

PHILIPPINE NATIONAL STANDARD

PNS/BAFS 307:2020

ICS 67.050

Establishment and Application of Microbiological Criteria related to Food



BUREAU OF AGRICULTURE AND FISHERIES STANDARDS

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Foreword

The Philippine National Standard (PNS) for the Establishment and Application of Microbiological Criteria related to Food was adopted by the Technical Working Group (TWG) organized by the Bureau of Agriculture and Fisheries Standards (BAFS) through a Department of Agriculture (DA) Special Order No. 442, Series of 2020. This has been approved by the secretary of the Department of Agriculture in 20xx.

This edition includes the following significant changes compared to the Codex standard CAC/GL 21 – 1997:

- modification of the scope in accordance with the Republic Act No. 10611 otherwise known as Food Safety Act of 2013 and the practices in the Philippines;
- inclusion of the normative references;
- inclusion of terms and definitions used in the document;
- inclusion of the latest version of the referred documents; and
- modification of the provisions in Clause 6.2.

This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2.

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1 Scope

This Standard intends to provide a framework for the national and local governments and food business operators on the establishment and application of microbiological criteria that can be applied for food safety and other aspects of food hygiene at any point of the food chain.

Microbiological criteria can be applied, but are not limited to, to the following:

- a) Bacteria, viruses, molds and yeast, protozoa, microalgae and their toxins/metabolites;
- b) Their markers associated with pathogenicity (e.g. virulence-related genes or plasmids) or other traits (e.g. antimicrobial resistance genes) where/when linked to the presence of viable cells where appropriate.

Microbiological criteria established for the monitoring of the food processing environment (e.g. air, equipment) are excluded in this standard.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

CAC/GL 69 – 2008 rev. 2013, *Guidelines for the Validation of Food Safety Control Measures*

CAC/GL 47 – 2003 rev. 2006, *Guidelines for Food Import Control Systems*

CAC/GL 30 – 1999 rev. 2014, *Principles and Guidelines for the Conduct of Microbiological Risk Assessment*

CAC/GL 27 – 1997 rev. 2006, *Guidelines for the Assessment of the Competence of Testing Laboratories involved in the Import and Export Control of Food*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1 appropriate level of protection

ALOP

level of protection deemed appropriate by the country establishing a sanitary measure to protect human life or health within its territory (This concept may otherwise be referred to as the “acceptable level of risk”)

3.2

attribute sampling plan

selecting a random sample of “n” units from the incoming lot of size “N” and then determining the number of defective components in the sample, and if this number does not exceed the pre-determined c, the lot is accepted; otherwise the lot is rejected

3.3

food

any substance or product whether processed, partially processed or unprocessed that is intended for human consumption and includes drinks, chewing gum, water and other substances which are intentionally incorporated into the food during its manufacture, preparation and treatment

3.4

food business operators

FBO

person engaged in the food business including one’s agents and responsible for ensuring that the requirements of Food Safety Act of 2013 are met by the food business under one’s control

3.5

food safety control system

combination of control measures that, when taken as whole, ensures that food is safe for its intended use

3.6

food safety objective

FSO

maximum frequency and/or concentration of a hazard in a food at the time of consumption that provides or contributes to the appropriate level of protection (ALOP)

3.7

log-normal distribution

continuous distribution of random variable “y” whose natural logarithm is normally distributed

3.8

lot

definite quantity of some commodity manufactured or produced under conditions, which are presumed uniform for the purpose of this standard

3.9

microbiological criterion

limit for specific or general groups of microorganisms that can be applied in order to ensure that food does not present a potential health hazard to the consumer and risk management metric which indicates the acceptability of a food, or the performance of

either a process or a food safety control system following the outcome of sampling and testing for microorganisms, their toxins/metabolites or markers associated with pathogenicity or other traits at a specified point of the food chain

3.10

pathogens

organisms (microorganisms and infective parasites) that can cause negative effects on human health

3.11

performance criterion

PC

effect in frequency and/or concentration of a hazard in a food that must be achieved by the application of one or more control measures to provide or contribute to a PO or an FSO

3.12

performance objective

PO

maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to a food safety objective (FSO) or appropriate level of protection (ALOP), as applicable

3.13

sample

set composed of one or several items (or a portion of matter) selected by different means in a population (or in an important quantity of matter) and is intended to provide information on a given characteristic of the studied population (or matter), and to form a basis for a decision concerning the population or the matter or the process, which has produced it

3.14

validation

obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome

3.15

variable sampling plan

those that control the lot or process fraction defective (or nonconforming) and plans that control a lot or process parameter (usually the mean), which are implemented by computing the statistic Z (either lower or upper specification limit) for use in the k and M methods

3.16

verification

application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended

4 General Principles

4.1 A microbiological criterion should be appropriate to protect the health of the consumer and where appropriate, also ensure fair practices in food trade.

4.2 A microbiological criterion should be practical and feasible and established only when necessary.

4.3 The purpose of establishing and applying a microbiological criterion should be clearly articulated.

4.4 The establishment of microbiological criteria should be based on scientific information and analysis and follow a structured and transparent approach.

4.5 A microbiological criterion should be established based on knowledge about the microorganisms and their occurrence and behavior along the food chain.

4.6 The intended as well as the actual use of the final product by consumers needs to be considered when setting a microbiological criterion.

4.7 The required stringency of a microbiological criterion used should be appropriate to its intended purpose.

4.8 Periodic reviews of microbiological criteria should be conducted, as appropriate, in order to ensure that microbiological criteria continue to be relevant to the stated purpose under current conditions and practices.

5 Establishment and application of microbiological criteria

5.1 General considerations

5.1.1 When considering the establishment of microbiological criteria, a variety of approaches can be used depending on the risk management objectives and the available level of knowledge and data. These approaches can range from developing microbiological criteria based on empirical knowledge related to Good Hygienic Practices (GHP), to using scientific knowledge of food safety control systems such as through Hazard Analysis and Critical Control Point (HACCP), or by conducting a risk assessment. The choice of the approach should be aligned with the risk management objectives and decisions relating to food safety and suitability. The validation for food safety control system shall be in accordance with Codex Alimentarius Commission's Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69 – 2008 rev. 2013).

5.1.2 Since the levels/prevalence of a microorganism can change over the course of manufacture, distribution, storage, marketing and preparation, a microbiological

criterion is established at a specified point in the food chain. There shall be an import control system and it shall be in accordance with Codex Alimentarius Commission's Guidelines for Food Import Control Systems (CAC/GL 47 – 2003 rev. 2006).

5.1.3 The need for a microbiological criterion should be demonstrated, e.g. by epidemiological evidence that the food under consideration may represent a significant public health risk and that a criterion is meaningful for consumer protection, or as the result of a risk assessment.

5.2 Purpose

5.2.1 There may be multiple reasons for establishing and applying microbiological criteria. The purposes of microbiological criteria include, but are not limited to, the following:

- a) Evaluating a specific lot of food to determine its acceptance or rejection, in particular if its history is unknown.
- b) Verifying the performance of a food safety control system or its elements along the food chain, e.g. prerequisite programs and/or HACCP systems.
- c) Verifying the microbiological status of foods in relation to acceptance criteria specified between food business operators.
- d) Verifying that the selected control measures are meeting Performance Objectives (PO) and/or Food Safety Objectives (FSO).
- e) Providing information to food business operators on microbiological levels, which should be achieved when applying best practices.

5.2.2 In addition, a microbiological criterion is a valuable risk management metric when applied to detect potential unforeseen problems in the design and/or operation of a food safety control system and for obtaining safety and suitability information that is not otherwise available.

5.3 Relationship between microbiological criteria, other microbiological risk management metrics and Appropriate Level of Protection (ALOP)

5.3.1 Microbiological criteria may be used by competent authorities and food business operators to operationalize the ALOP either directly or through other microbiological risk management metrics (e.g. PO, FSO). This requires the use of quantitative risk assessment. The risk estimation should include a combination of several factors such as the prevalence and concentration distribution of target microorganisms, as well as any changes in these after the step for which the microbiological criterion has been set. The risk assessment should include a characterization of the variability inherent to the food production system and express the uncertainty in the risk estimate. Ongoing efforts to reduce the complexity of risk assessment should help facilitate the development and use of risk-based microbiological criteria. The microbiological risk assessment shall be in accordance with Codex Alimentarius Commission's Principles and Guidelines for the Conduct of Microbiological Risk Assessment (CAC/GL 30 – 1999 rev. 2014).

5.3.2 A microbiological criterion can be linked directly to the ALOP, without explicit articulation of an FSO or a PO. One approach involves testing the acceptability of individual lots and evaluating the relative risk to public health of the lot as compared to the ALOP. Another approach is to link a microbiological criterion directly to an ALOP, using a risk assessment model to estimate the reduction in public health risk as a result of applying corrective actions to lots or processes that do not conform to the microbiological criterion.

5.3.3 Statistical models can be used to translate a PO or FSO to a microbiological criterion. The link between the PO or the FSO and the ALOP should also be demonstrated. To establish such a microbiological criterion for a food, an assumption needs to be made regarding the distribution of the target microorganism in the food. A log-normal distribution is often assumed and a default value for the standard deviation applied. Furthermore, the maximum frequency and/or concentration of the hazard needs to be defined in the FSO or PO. If a concentration is used as a limit, also the proportion (e.g. 95%, 99%) of the distribution of possible concentrations that satisfies this limit should be defined.

5.4 Components and other considerations

5.4.1 A microbiological criterion consists of the following components:

- a) The purpose of the microbiological criterion;
- b) The food, process or food safety control system to which the microbiological criterion applies;
- c) The specified point in the food chain where the microbiological criterion applies;
- d) The microorganism(s) and the reason for its selection;
- e) The microbiological limits (m, M; see Section 5.6) or other limits (e.g. a level of risk);
- f) A sampling plan defining the number of sample units to be taken (n), the size of the analytical unit and where appropriate, the acceptance number (c);
- g) Depending on its purpose, an indication of the statistical performance of the sampling plan; and
- h) Analytical methods and their performance parameters;

5.4.2 Consideration should be given to the action to be taken when the microbiological criterion is not met and the action should be specified (Refer to Clause 5.1).

5.4.3 Other considerations should include, but are not limited to, the following:

- a) Type of sample (e.g. type of food matrix, raw materials, finished product);
- b) Sampling tools and techniques;
- c) Prevalence and concentration data for the organism of concern (e.g. baseline data)
- d) Frequency and timing of sampling;
- e) Type of sampling (randomized, stratified etc.);
- f) Methodology used and, when appropriate, suitable conditions for pooling of samples;

- g) Economic and administrative feasibility, in particular in the choice of sampling plan;
- h) Interpretation of results;
- i) Record keeping;
- j) The intended and actual use of the food;
- k) The microbiological status of the raw material(s);
- l) The effect of processing on the microbiological status of the food;
- m) The likelihood and consequences of microbial contamination and/or growth and inactivation during subsequent handling, packaging, storage, preparation and use; and
- n) The likelihood of detection.

5.4.4 In addition, for a microbiological criterion targeting a foodborne pathogen, consideration should be given to:

- a) The evidence of actual or potential risks to health; and
- b) The population at risk and consumption habits.

5.5 Sampling Plan

5.5.1 In the development and selection of sampling plans consideration should be given to the principles in the General Guidelines on Sampling (CAC/GL 50-2004).

5.5.2 The type of sampling plan selected for the microbiological criterion will depend on the nature and purpose of the microbiological criterion. Variables sampling plans for inspection evaluate quantitative data without grouping it into classes. Variables sampling plans require information about the distribution of microorganisms and typically assume that the inspected variables follow a normal or log-normal distribution. Variables sampling plans are seldom used, in part because they are not applicable to presence/absence testing. For microbiological criteria based on quantitative levels, where information is available on within lot and between lot variability, variables sampling plans can be tailored for the specific condition of a particular production process, resulting in a more informative interpretation of results.

5.5.3 In practice, most microbiological sampling plans designed for lot acceptance are attributes sampling plans. For these, to assess the probability of acceptance as a function of the percentage of non-conforming units, no knowledge or assumption about the underlying distribution of the microorganism is required. For attributes sampling plans to be valid, all that is required is that some probability-based sampling technique (e.g. simple random sampling or stratified random sampling) is used to collect the sample units from the entire lot. For these plans, to assess the probability of acceptance as a function of the level of the target microorganism, it is necessary to know or estimate the distribution of microorganisms.

5.5.4. The number and size of analytical units should be those stated in the sampling plan and should not be modified where the microbiological criterion has been established for regulatory compliance. In unusual circumstances (e.g. during a foodborne outbreak situation or when a food business operator wishes to increase the likelihood of detecting contaminated lots before placing them on the market) a sampling plan with increased stringency may become appropriate and it may become

necessary to adopt an alternative microbiological criterion. The rules and procedures for switching from one sampling plan to another should be clearly stated in the sampling approach. Unless the sampling plan specifies otherwise, a lot should not be subjected to repeat testing.

5.6 Microbiological and/or other limits

5.6.1 Microbiological limits separate conforming from non-conforming analytical units.

5.6.2 Where the microbiological limits m and M are part of an attributes sampling plan further defined through n , c , and the size of the analytical unit, they are expressed as presence/absence or concentration of the microorganism in one analytical unit.

5.6.3 In the establishment of microbiological limits in the context of microbiological criteria, any changes (e.g. decrease or increase in numbers) in the levels of the target microorganism likely to occur after the point for which the microbiological criterion has been set should be taken into account, where appropriate. It should also be clearly stated in the microbiological criterion whether the limits apply to every analytical unit, to the average, or to another specific method of calculation.

5.6.4 In the case of a two-class attributes sampling plan, there is one upper microbiological limit on the acceptable concentration in the analytical unit, denoted by m , and the acceptance number c is the maximum tolerable number of analytical units above the limit.

5.6.5 For a three-class attributes sampling plan the microbiological limit m separates conforming from marginally acceptable, and a limit M defines non-conforming analytical units. In this case, the acceptance number c refers to the maximum allowable number of marginally acceptable analytical units.

5.6.6 Alternatives to microbiological limits m and M may be used in applying microbiological criteria to other risk management metrics or the ALOP.

5.7 Analytical methods

5.7.1 Depending on the microbiological limit (e.g. presence/absence of a specific foodborne pathogen), an appropriate analytical method should be selected. The methods used should be fit for purpose, meaning the method has been validated for relevant performance characteristics (e.g. limit of detection, repeatability, reproducibility, inclusivity, exclusivity). The validation study should be based on internationally accepted protocols and include an interlaboratory study and shall be in accordance with Codex Alimentarius Commission's Guidelines for the Assessment of the Competence of Testing Laboratories involved in the Import and Export Control of Food (CAC/GL 27 – 1997 rev. 2006). If not available, a validation should be done by the laboratory applying the method, according to a standardized protocol.

5.7.2 The analytical methods specified should be reasonable with regard to complexity, availability of media, equipment, ease of interpretation, time required and costs.

5.7.3 The results of testing may be impacted by compositing (i.e. pooling) of sample units prior to analysis. Compositing will affect the final concentration in the tested sample and is not appropriate for enumeration methods of analysis or within three-class sampling plans. Compositing may be considered in the case of presence/absence testing within a two-class sampling plan, as long as it is ensured that the result of testing will not be affected when compared to testing of individual analytical units.

5.8 Statistical performance

5.8.1 The statistical performance of a sampling plan is usually illustrated by its operating characteristic (OC) curve, which describes the probability of acceptance as a function of the actual proportion of non-conforming analytical units or concentration of the microorganisms in the food. An OC curve can be used to evaluate the influence of individual parameters of the sampling plan on the overall performance of the plan.

5.8.2 Web-based tools for evaluation of sampling plans developed by Food and Agriculture Organization (FAO) and World Health Organization (WHO) through Joint FAO/WHO expert meetings on microbiological risk assessment (JEMRA) or by others can be utilized to evaluate sampling plans under consideration.

5.9 Moving window

5.9.1 In a moving window approach a sufficient number of sample units (n) is collected for a defined period of time (the “window”). The results of the latest sample units (n) are compared with the microbiological limit(s) (m , M) using the acceptance number c . Each time a new result from the sampling period is available, it is added to the window while the oldest result is removed, creating the “moving window”. This approach can also be applied to a set of results, e.g. results obtained during a week. The window, always consisting of n results, moves one result or set of results forward in time. In determining the size of the moving window consideration should be given to the combination of the production frequency and sample frequency necessary to obtain a sufficient number of results that enables appropriate verification of performance of a process or a food safety control system.

5.9.2 The moving window approach is a practical and cost beneficial way of checking continuous microbiological performance of a process or a food safety control system. As in the traditional point-in-time approach commonly used in connection with microbiological criteria, the moving window determines the acceptability of the performance so that appropriate interventions can be made in case of unacceptable shifts in control.

5.9.3 The length of the moving window should be appropriate to enable corrective action to be taken in a timely manner. If more than c out of n results is above the limit m , or the limit M is exceeded, then corrective action is required.

5.9.4 The moving window approach should not be confused with trend analysis, which is described in the following section.

5.10 Trend analysis

5.10.1 Trend analysis is a procedure to detect a change in the patterns of observations over a period of time (usually over a relatively long period of time, often not predefined). It can be applied to many types of information including results of microbiological testing against a microbiological criterion. Trend analysis can detect a gradual loss of control that might not be detected by a moving window approach, as well as a more sudden loss of control.

5.10.2 Trend analysis may show changes or patterns in the data that are a result of unwanted changes in the manufacturing process enabling the food business operator to take corrective actions before the food safety control system is out of control. The trends (or patterns) can be visualized, e.g. by displaying the test results graphically.

5.11 Action to be taken when the microbiological criterion is not met

5.11.1 In situations of non-conformance with the microbiological criterion (unsatisfactory results), actions to be applied should include corrective actions related to the purpose of the testing. These actions should be based on an assessment of the risk to the consumer where relevant; the point in the food chain, and the food specified and may consider history of conformance. Food business operators should re-evaluate their food safety control systems, including GHP and operational procedures, and/or further investigation to determine appropriate preventative actions to be taken.

5.11.2 In the event of a non-conformance with a microbiological criterion for a foodborne pathogen, actions should include appropriate product containment and disposition. This may include further processing, diversion to an alternate use, withdrawal and/or recall, rework, rejection or destruction of product, and/or further investigation to determine appropriate actions to be taken. Other actions taken may include more frequent sampling, inspection and audits, fines or official suspension of operations.

5.12 Documentation and record keeping

5.12.1 Documentation and records are essential to support the microbiological criterion, e.g. documentation on scientific evidence underpinning the microbiological criterion, records on application/performance of the microbiological criterion. Records such as test reports should give the information needed for complete identification of the sample, the sampling plan, the analytical method, the results and, if appropriate, their interpretation. Reporting against the microbiological criterion may be required by some national governments.

5.12.2 Records should be maintained documenting all instances of non-conformance with the microbiological criterion, together with records of the corrective actions taken, both to manage food safety risks and to prevent further instances of nonconformance.

6 Review of microbiological criteria for foods

6.1 As establishing and implementing microbiological criteria is a part of Microbiological Risk Management (MRM) activities. The Principles and Guidelines for

the Conduct of Microbiological Risk Management (CAC/GL 63-2007 rev. 2008) should be referred to. In addition, revision of microbiological criteria should be considered in response to revision of other MRM Metrics and also in response to emerging issues or changes in the following, but not limited to:

- a) Taxonomy, prevalence or distribution for selected microorganisms;
- b) The incidence of disease including attribution to specific foods;
- c) Traits of microorganisms (e.g. anti-microbial resistance, virulence);
- d) The suitability of an indicator organism;
- e) Available analytical methods/tests/appropriateness of test;
- f) Food/ingredients/technology/process of food production;
- g) Food safety control system;
- h) Population(s) at risk;
- i) Consumer behavior or dietary intake pattern of the food concerned;
- j) Understanding/knowledge of risk;
- k) Trend analysis results; and
- l) Required level of assurance.

6.2 A review of the microbiological criterion may be initiated and carried out by competent authorities and/or food business operators.

6.3 A review will result in retention, adjustment or revocation of a microbiological criterion, as appropriate.

6.4 The risk management framework should be used to continuously improve, refine and adjust the relevant components of the microbiological criterion in relation to their effectiveness, to improve scientific knowledge and the increasing knowledge of public health risk and related food safety risk management metrics (FSO, PO and PC). The goal should ultimately be to achieve a more quantifiable estimation of the linkages between microbiological criteria, other metrics and public health outcomes.

6.5 When microbiological criteria have been developed to address specific risk outcomes they should be reviewed against those outcomes and, if shown not to be effective, they should be adjusted or revoked.

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