

**ASEAN PRINCIPLES AND CRITERIA FOR THE ESTABLISHMENT OF MAXIMUM
LEVEL FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED**

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Foreword

The ASEAN Principles and Criteria for the Establishment of Maximum Level for Contaminants and Toxins in Food and Feed is based on the *GENERAL STANDARD FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED (CODEX STAN 193-1995)* Adopted in 1995 Revised in 1997, 2006, 2008, 2009 Amended in 2010, 2012, 2013, 2014, 2015.

The development of this document has been led by the Prepared Foodstuffs Product Working Group established by the ASEAN Consultative Committee on Standards and Quality. The document has been prepared in consultation with the Agriculture Working Groups for Crops, Fisheries and Livestock. The ASEAN Principles and Criteria for the Establishment of Maximum Level for Contaminants in Food and Feed provides a basis for the establishment and maintenance of harmonised Maximum Levels (MLs) for contaminants in food and feed. This document is recommended to be used by other relevant sectoral bodies in ASEAN for the development of MLs for contaminants and toxins in food and feed.

This document adopts the principles and criteria for establishing contaminants and toxins in food and feed from CODEX STAN 193 1995. However the MLs and the associated sampling plans from CODEX STAN 193-1995 are not included in the ASEAN document. Relevant ASEAN Bodies are provided with guidance for the establishment of harmonised MLs in the format as prescribed in this document and based on the principles and criteria as defined. The document makes reference to the ASEAN Risk Assessment Centre (ARAC) established by the ASEAN Health Ministers decision in 2015 in order that the results of risk assessments conducted by ARAC provide information for the establishment of MLs for ASEAN and supplement recommendations from Joint FAO/WHO Expert Committee on Food Additives (JECFA). The format of the CODEX STAN 193-1995 has been adopted for documenting the ASEAN Standards Contaminants and Toxins in Food and Feed. References to the relevant ASEAN standards and guidelines on best practices for agriculture and manufacturing have been incorporated whenever these are available.

This document is an adoption of the *General Standard for Contaminants and Toxins in Food and Feed (CODEX STAN 193-1995)* with the following modification:

Clause / Sub-clause	Modification
1.1 Scope	Replace: “STANDARD” with “DOCUMENT”.
1.2.2 Contaminant	
1.2.4 Maximum level and related terms	Add: <u>and toxins</u>
1.3 Principles regarding Contaminants and Toxins in Food and Feed	Add: <u>and toxins</u>
1.3.1 General	Add: <u>and toxins</u> in the second para of the clause Replace : <u>GSCTFF</u> with <u>ASEAN Principles and Criteria for the Establishment of Maximum Levels for Contaminants and Toxins in Food and Feed</u>

	<p>Add : <u>in ASEAN</u> in the last sentence of the clause</p> <p>Delete : <u>internationally</u> in the last sentence of the clause</p>
1.3.2 Principles for establishing maximum levels in food and feed	<p>Replace : <u>(Section IV of the Procedural Manual)</u> with <u>(Annex III)</u> in the first para of the clause</p> <p>Add : <u>ASEAN</u> in the first sentence of the third para of the clause</p> <p>Replace : <u>worldwide</u> with <u>all ASEAN Member States</u> in the second sentence of second para of the clause</p> <p>Add : <u>ASEAN and/or</u> in the second sentence of second para of the clause</p>
1.3.3 Specific criteria	<p>Replace : <u>General Standard for Contaminants and Toxins in Food and Feed</u> with <u>ASEAN Principles and Criteria for the Establishment of Maximum Level for Contaminants and Toxins in Food and Feed</u></p>
1.4 Format of the General Standard for Contaminants in Food and Feed	<p>Replace : <u>General Standard for Contaminants in Food and Feed</u> with <u>ASEAN Standards for Contaminants and Toxins in Food and Feed</u> in the title of the clause</p>
Annex I Criteria for the Establishment of Maximum Levels in Food and Feed	<p>Add: <u>and toxins</u> in the bullet number 8</p>
Toxicological information	<p>Replace: <u>Codex Members</u> with <u>ASEAN Member States</u> in the second sentence of first para of the clause.</p> <p>Add : <u>ARAC or</u> in the second sentence of the first para of the clause</p> <p>Add: <u>Where needed, risk assessment carried out by other regions or countries should also be referred</u> in the last sentence of the first para of the clause.</p>
Risk assessment and risk management considerations	<p>Add: <u>taking into consideration scientific opinion based on risk assessment conducted by JECFA and/or ARAC</u> in the clause.</p>
Establishment of maximum level	<p>Replace : <u>(e.g by using full format as provided for schedule 1 and to mention in the box of maximum level “not necessary”)</u> with <u>(e.g by mentioning “not necessary” in the box of maximum level)</u> in first para of the clause</p> <p>Add : <u>ASEAN and/or</u> in the first bullet of second para of the clause</p>

	<p>Replace : <u>(Section IV of the Procedural Manual)</u> with <u>(Annex III)</u> in the second bullet of second para of the clause</p> <p>Add : <u>and where necessary, to also take into consideration available data in the ASEAN Food Consumption Database</u> at the end of the second bullet</p> <p>Replace : <u>various countries</u> with <u>“ASEAN Member States”</u> in the fourth bullet</p> <p>Add : <u>ASEAN and/or</u> in the fourth bullet</p>
<p>Procedure for risk assessment in relation to (proposed) MLs</p>	<p>Replace: <u>Codex MLs</u> with <u>ASEAN MLs</u> in the first sentence of first para of the clause</p> <p>Replace : <u>(Section IV of the Procedural Manual)</u> with <u>(Annex III)</u> in the fifth and seventh sentence of para three of the clause</p> <p>Replace: <u>Governments</u> with <u>ASEAN Member States</u> and <u>Codex MLs</u> with <u>ASEAN MLs</u> in the last sentence of para three of the clause.</p>
<p>Annex II</p>	<p>Replace : <u>GSCTFF</u> with <u>ASEAN Standards for Contaminants and Toxins in Food and Feed</u> in the title of the Annex</p> <p>Add : <u>ARAC or</u> in the third bullet</p> <p>Replace : <u>Codex</u> with <u>ASEAN in the last bullet</u></p> <p>Delete : <u>Schedule on Maximum and Guideline Levels for Contaminants and Toxins in Food (Index of Contaminant)</u></p>
	<p>Add : <u>Policy of the Codex Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups</u> as Annex III to the document</p>

March 16, 2016

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ASEAN PRINCIPLES AND CRITERIA FOR CONTAMINANTS AND TOXINS IN FOOD AND FEED

1.1 SCOPE

This document contains the main principles which are recommended by the Codex Alimentarius in dealing with contaminants and toxins in food and feed to be applied to commodities moving in intra-ASEAN and international trade.

This document includes only maximum levels of contaminants and natural toxicants in feed in cases where the contaminant in feed can be transferred to food of animal origin and can be relevant for public health.

1.2 DEFINITION OF TERMS

1.2.1 General

The definitions as mentioned in the Procedural Manual of the Codex Alimentarius Commission, are applicable. When reference is made to foods, this also applies to animal feed, in those cases where this is appropriate.

1.2.2 Contaminant

The definition from the Codex Alimentarius for a contaminant is adopted and is as follows:

“Any substance not intentionally added to food or feed for food producing animals, which is present in such food or feed as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter”.

This document applies to any substance that meets the terms of the Codex definition for a contaminant, including contaminants in feed for food-producing animals, except:

- 1) Contaminants having only food and feed quality significance (e.g. copper), but no public health significance, in the food(s) given that the standards elaborated within the Committee on Contaminants in Foods (CCCF) has the objective to protect public health.
- 2) Pesticide residues, as defined by the Codex definition that are within the terms of reference of the Committee on Pesticide Residues (CCPR).
- 3) Residues of veterinary drugs, as defined by the Codex definition, and residues of feed additives (*), that are within the terms of reference of the Committee on Residues of Veterinary Drugs in Foods (CCRVDF).
- 4) Microbial toxins, such as botulinum toxin and staphylococcus enterotoxin, and microorganisms that are within the terms of reference of the Committee on Food Hygiene (CCFH).
- 5) Residues of processing aids that are within the terms of reference of the Committee on Food Additives (CCFA) (**).

(*) Feed additives as defined in the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004): “Any intentionally added ingredient not normally consumed as feed by itself, whether or not it has nutritional value, which affects the characteristics of feed or animal products.

Residues of feed additives include the parent compounds and/or their metabolites in any edible portion of the animal product, and include residues of associated impurities of the feed additive concerned.

(**) Processing aids are any substance or material, not including apparatus or utensils, and not consumed as a food ingredient by itself, intentionally used in the processing of raw materials, foods or its ingredients, to fulfil a certain technological purpose during treatment or processing and which may result in the non-intentional but unavoidable presence of residues or derivatives in the final product.

1.2.3 Natural toxins included in this document

The Codex definition of a contaminant implicitly includes naturally occurring toxicants including toxic metabolites of certain microfungi that are not intentionally added to food and feed (mycotoxins).

Toxins that are produced by algae and that may be accumulated in edible aquatic organisms such as shellfish (phycotoxins) are also included in this document. Mycotoxins and phycotoxins are both subclasses of contaminants.

Endogenous natural toxicants, such as e.g. solanine in potatoes, that are implicit constituents of food and feed resulting from a genus, species or strain ordinarily producing hazardous levels of a toxic metabolite(s), i.e. phytotoxins are not generally considered within the scope of this document. They are, however, within the terms of reference of CCCF and will be dealt with on a case-by-case basis.

1.2.4 Maximum level and related terms¹

The ASEAN maximum level (ML) for a contaminant and toxin in a food or feed commodity is the maximum concentration of that substance recommended by the relevant ASEAN bodies to be legally permitted in that commodity.

1.3 PRINCIPLES REGARDING CONTAMINANTS AND TOXINS IN FOOD AND FEED

1.3.1 General

Contamination of food and feed may pose a risk to human (and/or animal health). Moreover in some cases they may also have a negative impact on the quality of the food or feed. Food and feed can become contaminated by various causes and processes.

Contaminant and toxin levels in food and feed shall be as low as reasonably achievable through best practice such as Good Agricultural Practice (GAP) and Good Manufacturing Practice (GMP) following an appropriate risk assessment. The following actions may serve to prevent or to reduce contamination of feed and food² :

- Preventing food and feed contamination at the source, e.g. by reducing environmental pollution.
- Applying appropriate technology control measure(s) in food and feed production, manufacture, processing, preparation, treatment, packing, packaging, transport or holding.
- Applying measures aimed at decontamination of contaminated feed or food and measures to prevent contaminated feed or food to be marketed for consumption.

¹ For the contaminants methylmercury, radionuclides, acrylonitrile, and vinylchloride monomer a Codex guideline level (GL) has been established.

A Codex GL is the maximum level of a substance in a food and feed commodity which is recommended by the Codex Alimentarius Commission to be acceptable for commodities moving in international trade. When the GL is exceeded, governments should decide whether and under what circumstances the food should be distributed within their territory or jurisdiction. Because the Commission has decided that the preferred format of a Codex Standard in food or feed is a maximum level, the present existing or proposed GL shall be reviewed for their possible conversion to a maximum level after a risk assessment performed by JECFA, if appropriate”

² In addition, reference is made to the Code of Practice for source Directed measures to reduce contamination of food with chemicals (CAC/RCP 49-2001) and the Code of Practice on Good Animal Feeding (CAC/RCP 54-2004).

To ensure that adequate action is taken to reduce contamination of food and feed a Code of Practice shall be elaborated comprising source related measures and Good Manufacturing Practice as well as Good Agricultural Practice and Good Aquaculture Practice in relation to the specific contamination problem.

The degree of contamination of food and feed and the effect of actions to reduce contamination shall be assessed by monitoring, survey programs and more specialized research programs, where necessary.

When there are indications that health hazards may be involved with consumption of food that is contaminated, it is necessary that a risk assessment should be undertaken. When health concerns can be substantiated, a risk management measure must be applied, based on a thorough evaluation of the situation and consideration of a range of risk management options. Depending on the assessment of the problems and the possible solutions, it may be necessary to establish MLs or other measures to control the contamination of food and feed. In special cases, specific advice on dietary recommendations may also have to be considered to complement other regulatory measures, when the measures are not sufficiently adequate to protect public health and safety.

National measures regarding food and feed contamination should avoid the creation of unnecessary barriers to ASEAN and/or international trade in food and feed commodities. The purpose of the ASEAN Principles and Criteria for the Establishment of Maximum Level for Contaminants and Toxins in Food and Feed is to provide guidance about possible approaches to eliminate or reduce the contamination problem and to promote harmonisation in ASEAN through recommendations, which in turn may prevent trade barriers and disputes.

For all contaminants, which may be present in more than one feed or food item, a broad approach shall be applied, taking into account all relevant information that is available, for the assessing of risks and for developing recommendations and control measures, including the setting of maximum levels.

1.3.2 Principles for establishing maximum levels in food and feed

MLs shall only be set for food in which the contaminant may be found in amounts that are significant for the total exposure of the consumer, taking into consideration the Policy of the Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups (Annex III).

The ASEAN maximum levels shall be set in such a way that the consumer is adequately protected. At the same time the other legitimate factors need to be considered. This will be performed in accordance with the *Working Principles for Risk Analysis for Food Safety for Application by Governments (CODEX)*.

The principles of Good Manufacturing Practice and Good Agricultural Practice³ as defined by Codex and ASEAN shall be used. Maximum levels shall be based on sound scientific principles leading to levels, which are acceptable in all ASEAN Member States, so that there is no unjustified barrier to ASEAN and/or international trade. MLs shall be clearly defined with respect to status and intended use.

1.3.3 Specific criteria

The following criteria should (not preventing the use of other relevant criteria) be considered when developing MLs and/or other measures in connection with the *ASEAN Principles and Criteria for the Establishment of Maximum Level for Contaminants and Toxins in Food and Feed* (Further details about these criteria are given in Annex I).

Toxicological information

³ The relevant ASEAN standards on GAP as referenced in section 1.3.1 refer.

- identification of the toxic substance(s);
- metabolism by humans and animals, as appropriate;
- toxicokinetics and toxicodynamics including information on possible carry-over of the toxic substance from feed to edible animal tissue/products;
- information about acute and long term toxicity and other relevant toxicity data; and
- integrated toxicological expert advice regarding the acceptability and safety of intake levels of contaminants, including information on any population groups which are especially vulnerable.

Analytical data

- validated qualitative and quantitative data on representative samples; and
- appropriate sampling procedures.

Intake data

- presence in food of dietary significance for the contaminant;
- presence in food that are widely consumed;
- presence in feed and feed components;
- food intake data for average and most exposed/high consumer groups;
- results from total diet studies;
- calculated contaminant intake data from food consumption models;
- data on intake by susceptible groups; and
- data on intake by food producing animals.

Technological considerations

- Information about contamination processes, technological possibilities, production and manufacturing practices and economic aspects related to contaminant level management and control.

Risk assessment and risk management considerations (cf. Working Principles for Risk Analysis for Food Safety for Application by Governments (Codex)).

- risk management options and considerations;
- consideration of possible maximum levels in food and feed based on the criteria mentioned above; and
- consideration of alternative solutions.

1.4 Annex II Format of the ASEAN Standards for Contaminants and Toxins in Food and Feed

A full description of the format is provided in Annex II.

CRITERIA FOR THE ESTABLISHMENT OF MAXIMUM LEVELS IN FOOD AND FEED

Introduction

In this Annex criteria are mentioned regarding information, which is considered necessary for evaluating contaminant problems in food and feed and for the establishment of maximum levels. The criteria mentioned here are elaborated in more detail than in Section 1.3.3 of the Preamble. Only those aspects that need further clarification are detailed; however, criteria or aspects that are not specifically detailed here should not be ruled out in the evaluation process.

Toxicological information

Integrated toxicological expert advice regarding a safe/tolerable intake level of a contaminant is essential when decisions about maximum levels in foods are considered. A recommendation from ARAC or the Joint FAO/WHO Expert Committee on Food Additives (JECFA) regarding the maximum allowable or tolerable intake, based on a full evaluation of an adequate toxicological database, should be the main basis for decisions by ASEAN Member States. In urgent cases, it may be possible to rely on less developed evaluations from ARAC or JECFA or on toxicological expert advice from other international or national bodies. Where needed, risk assessment carried out by other regions or countries should also be referenced.

When toxicological information is presented in relation to proposals for maximum levels for contaminants in food and feed, information about the following aspects is desirable:

- identification of the toxic substance(s);
- metabolism in humans and animals, as appropriate;
- toxicokinetics and toxicodynamics including information on possible carry-over of the contaminant from feed to edible animal tissue/products;
- information about acute and long term toxicity in animals and humans, including epidemiological
- data on humans and other relevant toxicity data;
- conclusions and advice of toxicological expert(s) (groups), with references, including information on especially vulnerable population groups or animals.

Analytical data

Validated qualitative and quantitative analytical data on representative samples should be supplied. Information on the analytical and sampling methods used and on the validation of the results is desirable. A statement on the representativeness of the samples for the contamination of the product in general (e.g. on a national basis) should be added. The portion of the commodity that was analyzed and to which the contaminant content is related should be clearly stated and preferably should be equivalent to the definition of the commodity for this purpose or to existing related contaminant regulation.

Information on appropriate sampling procedures should be supplied. Special attention to this aspect is necessary in the case of contaminants that may not be homogeneously distributed in the product (e.g. mycotoxins in some commodities).

Intake data

It is desirable to have information about the contaminant concentrations in those foods or food groups that (together) are responsible for at least half and preferably 80% or more of the total dietary intake of the contaminant, both for consumers with average and high consumption patterns.

Information about the presence of the contaminant in foods that are widely consumed (staple foods) is desirable in order to be able to make a satisfactory assessment of the contaminant intake and of risks associated with food trade.

For the contaminants, which can be present in food of animal origin as a consequence of the carry over from feed, information about the presence of the contaminant in the feed and feed components should be given. Furthermore the intake of contaminants by the different food producing animals and the resulting levels of the contaminant in the food of animal origin should be estimated.

Food consumption data for average, most exposed (high consumers) and susceptible consumer groups are desirable for evaluations of (potential) intake of contaminants. This problem, however, has to be addressed differently on a national and on an international scale. It is therefore important to have information about both average and high consumption patterns regarding a wide variety of foodstuffs, so that for every contaminant the most exposed consumer groups may be identified for every contaminant. Detailed information about high consumption patterns is desirable, both regarding group identification criteria (e.g. age or sex differences, vegetarian or regional dietary customs, etc.) and statistical aspects.

Dietary intake of contaminants: Reference is made to the Guidelines for the Study of Dietary Intake of Chemical Contaminants (WHO, 1985 - http://whqlibdoc.who.int/offset/WHO_OFFSET_87.pdf). It is important to supply all relevant details, such as the type of study (duplicate diet, total diet or market basket study, selective study), and statistical details. Calculated contaminant intake data from food consumption models may also be useful. When results about food groups and about effects of preparation and cooking etc. are available, these should also be supplied.

Technological considerations

Information about the source of the contaminant and the way in which the food and feed is contaminated, possibly including information, if available, about contamination being present in parts only of the product, is essential for assessing the possibilities to control the contamination process and to be able to guarantee a desired product safety and quality. Where possible Source-related measures should be proposed. **Good Manufacturing Practice (GMP) and/or Good Agricultural Practice (GAP)** should also be adapted to control a contamination problem. When this is possible, maximum levels may be based on GMP or GAP considerations to establish at a level as low as reasonably achievable and necessary to protect the consumer. Considerations regarding the technological possibilities to control a contamination problem, e.g. by cleaning, should also be taken into account when a primary risk assessment model (theoretical maximum daily intake) shows possible intakes exceeding the toxicological reference value. In such a case the possibilities of lower contamination levels need further careful examination. Then a detailed study about all the aspects involved is necessary, so that decisions about maximum levels can be based on a thorough evaluation of both the public health arguments and the potential problem with complying with the proposed standard.

Risk assessment and risk management considerations

Risk assessment and risk management are conducted in accordance with the *Working Principles for Risk Analysis for Food Safety for Application by Governments* (CAC/GL 62-2007) taking into consideration scientific opinion based on risk assessment conducted by JECFA and/or ARAC.

Establishment of maximum levels

In case it is decided that, on the basis of the outcome of the risk assessment, there is no need to establish a maximum level to protect public health as the level of hazard/risk does not pose a public health problem, this should be communicated in a transparent and accessible (e.g by mentioning “not necessary” in the box of maximum level)

The ***establishment of maximum levels (MLs) of contaminants and toxins in food and feed*** involves several principles, some of which have already been mentioned in this Preamble. Briefly stated, the following criteria will help in maintaining a consistent policy in this matter:

- MLs should be set only for those contaminants that present both a significant risk to public health and a known or expected problem in ASEAN and/or international trade.
- MLs should be set only for food that is significant for the total exposure of the consumer to the contaminant. When identifying the significance of certain foods in the total exposure to the contaminant, the criteria contained in Section 3 of the Policy of the Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups (Annex III) should be consulted and where necessary to also take into consideration available data in the ASEAN Food Consumption Database.
- MLs should be set as low as reasonably achievable and at levels necessary to protect the consumer. Providing it is acceptable from the toxicological point of view, MLs should be set at a level which is (slightly) higher than the normal range of variation in levels in food and feed that are produced with current adequate technological methods, in order to avoid undue disruptions of food and feed production and trade. Where possible, MLs should be based on GMP and/or GAP considerations in which the health concerns have been incorporated as a guiding principle to achieve contaminant levels as low as reasonably achievable and necessary to protect the consumer. Foods that are evidently contaminated by local situations or processing conditions that can be avoided by reasonably achievable means shall be excluded in this evaluation, unless a higher ML can be shown to be acceptable from a public health point of view and significant economic aspects are at stake.
- Proposals for MLs in products should be based on data from ASEAN Member States and sources, encompassing the main production areas/processes of those products, as far as they are engaged in ASEAN and or international trade. When there is evidence that contamination patterns are sufficiently understood and will be comparable on a global scale, more limited data may be enough.
- MLs may be set for product groups when sufficient information is available about the contamination pattern for the whole group, or when there are other arguments that extrapolation is appropriate.
- Numerical values for MLs should preferably be regular figures in a geometric scale (0.01, 0.02, 0.05, 0.1, 0.2, 0.5, 1, 2, 5 etc.), unless this may pose problems in the acceptability of the MLs.
- MLs should apply to representative samples per lot. If necessary, appropriate methods of sampling should be specified. MLs should not be lower than a level which can be analyzed with methods of analysis that can readily be set up and applied in food and feed control laboratories, unless public health considerations necessitate a lower ML which can only be controlled by means of a more elaborate and sensitive method of analysis with an adequate lower detection limit. In all cases, a validated method of analysis should be available with which a ML can be controlled.
- The contaminant and toxin as it should be analyzed and to which the ML applies should be clearly defined. The definition may include important metabolites when this is appropriate from an analytical or toxicological point of view. It may also be aimed at indicator substances which are chosen from a group of related contaminants.
- The product as it should be analyzed and to which the ML applies, should be clearly defined. In general, MLs are set on primary products. MLs should in general preferably be expressed as a level of the contaminant related to the product as it is, on a fresh weight basis. In some

cases, however, there may be valid arguments to prefer expression on a dry weight basis (this might be in particular the case for contaminants in feed) or on a fat weight basis (this might be in particular the case for fat soluble contaminants). Preferably the product should be defined as it moves in trade, with provisions where necessary for the removal of inedible parts that might interfere with the preparation and the analysis of the sample. The product definitions used by the CCPR and contained in the Classification of Food and Feed (CAC/MISC 4) may serve as guidance on this subject; other product definitions should only be used for specified reasons. For contaminant purposes, however, analysis and consequently MLs should preferably be on the basis of the edible part of the product

For fat-soluble contaminants, which may accumulate in animal products, provisions should be applied regarding the application of the ML to products with various fat content (comparable to the provisions for fat soluble pesticides).

- Guidance is desirable regarding the possible application of MLs established for primary products to processed products and multi-ingredient products. When products are concentrated, dried or diluted, use of the concentration or dilution factor is generally appropriate in order to be able to obtain a primary judgement of the contaminant levels in these processed products. The maximum contaminant concentration in a multi-ingredient food and feed can likewise be calculated from the composition of the food and feed. Information regarding the behaviour of the contaminant during processing (e.g. washing, peeling, extraction, cooking, drying etc.) is however desirable to give more adequate guidance. When contaminant levels are consistently different in processed products related to the primary products from which they are derived, and sufficient information is available about the contamination pattern, it may be appropriate to establish separate maximum levels for these processed products. This also applies when contamination may occur during processing. In general however, MLs should preferably be set for primary agricultural products and may be applied to processed, derived and multi-ingredient food and feed by using appropriate conversion factors. When these factors are sufficiently known, they should be mentioned in the suffix to the maximum level following the format of list of MLs as defined in Annex II.
- MLs should preferably not be set higher than is acceptable in a primary (theoretical maximum intake and risk estimation) approach of their acceptability from a public health point of view. When this poses problems in relation to other criteria for establishing MLs, further evaluations are necessary regarding the possibilities to reduce the contaminant levels, e.g. by improving GAP and/or GMP conditions. When this does not bring a satisfactory solution, further refined risk assessment and contaminant risk management evaluations will have to be made in order to try to reach agreement about an acceptable ML.

Procedure for risk assessment in relation to (proposed) MLs

It is more difficult to control food and feed contamination problems than in the case of food additives and pesticide residues. Proposed MLs will inevitably be influenced by this situation. In order to promote acceptance of ASEAN MLs, it is therefore important that assessments of the impact of those MLs on dietary exposure are done in a consistent and realistic way. The procedure involves assessment of the dietary intake in relation to the proposed or existing MLs and the toxicological reference value.

In case a contaminant is carried over from feed to food of animal origin, the intake of a contaminant by the different food producing animal species and the resulting levels in the food of animal origin should be estimated.

The best estimate of dietary intake involves the national dietary pattern and corrections for concentration changes during transport, storage, food preparation, for known levels in foods as consumed, etc. Caution is recommended when using other than average food consumption values, although it is considered appropriate to use relevant average food consumption data for identifiable

subgroups of the population. Food consumption patterns with a higher intake of critical foods may be used in the intake calculations when this is part of an accepted national, regional or international health protection and risk management policy. A harmonized approach using an appropriate intake estimation model that is as realistic as possible is recommended. (cf. the Policy of the Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups – Annex III). Calculated data should where possible always be compared with measured intake data. Proposals for MLs should be accompanied by intake calculations and risk assessment conclusions regarding their impact on dietary intake and use. The intake calculations should follow the methodology described in the Policy for Exposure Assessment and, if appropriate, be accompanied by the generation of distribution curves for the concentration in specific foods/food groups (see Sections 2 and 4 of the Policy of the Committee on Contaminants in Foods for Exposure Assessment of Contaminants and Toxins in Foods or Food Groups – Annex III). Statements from ASEAN Member States about the non-acceptance of (proposed) ASEAN MLs should refer to specified intake calculations and risk management conclusions, which support this position.

Format of the ASEAN Standards for Contaminants and Toxins in Food and Feed

Introduction

The format for the Schedule shall contain the following elements:

- **Name of the contaminant**
- Synonyms: symbols, synonyms, abbreviations, scientific descriptions shall be mentioned.
- **Reference to ARAC or JECFA meetings** (in which the contaminant was discussed).
- **PMTDI, PTWI or similar toxicological guidance value:** when the situation is complex a short statement and further references may be necessary here.
- **Contaminant definition:** definition of the contaminant as it shall be analyzed and to which the maximum level or guideline level applies.
- **Reference** to a source-directed measure or a related code of practice for the contaminant, if appropriate.
- **List of ASEAN maximum levels or guideline levels for that contaminant;** this list shall be composed of the following elements, in columns:
 - feed/food commodity/product name;
 - Numerical value of maximum level or guideline level and units in which it is expressed;
 - Portion of the Commodity/Product to which the maximum level or guideline level applies;
 - Notes/Remarks, including reference to relevant Codex commodity standards and where necessary, definition of the commodity product

EXPLANATORY NOTES

Reference to ARAC and/or JECFA	References to the ARAC or JECFA meeting in which the contaminant was evaluated and the year of that meeting.
Toxicological guidance value	Toxicological advice about the tolerable intake level of the contaminant for humans, expressed per kg body weight (bw). The year of recommendations and additional explanation are included.
Contaminant definition	Definition of the contaminant in the form of which the ML or GL applies or which may or should be analyzed in commodities/products.
Synonyms	Symbols, synonyms abbreviations, scientific descriptions and identification codes used to define the contaminant.
Commodity / product name	<p>The commodities or products, to which the ML or GL applies, other than the terms feed or food, are those that are intended for human consumption, unless otherwise specified.</p> <p>The ML or GL contained in Codex commodity standards apply to the commodities within the scope of the Codex commodity standard. Reference to the Codex Standard is provided and the definition of the commodity/product is the definition as provided in the Codex commodity standard.</p> <p>When the ML or GL applies only to the commodity within the scope of the Codex commodity standard then the reference is mentioned as “Relevant Codex commodity standard(s) is (are) ...”. In case the reference</p>

	<p>to Codex commodity standards is provided as example for commodities to which the ML or GL applies then the reference is mentioned as “Relevant Codex Commodity standards include ...”</p> <p>For the other commodities or products not contained in Codex commodity standards the definition of the commodity or product is provided in the Classification of Food and Feed (CAC/MISC 4), unless otherwise specified.</p> <p>In case a ML or GL applies to a product group (e.g. legume vegetables), the ML or GL applies to all individual products belonging to the group as defined in CAC/MISC 4</p> <p>For any other commodities or products other than those described above, where necessary, the definition of the commodity/product is provided in “Notes/Remarks”.</p>
<p>Portion of the Commodity/Product to which the maximum level (ML) or guideline level (GL) applies</p>	<p>The portion of the feed or food to which the ML or GL applies, is the portion defined in the Codex commodity standard or CAC/MISC 4 or defined at the establishment of the ML or GL, unless otherwise specified.</p>

DEFINITIONS OF SOME TOXICOLOGICAL TERMS

<p>PMTDI</p>	<p>Provisional Maximum Tolerable Daily Intake</p> <p>The endpoint used for contaminants with no cumulative properties. Its value represents permissible human exposure as a result of the natural occurrence of the substance in food and in drinking-water. In the case of trace elements that are both essential nutrients and unavoidable constituents of food, a range is expressed, the lower value representing the level of essentiality and the upper value the PMTDI.</p>
<p>PTWI</p>	<p>Provisional Tolerable Weekly Intake</p> <p>An endpoint used for food contaminants such as heavy metals with cumulative properties. Its value represents permissible human weekly exposure to those contaminants unavoidably associated with the consumption of otherwise wholesome and nutritious foods.</p>
<p>PTMI</p>	<p>Provisional Tolerable Monthly Intake</p> <p>An endpoint used for a food contaminant with cumulative properties that has a very long half-life in the human body. Its value represents permissible human monthly exposure to a contaminant unavoidably associated with otherwise wholesome and nutritious foods.</p>

ANNEX III

POLICY OF THE CODEX COMMITTEE ON CONTAMINANTS IN FOODS FOR EXPOSURE ASSESSMENT OF CONTAMINANTS AND TOXINS IN FOODS OR FOOD GROUPS

Section 1. Introduction

1. Maximum Levels (MLs) do not need to be set for all foods that contain a contaminant or a toxin. The Preamble of the *General Standard for Contaminants and Toxins in Foods and Feed* (GSCTFF) states in Section 1.3.2 that “maximum levels (MLs) shall only be set for those foods in which the contaminant may be found in amounts that are significant for the total exposure of the consumer. They should be set in such a way that the consumer is adequately protected”. Setting standards for foods that contribute little to dietary exposure would mandate enforcement activities that do not contribute significantly to health outcomes.
2. Exposure assessment is one of the four components of risk assessment within the risk analysis framework adopted by Codex as the basis for all standard-setting processes. The estimated contribution of specific foods or food groups to the total dietary exposure to a contaminant as it relates to a quantitative health hazard endpoint (e.g. PMTDI, PTWI) provides further information needed for the setting of priorities for the risk management of specific foods/food groups. Exposure assessments must be guided by clearly articulated policies elaborated by Codex with the aim of increasing the transparency of risk management decisions.
3. The purpose of this Annex is to outline steps in contaminant data selection and analysis undertaken by JECFA when requested by the Codex Committee on Contaminants in Foods (CCCF)⁴ to conduct a dietary exposure assessment.
4. The following components highlight aspects of JECFA’s exposure assessment of contaminants and toxins that contribute to ensuring transparency and consistency of science-based risk assessments. Exposure assessments of contaminants and toxins in foods are performed by JECFA at the request of CCCF. CCCF will take this information into account when considering risk management options and making recommendations regarding contaminants and toxins in foods.

Section 2. Estimation of Total Dietary Exposure to a Contaminant or Toxin from Foods/Food Groups

5. JECFA uses available data from member countries and from GEMS/Food Operating Program for analytical laboratories system on contaminant levels in foods and the amount of foods consumed to estimate total dietary exposure to a contaminant or toxin. This is expressed as a percentage of the tolerable intake (e.g. PTDI, PTWI, or other appropriate toxicological reference point). For a carcinogen with no clear threshold, JECFA uses available data on intake combined with data on carcinogenic potency to estimate potential population risks.
6. Median/mean contaminant levels in foods are determined from available analytical data submitted by countries and from other sources. These data are combined with information available for the GEMS/Food Consumption Cluster Diets to generate dietary exposure estimates for regions in the world. JECFA provides an estimate as to which of the GEMS/Food Consumption Cluster Diets are likely to approach or exceed the tolerable intake.

7. In some cases, available national contaminant and/or individual food consumption data may be used by JECFA to provide more accurate estimates of total dietary exposure, particularly for vulnerable groups such as children.
8. JECFA performs exposure assessments if requested by CCCF using the GEMS/Food Consumption Cluster Diets and, if needed, available national consumption data to estimate the impact on dietary exposure of proposed alternative maximum levels to inform CCCF about these risk management options.

Section 3. Identification of Foods/Food Groups that Contribute significantly to Total Dietary Exposure of the Contaminant or Toxin

9. From dietary exposure estimates JECFA identifies foods/food groups that contribute significantly to the exposure according to CCCF's criteria for selecting food groups that contribute to exposure.
10. The CCCF determines criteria for selecting foods/food groups that contribute significantly to total dietary exposure of a contaminant or toxin. These criteria are based upon the percentage of the tolerable intake (or similar health hazard endpoint) that is contributed by a given food/food group and the number of geographic regions (as defined by the GEMS/Food Consumption Cluster Diets) for which dietary exposures exceed that percentage.
11. The criteria are as follows:
 - a. Foods or food groups for which exposure to the contaminant or toxin contributes approximately 10%⁵ or more of the tolerable intake (or similar health hazard endpoint) in one of the GEMS/Food Consumption Cluster Diets; or,
 - b. Foods or food groups for which exposure to the contaminant or toxin contributes approximately 5% or more of the tolerable intake (or similar health hazard endpoint) in two or more of the GEMS/Food Consumption Cluster Diets; or,
 - c. Foods or food groups that may have a significant impact on exposure for specific groups of consumers, although exposure may not exceed 5% of the tolerable intake (or similar health hazard endpoint) in any of the GEMS/Food Consumption Cluster Diets. These would be considered on a case-by-case basis.

Section 4. Generation of Distribution Curves for Concentrations of the Contaminant in Specific Foods/Food Groups (concurrent with Section 2, or subsequent Step)

12. . If requested by CCCF, JECFA uses available analytical data on contaminant or toxin levels in foods/food groups identified as significant contributors to dietary exposure to generate distribution curves of contaminant concentrations in individual foods. CCCF will take this information into account when considering risk management options and, if appropriate, for proposing the lowest achievable levels for contaminants/toxins in food on a global basis.
13. Ideally, individual data from composite samples or aggregated analytical data would be used by JECFA to construct the distribution curves. When such data are not available, aggregated data would be used (for example mean and geometric standard deviation). However, methods to construct distribution curves using aggregated data would need to be validated by JECFA.
14. In presenting the distribution curves to CCCF, JECFA should, to the extent possible, provide a comprehensive overview of the ranges of contamination of foods (i.e., both

⁵ Rounded to the nearest 1/10th of a percent

the maximum and outlier values) and of the proportion of foods/food groups that contain contaminants/toxins at those levels.

Section 5. Assessment of the Impact of Agricultural and Production Practices on Contaminant Levels in Foods/Food Groups (concurrent with Section 2, or subsequent Step)

15. If requested by CCCF, JECFA assesses the potential impact of different agricultural and production practices on contaminant levels in foods to the extent that scientific data are available to support such assessments. CCCF takes this information into account when considering risk management options and for proposing Codes of Practice.
16. Taking this information into account, CCCF proposes risk management decisions. To refine them, CCCF may request JECFA to undertake a second assessment to consider specific exposure scenarios based on proposed risk management options. The methodology for assessing potential contaminant exposure in relation to proposed risk management options needs to be further developed by JECFA.