricultural chemicals registration is requested with the submission of residue test results among agricultural chemicals registered and applied in Japan. These standards are based on the withholding of agricultural chemicals registration or residues test results adopted as necessary after individual verification of test results.
39	4	Residue standards and application standards should be uniformly reviewed, especially for those with standards for correct use established by the Agricultural Chemicals Regulation Law. Their safety and residues are assured by national regulations, and standards for the withholding of agricultural chemicals registration should surpass Codex standards. However, since application standards (timing of application, frequency, dilution rate etc.) have not been reviewed in establishing the provisional MRLs, some cases complying with correct use standards based on the Agricultural Chemicals Regulation Law may not meet provisional MRLs. The following procedures are considered necessary for cases prioritizing Codex standards over agricultural chemicals registration withholding standards; residues complying with the existing standards for correct use; reviewed application methods in establishing provisional MRLs.	Nichirei Corporation	30	See No.38
40	4	Feed additives are based on "LODs or LOQs specified by the Feed Safety Law". However, LOQs without the consideration of ADIs may result in detection of residues above standards depending on metabolic conditions of animal or aquatic products even under appropriate raising. Provisional MRLs should be scientifically established by promoting the coordination of national regulations such as the Feed Safety Law and foreign feed specifications, and understanding the current status of ADIs and residues.	Nippon Suisan Kaisha, Ltd.	19	Provisional MRLs for feed additives are established with consideration of residues under the appropriate condition of use. Specific cases will be individually dealt upon requests.

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41	4	As a rule, no residue standards should be established for agricultural chemicals not registered in Japan without data of application or toxicology information. They should be established following a review of proposed values based on survey results concerning registration and application condition in foreign countries and toxicological data. The principle of “no standards established” should be maintained as necessary especially for agricultural chemicals used exclusively in foreign countries with high standards. Standards should be reviewed for those with theoretical intake estimates (food factor × residue standard ÷ body weight (50 kg)) above 80% of ADIs for agricultural chemicals with Codex or foreign standards where residue standards are established.	Anti-agricultural chemicals Tokyo Group	115	Required kinds or ways of application of agricultural chemicals are different between Japan and foreign countries due to the diversity of crops, types and degrees of diseases and pests for each product, and types of operations. Residue standards of agricultural chemicals are established based on correct usage. It is believed that reference international standards, standards for the withholding of agricultural chemicals registration, and 5 national or regional standards including those of the US are established to ensure safety based on toxicological evaluation for registration. “For agricultural chemicals used exclusively in foreign countries with high standards, the principle of ‘no standards established’ should be maintained” is against the principle of “no discrimination between internal and external markets” of the WTO agreement that Japan has ratified. Provisional MRLs will be reviewed according to risk evaluation and exposure evaluation based on national food intake derived from safety test results including high priority toxicological tests determined by the actual intake investigated by a market basket method.
42	4	Foreign countries should be required not to employ their standards as they are, but to adopt Japanese registered agricultural chemicals and cultivation strategies consistent with Japanese standards. For example, sulfuryl fluoride has been registered as an agricultural chemical exclusively for fumigation of woods in Japan, but the residue standard for crops established in the US was adopted for Dow Chemical Japan Ltd. German standards are often employed as they are for hop.	Anti-agricultural chemicals Tokyo Group	115	See No.41

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43	4	The lowest standards among Codex and foreign standards should be adopted based on the following reasons: 1) The emphasis of Codex standards by the Ministry can be attributed to the "Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)". This was aimed at smooth international crop trade among WTO related agreements in 1995. The agreement specifies that sanitary and phytosanitary measures leading to higher level of protection than the international standards can be introduced or maintained if they are scientifically correct. Foreign standards adopted by the Ministry in other parts (US, Australia, New Zealand, EU and Canada) that are considered scientifically correct can be regarded as equivalent to Codex standards. 2) Codex standards, one of the international standards, shall be established to ensure food safety and promote international food trade. Human safety is not the top priority. In addition, the Codex committee consisting of members representing national agencies and chemical or food related companies tends not to reflect Consumers' needs. Since Codex does not prioritize toxicological evaluation, they should be treated equivalently to foreign standards, and the lowest value should be adopted. 3) The average values of foreign standards are adopted as proposed MRLs for some substances. SPS Agreement doesn"t require the adoption of such averages. Values established in a scientifically sound fashion should be treated equally. 4) Establishment of low standards will lead to the reduction of the total amount of agricultural chemical intake.	Anti-agricultural chemicals Tokyo Group	115	In implementing the positive list system, Codex standards should be adopted, if any, based on Japan"s membership in the WTO agreement. For substances without Codex standards or standards for the withholding of agricultural chemicals registration, a foreign standard or average of standards shall be adopted. This is because reference foreign standards are adopted not only to domestic products but also to imports; risk analysis of individual agricultural chemicals including the review of ADIs; residues; difficultly of intake due to many agricultural chemicals subject to the positive list system. It is recognized that international standards, reference domestic, or foreign residual agricultural chemicals standards are established to ensure safety under correct use.
44	4	Some residue standards are established based on Japanese standards for the withholding of agricultural chemicals registration. No standard should be established for crops with no application in Japan.	Anti-agricultural chemicals Tokyo Group	115	See No.12
45	4	Standards should be established based on standards of 5 reference countries including the current ones. (Original in English)	The United States Government	142	For substances with no internationally approved Codex standards or domestic standards, provisional MRIs are established based on standards of 5 reference nations. The current standards have no references.
46	4	Adoption of standards for the withholding of agricultural chemicals registration is inappropriate. Foreign standards are adopted for substances with high import ratio, but the foundation is unclear. (Original in English)	The United States Government	142	Standards for the withholding of agricultural chemicals registration are established based on exposure evaluation according to standards determined by residue test results under the GAP conditions after toxicological test evaluation. The procedure is equivalent to those applied for international residue standards, and it should be referred to them in establishing provisional MRLs. Substances with high import ratio for which foreign standards are adopted are specified as those with self-supply rate of less than 50 % and with any of the 5 reference nations or areas included in the major 3 exporters.
47	4	Averages should not be employed. Foundations for exceptional adoption of average due to deviations are unclear. (Original in English)	The United States Government	142	See No.37 for the adoption of averages. Since exceptional adoption of averages due to deviations (Type 5-2) is extremely limited in the second draft, and the possibility is considered low, it will be deleted from the list of types.

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48	4	Some provisional MRLs lower than those in Australia are not taken into consideration. How will these be reflected in standards for agricultural chemicals in the future? (Original in English)	Australian Government	133	For substances with no internationally approved Codex standards or domestic standards, provisional MRLs are established based on standards of 5 reference nations. For agricultural chemicals, etc. to be registered in the future, establishment or revision of the standards can be requested according to the "Guidelines on establishment and revision of residue standards for agricultural chemicals abroad" (Announcement of Director, Department of Food Safety, Ministry of Health, Labour, and Welfare, February 25, 2004). See also No.9.
49	4	It is not reasonable to adopt the averages since residue standards are established based on scientific evaluation. (Original in English)	Australian Government	133	See No.47
50	4	Scientific foundations such as ADIs should be provided. The standards should be established based on the standards of 5 nations and trading balances. (Original in English)	Chinese Government	134	In establishing the current provisional MRLs, Codex standards subject to the WTO SPS Agreement are prioritized to focus on international trade and ensure consumer safety.
51	4	Significant differences in standards can be found in same crop groups. Standard for imports are more strict than that of domestic. (Originals in English)	Chinese Government	134	Residual agricultural chemicals shall be reviewed by focusing on the residue amount under correct usage according to the methods specified for each product domestically and abroad. Therefore, residue amounts can be largely different even though they are within the same crop groups. Japanese standards are applied equally to domestic and imported products, and such problem should not be considered.
52	4	It is unreasonable that Japanese residue standards vary depending on types of food within the same categories. Daily intake per CAPITA significantly varies theoretically, and Japanese standards for food are sometimes not elaborated. Standards are stricter for products with high import ratio than those for domestic products. Discrimination against imports is apparent and it is against the policy of the WTO. For example, residue standard of apramycin (39) is set at 0.006 ppm for swine, while 0.1 ppm for cattle, even though they are both mammals. The standard of tylosin (659) is set at 0.05 ppm for chicken, while 0.2 ppm for other poultry. (Original in English)	Chinese Government	134	In establishing the current provisional MRLs, Codex standards subject to the WTO SPS Agreement are prioritized. The next priorities are national standards and reference foreign residue standards (5 nations) in the descending order. Standards are never established differently for imported and domestic products.
53	5	Procedures for adopting standards for processed food are unclear. Internationally adopted standards such as concentration factors should be adopted. How are processed food dealt with when there are no standards for spices? Guidelines for foreign countries and importers should be provided. (Original in English)	The United States Government	142	See No.54. "Internationally adopted concentration factors" should be provided for reference, if any.
54	5	How is the compliance of processed food determined? (Original in English)	California Farm Bureau Federation, Australian Government	12, 133	The compliance is determined based on ingredients. Criterion such as ratios of ingredients and concentration factors will be clarified in the announcement of implementation.
55	5	When agricultural chemicals exceeding the standards are detected in processed food, conversion to source vegetable is possible for single ingredient foods, while it may be impossible for multiple ingredient foods. How would one respond to such situation? (Three other similar comments)	Kunihiko Ogawa, Quality and Safety Committee for Imported Frozen Vegetable, Maruha Corporation	18, 96, 100	See No. 54

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56	5	The range of “dairy products” should be clarified for carbaryl. The proposed standard for carbaryl is 0.1 ppm for “dairy products” for residual agricultural chemicals in processed food according to Attached Table 3. However, the proposed standard for carbaryl is 0.05 ppm for “milk”. The proposed standards are reportedly based on Codex standards. The amounts of “milk” used for production of dairy products vary depending on the types of products. For example, since concentration of whole milk powder is 10 times “milk”, residual carbaryl in whole milk powder will be less than half of the standard, even if it is made from “milk” complying with the proposed standard, 0.05 ppm. In order to avoid these kinds of inconsistency, the difference between dairy products defined in “Ministerial Ordinance concerning milk” and “dairy products” indicated in Codex should be clarified to indicate concrete range of “dairy products”.	Japan Dairy Industry Association	84	The standard of carbaryl shall be deleted from the list of proposed provisional MRLs since the standard of carbaryl for “dairy products” has been deleted from Codex standards.
57	5	Conversion factors to raw milk of dairy products classified into processed food should be developed. The compliance of dairy products is judged based on the ratio of the estimated amount of agricultural chemicals in raw milk. When agricultural chemicals exceeding the uniformed standard are detected, it is considered to be derived from raw milk. To avoid confusion, the development of “conversion factors to raw milk” is essential for basic dairy products (e.g. skim milk, whole milk powder, butter and cheese).	Japan Dairy Industry Association	84	See No. 54.
58	5	It is understood that dried vegetables should be evaluated under hydrated conditions with the same water content as those of original raw vegetables. Since dried vegetables are derived only from edible parts of raw vegetables, they weigh 80% of the originals. This results in the addition of over 8-fold volume of water. There is much difference in residue standards between the addition of 8.5-fold and 8-fold volume of water. As shown in the tables below (skipped), values vary depending on individual vegetables. Therefore, the ratio of the addition of water should be established for each vegetable, or a uniform value around 10 should be established. It is desirable that these values are noted for each list of standards.	Japan Dried Vegetable Association	82	Suggestions will be taken into consideration in conducting the investigation. Please note that the compliance is judged based on source vegetables, and review of water content is only pre-screening.
59	5	I would like to verify information on concentrated fruit and vegetable juice of processed food. A list of residue standards for processed food includes “apple juice”, “citrus juice”, “orange juice”, “grape juice”, and “tomato juice”. In fact, many other fruit or vegetable juice is used as ingredients. Is it reasonable to use residue standards established for crops according to the explanation in the proposal of the first draft? For example, can 8-fold standard be applied to 8-fold concentrated “peach juice”?	Nisshin Trading Co.. Ltd.	103	See No.54. Yes, 8-fold standards can be applied to 8-fold concentrated juice.
60	5	In the current proposal for processed food, “citrus juice”, “orange juice”, “apple juice” and “grape juice” are used as names of juice. Do “juice” mean “strait” and “100% fruit juice from concentrate” according to JAS regulations, excluding “concentrated fruit juice” and “fruit drink with less than 100% fruit juice”? If it includes concentrated juice and fruit drink with less than 100% fruit juice with conversion, should “juice” not be used in relation to JAS regulations?	Japan Fruit Juice Association	112	The suggestion is correct.
61	5	It is stated that “products produced or processed from ingredients complying with standards can be distributed with no specific standards” for processed food, except for those with (proposed) standards. However, it is difficult to confirm that products are “produced or processed from ingredients complying with standards” especially for those that are imported. Therefore, the analysis of “products” becomes unavoidable. For juice, there are additional complicated factors such as squeezing ratio or transition rate of agricultural chemicals, etc. Detailed calculation of “standards for juice” should be indicated with standards for raw fruits taken into consideration.	Japan Fruit Juice Association	112	See No.59

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62	5	It should be clearly stated that standards for “raw fruits” can be applied if it is difficult to indicate how to calculate “standards for juice”. Additionally, it should also be clearly stated whether standards for the above-mentioned “concentrated juice” and “fruit drink with less than 100% fruit juice” should be converted based on the standards for “juice” or “raw fruit”.	Japan Fruit Juice Association	112	For juice squeezed from raw fruits without processes like concentration, standards for raw fruits shall be applied, except for those with established standards based on Codex standards. For juice such as those that are concentrated, standards for “juice” can be used for calculation, if applicable.
63	5	In calculating standards for concentrated juice, juice from concentration, and fruit drink with less than 100% fruit juice (according to indicated juice content), is it reasonable to use Brix values? If so, basic Brix values should be JAS based ones, not Codex based ones. (e.g. 11° Brix for orange juice, 10° Brix for apple juice)	Japan Fruit Juice Association	112	For JAS regulated products, JAS regulations shall be applied.
64	5	The procedures for the application of Japanese provisional MRLs for processed potatoes should be clarified. The previous response to our inquiry was that a standard for raw potato is applicable to hydrated samples. This should be indicated in writing. (Original in English)	National Potato Council	3	Although it varies on the degree of processing, the standard for raw potato is applicable after adjusting water content.
65	5	The definition of “whole grain” as processed food should be clarified. (Three similar comments submitted)	Nippon Flour Mills Co., Ltd., Nisshin Seifun Group, and Flour Millers Association	43, 46, 127	Standards for ingredients such as wheat shall be applied for “whole grain”.
66	7	For a uniform standard, the concept of risk control should be employed.	Japanese Consumers’ Co-operative Union	144	The Food Safety Committee conducted an investigation and discussion on a uniform standard based on Article 23, Paragraph 1, Subparagraph 5 of the Food Safety Basic Law, but no comments on the concept was submitted.
67	7	It is not appropriate to say that substances with carcinogenicity in the amount below toxicological threshold are safe.	Japanese Consumers’ Co-operative Union	144	The description pointed out was cited from policies of international institutions or academic reports.
68	7	It is against the provision of Article 11, Paragraph 3 of the Food Safety Basic Law to establish a uniform standard for agricultural chemicals, etc. (agricultural chemicals, feed additives and veterinary drugs) with established ADIs, for those with no standards, or for those which standards were repealed due to toxicological concerns. Different uniform standards should be established for agricultural chemicals with or without established ADIs. (Two similar comments submitted)	Japan Crop Protection Association, Nippon Suisan Kaisha, Ltd.	17, 19	See No.66. In foreign countries that have already adopted a positive list system, such cases have never been found. In addition, no legal inconsistency is raised.
69	7	In establishing a uniform standard, characteristics of the relevant agricultural chemicals, feed additives, and veterinary drugs should be considered. Although approximately 70% of substances are “agricultural chemicals”, a uniform standard is proposed based on extremely low ADIs for veterinary drugs. The proposed uniform standard is too low especially for agricultural chemicals with established ADIs. Different uniform standards should be established separately for veterinary drugs, c.f. physiochemical substances for humans and animals, as well as agricultural chemicals.	Japan Crop Protection Association	17	See No.66. In the previously mentioned policies, various trial calculations other than those based on ADIs for veterinary drugs were conducted. The EU set a default corresponding to a uniform standard of 0.01 ppm for agricultural chemicals in January this year.
70	7	It is appropriate to apply 100 ppb adopted by New Zealand as a uniform standard for substances included in the positive standard list based on ADIs according to scientific evaluation in foreign countries. Ten ppb adopted by the EU may be excessive since they are not chemicals used for animals. Although strict control of substances not included in the list of standards is also conducted in foreign countries, strict standards such as 10 ppb are not applied to the listed substances. This should be reconsidered.	Eli Lilly Japan K.K.	122	See No.66. A uniform standard in New Zealand is based on the Canadian one. It is recognized that Canada has been reviewing it.

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71	7	A proposed uniform standard seems to focus on compounds with insufficient information such as toxicological information, and reference ADI below 0.03 ug/kg/day is based on a compound with extremely high toxicity. Compounds approved by the Ministry of Agriculture, Forestry and Fisheries as veterinary drugs are generally accompanied by sufficient toxicological information, and their ADIs are much higher than the referred in most cases. Residue standards should be established based on ADIs scientifically. For compounds with high ADIs, it is not scientific to establish a uniform standard of 0.01 ppm with reason of no residue standards established for specific tissues in foreign countries.	Merial Japan	105	See No.66. A uniform standard will be applied to those not approved in reference nations.
72	7	The employment of the concept of default such as “causing damage to human health” should be limited to novel agricultural chemicals or those not registered in Japan (due to default).	Edible Oil Trade Association	85	See No.66. Agricultural chemicals, etc. are applicable to specific crops, and prohibited to other products.
73	7	A uniform standard at low level should not be applied to agricultural chemicals registered in Japan with established ADIs without specific reasons. A uniform standard of 0.05 ppm higher than the proposed 0.01 ppm should be reasonably applied. Based on the established ADIs, it is proved to “have no potential of damage to human health”.	Japan Crop Protection Association	17	See No.66. A uniform standard (default) is applied to those with no established standard regardless of national registration in the EU.
74	7	According to the survey results of food intake by food group in FY 2002, among raw food except for rice, the highest intake was found in “other fruits” accounting for 49.3 kg for the whole nation (the highest was 59.1 kg in the Tohoku region). If it is appropriate to regard 1.5 μg/day as an acceptable level, acceptable residue in food weighing 50 g is 0.03 ppm on average reaching 1.5 μg/day. Thus, when a uniform standard is established for substances not actually applied (0.01 ppm), there is little difference between 0.03 ppm and 0.1 ppm.	Nichiro Corporation	121	See No.66. The basic concept previously published includes various trial calculations in addition to 1.5 μg/day.
75	7	The establishment of a uniform standard for various agricultural chemicals has no sound reasons in regards to risk control. The lowest standard in the current regulations should be applied as a uniform standard for agricultural chemicals, etc. with established standards and those with similar structure or toxicity. Additionally, the establishment of a uniform standard of about 0.01 ppm for those unlikely to be applied has no sound reasons regarding risk control. Values around 0.1 ppm are considered appropriate (0.01ppm and above occupies 84.8% of the current standards of residual agricultural chemicals). (Four similar comments submitted)	Japan Frozen Food Association, Nara Prefectural Institute for Hygiene and Environment, Nichiro Corporation, Quality and Safety Committee for Imported Frozen Vegetable	42, 63, 96, 121	See No. 73
76	7	It is stated that the uniform standard is employed “when agricultural chemicals etc. with established MRLs for some crops etc. remain in crops etc. with no established MRLs for the agricultural chemicals in question”. However, agricultural chemicals with established MRLs for “vegetables other than above-mentioned ones” should be exempted from the subject of the uniform standard so that the MRLs for “vegetables other than above-mentioned ones” are applied to other crops.	Nippon Suisan Kaisha, Ltd.	19	See No.66. “Vegetables other than the above mentioned” means vegetables within specific range, and its standard is different from a uniform one.
77	7	In establishing a uniform standard, alternative measures such as gradual establishment between 1 and 0.01 ppm should be discussed, taking into consideration the current standards, Codex standards, and foreign standards, if applicable. Gradual establishment will allow more agricultural chemicals to be covered by simultaneous analysis, easier access to safety confirmation. However, it is still important to consider toxicological aspect. (Five similar comments submitted)	Japan Crop Protection Association, Nisshin Seifun Group, Kikkoman Corporation, Kyowa Hakko Co., Ltd., Japan Fruit Juice Association	17, 46, 69, 80, 112	See No.66. No reasons of gradual establishment of a uniform standard can be found at the present time. In foreign countries, a uniform standard is established as discussed previously.
78	1	In New Zealand, agricultural chemicals that pose residues under a uniform standard (0.1 ppm) can be used. It is desirable that a uniform standard is set at 0.1 ppm within the applicable range. (Original in English)	The New Zealand Food Safety Authority	135	As described in response to No. 31, specific standards would be added as references if presented.
79	7	Due to no potential in causing damage to human health, 0.1 ppm should be applied like the Canadian uniform standard. (Original in English) (Two similar comments submitted)	The California Cherry Advisory Board, California Farm Bureau Federation	2, 12	See No.66. It is recognized that Canada has been reviewing its standard of 0.1 ppm.

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80	7	If a uniform standard of 0.01ppm is established, only 10 to 20 % of agricultural chemicals can be covered by a simultaneous analysis method. A uniform standard covering a simultaneous analysis method should be established assuming it “has no potential to cause damage to human health”. (Three similar comments submitted)	Japan Food Industry Center, Ajinomoto Co., Inc., Japan Oilseeds Processor Association	71, 107, 128	Values corresponding to LOQs shall be adopted as standards for agricultural chemicals difficult to quantify 0.01ppm by analysis methods developed in monitoring and controlling local governments.
81	7	LODs of analysis methods for some drugs will be higher than the uniform standard. Desirable responses to LODs higher than the uniform standard should be clarified. (Four similar comments submitted)	Kunihiko Ogawa, Snow Brand Milk Product Co., Ltd., Japan Imported Food Safety Promotion Association Kikkoman Corporation	18, 31, 49, 69	See No. 80.
82	7	A uniform standard of 0.01 ppm seems to have no solid basis, and standards for all agricultural chemicals are not necessarily 0.01 ppm from the viewpoint of toxicity. LODs of many agricultural chemicals are 0.01 ppm or above, even with a GC/MS/MS method with higher accuracy than a GC/MS method. Therefore, many agricultural chemicals should be analyzed by the official method (individual analysis). However, the official method will be difficult to conduct due to burdens such as cost.	Kikkoman Corporation	69	See No.80.
83	7	The range of substances for which analysis methods will be developed is not clearly specified. It is stated that an analysis method is to be announced for drugs that should be “not detected”. It should be clarified whether the announcement will be for all drugs including those subject to a uniform standard (drugs applied all over the world), or only for those (669 drugs) with established provisional MRLs. If analysis methods for drugs with a uniform standard will not be announced, interested parties cannot respond. In which case, some criteria should be indicated.	Kunihiko Ogawa	18	Drugs with established standards including “not detected” will be announced. Cases subject to a uniform standard are divided into: 1) agricultural chemicals with established standards for certain crops which standards are not established, and 2) agricultural chemicals with no established standards remaining as food. Cases of 2) are not regulated by the regulations and impossible to be identified.
84	7	The US FDA defines LOQs for each item (reference skipped). They vary depending on agricultural chemicals, but some of them are just 0.1 ppm. In order to establish a uniform standard of 0.01 ppm, the assay systems must assure 0.01 ppm as LOQ for 669 substances. If assurance is difficult, confusion is likely to arise concerning analysis values and food handling. This is not in compliance with a uniform standard after implementing the system.	Nichiro Corporation	121	See No. 80.
85	7	When a uniform standard is set at 0.01 ppm, is one-tenth or one-fifth of it required to be LOQs of the analysis methods? As an analyst of agricultural chemical residues, it can be said that the lowest LOQ assured by typical analyses is 0.01ppm, and a considerably high level of technique is required to assure the lower limits. What kind of uniform standard control does the government expect? Is it necessary to accurately determine 0.01 ppm, or is it enough to prove its superiority over an LOQ for analysis at 0.1 ppm?	Masataka Hirota	68	LOQ of 0.01 ppm will cause trouble if a uniform standard is set at 0.01 ppm. Analysis methods should be improved continuously.

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86	7	According to the data of drift contamination shown in reference 1) to 3) (skipped), 5 % of drift is confirmed at the point 100 ft apart from the place of agricultural chemical application, and 1% at the point 300 ft apart from the place. If 1.5 ppm level of application is conducted for a product with an established residue standard of 2 ppm, 5% of it, c.f. 0.075 ppm of drift contamination will occur in the neighboring farm. According to the data of residual agricultural chemicals in organic vegetables shown in reference 4) (skipped), insecticide was detected in 25 % of the vegetables. Thus, a uniform standard should be established based on data including survey results of drift contamination of organic crops imported or domestically produced. Based on the fact that standards of 0.01 ppm and under account for only 156 (1.63%) among about 9000 residual agricultural chemicals standards currently established in Japan, a uniform standard of 0.01 ppm may be too strict. In order to avoid social concerns for agricultural chemicals and social loss for food with no practical health hazard, a uniform standard should not be at 0.01 ppm, since it is equivalent to the level for extremely harmful substances, but 0.1 ppm (level accounting for approximately 70% of all residual agricultural chemical standards). (Five similar comments submitted)	Japan Crop Protection Association, Maruha Corporation, All Nippon Kashi Industry Association, Japan Biscuit Association, Nichiro Corporation	17, 75, 83, 100, 121	See No.66. Data concerning residuals by drift are limited, and no significant influence can be found based on the results of examinations conducted by local governments or inspection offices in 2000 and 2001. If significant residues by drift can be found, measures should be taken to improve it. The EU set a uniform standard at 0.01 ppm in January this year.
87	7	Data concerning the degree of accumulation of agricultural chemicals drained into the sea in marine products cultivated off the shore, and the duration of their disappearance is not available. A uniform standard may cause social confusion. Due to insufficient understanding of the actual status, discussion on the application of a uniform standard to aquatic products should be continued, and the establishment of flexible standards based on ADIs and data on residues should be reviewed. In addition, cares should be taken for suspension of recall and the establishment of suspension period for penalties. (Two similar comments submitted)	Maruha Corporation, Aquatic Food Sanitary Committee	100, 113	See No.66. A uniform standard shall not be established based on the actual status of residues, but the suggested cases are limited based on data including survey results conducted by the Ministry of Environment.
88	7	Establishment of a uniform standard of 0.01 ppm will result in increased ratio of imported vegetables not complying with the regulation. It will also result in the prohibition of import or voluntary limitation of export, possibly leading to economic loss in distribution of vegetables. Since the current situation of application in foreign countries is unclear, a uniform standard of 0.01 ppm appears too extreme.	Quality and Safety Committee for Imported Frozen Vegetable	96	See No.66. The EU made a decision to apply a uniform standard (default) regardless of domestic or foreign registration.
89	7	Some figures such as 0.01 ppm in Germany, 0.01-0.1 ppm in the US (operational) and 0.01 ppm in the EU (proposed) are shown. Details of actual operational situations in each country (number of examinations, frequency, violation rate, situation for each product concerning countermeasures for violation, and social responses and countermeasures to violated products) should be provided.	Nichiro Corporation	121	See proceedings of the Meeting (Dec. 14, 2004) of the Division of Agricultural Chemicals and Veterinary Drugs, Department of Food Sanitary, Pharmaceutical Affairs and Food Sanitary Committee for information, at http://www/mhlw.go.jp/shingi/2004/12/dl/s1214-6h.pdf
90	7	A uniform standard should be reviewed scientifically.	Japanese Consumers' Co-operative Union	144	The suggestion is reasonable.
91	8	The relationship between substances not requiring the establishment of ADIs according to evaluation of food effects on human health based on Article 11 of the Food Safety Basic Law and unregulated substances is unclear.	Japanese Consumers' Co-operative Union	144	Crops, animal products, and aquatic products with residual agricultural chemicals that apparently have no potential of causing damage to human health based on residue amounts are unregulated. The establishment of MRLs is also unnecessary for substances not requiring the establishment of ADIs (according to the evaluation of food effects on human health based on Article 11 of the Food Safety Basic Law). These agricultural chemicals shall be regarded as unregulated substances. For ADIs and MRLs, JECFA has indicated similar policies.

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92	8	The concept and regulations for the establishment of unregulated substances should be harmonized. For example, handling of substances not included in unregulated substances with no established provisional MRLs should be clarified.	Japanese Consumers' Co-operative Union	144	See the above description for the concept of unregulated substances. Substances mentioned in the left column are subject to a uniform standard with the exception of contaminants.
93	8	All of the unregulated substances in the US should be included in the unregulated substances. In which case, these substances with the exception of those for which Japan considers inappropriate should be evaluated. (Original in English)	The United States Government	142	Unregulated substances shall include agricultural chemicals with no limitations on methods of application. Among these are substances requiring no established residue standards in foreign countries, since it is difficult to limit methods of application.
94	8	Since 32 kinds of vitamins and 12 kinds of amino acids are designated as feed additives by the Minister of Agriculture, Forestry and Fisheries, these vitamins and amino acids should be clearly indicated as unregulated substances.	Japan Scientific Feeds Association	22	The suggested substances shall be included in unregulated substances based on the announcement of Director, Office of Veterinary Drugs, Ministry of Agriculture, Forestry and Fisheries (Reference 3-2, Meeting of Department of Agricultural Chemicals and Veterinary drugs, March 10, 2005).
95	8	A list of proposed unregulated substances and drugs should be developed as provisional MRLs.	Nippon Suisan Kaisha, Ltd.	19	Unregulated substances shall be indicated individually. Because applied agricultural chemicals can be chemically altered, potential residues will be included.
96	8	A list of unregulated substances should be established and reviewed on a regular basis.	Japanese Consumers' Co-operative Union	144	The suggestion sounds reasonable.
97	9 (5)	According to "Guidelines on establishment and revision of abroad residue standards for agricultural chemicals" published by the Ministry of Health, Labour and Welfare, information on how substances are evaluated and when regulations are applied in Japan should be provided. (Original in English) (Three similar comments submitted)	California Table Grape Commission, California Farm Bureau Federation, The united States Government	5, 12, 142	For substances applied according to the guidelines, regulations shall be applied after a risk evaluation conduct by the Food Safety Committee, an inspection by the Pharmaceutical and Food Sanitation Committee, and procedures including communication with the WTO.
98	9 (5)	Although JECFA recommends MRLs based on raw milk, lipid residue concentration of lipid soluble substances is possibly 25 times higher than that of raw milk, conceivably leading to extremely high residual concentration in high-fat processed food such as cheese and butter. This should be discussed.	Japanese Consumers' Co-operative Union	144	Handling of lipid soluble substances has been reviewed by international expert meetings (JMPR and JECFA). Responses based on the results should be implemented.
99	9 (6)	Consistency with international regulations on fungicide applied after harvest should be considered. (Original in English) (Four similar comments submitted)	California Cherry Advisory Board, California Farm Bureau Federation, Australian Government, The United States Government	2, 12, 133, 142	According to the Japanese Food Sanitation Law, fungicide applied after harvest is regarded as agricultural chemical. It is also considered additive. The data and period are required to establish the standards, so please ask the questions more specifically.
100	9 (6)	Sufficient risk communication should be provided for established standards. "Food education" including the announcement of the meaning of ADIs should be more specific in order to avoid overreaction of consumers to the detection of substances under the standards. (Many similar comments submitted)	Nippon Suisan Kaisha, Ltd., JFIC (Japan Food Information Center), Japan Imported Food Safety Promotion Association, etc.	19, 38, 49, etc.	We will correspond to the risk communication with individual consumers on a regular basis
101	9 (6)	Understanding of the system by South-Eastern Asian Nations in addition to producers and manufacturers should be promoted.	Japanese Consumers' Co-operative Union	144	Efforts have been and will be made to keep every nation informed of the system through organizations such as FSG.

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To be transferred from comments that are major to those in specific standard levels

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26	2	Inorganic compounds such as “copper cupric sulfate” and “copper cupric hydroxide” are considered as subject to the regulation based on the provision, “for substances equivalent to those intrinsically contained in food, the content should not be over the normal level of the substance in the food”. It is important that “the normal level of the substance in the food” should be specified, or that the sources of the levels be clarified.	Nippon Suisan Kaisya, Ltd.	19	See above. (Residue derived from copper sulfate should be discussed.)
95	8	Antibacterial agents derived from copper, sulfur, petroleum, fatty acid salt and fatty ester should be added to unregulated substances. In addition, unregulated substances should not be limited to those with no application regulations. Most of application regulations are established from the viewpoint of GAP or environmental assessment. (Original in English)	The New Zealand Food Safety Authority	135	Individual substances will be reviewed in consultation with experts.
97	8	Some kinds of substances are not included in the second draft of the positive list (See Attachment 2 (skipped)). All substances listed in (EEC) No.2377/90 in Supplement II (substances requiring no MRLs to protect public health) should be included in a list of “exempted substances”(approved by the Minister of Health, Labour and Welfare, as substances that apparently have no potential of damage to human health).	Intervet K.K.	108	Suggested lists will be reviewed individually.
99	8	It should be clarified whether sex pheromone that is not directly applied to crops is subject to regulation or not.	Kikkoman Corporation	69	
100	8	Is it reasonable that neem extracts (mainly oil) (source plant: margosa), applied mainly in India, and its active ingredient (Azadirachtin) are unregulated.	Japan Tea Association	123	
101	8	The US EPA and CAL DPR state that copper, sulfur, garlic oil, Azadirachtin, mineral oil, neem oil, bacillus thuringensis, iron phosphate, insecticidal soap, cinnamaldehyde, potassium bicarbonate, and ampelomyces quisqualis are safe natural substances for pest control, and require no tolerance. The Ministry of Health, Labour and Welfare clearly states that sulfur, bacillus thuringensis, and potassium bicarbonate are unregulated. It should be clarified whether they are included in the final draft of MRLs or a list of unregulated substances, and whether other substances are included in the final draft of MRLs or a list of unregulated substances. (Original in English)	California Strawberry Commission	9	