

codex alimentarius commission



FOOD AND AGRICULTURE
ORGANIZATION
OF THE UNITED NATIONS

WORLD
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ORGANIZATION



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Agenda Item 7

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD HYGIENE

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PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS (At Step 3 of the Procedure)

In response to CX/FH 007, the following Governments and Organizations submitted comments: Canada, Brazil, Denmark, Kenya, Mexico, New Zealand, the United States of America, International Dairy Federation, and The Office International des Epizooties (OIE)

General Comments

Canada

Canada would like to commend the work done since the last session as this draft proposal is much clearer and user friendly. We support the use of Annexes as proposed because this will actually make the Proposed Draft Code more operational and practical for use.

Canada supports the proposal that CCFH develop a definition for suitability for application across the commodities.

Both parts of Annex II (Part A and B) address microbiological hazards and we understand the importance of appropriate information on the control of microbiological hazards. Canada invites CCFH to examine the opportunity to make more information available on chemical and physical hazards (examples include allergen control and metal detection).

Brazil

Brazil would like to congratulate the Drafting Group for its excellent work.

Denmark

Denmark generally supports the approach taken and the suggested structure of the draft Code.

A definition of the concept of Food Safety Objectives and its relationship with Appropriate Level of Protection is needed. We note that reference is made to Appropriate Level of Protection several places in the Draft Code, which, at present, does not seem sufficiently transparent.

Until the detailed guidelines supporting the principles are not sufficiently developed (whether contained in annexes or within the main body of the Code), it is difficult to reflect on the suggested principles presented the main body of the Code, i.e. whether they are appropriate, adequately worded, and sufficient.

Therefore, Denmark may later have comments to the draft principles, when the rest of the Draft is crystallizing.

Mexico

Mexico is in agreement with the document in general, however, we suggest that the Spanish translation be carefully reviewed. We support the proposal that composite milk products be considered in the Draft Code of Hygienic Practice for Milk and Milk Products.

In the Spanish version of the document, the wording in the appendix for time/temperature should be very clear.

New Zealand

New Zealand supports the continued development of these draft guidelines and the use of annexes as proposed in this draft.

New Zealand recommends that the committee ask the drafting group to continue its work to further develop these guidelines taking into account the comments made by member states on this agenda item.

United States of America

The United States strongly supports the *Proposed Draft Code of Hygienic Practice for Milk and Milk Products* and encourages its further development by the Committee with the continued assistance of the Drafting Group.

The United States would like to acknowledge the efforts of our drafting partners in revising this Proposed Draft Code. This current revision represents a further refinement of the framework document that was presented to the Committee during its last (32nd Session). The Drafting Group took into account the comments received prior to and during the last Session as well as those received prior to the meeting of the Drafting Group via circulation of the Code to the L list. Issues discussed and resolved during the Drafting Group meeting included:

- The distinction between what is a principle and what is a guideline.
- The appropriate placement of principles and guidelines for their application.
- The appropriate organization of the annexes.
- The basic outlines of the annexes.

The United States recognizes that significant work remains in the development of the Code, principally in the constructing the detailed content of the Annexes. For this reason, the United States recommends the Committee keep the Code at Step 3 and charge the Drafting Group to develop the various Annex for the Committee's consideration at its next (34th) Session.

The United States notes that the issues of Validation and Suitability have been referred to the Committee for consideration on a cross-commodity basis and await the further development of these issues so they can be fully incorporated into the Milk Code.

International Dairy Federation

The IDF generally supports the approach taken and the suggested structure of the draft Code, recognizing that a comprehensive drafting process is still to follow.

In order to facilitate the further drafting, it is necessary that the CCFH provides guidance on how to approach the concept of "suitability" in practice. Also, the Committee's elaborations with respect to less developed businesses need to be considered in the context of this Code.

Further, a definition of the concept of Food Safety Objectives (FSO), in particular, its relationship with Appropriate Level of Protection (ALOP) is needed as reference is made to the latter throughout the Draft Code. The consequences of such reference are, at present, not transparent and quite unclear. As the Code is intended to be used by those practising dairy manufacturing, we find it more appropriate to relate the Code to FSO rather than to ALOP.

Until the detailed guidelines supporting the principles will be sufficiently developed (whether contained in annexes or within the main body of the Code), it is difficult to reflect on the suggested principles presented the main body of the Code, i.e. whether they are appropriate, adequately worded, and sufficient.

Therefore, our comments at this stage can only be of a preliminary nature.

INTRODUCTION

Mexico

In the second paragraph, fourth line, the text "... que son una fuente rica y práctica de recursos alimenticios para la población de muchos países..." // "... are a rich and convenient source of food resources for the population in many countries..."//, we suggest "que son una fuente rica y conveniente de ..." // "... are a rich and convenient source of ..."//

2.1 SCOPE

International Dairy Federation

It is stated that the Code applies to composite products as well. Throughout the rest of the Code, references are only made to milk and milk products. The approach to composite milk products in the scope should be reconsidered.

2.3 PRINCIPLES APPLYING TO THE PRODUCTION, PROCESSING AND HANDLING OF MILK, MILK PRODUCTS AND COMPOSITE MILK PRODUCTS

Brazil

Number 3: Milk and milk products should be produced, handled, stored and transported under such condition that assures a safe product.

Justification: To clarify the necessity of control in these steps. The word “best” is subjective.

Number 4, 2nd. para: to complement with: However, the 1st. Principle should be developed in order to identify adequate control measures.

Justification: Although not all principles are applicable, it is indispensable to identify the hazards and adequate control measures to be applied.

Denmark

Overarching Principles

We wonder whether the principle stated in square brackets in principle 6 really belongs in a commodity specific Code taking into account that the concepts mentioned are integrated in a number of more general Codex (draft) texts.

Mexico

In point 2.3 in relation to the applicable principles, we suggest that Item 3 be eliminated, given that this indicates a part of the food chain that is mentioned in item 2.

International Dairy Federation

We wonder whether the principle stated in square brackets in principle 6 really belongs in a commodity specific Code taking into account that the concepts mentioned are integrated in a number of more general Codex (draft) texts.

2.4 Relative roles of milk producers, manufacturers and control authorities

Brazil

1st. para.: to be added between 2nd. and 3rd. phrase: “Considering the results of risk assessment step, management systems should consider the application of the most effective option for the risk control”.

Justification: To clarify the basis and necessities for management systems.

First dash, to complement “animal illness” add as follows: "its prevention and control (e.g. vaccination schedule). "

Justification.: to assure the importance of preventive measures related with animal illness.

Fifth paragraph, suggest to eliminate the brackets and substitute for: Record keeping must be at farm level.

Justification. To assure record keeping at farm level and traceability of problems, when necessary.

2.5 DEFINITIONS (TO BE FURTHER DEVELOPED)

Brazil

Would like to present the following suggestions:

- **Definition of Food Safety Objective:** A statement of a maximum level of a hazard considered acceptable for an appropriate level of protection.
- **Consideration about Hurdle, Hurdle Technology and Microbiocidal Step:** Brazil considers that these concepts should be clear and that is necessary a better definition, in order to have a better understanding between these definitions and the text in Annex II. (e.g. UHT milk is considered safe if the thermal treatment is allied with an inviolate packaging. The thermal treatment is microbiocidal, so the safety of this product is not restrict only to one factor or process).

Denmark

If reference to Acceptable Level Of Protection is retained, a definition is necessary. Otherwise, the Code will not be practicable to implement.

Mexico

We suggest that the definition for suitability should be the same one that is established in the Recommended International Code of Practices – General Principles of Food Hygiene, which says: Suitability of Food. The guarantee that food is acceptable for human consumption, according to the intended use.

We suggest keeping the second option (short version) for the definition of “hurdle”.

We suggest the first option (long version) for the definition for “Hurdle technology,” however, the word “hurdle” would be changed to “factor”.

We suggest that the definition “Microbiocidal step” be considered as “Microbiocidal treatment: the step in the process in which...”, in order to be consistent with subsequent uses of the term.

In the definition for “Equivalent sanitary measure”, we suggest deleting the text in brackets, since even without it, the definition meets the objective of protecting consumer health.

We suggest the following definition for validation: Operational and sequential procedure to establish the reliability of the system, supported by documented information and statistical data obtained through experimentation.

We suggest defining a raw milk product as: “Those that have been processed with milk that has not been submitted to pasteurization or a similar process.

International Dairy Federation

If reference to Acceptable Level of Protection is retained, a definition is necessary. Otherwise, the Code will not be practicable to implement.

The first option suggested for Hurdle Technology is preferred. The use of capital letters suggests a concept that, when referred to, relates to a specific outcome (safe and suitable product).

We prefer reference to Microbiocidal Step rather than treatment, as a treatment could easily mean a series of steps. We suggest the following definition for Microbiocidal Step:

“Microbiocidal Step is a single processing step that, by means of killing, elimination or removal, reduces the number of micro-organism including pathogens in the treated (final or intermediate) product to a level that does not compromise food safety or suitability.”

The objectives of making reference to “raw milk product” need further consideration. The intention is that the Code provides sufficient guidance to ensure that milk products made from non-heat treated milk are safe and suitable, whether achieved by Hurdle Technology and/or by non-thermal Microbiocidal Step(s). As a logical consequence, it is necessary to consider thoroughly the term “raw”, whether it relates only to the application of heat and/or whether it also relates to other microbiocidal steps and hurdle technology.

3. PRIMARY PRODUCTION

Brazil

First para., suggestion to substitute “The raw milk...as possible”: “The hygienic and sanitarian condition of raw milk should be appropriate”.

Justification: To clarify objective of safety, not only of a “clean” product.

Fifth para., to complement with: “However, the 1st. principle should be developed in order to identify adequate control measures”.

Justification.: same of Item 2.3, number 3.

Denmark

A more descriptive word than “clean” (Paragraph. 3) is preferred. The term is old fashioned.

Kenya

Should make reference to the CAC/GL 13-1991 Guidelines for the preservation of raw milk by use of the lactoperoxidase system to prevent bacterial spoilage of raw milk during collection, and transportation to a dairy processing plant when refrigeration of raw milk is not feasible.

This is important because the guidelines are available for the purpose of preventing bacterial spoilage of raw milk during collection and transportation to a dairy processing plant when refrigeration of raw milk is not feasible and it is a practical situation in many developing countries where the dairy industry Infrastructure is being developed.

We therefore propose that this system (LPS) be recognised as an acceptable process for prevention of bacterial spoilage of raw milk and be included or cross-referenced in the DRAFT CODE OF HYGIENE PRACTICE FOR MILK AND MILK PRODUCTS.

Mexico

First subtitle (Principles Applying the Primary production of Milk), first sentence (Paragraph), where it says “la leche cruda debe ser lo más pura posible” //“raw milk should be as clean possible”//, we suggest changing it to read: “la leche cruda debe ser tan limpia como sea posible” //“raw milk should be as clean as possible.”//

Second paragraph, where it says “Durante... o extrínseco ambiental” // “During ... and extrinsic (environmental)”//, we recommend changing the order of the translation in the following manner: “Durante la producción primaria deberá reducirse al mínimo, en la medida de lo posible, la contaminación de origen intrínseco o extrínseco de la leche cruda.” // “During primary production, intrinsic and extrinsic contamination of the raw milk should be minimized as much as possible.”//

We suggest modifying the fourth paragraph, resulting in the following wording: “Any contaminant in raw milk that represents a risk to human health should not exceed the specified limit that compromises consumer health.”

International Dairy Federation

A more descriptive word than “clean” is preferred. It may be confused with “cleaned”.

3.2.2 Animal Health

Brazil

Second paragraph, To (should) be deleted.

Justification.: To not permit utilization of milk from diseased animal.

Fourth paragraph, delete “or via feces”.

Justification. To not accept feces in milk.

International Dairy Federation

The second principle should more correctly read as follows:

“Milk from diseased animals should not be used for human consumption when, considering the end use, the disease may affect such milk or milk products to present a risk to human health or adversely affect suitability.”

The Office International des Epizooties (OIE)

This section, in its present wording, seems to me to be a potential source of confusion as to the respective responsibilities of the Codex Alimentarius and the OIE regarding animal health and human health. In particular, I note that the first paragraph refers to hazards without specifying whether they are hazards to human beings or animals, and that the third paragraph, which is very vague and imprecise, could lead to sanitary measures being taken (destruction of milk, for instance) that go farther than is necessary. I

therefore propose the following alternative wording in order to remedy the problems referred to above:

3.2.2 Animal Health

The health status of milking animals should be managed in a manner that addresses the hazards of concern for human health.

The OIE is the international standard-setting organisation recognised by the WTO/SPS Agreement for standards, guidelines and recommendations dealing with animal health and zoonoses.

Zoonotic diseases which present a risk to human health from the consumption of milk and milk products include in particular :

- Q fever
- Listeriosis
- Tuberculosis (M. bovis)
- Brucellosis (B abortus, B. melitensis)

Refer to the relevant chapter in the OIE International Animal Health Code for the applicable conditions.

This alternative wording is a preliminary draft recommendation and will require more detailed examination as it has not yet been the subject of discussion by the OIE International Animal Health Code Commission (this point will be included on the agenda for the meeting of the Commission at the end of September 2000). It nevertheless contains a principle of the utmost importance, namely a reference to the OIE International Animal Health Code on the subject of zoonoses in a Codex Alimentarius document, thus strengthening the technical cooperation links that have existed between our two organisations for so many years.

3.2.3.3 Veterinary Drugs

Brazil

1st three paragraphs: change its ordination as follows: 1st para: "Diseased animals...should not be used";

2nd para: "Milk from animals which....has been achieved.";

3rd. para: "Milk from animals that have...unacceptable levels."

5th. para: suggestion to delete.

Justification Explanation not necessary in the text, since Reference of CCRVDF is included.

International Dairy Federation

The principles raise a question on point of application. Clearly, the first two principles apply at individual animal level. The third principle states that milk exceeding MRLs established should not be used. From a safety point of view, the point of application would be the bulk milk used for processing at dairy plant level as the important issue is exposure to products (suitability) and humans (safety).

Additionally, the text does not take into account treatment with substances other than “veterinary drugs” such as homeopathy, herbal remedies, etc.. Appropriate text that adequately addresses risks and suitability affected by such substances should be developed.

3.3.2 Storage Equipment

Denmark

Retain the objective of “minimizing”. The principle of ALARA (as low as reasonably achievable) is an important approach to be followed.

International Dairy Federation

Section 3.3.2 and 3.3.3. Some overlapping occurs. Should be reviewed.

Retain the objective of “minimizing”. Such objective would achieve both safety and suitability.

3.3.4 Delivery and Collection Procedures

Mexico

we suggest using the phrase “Procedimientos de recolección y distribución” // “Collection and distribution procedures”// for this subtitle. Also, in the first paragraph, the word “injustificados” // “not justified”// should be changed to “indebidos” // “improper”//.

3.3.6 Transport Procedures

Denmark

Retain the objective of “minimizing”. The principle of ALARA (as low as reasonably achievable) is an important approach to be followed.

International Dairy Federation

Retain the objective of “minimizing”. Such objective would achieve both safety and suitability.

5.2.1 Temperature Control

Mexico

We suggest removing the brackets and substituting “la aparición” //“the appearance”// for “el desarrollo” //“the development”//.

5.2.3 Microbiological and Other Specifications

Denmark

We recommend that the Drafting Group consider developing principles for analytical methodology to verify any microbiological specification. In particular, the use of routine methods versus reference methods should be addressed, in order to provide guidance on the prerequisites for applying routine methods and encourage the use of them.

5.2.3.1 Raw milk

Brazil

2nd.para. 2nd.phrase: “Other criteria (e.g.)... should be used to detect unacceptable conditions.

Justification. Other criteria are necessary and should be used (not may be used) to detect unacceptable conditions.

5.2.3.2 Microbiological end product specifications

5.2.4 Microbiological cross contamination

Mexico

Modify point 5.2.4 (First Paragraph) in the following manner: “ ... should... and intermediates ... from the environments or contact with materials at an earlier processing phase.”//

6.1 MAINTENANCE AND CLEANING

Brazil

2nd para.: to delete the word “wet”.

Justification: Whenever possible, any cleaning method should not be used.

Mexico

We suggest modifying point 6.1, second paragraph, in the following manner: “All fill machines should be adequately washed and disinfected.”

6.2 CLEANING PROGRAMS

Mexico

In point 6.2 (first paragraph), we suggest eliminating the word “cleaned”.

ANNEXES

PROVIDING GUIDELINES FOR THE APPLICATION OF THE DIFFERENT APPROACHES TO THE PRIMARY PRODUCTION AND PROCESSING OF MILK AND MILK PRODUCTS

ANNEX I, PART A

GUIDELINES FOR THE APPLICATION OF THE ‘GENERAL’ APPROACH TO PRIMARY PRODUCTION

Introduction and objectives

International Dairy Federation

The introductory parts need revision once the content of the different parts have been drafted in more detail.

ANNEX 1, PART B

GUIDELINES FOR THE PRODUCTION OF MILK BY SMALL HOLDER DAIRY FARMS

General Comments

Mexico

Instead of using the term “zonas” // “areas”//, the word “áreas” //“areas”// should be used.

3.3.4 Collection and Delivery Procedures

In point 3.3.4, we suggest using the phrase “Procedimientos de recolección y distribución” // “Collection and distribution procedures”// for this subtitle. Also, in the first paragraph, the word “injustificados” // “not justified”// should be changed to “indebidos” // “improper”//.

ANNEX II, PART A

GUIDELINES FOR THE APPLICATION AND MANAGEMENT OF HURDLE TECHNOLOGY

INTRODUCTION AND OBJECTIVES

International Dairy Federation

Additionally, we find it appropriate to develop a separate annex containing support information on the establishment of product shelf life. Such an annex can replace the texts foreseen on this area in Annex II, parts A and B.

Shelf Life

Mexico

In Annex II Part A in definitions to be developed, this should be worded as “vida útil” //“useful life”//.

ANNEX II, PART B

GUIDELINES FOR THE APPLICATION AND MANAGEMENT OF MICROBIOCIDAL TREATMENTS

ANNEX III

International Dairy Federation

We recommend the development of specific support information on water re-use.

[To be developed. To contain annexes providing support information (e.g., water reuse.)].