Provisional Translation
Original: *Japanese*

Regarding Establishment of the "level to be determined by the Minister of Health, Labour and Welfare, at the Pharmaceutical Affairs and Food Sanitation Council's advice, as that having no potential to cause damage to human health" as Specified in Article 11, Paragraph 3 of the Food Sanitation Law (Draft)

The execution of Article 11, Paragraph 3 of the Food Sanitation Law requires the establishment of the "level to be determined by the Minister of Health, Labour and Welfare, at the Pharmaceutical Affairs and Food Sanitation Council's advice, as that having no potential to cause damage to human health" and the "substances 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 the same paragraph, in accordance with the preparation of the standards (including provisional standards) pursuant to Article 11, Paragraph 1 of the same law.

Regarding, among these, the "level to be determined by the Minister of Health, Labour and Welfare, at the Pharmaceutical Affairs and Food Sanitation Council's advice, as that having no potential cause damage to human health", this paper summarizes current knowledge and findings with respect to possible ideas for establishing such level, by showing the legislative background and examples found in foreign countries that employ a safety assessment system and a "positive list" system for agricultural chemicals and the like.

Regarding the present issue, a request for a health impact assessment of food will be made to the Food Safety Commission pursuant to the provisions of Article 23, Paragraph 1 of the Food Safety Basic Law.

I. Regarding legislative background, etc.

Article 11, Paragraph 3 of the revised Food Sanitation Law

Food[6] in which residues of any agricultural chemicals[1] (meaning agricultural chemicals stipulated in Article 1-2, Paragraph 1 of the Agricultural Chemicals Control Law (Law No.82 of 1948); hereinafter the same applies in the following article), materials added to, mixed in, soaked into or otherwise used in feed (meaning feed specified in Article 2, Paragraph 2 of the Law for Safety Assurance and Quality Improvement of Animal Feed (Law No.35 of 1953))[2] for any of the purposes specified in the Ministry of Agriculture, Forestry and Fisheries Ordinance issued pursuant to Article 2, Paragraph 3 of the same law, or substances that are ingredients of medical drugs for use in animals[3] specified in Article 2, Paragraph 1 of the Pharmaceutical Affairs Law (including substances formed by chemical changes of such substances, and excluding substances to be determined by the Minister of Health, Labour and Welfare as those that apparently have no potential to cause damage to human health[4]) are found at levels above the level to be determined by the Minister of Health, Labour and Welfare, at the Pharmaceutical Affairs and Food Sanitation Council's advice, as that having no potential to cause damage to human health[5] shall not be produced, imported, processed, used, cooked or stored for sale, or sold; provided, however, that the foregoing shall not apply in cases where the specifications for food ingredients as stipulated in Paragraph 1 have been established with regard to the limits of residual levels of such substances in food of interest[7].

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

The "level to be determined by the Minister of Health, Labour and Welfare, at the Pharmaceutical Affairs and Food Sanitation Council's advice, as that having no potential to cause damage to human health" (hereinafter referred to as the "uniform limit") means the residual level of agricultural chemicals, feed additives and animal drugs (excluding substances determined by the Minister of Health, Labour and Welfare as those that apparently have no potential to cause damage to human health; hereinafter referred to as "agricultural chemicals, etc.") present in food above which the sale, etc. of food containing such residual agricultural chemicals, etc. will be restricted. However, if the specifications stipulated in Article 11, Paragraph 1 of the Food Sanitation Law have been established, such specifications will be applied instead of the aforementioned level.

In other words, the uniform limit will be applied if no residue standards have been established pursuant to the provisions of Article 11, Paragraph 1 of the Food Sanitation Law. Specifically, there are two types of cases as follows:

(1) Cases where agricultural chemicals, etc. for which there are no residue standards in any crops, etc. are found in crops, etc.

(2) Cases where agricultural chemicals, etc. for which residue standards have been established for some crops, etc., but not for the crops, etc. in question, are found in said crops, etc.

Any use of agricultural chemicals, etc. in Japan is subject to the Agricultural Chemicals Control Law and the Pharmaceutical Affairs Law, and, in principle, residue standards have been established for all crops, etc. on which use of agricultural chemicals, etc. is allowed. It is thus considered that the uniform limit will be applied to cases where agricultural chemicals, etc. that are not allowed to be used in Japan are found in crops, etc., or where agricultural chemicals, etc. that are allowed to be used on some crops and for which there are established residue standards are found in crops, etc. on which use of such agricultural chemicals, etc. is not allowed.

In addition, use of agricultural chemicals, etc. is generally regulated in foreign countries as well by laws and regulations similar to the Japanese Agricultural Chemicals Control Law, and because we have established some provisional standards by taking into consideration the Codex standards and the standards adopted by other countries (five countries (regions) including the United States, Canada, EU, Australia and New Zealand) which have established residue standards, in order to implement a positive list system, based on data such as results of toxicology studies required for scientific assessments by the JMPR (Joint FAO/WHO Meeting on Pesticide Residues) and the JECFA (Joint FAO/WHO Expert Committee on Food Additives), and because we have also established a system in which we request other countries to establish residue standards for agricultural chemicals, etc. used on crops, etc. to be imported from such countries to Japan, it is considered that the uniform limit will basically be applied to cases where use of agricultural chemicals, etc. in question is not allowed in such countries as well.

(Reference) Main types of specifications for residual agricultural chemicals, etc. found in food, established pursuant to the provisions of Article 11, Paragraph 1 of the Food Sanitation Law (including provisional standards; hereinafter referred to as "Residue Standards"):

(i) Standards established for each agricultural chemical, etc. and crop, etc.
(ii) "Non-detectable" standards established for agricultural chemicals, etc. for which an acceptable daily intake (ADI) has been considered to be incapable of being established
(iii) Standards expressed in terms of "shall not be contained", established for antibiotics and other chemically synthesized antibacterial agents (excluding cases falling under (i) above)

II. Examples found in foreign countries employing a positive list system

(1) Examples of countries employing a positive list system

	Uniform limit
Canada	0.1 ppm (under revision)
New Zealand	0.1 ppm
Germany	0.01 ppm
United States	There is no uniform limit, but the standards between 0.01 ppm and 0.1 ppm are used in practice.

(2) EU's case where a shift to a positive list system is under consideration

(Reference 1: Proposal for a Regulation of the European Parliament and of the Council on maximum residue levels of pesticides in products and animal origin, COM(2003) 117 final, 2003/0052(COD))

The EU is currently considering shifting its regulation of agricultural chemical residues to a positive list system and has proposed that, in cases where chemical residues are found in crops other than those for which such chemicals are intended (i.e. cases where chemical residues are found in crops, etc. for which there are no residue standards for such chemicals) and cases where there are no safety data (i.e. cases such as where agricultural chemicals, etc. for which there are no standards for any crops are found in crops), the level of 0.01 mg/kg should be the limit above which any chemical residues are prohibited. This is based on the following grounds: (i) zero tolerance is not achievable considering analytical techniques; (ii) this limit is sufficient for the protection of consumers' health when applied to existing agricultural chemicals (however, in exceptional cases a lower residue limit will be established); and (iii) test efficiency will have priority over detailed testing in the implementation of the system.

In the EU, the standards called "Level of Determination (LOD)" are currently applied to, among others, cases where there is no possibility that certain agricultural chemicals are found in crops, etc. because their registration has expired, or because, even though registered, they are not intended for that particular crop, and there is a demand for uniform treatment of such chemicals. This is because, under the circumstances where many agricultural chemicals currently used in member states can no longer be used due to economical reasons related to re-assessment, etc. involved in the shift to a positive list system, if food containing chemicals for which there are no standards were not

allowed to be distributed or imported within the EU and if any such chemical is found in food, then the judgment as to whether or not such food may be distributed would be made case-by-case and would thus be uncertain; and also because when considering using LOD in the regulation of agricultural chemicals, there is a lack of formally approved analytical methods which will require definitions of residual substances and analytical techniques, among others. Considering these factors, they proposed the idea of setting the limit of 0.01 mg/kg.

The person responsible for this issue at the Plant Protection Division, Health and Consumer Protection Directorate-General, European Commission commented on the uniform limit under consideration at the European Commission as follows:

(i) The potential uniform limit of 0.01 ppm is the lowest of the residue limits that have been set so far. In addition, residue limits that are severer than the uniform limit of 0.01 ppm may be set in accordance with Good Agricultural Practices (GAP).
(ii) Draft regulations are currently under consideration at the European Parliament and the European Council, and although the provisions for the uniform limit of 0.01 ppm still remain, there is a possibility that the uniform limit may be set at default LOD.
(iii) The European Commission sought advice from the Scientific Committee on Food as to whether or not the level of 0.01 ppm was appropriate for the residue limit of agricultural chemicals found in baby food, and the resulting advice was given in 1997. According to the advice, the level of 0.01 ppm is safe in most cases of babies, the most susceptible group among the population.
(iv) As the result of assessment, the Scientific Committee on Food concluded that: if a baby's food intake is estimated to be 48 g/kg bw/day, the potential residue limit of 0.01 ppm on which the European Committee had sought advice might result in a daily intake in excess of the ADI if it is set at or below 0.0005 mg/kg bw/day; and, although the level of 0.01 ppm was not based on toxicological assessment, if the ADI is set above 0.0005 mg/kg bw/day, baby food in which chemicals are found at levels above 0.01 ppm does not necessarily pose health risks to babies.

(3) New Zealand's case where a positive list system is employed

In New Zealand, Maximum Residue Limits (MRLs) of agricultural compounds are specified in the Minister for Food Safety's notice issued under the Food Act of the same country, which notice states that these limits are applied to agricultural compounds other than those for which there are standards for different foods and to agricultural compounds for which there are standards for different foods but not for that particular food, and that a person may sell a food containing residues of an agricultural compound not exceeding 0.1 ppm.

The uniform limit was established in 1987 by taking Canada's case into consideration and was based on the following grounds: (i) the level of 0.1 ppm was generally considered to be the limit of detection at that time, and it was considered efficient to establish a uniform limit instead of setting various detection limits of different analytical methods as residue limits; and (ii) it had been shown, from the toxicological assessment of all agricultural compounds used at that time and the exposure assessment based on TMDI (theoretical maximum daily intake), that levels at or below 0.1 ppm had no effect

of long-term exposure.

Today more sensitive analytical methods have been developed, but New Zealand still maintains the uniform limit of 0.1 ppm in order to allow for flexible chemical use for producers of minor crops that are not listed in agricultural chemical labels. However, as the agricultural chemical residue limit is a means to assure Good Agricultural Practices (GAP), the country has adopted a policy that allows setting of appropriate residue limits in accordance with GAP, including those below 0.1 ppm.

III. Regarding safety of food containing residual agricultural chemicals, etc. covered by the uniform limit

As described above, agricultural chemicals, etc. to be subject to the uniform limit will include those for which there are no Residue Standards, i.e. those for which a separate risk assessment based on safety test results, etc. has not been performed. It is thus necessary to assess the safety of such agricultural chemicals, etc. based on assessments of similar chemicals for which risk assessments of agricultural chemicals, etc. have been performed.

1. Safety assessment of agricultural chemicals, etc. for which a separate risk assessment based on safety test results, etc. has not been performed

(1) Although not of agricultural chemicals, etc., examples of cases where an acceptable exposure limit was assessed of chemicals for which a separate risk assessment based on safety test results, etc. had not been performed are as follows:

(i) Assessment of flavors by JECFA (Joint FAO/WHO Expert Committee on Food Additives)
(Reference 2: Evaluation of Certain Food Additives and Contaminants – Forty-forth report of the Joint FAO/WHO Expert Consultation on Food Additives, 1995)

In the safety assessment of flavors, the acceptable exposure threshold has been set at 1.5 μg/day for chemicals, whether carcinogenic or not, for which a sufficient toxicological assessment has not been performed.

Based on the facts that many flavors are common food ingredients, that the amounts of flavors used in food are limited, and that flavors can be divided into groups based on their chemical structures, the JECFA has recommended that judgments be made using a decision tree, by utilizing structure-activity relationships and using data on metabolism, intakes and toxicology, in order to promptly conduct safety assessments of flavors in general, including those with limited toxicology data.

Using the decision tree, checks are done as to: (i) classification into the structural classes; (ii) the prospect of being metabolized into safe products; (iii) whether or not the condition of use is within the acceptable exposure threshold for the relevant structural class; (iv) whether or not the substance or its metabolites are biological components; (v) whether or not the substance is sufficiently safe in the condition of use intended in the context of the no observable effect level (NOEL);

and (vi) whether or not the actual amounts consumed are within 1.5 μg/day. Substances judged to be within the threshold are considered free from safety concerns, and those that could not be judged are considered to require additional data.

(ii) Assessment of indirect additives by FDA (U.S. Food and Drug Administration) (Reference 3: Food Additives: Threshold of Regulation for Substances Used in Food Contact Articles; Final Rule, 21 CFR Part 5, et al, 1995)

In the regulation of indirect food additives, such as substances dissolved from containers, the acceptable exposure threshold has been set at 1.5 μg/day, whether carcinogenic substances or not.

Specifically, it is stated that, of substances used in containers, packages or tools, those whose ingredients are or may be incorporated into food shall be considered to be free from other health and safety concerns and be excluded from regulations for food additives, if it has been established or expected that their levels in food upon their use are at or below 0.5 ppb (corresponding to the exposure level through food of 1.5 μg/person/day or below (if 1,500 g/person/day of solid food and the same amount of liquid food is ingested)).

(iii) Other references

The concept of the Threshold of Toxicological Concern (TTC), on which part of the assessments described in (i) and (ii) above are based, is summarized in references such as reference 4: Kroes, R. et al, Threshold of Toxicological Concern for Chemical Substances Present in the Diet: A practical tool for assessing the need for toxicity testing. Food and Chemical Toxicology, Vol. 38, No.2-3, pp255-312, 2000.

The above analysis was performed in order to check whether or not the TTC of 1.5 μg/person/day, which had been calculated from carcinogenic endpoints derived from the chemical database created by Dr. Munro et al. in 1996, sufficiently low in terms of toxicological parameters other than carcinogenicity by assessing carcinogenic and non-carcinogenic toxicological parameters (neurotoxicity, immunotoxicity, developmental toxicity, etc.) based on the same chemical database.

The analysis found that all of the non-carcinogenic endpoints had higher sensitivities than the carcinogenic endpoints, and concluded that the TTC of 1.5 μg/person/day based on the carcinogenic endpoints allowed for appropriate safe margin and that the consumption of chemicals present in food at levels below this threshold did not pose particular risks. The carcinogenic endpoints had been established using as a criterion the lifetime carcinogenic risk of not exceeding 1×10^{-6}.

Other references include the following:

(Reference 5: Munro, I.C., et al., A Procedure for the Safety Evaluation of Flavoring Substances., Food Chemical Toxicology Vol.37, pp 207-232 (1999))
(Reference 6: Kroes, R., Kozianowski., G., Threshold of toxicological concern (TTC) in food safety assessment. Toxicology Letters Vol.127:pp 43-46 (2002))
(Reference 7: Kroes, R., et al., Structure-based thresholds of toxicological concern (TTC): guidance for application to substances present at low levels in the diet. Food Chemical Toxicology Vol.42, pp 65-83 (2004))

(Reference) Lifetime risk of leading causes of death in Japan (excerpts from a report of the Central Environment Council)

Traffic accidents	6×10^{-3} (six one thousandth)
Disasters by water	7×10^{-4} (seven ten thousandth)
Fire	6×10^{-4} (six ten thousandth)
Natural disasters	3×10^{-5} (three one hundred thousandth)
Lightning	2×10^{-6} (two one millionth)

(2) Safety assessments of agricultural chemicals, etc. for which a safety risk assessment has been performed

Of the ADIs for 240 agricultural chemicals assessed in Japan for the establishment of the standards for agricultural chemical residues in food and those for 224 agricultural chemicals assessed through an international process by the JMPR, low ADIs have been found for the following chemicals:

Name of agricultural chemical	ADI (μg/kg/day)
Aldrin	0.1
Dieldrin	0.1
Quinalphos	0.11
Terbufos	0.16
Endrin	0.2
Fipronil	0.2

Note: Registrations of Aldrin, Dieldrin and Endrin have been expired.

Of the ADIs for 29 animal drugs assessed in Japan for the establishment of the standards for animal drug residues in food and those for 54 animal drugs assessed through an international process by the JECFA, low ADIs have been found for the following animal drugs:

Name of animal drug	ADI (μg/kg/day)
Clenbuterol	0.004
Dexamethasone	0.015
Trenbolone acetate	0.02
Melengesterol acetate	0.03
Estradiol-17β	0.05

2. Exposure assessment of agricultural chemicals, etc.

If it is assumed that a flavor or an indirect additive is present in a food at the acceptable exposure threshold used in the assessment of flavors by the JECFA and the assessment of indirect additives by the U.S. FDA (1.5 μg/day) described in 1. (1) (i) and (ii) above, respectively, converted to an acceptable intake for a 50 kg person (0.03 μg/kg/day), and, among substances listed in 1. (2) above, the agricultural chemical and the animal drug that has the lowest acceptable intake in each category (aldrin and clenbuterol, respectively) are each present in a food at the level of 0.01 ppm (10 ppb), then the amounts of such foods required for reaching the acceptable exposure limit for the relevant agricultural chemicals, etc. can be calculated as follows:

	0.1 μg/kg/day	0.03 μg/kg/day	0.004 μg/kg/day
Acceptable intake	The lowest of all levels set by Japan and JMPR for agricultural chemicals (aldrin)	Toxicological threshold for flavors (JECFA) and additives (FDA) (corresponding to 1.5 μg/day)	The lowest of all levels set by Japan and JECFA for animal drugs (clenbuterol)
Amount of food required for reaching acceptable exposure limit assuming the presence at 0.01 ppm (10 ppb)	0.1 μg/kg/day × 50 kg÷10 ppb (μg/kg) = 0.5 kg (500 g)	0.03 μg/kg/day × 50 kg÷10 ppb = 0.15 kg (150 g)	0.004 μg/kg/day × 50 kg÷10 ppb = 0.02 kg (20 g)

For all foods except rice, daily food intakes (national average) found by national nutrition surveys are below 150 g, which is the amount of food corresponding to the toxicological threshold for flavors (JECFA) and additives (FDA).

(Daily intakes found by the national nutrition survey (1998-2000))

Agricultural or livestock product	Daily intake (national average)
Rice	190 g
Wheat	118 g
Soybeans	56 g
Japanese radish	47 g
Mandarin oranges	46 g
Milk and milk products	143 g
Pork and processed pork products	36 g
Beef and processed beef products	21 g
Chicken eggs and processed chicken egg products	20 g

IV. Regarding the establishment of the uniform limit (draft)

Regarding the establishment of the uniform limit, a request for a health impact assessment of food shall be made to the Food Safety Commission pursuant to the provisions of Article 23, Paragraph 1 of the Food Safety Basic Law, but factors under consideration at this point can be summarized as follows:

(1) In general, agricultural chemicals, etc. used in and outside Japan are assessed for toxicity, etc. prior to use and then used under the regulation of crops on which such chemicals may be used, the amount of use, etc. In addition, application methods and residue standards based on toxicological assessments are established for crops, etc. on which such chemicals will be used. Therefore, the uniform limit will basically be applied to cases where agricultural chemicals, etc. may found in agricultural products, etc. on which use of such chemicals, etc. is not allowed.

(2) Although the safety assessments by the JECFA and U.S. FDA are those of flavors, indirect additives and the like, they are considered applicable to agricultural chemicals, etc. from the viewpoint of chemical safety. It is thus considered reasonable to a certain extent to establish the acceptable exposure threshold of 1.5 μg/day. This acceptable intake is defined as the level that assures safety even if a person ingests relevant chemicals at such level for life.

(3) Of the agricultural chemicals and animal drugs (419 agricultural chemicals, etc.) that have been assessed in Japan or through international processes by the JMPR and JECFA, only three animal drugs (0.7% of all agricultural chemicals, etc.) have been assigned acceptable daily intakes (ADIs) below 0.03 μg/kg/day, which is an ADI for a 50 kg person derived from the acceptable exposure limit of 1.5 μg/day as described in (2) above. This is considered another reason for considering the setting of the acceptable intake at 1.5 μg/day appropriate.

In addition, in cases of agricultural chemicals, etc. which are assigned an ADI below 0.03 μg/kg/day, if no limit is to be set for certain agricultural products, such chemicals could be regulated by establishing analytical methods for each agricultural chemical, etc. and setting a “Non-detectable” standard, similarly to the agricultural chemicals, etc. for which ADIs could not have been established due to such reasons as carcinogenicity.

(4) The ingestion of 150 g of food containing residual agricultural chemicals, etc. at the level of 0.01 ppm would result in the exposure to such chemicals at the level of 1.5 μg/day; however, considering that an acceptable intake is a level that can assure safety even if a person ingests relevant chemicals at such level for life, that Japanese people’s actual food intakes do not exceed 150 g with the only exception of rice, and that Japan is almost self-sufficient in rice and the use of agricultural chemicals, etc. in Japan has strictly been regulated by such means as the revision of the Agricultural Chemicals Control Law, it is considered impossible for a person’s intake of agricultural chemicals, etc. to exceed the acceptable exposure limit of 1.5 μg/day for life.

(5) Other countries that have introduced a positive list system for agricultural chemicals, etc. have set the uniform limit at levels between 0.01 ppm and 0.1 ppm. In addition, the EU, which is considering the introduction of a positive list system for agricultural chemicals, has proposed the possible uniform level of 0.01 ppm.

(Reference)

(1) Regarding the view that a limit should be established for each agricultural chemical or that a uniform limit should be established separately for known and unknown chemicals

Although any uniform limit(s) will be established as a limit/limits that can ensure safety even if a person ingests relevant chemicals for life, it is considered appropriate to establish one uniform limit for the following reasons, among others:

(i) The uniform limit will in principle be applied to agricultural and livestock products on which use of agricultural chemicals, etc. is not allowed in and outside Japan and which thus should not basically contain residual chemicals.
(ii) Other countries have also established one uniform limit for different agricultural chemicals as well as for known and unknown chemicals.

(2) Regarding cases where a residue limit below the uniform limit will be set

1. Residue standards for agricultural chemicals, etc. are based on residual levels found as a result of studies conducted using proper application methods for such chemicals in agricultural and livestock products on which use of such chemicals is allowed. Therefore, the actual situation, such as the levels of residual agricultural chemicals, etc. found in agricultural and livestock products, is different depending on the actual application methods and other factors.

2. Therefore, in cases such as where the residual levels of chemicals found in agricultural and livestock products are extremely low if such chemicals are used properly, lower limits are to be established both in and outside Japan from the viewpoint of the assurance of proper use, and residue standards below the uniform limit may be established. In other words, proper use of chemicals is one of the premises of the regulation of residual agricultural chemicals, etc., whose purpose is different from that of the uniform limit to be applied to agricultural chemicals, etc. whose use is not allowed.

(Reference) Regarding current limits in Japan

Our review of approximately 9,000 established residue limits for agricultural chemicals found in foods in Japan has found that the lowest limit is 0.005 ppm (9 levels for 2 agricultural chemicals), followed by 0.01 ppm.

Limit (ppm)	Number of limits	Percentage in all limits
0.005	9	0.010%
≤ 0.01	147	1.63%
≤ 0.05	1,367	15.2%
≤ 0.1	2,688	29.8%
≤ 1.0	6,213	68.9%

In addition, slightly more than 70% of the current established limits for agricultural chemicals are above 0.1 ppm. The detection limits for analytical methods for such residual limits have been established at levels of approximately between one fifth and one tenth of the respective limits.

On the other hand, our review of the provisional standards for 647 agricultural chemicals, etc. to be subject to a positive list system (the first draft) published in October 2003 has found that 293 out of a total of 39,035 limits (0.8% of all) have been set below 0.01 ppm and that the lowest limit is 0.00003 ppm (0.03 ppb (μg/kg)). These limits have been established for cases where residual animal drugs such as hormones are found in livestock products and where residual agricultural chemicals, etc. are found in livestock products via feed, etc.

Limit (ppm)	Number of limits	Percentage in all limits
ND (non-detectable)	90	0.2%
< 0.0005	24	0.1%
≥ 0.0005 , < 0.001	36	0.1%
≥ 0.001 , < 0.005	71	0.2%
≥ 0.005 , < 0.01	72	0.2%
Subtotal	293	0.8%
Total	39,035	100%

(3) Regarding application of the uniform limit to processed food

Because the uniform limit will be applied to crops, etc. on which use of agricultural chemicals, etc. is not allowed, and because whether or not a processed food is subject to the residue limit will be determined based on the limits for its ingredients, a processed food containing any residual agricultural chemicals, etc. will be subject to the uniform limit if any of its ingredients is subject to said limit.