

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 7

CX/MAS 19/40/7-Add.1

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

40th Session

Budapest, Hungary, 27 -31 May 2019

REVISION OF THE *GENERAL GUIDELINES ON SAMPLING* (CXG 50-2004)

Replies to CL2019/17-MAS

Comments from Canada, Ecuador, Egypt, Japan, Norway, Peru, Uruguay and USA

CANADA

Canada is pleased to provide the following responses to the questions posed as part of CL 2019/17-MAS.

Canada feels that Codex sampling plans support the confirmation that provisions (e.g., maximum levels [ML]) are accurately respected for applicable commodities.

Q1. In what context is it that Codex sampling plans are intended to be used?

Codex sampling plans are intended to guide food surveillance activities and ensure accurate representation of chemical residues in specific food commodities. Validated sampling plans are also required for associated compliance and enforcement activities. The sampling plans may be used as examples for others to follow when developing their own sampling plans or to facilitate dispute resolution between parties.

Q2. What do Codex sampling plans hope to achieve?

Codex sampling plans may be used to support the relevance and applicability of a residue dataset or may be used as a source of information when interested parties are involved in creating sampling plans. The application of the plans may be used to avoid or aid in settling trade disputes.

Q3. How Codex sampling plans can be used by exporting and importing countries in real situations?

With the development of sampling plan guidance, creation of a sampling plan tool and provision of examples with sufficient detail, countries may be better able to develop and implement mutually agreeable sampling plans and thus avoid trade disputes.

Q4. Are Codex sampling plans intended for use in international trade disputes?

Codex sampling should be considered as equivalent or exceeding robustness of any related domestic sampling plans, therefore should be considered as applicable for use in international trade disputes.

Q5. What situations where Codex sampling plans are used, are covered or not covered?

Additional clarity would be useful for sampling of bulk commodities where "lots" may not be easily defined as small, manageable portions.

ECUADOR

With reliance on the request made by means of circular letter CL 2019/17-MAS, Ecuador wishes to present their answers to the following questions:

In what context is it that Codex sampling plans are intended to be used?

Codex sampling plans may help us ensure the use of sampling procedures that are valid and reliable when foods are analyzed to verify whether they comply or not with a specific standard.

In addition, would be used as a guide for the elaboration of the sampling plans in the National Program of Control and Monitoring of Contaminants in Food.

What do Codex sampling plans hope to achieve?

To integrate in the national plans of control and monitoring the groups of foods of mass consumption as to ensure fair and valid procedures.

Additionally, the use of Codex sampling plans would ensure that food samples taken – in particular in food processing plants – are representative and in this way, reliable results are obtained in subsequent analysis, avoiding in this way possible conflicts with producers and manufacturers.

How Codex sampling plans can be used by exporting and importing countries in real situations?

The use of Codex sampling plans by exporting and importing countries would enable them to avoid discrepancies arising from the differences in legal and technical assumptions concerning sampling.

Furthermore, when phytosanitary or veterinary notifications are issued and when safety controversies arise in food trade.

Are Codex sampling plans intended for use in international trade disputes?

They would serve the member countries of the World Trade Organization, where they abide by the Codex guidelines.

What situations where Codex sampling plans are used, are covered or not covered?

The control and monitoring of food safety would be used for primary production and manufacturing, with qualitative characteristics.

As for sampling of packed or canned products, all the situations would be covered.

EGYPT

Egypt appreciates the work done by the EWG led by New Zealand and agrees the document, with the following general comments responding to the mentioned questions in the CL which will reflect to the content and contribute to the introduction in the revised CXG 50, as follows:

Q1. In what context is it that Codex sampling plans are intended to be used?

Egypt supports the current context of sampling plans in (CXG 50) to be used in the food standards and regulations and recommends adding the link of e-book of sampling plan applications to the revised CXG 50 to facilitate the practical usage of the document.

Q2. What do Codex sampling plans hope to achieve?

Codex sampling plans hope to minimize the international trade disputes accruing sampling between countries by using unified guidelines for sampling plans to avoid incorrect decisions.

Q3. How Codex sampling plans can be used by exporting and importing countries in real situations?

It can be used by implementing CXG 83 "PRINCIPLES FOR THE USE OF SAMPLING AND TESTING IN INTERNATIONAL FOOD TRADE" in addition to the current document (CXG 50).

These principles are intended to assist governments in the establishment and use of sampling and testing procedures on a scientific basis, whether foods intended to be traded locally or internationally.

Compliance with these principles will also assist in avoiding potential disputes.

The explanatory notes are intended:

- to explain the principles and their use in sampling and testing procedures; and
- to help governments and other interested parties to understand the principles and;
- to establish and use sampling and testing procedures to assess the compliance of traded foods with required specifications.

Q4. Are Codex sampling plans intended for use in international trade disputes?

In major cases of international trade disputes related to sampling plans, countries use the codex guideline of sampling plans, but there is no obligation to use it, as there is no convention text on that; so, using codex guideline of sampling plans is achieved by bilateral agreement between disputed countries.

Moreover; there is no official guidance on how to interpret analytical results in the framework of Codex.

Q5. What situations where Codex sampling plans are used, are covered or not covered?

Most of the plans are covered in the current GL50, while the revised CXG 50 will cover areas that are not currently covered such as:

- Where there is significant measurement error.
- Assessment of bulk materials against minimum or maximum limits.

JAPAN

These questions should have been asked at the time of deciding revision of the General Guidelines on Sampling (CXG50). Nonetheless, for the sake of cooperation to the revision of CXG50, in response to the questions shown in the CL 2019/17-MAS, Japan would like to submit the following response.

- **In what context is it that Codex sampling plans are intended to be used?**

As clearly stated in the “Principles for the Establishment or Selection of Codex Sampling Procedures” (page 92 of the Codex Procedural Manual 26th Edition, hereinafter referred to as “Codex sampling principles”), Codex methods of sampling for commodity standards are intended to be used by member countries as international sampling methods for conformity assessment.

<Reference>

Page 92 of the Codex Procedural Manual 26th Edition

Purpose of Codex Methods of Sampling

Codex Methods of Sampling are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard. The sampling methods are intended for use as international methods designed to avoid or remove difficulties which may be created by diverging legal, administrative and technical approaches to sampling and by diverging interpretation of results of analysis in relation to lots or consignments of foods, in the light of the relevant provision(s) of the applicable Codex standard.

Codex General Guidelines on Sampling, CXG 50, intend to be used for designing or selecting one of appropriate sampling methods to control conformity of products with the specific Codex commodity standard. Codex sampling principles are closely related to the existing CXG 50 and the Procedural Manual refers to the corresponding parts of the existing CXG 50 to select a sampling method which is appropriate for the specific situation.

<Examples>

Page 93 of Codex Procedural Manual 26th Edition

Types of Sampling Plans and Procedures

(a) Sampling Plans for Commodity Defects:

Such plans are normally applied to visual defects (e.g. loss of colour, misgrading for size, etc.) and extraneous matter. They are normally attributes plans, and plans such as those included in Section 3.1 and 4.2 of the General Guidelines on Sampling (CAC/GL 50-2004) (hereinafter referred to as "General Guidelines") may be applied.

Page 93 of Codex Procedural Manual 26th Edition

General Instructions for the Selection of Methods of Sampling

(a) Sampling methods described in the General Guidelines or official methods of sampling elaborated by international organizations occupying themselves with a food or a group of foods are preferred. Such official methods may be written using the General Guidelines when attracted to Codex standards.

(b) When selecting appropriate sampling plans, Table 1 in the General Guidelines may be utilized.

Page 95 of Codex Procedural Manual 26th Edition

Recommendations

It is recommended that when a Commodity Committee discusses and agrees on a commodity specification and the analytical methods concerned, it states the following information in the Standard:

1. Sampling Plans

The appropriate sampling plan, as outlined in the Guidelines for Sampling (CAC/GL 50-2004), Section 2.1.2 Guidelines on Sampling to control conformity of products with the specification.

- **What do Codex sampling plans hope to achieve?**

Codex Committees should consider designing or selecting appropriate sampling methods for the specific commodity standards, based on the codex sampling principles. This means that the Codex method of sampling for compliance with respective Codex standard should be designed or selected in accordance with CXG 50. The sampling methods will be used by Codex member countries for conformity assessment on the international food trades, and for settling dispute situations.

The countries also can use CXG 50 to consider the sampling methods used in their own countries. CXG 50 and the sampling methods for commodity standards are needed to be as easy as possible while some statistical basis is also needed. As the revised CXG 50 will be a new Codex general guidance, it should be harmonized to and based on the internationally recognized standards such as ISO standards for ensuring the validity and transparency. Commodity specific issues relating to sampling (lot size, increment size, sample size, AQL, LQ etc.) in real trade situations should be taken into account and Commodity Committees should propose appropriate sampling methods for the commodity to CCMAS. In order to keep the consistency with the Codex Procedural Manual and to help commodity committees, the updating and harmonization of terms, the addition of basic information on how to design or select appropriate sampling plans, and/or concrete examples may be useful rather than re-constructing the whole documents of CXG 50 completely. General guidance on sampling methods for in-homogeneous lots and *ad hoc* sampling plan assuming various situations will also be useful for Commodity Committees and member countries. However, the priority to consider in-homogeneous lot and ad hoc sampling may not be so high.

- **How Codex sampling plans can be used by exporting and importing countries in real situations?**

In Japan, Codex sampling methods and the relevant international standards such as ISO standards are taken into consideration when the Government of Japan develops a new sampling method for inspection of imported foods and feeds. For example, the sampling method for aflatoxin in feed was revised referring the General Guidelines of Sampling (CXG 50), the General Standard for Contaminants and Toxins in Food and Feed (CXS 193) and the relevant international standards. When developing sampling methods, if necessary, practical legitimate factors such as cost and/or time-flame will also be taken into consideration.

- **Are Codex sampling plans intended for use in international trade disputes?**

Article 3 of the WTO SPS Agreement stipulates harmonization to the international standards and guidelines. The Annex A of the WTO SPS Agreement stipulates that the term "international standards and guidelines and recommendations" means those established by the Codex Alimentarius Commission. For this reason, we understand that Codex sampling plan is intended for use to settling international trade disputes.

<Reference>

Agreement on the Application of Sanitary and Phytosanitary Measures

Article 3

Harmonization

1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.

ANNEX A

DEFINITIONS

3. International standards, guidelines and recommendations

(a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;

- **What situations, where Codex sampling plans are used, are covered or not covered?**

Sampling plans for commodity defects, sampling plans for net contents and sampling plans for compositional criteria are covered by the existing CXG50. The revised CXG 50 should cover sampling of bulk materials and/or sampling of non-homogeneous lots which are shown in the project document, page 34 Appendix V, REP18/MAS.

<Reference>

Page 92 of Codex Procedural Manual 26th Edition

Types of Sampling Plans and Procedures

(a) Sampling Plans for Commodity Defects:

Such plans are normally applied to visual defects (e.g. loss of colour, misgrading for size, etc.) and extraneous matter. They are normally attributes plans, and plans such as those included in Section 3.1 and 4.2 of the General Guidelines on Sampling (CAC/GL 50-2004)

(b) Sampling Plans for Net Contents:

Such plans are those which apply to pre-packaged foods generally and are intended to serve to check compliance of lots or consignments with provisions for net contents. Plans such as those included in Section 3.3 and 4.4 of the General Guidelines may be applied.

(c) Sampling Plans for Compositional Criteria:

Such plans are normally applied to analytically determined compositional criteria (e.g., loss on drying in white sugar, etc.). They are predominantly based on variable procedures with unknown standard deviation. Plans such as those included in Section 4.3 of the General Guidelines may be applied.

(d) Specific Sampling Plans for Health-related Properties:

Such plans are normally applied to heterogeneous conditions, e.g. in the assessment of microbiological spoilage, microbial by-products or sporadically occurring chemical contaminants.

NORWAY

Norway would like to thank New Zealand for their work in revising CXG 50 and their effort to improve the area of sampling in Codex.

(i) General Comments

We support the revision of CXG 50 with the aim of improving the user friendliness of the standard, as also requested by CCFFP, however there is a need to take into account the reader/user of the guideline, which may not have statistical background.

We welcome the development of apps to facilitate the selection of sampling plans, which at the same time visualizes the risks to both consumer and producer in an accessible manner. While the tables in the current CXG 50 makes the standard big and cumbersome, the benefit of the tables in the current CXG 50 gives an easy overview for the reader/user on how many samples different scenarios would lead to.

It is important that the apps remain traceable to the corresponding ISO standards and tables. The code used in the apps should be available and transparent for the users.

As regards the future revised CXG 50, we would advocate to retain, and improve if possible, the flowcharts for selection of sampling plans since the flowcharts provide an accessible overview of how sampling plans can be selected. This includes the selection of sampling plans for both chemical, physical as well as microbiological characteristics.

PERU

General Comments

Our country thanks New Zealand for the work done in the review of standard CXG 50-2004 General guidelines on sampling.

Specific Comments

In line with the request stated in the Circular Letter, Peru is sending their comments concerning the following questions:

1. In what context is it that Codex sampling plans are intended to be used?

Sampling plans are applied in export and import operations, as well as in domestic production and manufacturing.

2. What do Codex sampling plans hope to achieve?

Sampling plans help taking representative samples from lots or a specific production to verify compliance with the requirements established in the standards on requirements for products.

3. How Codex sampling plans can be used by exporting and importing countries in real situations?

An example of the use of sampling plans is in export and import shipments in the overall product process chain, as well as in the case of countries importing or exporting goods.

4. Are Codex sampling plans intended for use in international trade disputes?

Codex sampling plans are used for standardizing criteria in international trade. Additionally, they are widely used in disputes between parties.

5. What situations where Codex sampling plans are used, are covered or not covered?

The use of sampling plans in high-cost finished goods, and also when destructive tests are performed on high-cost products. However, sampling plans are to be used in product development processes.

URUGUAY

We appreciate the coordination and work done by New Zealand in the EWG on the Revision of the Guidelines on Sampling (CXG 50-2014).

Codex members and observers are invited to submit comments through their respective points of contact concerning the following questions. Comments received in response to these questions would be used to base the technical contents and would help to introduce the revised Guidelines CXG 50.

• In what context is it that Codex sampling plans are intended to be used?

Sampling plans are intended to be used as a reference in the preparation of national regulations for food control, or in international trade, in the control of food imports, or when there are trade disputes.

• What do Codex sampling plans hope to achieve?

To have an international reference such as Codex that provides criteria for the development of sampling plans. They must be easily understandable.

• How Codex sampling plans can be used by exporting and importing countries in real situations?

They could be used as a reference to establish sampling plans in commercial agreements, for the purpose of solving controversies. To be used as a complementary tool in sampling systems of lots or when there are no agreements for recognition of certifications between the states, providing greater transparency and based on an international recommendation.

Also, they could be included in the documents that are elaborated by the different Commodity Committees for the control of diverse parameters, for which they must be of very easy understanding so that experts in diverse subjects can use them without having to rely on sampling experts.

• Are Codex sampling plans intended for use in international trade disputes?

They could be used as reference documents or when there is no established mechanism to solve commercial disputes.

• What situations where Codex sampling plans are used, are covered or not covered?

We find that the presented document covers sampling. Currently Codex sampling plans are not easy to use for some parameters, although they are for microbiological parameters. Therefore, the new version is expected to be more user-friendly and easier to apply both for components and non-microbiological contaminants.

Also, it is expected to be used to establish the sampling plans in the standards elaborated by the various Codex Committees when appropriate.

One of the complex issues concerning the application of the sampling plans is the number of samples required, which implies a high cost for the manufacturer or importer.

Regarding the examples, as discussed in the General Principles meeting, we consider that they should be included in a CCMAS information document and the sampling guideline should not refer to said information document.

3. Comments should be submitted in writing in accordance with the uniform procedure for the elaboration of Codex Standards and related texts (see Procedural Manual of the Codex Alimentarius Commission).

USA

The US thanks New Zealand for their work on creating the draft REVISION OF THE GENERAL GUIDELINES ON SAMPLING (CXG 50 - 2004) and for their chairing of the electronic working group (EWG). The US has reviewed the document and the accompanying "Concept Paper" that was provided in the EWG. Below please find the US response to the Request for Comments (CL 2019/17-MAS). The US has answered the specific questions in CL 2019/17-MAS and then provides additional comments.

1) In what context is it that Codex sampling plans are intended to be used?

Codex sampling plans are intended for use with Codex commodity standards for inspection of isolated lots at border points and other receiver-oriented situations. They are not intended for use by processors, who use HACCP and defect action plans (DAP) to control hazards and defects more effectively than end-product testing. In addition, CXG50 is not intended to cover statistical process control of processed foods.

Most provisions in Codex standards are not associated with prescriptive or defined sampling plans. Competent authorities, and other users, use CXG50 to design appropriate sampling plans for standards based on risk management and economic decisions.

Codex standards mainly address food safety and suitability, and some critical workmanship defects. Food safety and suitability provisions have low tolerance for non-compliant units (e.g. zero, <0.01%) and consumer protection is usually limited by practical sample size.

2) What do Codex sampling plans hope to achieve?

Codex Methods of Sampling are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard, which have been developed to assist in the protection of consumers' health and ensure fair practices in the food trade

3) How Codex sampling plans can be used by exporting and importing countries in real situations?

Codex standards and sampling guidelines may be more commonly used by smaller firms and developing countries that do not have their own standards and sampling expertise.

Sampling guidelines are used by importing countries and importing firms. Exporting countries and firms generally only inspect exports if the importing country or firm imposes testing requirements, in which case the exporter uses the sampling plan provided by the importer.

Import inspections may be regular but are usually infrequent, particularly by competent authorities who may test less than 1% of imported lots. Frequency is based on many factors balancing risk and cost.

4) Are Codex sampling plans intended for use in international trade disputes?

Codex standards are recognized in the SPS agreement and may be referred to in a trade dispute, however if sampling was needed to settle an international dispute, the sampling plan would certainly be designed on a case-by-case basis.

5) What situations where Codex sampling plans are used, are covered or not covered?

The following items should be discussed in the General Guidelines on Sampling:

- Considering the purpose of sampling (lot compliance with a standard, surveillance, screening)
- Selecting representative samples (lot definition, sample unit size, random sampling, handling)
- Types of provisions in Codex standards
 - Physical, chemical, and biological hazards (health)
 - Nutritional content (health)
 - Filth, decomposition (suitability for human consumption, health)
 - Critical quality/workmanship defects (fair trade)
 - Focus on health-related provisions
- Types of parameters (continuous and discrete variables, attributes, averages)
- Types of statistical approaches
 - Attribute sampling plans
 - 2-class attribute (typical)
 - 3-class attribute (when appropriate, selecting levels)
 - Zero acceptance number (ZAN) plans
 - Plans with non-zero acceptance numbers (when appropriate)
 - Binomial distribution / hypergeometric distribution
- Determining relative performance of different sampling plans
- Applicability of the usual and customary sampling plans in the guidelines to inhomogeneous lots. The distribution of food safety hazards and defects in foods is usually highly heterogeneous (except in well mixed liquids). Inhomogeneity does not affect the validity of the sampling plans in CXG50.

- Performance of attribute plans is unaffected by heterogeneity when samples are collected randomly.
- Variables plans (sampling for an average) use estimates of the standard deviation (a measure of inhomogeneity) to select a sample size to achieve specified levels of performance.
- Assuring homogeneity is important when minimizing measurement error; e.g., when blending a sample unit for testing or blending an aggregate sample for determining an average.

Additional Comments

“AQL”/“LQ” terminology

The draft uses ISO terminology “AQL/LQ”, which may be appropriate for some quality defects, but not for health-related provisions. Codex Alimentarius, and competent authorities, differentiate ‘food quality’ and ‘food safety’. “AQL” is awkward terminology for food safety provisions, particularly when no level of food safety defects can readily be called “acceptable” per se. We recommend removing these terms and using clear descriptive language that can be applied to both food quality and food safety. The FAO/WHO 2016 *Statistical Aspects of Microbiological Criteria Related to Foods* provides the same guidance without using “AQL/LQ” terminology.

The guidance should be broadened to cover sampling approaches used for health-related provisions (e.g. physical, chemical, and biological hazards, nutritional content, decomposition) because these are the types of sampling plans that Codex committees spend the most time developing.

Limitations of the consumer-risk / producer-risk approach

Because the AQL/LQ approach was designed for machine parts, it has practical limitations when applied to food because inspection costs for food are high. The guidelines should discuss this limitation and how it is handled.

Food standards are created, most importantly, to ensure consumers receive safe and wholesome food. Therefore, when developing trade standards, consumer requirements should be the first consideration, and then any limitations of producer control systems are considered. Therefore, the level of nonconformities that should be rejected most of the time (LQ) is determined first. Then the resulting level of nonconformities that the plan will accept most of the time (AQL) is reviewed and changed when necessary. This is the approach used in FAO/WHO 2016, *Statistical Aspects of Microbiological Criteria Related to Foods*, which should be implemented in Codex Guidelines and Sampling Plans.

Re-inspection Sampling (i.e. Re-sampling)

Simply re-sampling rejected lots is statistically invalid because it introduces producer bias since accepted lots are not resampled. Industry promotion of “sampling into compliance” is unfair to the consumer.

Proper use of HACCAP and defect control systems in Codex guidelines maintains hazards and defects at levels far below levels that can typically be detected by sampling. When a problem is detected, it usually indicates a problem with the production control system, and not sampling error.

If a control system failure allows a problem, the problem can occur in any lot, or part of a lot, produced by that system. For this reason, re-sampling sublots based on code dates, etc., is ineffective, except in rare situations where auxiliary information (e.g. production control records) clearly indicate that the problem is restricted to an identifiable portion of the lot in question. This information can then be used to define unaffected sublots that may be re-sampled using a rigorous confirmatory sampling plan. In most cases, there is inadequate information to segregate and resample a lot, and the correct action is to reject the lot and ensure the cause of the problem is determined and corrected.

The Guidelines should explain how re-sampling is misused, and when it might be used, such as given in FAO/WHO 2016, Section 2.2:

“Sometimes a problem is found with a lot of food as a result of sampling and the lot cannot be accepted. It may be tempting to redefine the lot by breaking it into sub-lots and retesting each of these, especially when the lot is large. The aim in this case is to identify one or more contaminated sub-lots (and simultaneously one or more uncontaminated sub-lots) and thereby reduce the amount of product that may be subject to control action, e.g. withdrawn from commerce.

However, irrespective of the type of sampling plan that is used, it is not appropriate to repeatedly test a lot (CAC, 2013a; ICMSF 2002), nor to redefine a lot in this way, i.e. after a lot has been defined, sampled and subsequently rejected...

Guidance format

Quotes from other Codex documents (e.g., Procedural Manual, and CXG83) should be removed and replaced with references where necessary. Codex documents generally do not repeat information found in other Codex documents to avoid repetition, and because documents are revised, and it is difficult to find and update quotes in other documents.

Definitions should be listed at the beginning of the document and are only needed for terms that are repeated more than once in the document, otherwise the term should be defined where it is used.

Practical formulas used in the sampling tool should be listed in an appendix for confirmation, and for use in locations without access to computers and/or internet. The tool should be downloadable in a spreadsheet for local use when not on internet.

