

codex alimentarius commission



FOOD AND AGRICULTURE
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Agenda Item 8

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

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COMMENTS ON THE

PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS

Submitted by

**Argentina, Brazil, Canada, Egypt, Mexico, New Zealand, Switzerland, the United States of
America, Consumers International, and International Dairy Federation**

Notes from the Drafting Group Meeting, May 13 – 17, 2002, Brussels, Belgium

The Drafting Group met May 13-17, 2002 in Brussels, Belgium at the kind invitation of the European Commission to revise the *Proposed Draft Code of Hygienic Practice for Milk and Milk Products* (Milk Code).

The Drafting Group considered a revised document prepared by the United States, as the lead drafting country for the Code, taking into account written comments submitted to the 34th Session of the Codex Committee on Food Hygiene (CCFH) and the discussion on the Milk Code at the 34th Session. The revised document was submitted to member countries for comments via the Codex “L” list prior to the convening of the Working Group.

Taking into account the views expressed by the 34th Session of CCFH, the revised document contained a reworked Annex I relating to primary production that combined the various approaches to primary production originally contained in three separate annexes. The revised Milk Code also contained a reworked Section 5 of the Base Code, and a reworked Annex II on the processing of milk and milk products that was substantially simplified over the previous version.

Twenty-four (24) individuals from 10 countries (Argentina, Canada, France, Germany, India, Netherlands, New Zealand, Switzerland, United Kingdom, United States) and one international non-governmental organization (International Dairy Federation) attended the meeting of the Drafting Group.

The Drafting Group made numerous changes to the revised document prepared by the United States. Major points to note in this regard are summarized below.

Importantly the Drafting Group prepared a document that contains no square bracketed text other than references to Food Safety Objectives (FSO). The Drafting Group recognized that the definition for an FSO is under discussion in the context of the *Proposed Draft Principles and Guidelines for the Conduct of Microbiological Risk Management*, currently under development by CCFH.

Notes on revisions to the milk code undertaken by the drafting group

The Drafting Group discussions and recommendations included the following:

Structure of the Document: Agreed to retain the basic formatting of the document in which the base code contains principles and explanatory narrative relating to the production, processing, labeling of milk and milk products and related areas with detailed guidelines for the application of the principles in annexes. Also agreed to combining the various approaches to primary production, including information relating to the production of milk used for raw milk products and small holder dairies into a single annex. Special provisions relating specifically to the production of milk used for raw milk products and small holder dairies are clearly identified. Additionally, the Drafting Group substantially revised the text of Annex II, primarily reordering and supplying text but also adding text to more fully explain the application of HACCP to milk and milk products, including the furnishing of preliminary data for hazard analysis, hazard analysis and the design of the control system.

Chemical and Physical Hazards: Recognized that food hygiene as applied to milk and milk products included chemical and physical hazards as well as microbiological hazards and agreed to incorporate provisions with respect to these hazards, as appropriate, throughout the document.

Small Holder Dairies: Agreed to a definition for small holder dairies (see Annex 1) as follows: Small holder dairies refers to farms where the number of animals per farmer usually does not exceed 10, milking machines are not generally used, milk is not chilled at the producer level and the milk is transported in cans. Flexibility in the application of certain requirements of primary production was provided, so long as the milk is received by dairy plants and is intended to be subjected to a combination of microbiological control measures sufficient to obtain a safe and suitable product. The Drafting Group also recognized that certain types of dairy farms may also have some of the characteristics of small holder dairies but maintain animal herds that are larger than 10; to cover these situations, the Drafting Group added text (see Annex 1) that states “flexibility as above may also apply to farms with a larger number animals but having similar economic constraints preventing investment in technological facilities and infrastructure, or limited water and/or power supplies.

Special Provisions Relating to the Production of Milk Used for Raw Milk Products: Agreed to add additional language to the introductory section of Annex 1 relating to this area that noted that additional measures are set out in the Annex relating to the production of milk used for raw milk production and that the respect of these measures by the producer is indispensable/compulsory so as to allow the milk to

be used for the production of raw milk products. Further, the Drafting Group added additional language in this section that noted that a system of preventative control which may include monitoring and record keeping requirements should be used to focus appropriate attention to the management of activities that are necessary to assure the safety of raw milk products.

Milking Animals: Agreed that the Milk Code applied to all milk and milk products obtained from all milking animals, not just bovine species, and incorporated a footnote in this regard.

Animal Health: Provisions relating to animal health were strengthened, particularly as related to the production of raw milk intended for the production of raw milk products, including reference to pertinent provisions developed by the Office International des Epizooties (OIE).

Consideration of incorporating the Principles found in the *Proposed Draft General Principles of Meat Hygiene*: Reviewed these general principles currently under development by the Codex Committee on Meat Hygiene with a view to incorporating them (suitably amended to apply to milk and milk products) into the Milk Code. While the Drafting Group considered the principles generally helpful and appropriate, the Drafting Group felt that the principles were, for the most part, overarching principles that could apply to food generally and, thus, were probably more appropriate to include in a revision to the *Recommended International Code of Practice: General Principles of Food Hygiene*.

Definition of Validation: Discussed extensively the areas of validation and the determining the performance of food hygiene control measures (see below) and agreed to incorporate the definition for validation currently proposed in the Codex *Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures* (document under development by CCFH). In this document, validation is defined as “the obtaining of evidence that the food hygiene control measures selected to control a specific hazard(s) in a specific food(s) are effective in controlling the hazard to the level intended”.

Control Measures: Recognized that control measures were broad in scope, incorporating both preventative measures as well as microbiocidal and microbiostatic measures, and extending from primary production through processing to storage, distribution and retail sale. The Drafting Group incorporated the definition of control measure from the HACCP annex to the *Recommended International Code of Practice: General Principles of Food Hygiene*. Additionally, the Drafting Group added a footnote to this definition indicating the type and scope of control measures, deleted a definition for “preventative measure” from Annex II and replaced the term “preventative measure” with “control measure” throughout the text.

Suitability: Noted that the section on suitability referenced the definition for suitability in the *Recommended International Code of Practice: General Principles of Food Hygiene*, that the section on suitability more fully explained the term with respect to milk and milk and products, and agreed to delete the definition from the Milk Code.

Definitions of Raw Milk Product, Raw Milk: Agreed to delete the definition for raw milk product and to incorporate a definition for raw milk, noting the difficulty in appropriately defining the broad range of raw milk products. The Drafting Group agreed to incorporate into Annex I under “Special Provisions for the Production of Raw Milk Used for Raw Milk Products”, a discussion of the nature and scope of raw milk products

Time and Temperature Controls: Recognized that time and temperature controls considered to be appropriate for milk and milk products varied depending upon the product type and national legislation requirements and, therefore used language in both the base code and the Annexes (except for special provisions for raw milk products) specifying that storage times and temperatures should be such that they minimize any detrimental effect on the safety and suitability of milk.

Intrinsic and Extrinsic Factors: Noted that the use of these terms could be confusing and agreed to provide an explanation of the terms as they were used in the Milk Code. Extrinsic factors were explained as external factors impacting on the product from the outside, including the product's environment. Intrinsic factors were explained as internal factors in the food product itself that have an impact on the growth and/or survival of microorganisms. Intrinsic factors may be affected by extrinsic factors.

Performance of Microbiological Control Measures: Discussed at length the need to include text relating to determining the performance of control measures. The Drafting Group agreed that this subject was very important but that it was a cross-cutting one and should more properly be considered in the context of the *Proposed Draft Guidelines for the Validation of Food Hygiene Control Measures* (document under development). The Drafting Group encouraged the International Dairy Federation, which proposed inclusion of this subject in the Milk Code, and which also provided a specific approach to determine the effectiveness of food hygiene control measures, to bring detailed information on this subject forward at the next Session of CCFH for consideration within the larger context of validation of food hygiene control measures.

Water Reuse: Consideration was given to including the principles on water reuse appearing in the *Proposed Draft Guidelines for the Hygienic Reuse of Processing Water in Food Plants*, recognizing that it was not likely that CCFH would continue work on this document. Additionally, consideration was given to including the more detailed guidelines for water reuse relating to the processing of dairy products that was included as an Annex to a previous version of the same water reuse document. The Drafting Group ultimately decided not to use this information directly but did include in Section 5.5 specific principles relating to the use of water.

Allergens: Agreed that mention should be made in Section 9 of the Base Code to Section 4.2.1.4 of the *Codex General Standard for the Labelling of Prepackaged Food* relating to the need for mandatory declaration in the food product ingredient statement of foods known to cause hypersensitivity. Milk and milk products are included in the list of foods known to cause hypersensitivity.

Labeling of Raw Milk Products: Agreed to insert as an additional special provision relating to raw milk products that such products should be labeled to indicate they are made from raw milk.

Consumer Education with Respect to Raw Milk Products: Agreed to include a provision in Section 9.4, Consumer Education, that "vulnerable populations should be informed of the risk associated with certain products.

Verification of Performance for Heat Treatments: Agreed to incorporate text indicating that the appropriateness of the alkaline phosphatase test to indicate proper pasteurization of milk is animal specie dependent and may not be appropriate to use for species other than bovine.

**COMMENTS ON THE
PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK
PRODUCTS (CX/FH 03/09)**

GENERAL COMMENTS

ARGENTINA

In general, the comments for this document are the same as were sent to the Working Group. Of the three that were sent to the Working Group in August, our opinion on the definition of small holder dairies was the only one taken into consideration.

Therefore, we reiterate the comments sent in reference to the two issues for which the observations from our country were not taken into consideration in the document edited by the Working Group. The observations on both points, Lactoperoxidase and Irradiation, are considered important, and it is our position that our suggestions should be re-considered.

BRAZIL

Brazil congratulates the Drafting Group for the progress shown in the document. Although Brazil agrees that detailed information should be kept to the minimum necessary to ensure the flexibility for all systems of milk and milk production in different parts of the world, we believe that a significant number of issues need further specification. Therefore Brazil believes that all efforts should be taken in order to grant a specific and objective approach to the document.

CANADA

Canada would like to thank the United States for leading the Drafting Group responsible for the development of the revised document. It provides specific information that will be useful for the users.

EGYPT

EOS suggests designating separate guidelines and instructions for Milk and Milk Products as follows:

Primary Production:

- Animal Health
- Workers Health
- The Dairy Plant: small-holder dairies

The production of raw milk used for processing milk products.

Guidelines for control measures applied after and during milk products processing.

Microbiological control measures for:

- Killing microorganisms.
- Inactivation of microorganisms.
- Removal of microorganisms.

MEXICO

Mexico is generally in agreement with the document; however, we suggest reviewing the Spanish translation, since there are points that cause confusion in the theoretical content and between the versions in the different languages.

NEW ZEALAND

We are pleased to see the progress that has been made on this code, and we are generally satisfied that it is ready to advance to Step 5.

UNITED STATES OF AMERICA

The United States strongly supports the *Proposed Draft Code of Hygienic Practice for Milk and Milk Products* and believes that this document is now sufficiently developed and ready for advancement to Step 5.

The United States would again like to express its appreciation by acknowledging the efforts of its drafting partners in revising this Proposed Draft Code. The current document is the result of considerable and determined effort on the part of the drafting group partners and the Committee since the 34th Session. As directed by the Committee, the drafting group revised the document based on comments received prior to and during the 34th Session as well as those received prior to the meeting of the drafting group via circulation of the Code to the Codex L list.

The United States looks forward to a detailed and substantive discussion of the Proposed Draft Code during the 35th Session.

CONSUMERS INTERNATIONAL

Consumers International appreciates the opportunity to comment on this draft process and commends the committee for developing such a detailed proposal. Where we recommend additional text this has been written in capital letters.

In the whole text of the Code there are several places where it talks about "minimizing" contamination. Consumers international believes it would be better to change this to "PREVENT OR MINIMIZE" or "PREVENT OR AVOID".

INTRODUCTION**CONSUMERS INTERNATIONAL**

We believe that the importance of milk and milk products to the diet of sensitive subpopulations should be made explicit in this section. The following sentence should be added after "It is the purpose of his Code to provide guidelines to countries so that their appropriate level of public health protection for milk and milk products may be achieved."

“It is also the purpose of this code to prevent unhygienic practices and conditions in the production, processing, and handling of milk and milk products, as in many countries milk and milk products form a

large portion of the diet for sensitive subpopulations (infants, children, and pregnant and lactating women)."

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

BRAZIL

In the first principle, it is suggested that the term “dairy products” should be altered to “milk and milk products”. This suggestion is proposed considering that the last term has been used in the scope of the body document. In the case the Committee decides to keep the term “dairy products”, we recommend to insert its definition in the item 2.5.

MEXICO

For point 2.3, 3rd bullet, Keeping the explanatory note in mind, we suggest that the principle should deal with said explanation, thereby reading as follows: “Wherever necessary and possible, hygienic practices for milk and milk products should be implemented within the context of HACCP as described in the Annex to the Recommended International Code of Practice – General Principles of Food Hygiene“

2.4 Relative roles of milk producers, manufacturers, distributors and competent authorities

BRAZIL

In the title, it is proposed the introduction of the terms "retailers", “transporters” and “consumers”, resulting in the following phrasal construction: “Relative Roles of Milk Producers, Manufacturers, Distributors, Retailers, Transporters, Consumers, and Competent Authorities”.

In the second paragraph, first sentence, we suggest the introduction of "retailers”, resulting in the following wording: “... with through communication and interaction between milk producer, the manufacturer, the distributor and the retailer.”

In the third paragraph, third bullet, we suggest the introduction of "retailers”, resulting in the following wording: “Distributors, transporters and retailers should assure that milk and milk products under their control are handled and stored properly and according to the manufacturer’s instructions.”

The justification to the inclusion of this term relates to the explanatory note, presented in the item 2.3, which states that: “The Code should only be used within the context of an understanding that there is a continuum of controls that are applied from production to consumption”. Therefore, it is important to emphasize the role performed by retailers (by retailers, Brazil means “*person who sales milk and milk products in small quantities to the consumers*”). In order to assure the clear distinction between the terms “retailers” and “distributors”, we suggest the inclusion of the latter definition, as well as the definition of “distributor” (*person who distributes milk and milk products from manufacturer to retailers*), in the item 2.5.

CONSUMERS INTERNATIONAL

the first paragraph states "Although the responsibility lies with the manufacturer for ensuring that all foods manufactured are safe and suitable, there is a continuum of effective effort or controls needed by other parties, including milk producers, to assure the safety and suitability of milk products." Therefore in section 5.1.1. *Hazard identification*, we believe that it should be made clear that the manufacturer, in the first instance, has the specific responsibility to identify potential hazards. Consumers International suggests that the second sentence to this section should read:

"The identification MADE BY THE MANUFACTURER should be based on the initial descriptions developed during preliminary steps and on experience, external information, as well as epidemiological and other historical data that have been associated with the type of food under consideration, the type of raw materials and ingredients used, and that may be introduced during processing and distribution."

If other parties have roles in this identification then these should also be stated clearly.

2.4 DEFINITIONS**BRAZIL**

Brazil also proposes the insertion of the definitions of "milk products" and "composite milk products" in this item, as established in the *Codex General Standard for Use of Dairy Terms*.

Raw milk**BRAZIL**

It is suggested the definition of "raw milk" to be altered to: "milk that has not been heated or undergone any treatment that eliminate a food safety hazard or reduce it to an acceptable level."

3 PRIMARY PRODUCTION**Principles Applying to the Primary Production of Milk:**

Milk should have a microbial load as low as possible.

NEW ZEALAND

The third principle (the text in bold) implies a constant pressure to reduce the microbial load, whereas the commentary does not indicate such a need. It should be modified to read:

"The microbial load of milk should be as low as achievable using good milk production practices."

In the commentary following the principle, "severity" or "stringency" should replace the word "effectiveness". This makes the wording consistent with the Scope in Annex 1, and avoids a conflict with the 4th principle in 2.3, which requires control measures to be effective.

3.1 ENVIRONMENTAL HYGIENE

BRAZIL

Assuming that the second principle established that the water used in primary production operations could be other than potable water (suitable for its intended purpose), Brazil recommends the introduction of a new explanatory narrative as follows: “Appropriate safety and suitability criteria that meet the intended outcomes should be established for any water used in a primary production.”

3.2.3.1 Feeding

BRAZIL

Brazil recommends the suppression of sentence “*With consideration given to the end use of the milk*”, in order to retain the general approach characteristic to the principles presented in the body document. When the inclusion of specific or exceptional situations is necessary, we suggest its insertion in the explanatory note or in Annex I.

CONSUMERS INTERNATIONAL

we believe that it is better to refer to ensuring safety, rather than preventing unacceptable risks. We therefore suggest deleting “in amounts that present an unacceptable health risk..” so that the sentence reads:

“With consideration given to the end use of milk, forage, and feed for lactating animals should not introduce, directly or indirectly, microbiological or chemical contaminants into milk in amounts that present an unacceptable health risk to the consumer or adversely affect the suitability of milk or milk products SO AS TO ENSURE THE SAFETY AND SUITABILITY OF MILK AND MILK PRODUCTS.”

3.2.3.2 Treatment for Pests

MEXICO

In point 3.2.3.2, we propose changing the title to: “3.2.3.2 Pest Control”.

3.2.3.3 Veterinary Drugs

BRAZIL

On the second paragraph, Brazil suggests the inclusion of the following explanatory narrative: “When use of antimicrobials is necessary, it should be used in a manner that minimize the occurrence of antimicrobial resistance.” This suggestion is related to the implementation of measures that control existing misuse of antimicrobials (such as the use of antimicrobials at lower than therapeutic dose).

CANADA

The second paragraph related to discarding milk appears to be a guideline not a narrative. Since this same statement is already included in Annex I, we suggest its removal from the main Code.

MEXICO

We propose the following wording for the principle: “Animals should be treated only with those veterinary medicines permitted for the particular use and prescribed by a Veterinarian, so that they do not negatively impact the safety and suitability of the milk, including compliance with the specified withdrawal period”.

3.3 HANDLING, STORAGE AND TRANSPORT OF MILK**BRAZIL**

Brazil recommends the suppression of sentence “*With consideration given to the end use of the milk*”, in order to retain the general approach characteristic to the principles presented in the body document. When the inclusion of specific or exceptional situations is necessary, we suggest its insertion in the explanatory note or in Annex I.

3.3.1 Milking Equipment**CANADA**

The second paragraph is more than a narrative statement. We suggest that the concepts in sentences two and three be moved to Annex I, “Guidelines for the Primary Production of Milk”. The remaining narrative statement could be :”*Milking equipment which is improperly designed and constructed may introduce contaminants into milk and incorrect usage of it could transfer disease between animals.*”

3.3.2 Storage Equipment**INTERNATIONAL DAIRY FEDERATION**

The principle should also refer to minimizing the growth of microorganisms.

3.3.4 Collection, Transport and Delivery Procedures and Equipment**INTERNATIONAL DAIRY FEDERATION**

The 2nd principle should also refer to minimizing the growth of microorganisms.

3.4 DOCUMENTATION AND RECORD KEEPING**BRAZIL**

Brazil suggests that item 3.4 approaches the subject Cleaning, Maintenance and Personnel Hygiene at Primary Production, maintaining the format of the document in accordance with the *Recommended International Code of Practice – General Principles of Food Hygiene*, CAC/RPC 1-1969, Ver. 3, 1997. In the case the Committee believes there are no specific principles to be approached in the suggested item, we recommend the inclusion of the following paragraph: “No specific requirements beyond those contained in the Recommended International Code of Practice – General Principles of Food Hygiene, CAC/RPC 1-1969, Ver. 3, 1997 are needed.” Once this suggestion is accepted, the item Documentation and record keeping will be numbered as 3.5.

4 ESTABLISHMENT: DESIGN AND FACILITIES

5.1 CONTROL OF FOOD HAZARDS

BRAZIL

Brazil believes the subject current in items 5.1.1 to 5.1.3 constitute a partial supplementation of the components of HACCP stated in *Annex: Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application*. Therefore, these items should be complemented in a way to include all other components, or they should be eliminated.

NEW ZEALAND

In the 3rd paragraph, a comma should follow the word "*appropriate*" to make the meaning clear.

5.1.1 Hazard Identification

NEW ZEALAND

Potential hazards associated with each step in the process are "those that may be reasonably expected to occur". This is not clear in this section. We suggest new wording at the beginning of the first paragraph (after the italicized sentence), to clarify and align with the Codex HACCP Guidelines (Annex to CAC/RCP 1-1969, Rev, 3 (1997), as follows:

"Identify all the hazards that may be reasonably expected to occur at each step. The identification should be based..."

The second paragraph makes specific reference to allergens and not to other hazards, this is inconsistent and we suggest it is not appropriate to highlight just one hazard. The reference to product labelling with respect to allergens also seems inconsistent and we suggest that as labelling is adequately covered by the GSLPF it need not be duplicated here.

This paragraph is also problematic in that in the last sentence (in bold), it refers to hazard evaluation for severity and likelihood of occurrence. What is a severe hazard? We suggest the wording "*unacceptable levels*" is more easily understood. Likelihood of occurrence should already be covered in the initial hazard identification process as per the first paragraph and the Code HACCP Guidelines, as mentioned above. Therefore, rewording for this last sentence is suggested as follows:

INTERNATIONAL DAIRY FEDERATION

The current text of the 3rd para. relating to allergens contains two provisions:

1. that they need be identified as hazards to be subject to hazard analyses (first sentence of 2nd para.)
2. that ingredients such as nuts, eggs, cereal grains and milk products used in any food need be listed as ingredients in the product labelling (rest of 2nd para.)

This para. should be deleted for the following reasons:

- Allergens are important hazards – likewise many other agents. Although, focus on the fact that allergens need to be addressed as hazards have been increasing in recent years, we see no need to highlight these hazards without mentioning others.
- The reference to product labeling is not needed as the principle is already covered by the GSLPF in an adequate way – in fact the GSLPF is even more precise, whereas limited reference in this Code as to which ingredients need to be labelled may only raise confusion.
- The proposed reference to labelling also implies that product labelling is the principal control measure – other measures are more important, such as cleaning of equipment, selection/separation of ingredients).

The fourth paragraph should be reworded as a consequential change to the suggestions above, we suggest: “Potential hazards that are determined to be at unacceptable levels, should be subject to control by appropriate control measures.”

5.1.2 Control Measure Selection

NEW ZEALAND

Second paragraph, first sentence, New Zealand suggests consequential changes to “*identified as severe and/or likely to occur*” as a result of changes mentioned above, to “*identified at unacceptable levels*”. The commentary also needs to be changed as a consequential to accepting the above suggestions.

Control measures and control measure combinations should be selected that will control the hazards identified as severe and/or likely to occur.

5.1.3 Establishment of Process Criteria (Critical Limit Determination)

CANADA

Since process criteria are broader than critical limits, and it appears that this section is addressing process criteria, we suggest the removal of the phrase within the brackets (critical limit determination).

INTERNATIONAL DAIRY FEDERATION

Delete the phrase in between brackets, as the text in this section does not address critical limit determination – it only addresses process criteria. Process criteria and critical limits differ in regard of their role and purpose and they are not necessarily equivalent.

5.2.1 Temperature and Time Controls

NEW ZEALAND

We suggest the principle be reworded to read “...for appropriate times such that the growth of a food safety hazard would be minimised”. “Growth” is a more commonly used term in association with potential temperature abuse.

5.2.1.1 Management of products within the plant

Intermediate Products

INTERNATIONAL DAIRY FEDERATION

In the italic text, the term “subsequently” has been omitted in the 3rd line just before the word “preventing”.

To the second principle (first in, first out), add “whenever practically” to accommodate for those few situations where the drafted principle cannot be followed.

5.2.1.2 Distribution of Finished Products**CANADA**

We suggest the removal of all but the first sentence in the second paragraph since these guidelines are already included in Annex II, “Guidelines for the Management of Control Measures During and After Processing”.

5.2.2 Specific Process Steps**CANADA**

We suggest the removal of all but the first sentence in the second paragraph since these guidelines are already included in Annex II, “Guidelines for the Management of Control Measures During and After Processing”.

5.2.3.2 Microbiological end product specifications**CANADA**

In order to follow the concepts of HACCP, we suggest the replacement of the current principle statement with the following:

“Microbiological criteria may be necessary to verify that the finished product has been produced using effective control measures.”

NEW ZEALAND

New Zealand suggests that changes need to be made to align this section with the Codex Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21 – 1997).

INTERNATIONAL DAIRY FEDERATION

The principle needs to be aligned with the Codex Principles for the Establishment and Application of Microbiological Criteria for Foods (CAC/GL 21-1997).

According to these principles, the microbiological criteria may be used to formulate design requirements and/or to verify the efficacy of HACCP and/or GHP systems when other means of verifying the efficacy are not available.

The use of microbiological criteria to evaluate the safety of finished products is only relevant when the product is of unknown or uncertain origin. Products produced and manufactured according to the Code will have to meet any FSOs established (otherwise they are not produced according to the Code) – such products can hardly be regarded as of unknown/uncertain origin.

In other words, the primary role of microbiological criteria is to verify the efficacy of HACCP and/or GHP systems.

Further, we do not see a need to recommend that the use of microbiological criteria for system verification is to be restricted to raw milk products. The principle is horizontal in nature.

We suggest replacing the proposed draft principle with the following:

“Microbiological criteria may be necessary to be established for carrying out the design of control measure combinations and for the verification of that the control system has been implemented correctly.”

5.2.4 Microbiological cross contamination

INTERNATIONAL DAIRY FEDERATION

The meaning of the second principle is confusing. We suggest the following rewording:

“The flow of contaminating materials should not cross the flow of materials that are not ~~should not be contaminated~~ and that is not subject to decontamination at a later step.”

5.2.5 Physical and chemical contamination

CANADA

Both the second and third paragraphs appear to be guidelines specific to Management of Control After Processing and should be moved to Annex II. The second paragraph needs to be reworded in order to clarify the intent.

5.3 INCOMING MATERIAL (OTHER THAN MILK) REQUIREMENTS

INTERNATIONAL DAIRY FEDERATION

The last part of the principle is confusing. We suggest the following rewording:

“....., and their compliance with these specifications should be verified prior to use.”

5.5 WATER

CANADA

The fourth paragraph appears to be more of a guideline than a narrative and we suggest that it be moved to Annex II as the following statement:

“Filter systems should be monitored, cleaned and replaced at an adequate frequency.”

NEW ZEALAND

We suggest the words “*dairy establishments*” should be replaced by “*dairy processing plants*” to avoid confusion between farm milking sheds and dairy manufacturing plants.

9.3 LABELLING

NEW ZEALAND

We are not convinced that it is necessary to include a requirement to label raw milk products in this code. All products produced in accordance with the code are expected to achieve the appropriate level of public health protection, and there is therefore no hygiene justification for singling out raw milk products for labelling.

CONSUMERS INTERNATIONAL

we think that there is a need to include safe handling instructions, saying more than just “Raw milk products should be labeled to indicate they are made from raw milk”. Earlier, in section 2.4 the fourth bullet point states that “consumers should accept the responsibility of ensuring that milk and milk products in their possession are handled and stored properly and according to the manufacturer’s instructions”. But yet there are no specific instructions given for raw milk products. Consumers International recommends that the following text be added:

"Raw milk products should be labeled to indicate they are made from raw milk. A STATEMENT REGARDING THE NEED FOR REFRIGERATION OR FREEZING OR OTHER SAFE HANDLING INSTRUCTIONS SHOULD BE INCLUDED ON THE LABEL OF THE PRODUCT".

INTERNATIONAL DAIRY FEDERATION

The reference to product labeling of allergens is already covered by the GSLPF in an adequate way – in fact the GSLPF is even more precise, whereas limited reference in this Code as to which ingredients need to be labelled may only raise confusion.

9.4 CONSUMER EDUCATION

CONSUMERS INTERNATIONAL

we believe that it should be made clear who the vulnerable populations are. Consumers International recommends the following changes to the text:

" RECOGNIZED vulnerable populations LIKE INFANTS, CHILDREN, PREGNANT AND LACTATING WOMEN, AND ELDERLY PEOPLE should be informed of the risks associated with certain products".

INTERNATIONAL DAIRY FEDERATION

Education of vulnerable populations is a horizontal risk management issue, which is not specifically related to milk and milk products. We suggest that this be handled in a horizontal matter, for instance, within the Principles and Guidelines for Microbiological Risk Management, which are currently being developed by the CCFH.

ANNEX I - GUIDELINES FOR THE PRIMARY PRODUCTION OF MILK

SCOPE

CANADA

We believe the statement that the code does not extend to the production of raw drinking milk should be moved from Annex I and placed into the main body of the Code under Section 2.1.

USE OF ANNEX I

Additional Provisions for the Production of Milk Used for Raw Milk Products.

CANADA

The use of the term “shall” is not used consistently in the various sections where these provisions are added. For example, under 3.2.1.2, 3.2.4.3, and 3.3.2.

3.1.1.1 Animal holding areas

CONSUMERS INTERNATIONAL

“ADDITIONAL PROVISIONS FOR THE PRODUCTION OF MILK USED FOR RAW MILK PRODUCTS” talks about animal holding areas not adversely affecting the health of animals and minimizing the risk of teat injuries and udder diseases. Consumers International believes that this should apply to all milk products, not only raw milk products. We suggest that the sub-heading - “Additional Provisions for the Production of Milk Used for Raw Milk Products” - be removed and the text following remains.

3.2.1.2 Milk areas and related facilities

MEXICO

In the last bullet in point 3.2.1.2, the provision should be broadened to say: “the effective protection against harmful fauna”.

3.2.2 Animal health

NEW ZEALAND

We suggest “*sanitary authorities*” be changed to “*competent authority*” and consequential changes be made throughout the document. Similarly “*national authority*” and “*authority having jurisdiction*” are mentioned elsewhere and should be changed to “*competent authority*”. This aligns with recent Codex work and produces a consistent approach throughout the document.

Additional Provisions for the Production of Milk Used for Raw Milk Products

SWITZERLAND

Third paragraph, "In particular, preventative measures are needed to prevent disease including", first bullet, delete in its entirety and substitute the following: "Only healthy animals should be introduced in the herd."

It is not applicable that a farmer who buys a cow has put the cow first into quarantine and examines its health status. On small farms there is no possibility of quarantine. Neither makes it much sense to examine every single cow. Additionally according to OIE Switzerland is free from zoonosis such as brucellosis and tuberculosis. Also with reference to this fact we are not examining every single animal.

Third paragraph, "In particular, preventative measures are needed to prevent disease including", second bullet, We suggest to amend the sentence in the following manner:

"The owner shall keep record of relevant information, ~~i.e. results of tests carried out to establish the status of an animal just being introduced,~~ and the identity of each animal either being introduced or leaving the herd." Since, it is impossible for a farmer to test every single animal he is buying and introducing into the herd. From an economic point of view it wouldn't be affordable.

CONSUMERS INTERNATIONAL

Fourth paragraph, "Adequate measures shall be implemented in order to prevent udder infections, especially:..." and ends with "the management of dry and lactation periods (e.g., treatment for the drying off).", should be placed before the section on "*Additional Provisions for the Production of Milk Used for Raw Milk Products*". This paragraph would then apply to all products, not just milk used for raw milk products

3.2.3.2 Pest

MEXICO

We propose that the title for the point 3.2.3.2 should be changed to: "3.2.3.2 Pest Control."

On the other hand, we propose including an additional paragraph, to read as follows: "Empty containers with residues from toxic substances or pesticides should be disposed of properly".

3.2.3.3 Veterinary Drugs

INTERNATIONAL DAIRY FEDERATION

The third paragraph currently requires national authorities to authorize all medical products. This is obviously not correct.

We suggest the following rephrasing of the paragraph:

"Only those medicinal products and medicinal premixes that have been authorized for inclusion in animal feed should be used."

3.2.4 Hygienic milking

BRAZIL

In the last paragraph, Brazil proposes to add the following sentence: “Animals should remain standing after milking to allow the teat sphincter to close”. This suggestion aims to avoid the introduction of pathogens into mammary gland after the milking activity.

MEXICO

Despite the fact that it could be thought of as a translation problem, it is essential that the second sentence of the last paragraph in point 3.2.4 (page 33) be corrected in the Spanish text to read: “La cantidad de leche deberá vigilarse por medio directos o indirectos, para verificar que la leche tenga una apariencia normal” //”The quantity of milk should be directly or indirectly monitored to verify that the milk has a normal appearance”//.

NEW ZEALAND

The last paragraph refers to monitoring the initial milk to verify that the milk appears normal. We suggest other methods for ensuring that milk is normal should also be mentioned, for instance visual checking for inflammation and swelling, and records and identification of treated animals. We offer the following rewording:

“The milker should ensure by appropriate means that the milk is normal, for example by careful observation of the condition of milking animals, by checking the initial milk, and by using records and identification of treated animals.”

The stringency of control measures at this point relates to other measures that may be applied. For instance in New Zealand, raw milk supplied is monitored frequently for somatic cell count and bacterial count, and incentive or penalty schemes are used to ensure that standards are achieved. In this situation specific requirements for checking the initial milk are less necessary.

INTERNATIONAL DAIRY FEDERATION

In the 4th para. starting with “Animals showing.....” we suggest adding the following at the end of the paragraph:

“...and should not contaminate milk from healthy animals.”

3.2.4.4 Health and personal hygiene of Milking Personnel

NEW ZEALAND

The third and fourth sentences can apply in situations where there is a management structure in the milking area. The sentences can be deleted since the essential requirement is covered in the first sentence.

3.3.2 Milk Storage equipment

Additional Provisions for the Production of Milk Used for Raw Milk Products

SWITZERLAND

First Paragraph, amend it to read: "“Milk tanks and cans can be used only to store milk **or whey**”.

Some dairy farmers who are delivering milk for cheese making get returned whey within the can in which they are delivering milk.

3.3.3 Premises for, and storage of, milk and milking-related equipment***Additional Provisions for the Production of Milk Used for Raw Milk Products*****BRAZIL**

In relationship to the second point of the first paragraph, in case where milk is not daily collected, we suggest the establishment of a maximum limit of time after milking for the storage of milk at the temperature equal to or below 4°C. More precisely, Brazil proposes the maximum limit of 48 hours after milking for the storage of milk at the temperature equal to or below 4°C.

NEW ZEALAND

It is the manufacturer that should approve use of milk held above the temperatures (although the authority having jurisdiction should still approve the temperature), as the manufacturer is responsible for the safety of the product and will know the intended use of the product.

INTERNATIONAL DAIRY FEDERATION

Under the additional provisions, the last para, states that deviations from the temperatures specified above may be granted by the authority having jurisdiction.

It is necessary to require the approval by the manufacturer that receives the milk, since the manufacturer has the primary responsibility for the end product safety. No manufacturer would like to see a farmer being granted deviations without having agreed to it beforehand, as such changes need be addressed in the hazard analysis and, as necessary, additional control measures may have to be implemented during or after manufacturing in order to compensate for the amendment.

It may also be the case that the effect of such temperature deviations cannot be compensated for during or after manufacturing.

Further, in most cases, the authority having jurisdiction does not know the intended use, or the actual use, of the milk produced at the farm.

The para. in question should therefore be reworded as follows:

“Those temperatures can be exceeded, when necessary for manufacturing requirements, if those deviations will not result in an increase risk of microbiological hazards, have been approved by the manufacturer receiving the milk and by the authority having jurisdiction (~~and communicated to the manufacturer~~), and the end product will still meet the microbiological specifications as defined under 5.2.3.2.”

3.3.4.3 Transport Time and Temperature***Special Provisions for the Production of Milk Used for Raw Milk Products***

INTERNATIONAL DAIRY FEDERATION

Similar to section 3.3.3, the text under the additional provisions should allow for deviations from the temperature specified provided that it will not result in an increase risk of microbiological hazards.

3.4 RECORDKEEPING**BRAZIL**

In the first paragraph, Brazil suggests the inclusion of two points, as follows: “Time and temperature of storage” and “Control of water”.

ANNEX II - GUIDELINES FOR THE MANAGEMENT OF CONTROL MEASURES DURING AND AFTER PROCESSING

USE OF ANNEX II

CANADA

The third paragraph, last sentence refers to critical limit determination but this Annex does not specifically provide further details on those limits, therefore, we suggest removal of the reference to critical limit determination.

The word “burnetii” is misspelled, it should have only one “t”.

DEFINITIONS

Pasteurization

NEW ZEALAND

It is not appropriate to reference a verification process (phosphatase test) and we suggest the last sentence be deleted. Other definitions do not include a verification process. Including a verification process also unnecessarily restricts the use of alternative methods.

INTERNATIONAL DAIRY FEDERATION

We are concerned that a reference to phosphatase test has been included in the definition for the following reasons:

- It is not appropriate to include verification methods as part of any definition – mainly because it will exclude new verification methodology to be developed*.
- *) This would be similar to including the verification test in the definition of UHT, i.e. that it is stable after incubation at 55 °C for 7 days.
- Alkaline phosphatase is not a good method, although it is the best that is currently available – see explanatory material included in Part B.1.2 – section on verification of process, which is more informative than the current footnote to the definition.

Depending on the quality of the material subjected to pasteurization, and if pasteurization is the decisive control measure applied, a negative phosphatase result may not always guarantee that the number of harmful organisms have been reduced to a level at which they do not constitute a significant health hazard

5.1.1 Hazard Identification

NEW ZEALAND

Similar problems arise in this section as mentioned above in reference to Section 5.1 in the body of the Code. Consequential changes would address this section if the suggestions for section 5.1 within the body of the Code were accepted.

We suggest rewording the last sentence of the fourth paragraph, as follows: *“Consultation with the competent authority in relation to the herds, is appropriate.”*

5.1.2 Control Measure Selection

NEW ZEALAND

New Zealand suggests a partial rewording of the italicised note to read *“...the concepts also can be applied to the control of chemical and physical hazards.”* This improves readability of the sentence.

We also suggest rewording the beginning the first paragraph to read *“Once unacceptable hazards have been identified, the next step...”* This is a consequential to changes in 5.1.1 as suggested above.

INTERNATIONAL DAIRY FEDERATION

Segregate the texts in the last paragraph

The text addresses two different situations as follows:

- handling of consequences of granting flexibility for small holder dairy farms
- special attention in the case that certain animal diseases are present in the herds

The current joint location of the texts describing these two situations gives the impression that they both relate particularly to small holder dairy farms, which is not true. The second situation is general and can be the case in all types of dairy productions. Therefore, a new para. should be allocated to the last sentence and the word “Similarly” be deleted

Improvement of the second sentence

The sentence starting with “Attention should also be paid.....” could be slightly improved to ensure that the attention is focused on the potential consequences of the deviations granted. We suggest the following rephrasing of the sentence:

“Attention should also be paid to the assessment of probabilities for any additional zoonotic hazards and/or any increased levels of microbiological hazards that may likely result from the deviations granted and to the subsequent application of microbiological control measures with such performance that they effectively control them eliminate any additional risks associated with the transfer of additional zoonotic hazards to the milk as well as any likelihood of higher levels of microbiological hazards.”

5.1.3 Establishment of Process Criteria (Critical Limit Determination)

CANADA

As per our earlier comment on this section, in the main body of the Code, remove the phrase within the brackets - (Critical Limit Determination). As well, delete the last sentence of the first paragraph, which also refers to critical limits.

INTERNATIONAL DAIRY FEDERATION

Reword the section heading into “*Establishment of Performance and Process Criteria*”, for the following reasons:

- the text in this section does not address critical limit determination
- the first para. of this section addresses process criteria whereas the last 3 paragraphs address performance.

First para.

Process criteria and critical limits differ in regard of their role and purpose and they are not necessarily equivalent.

Process criteria are parameters used in the set-up of the processing step and these are not necessarily the same as critical limits. For instance, a typical control parameter for pasteurization is 72°C, 15 sec. while the typical critical limit would be minimum temperature setting and minimum flow rate. A critical limit is established for monitoring purposes, whereas a process criterion is established to control the operation. Consequently, holding time for pasteurization is a process criterion but not a critical limit, as time is not subject to monitoring when using a pre-designed heat exchanger (with fixed dimensions of the holding tube). Instead, flow rate can constitute a critical limit as the determining factor for the holding time within the tube.

In order not to confuse, the word “typically” in the last sentence of the first para. should be replaced by “may and may not” and the above should be reflected in an explanatory note.

It should be noted that the ICMSF has defined this term as “the parameters of a step or combinations of steps that can be applied to achieve a performance criterion”.

APPENDIX A: MICROBIOSTATIC CONTROL MEASURES

INTERNATIONAL DAIRY FEDERATION

Introductory notes, the introductory note assumes that none of the measures listed have been validated. This is not true – many scientific papers published provide validation results on many of these measures.

The important message of such note should be to avoid the perception that the control measures listed could be used unconditionally. As stated in the section 2.3 of the main body of the Code, all control measures should be validated prior to use.

We suggest the notes be rephrased into the following:

“Note: The control measures described in this appendix are presented as descriptive examples only and require validation prior to use ~~have not been [validated]~~.”

Lactoperoxidase system: **FOOTNOTE 12**

ARGENTINA

In the explanatory note about the use of Hydrogen peroxide-catalase method and Lactoperoxidase system, **we suggest to add the following reference:** “ALINORM 99/11 paragraphs 92 to 96”.-

INTERNATIONAL DAIRY FEDERATION

The following should be added to the text in the foot note:

“A revision of CAC/GL 13-1991 has been proposed and JECFA has been requested to carry out an assessment of the safety of the use of lactoperoxidase system (ALINORM 03/03A).”

Modified atmosphere: **CANADA**

The last sentence should be rewritten as follows:

Establishing anaerobic environment to limit growth of aerobic microorganisms may allow for the proliferation of certain anaerobic pathogenic microorganisms.

APPENDIX B: MICROBIOCIDAL CONTROL MEASURES

CANADA

The last sentence of the fourth paragraph which refers to non-thermal microbiocidal control measures that will not render the milk product safe, should be deleted since this statement may become outdated in the future as technologies advance and are able to achieve similar efficiencies.

Irradiation:

ARGENTINA

we suggest procuring technical information on the use of irradiation as a microbiological control measure in milk and milk products before including it in the Annex

WE ALSO SUGGEST PLACING THE ITEM “IRRADIATION” BETWEEN BRACKETS.

B.2.1 Description of process

CANADA

The second paragraph does not match the definition of UHT treatment. We suggest the first sentence end after the word “eventual”. The next sentence should read:

“Only when this treatment is combined with aseptic filling and packaging will the dairy product result in a commercially sterile product.”

The last sentence is unclear and requires re-wording.

Comments on the Spanish translation:

MEXICO

In the 2nd paragraph of point 3.2.3.1, we suggest changing the text in the following manner: “Se ha demostrado que una inadecuada obtención, fabricación y manipulación de los piensos para el ganado puede dar lugar a la introducción de microorganismos patógenos, organismos de alteración y agentes químicos peligrosos, tales como residuos de plaguicidas, micotoxinas y otros contaminantes, que pueden afectar la inocuidad e idoneidad de la leche y los productos lácteos”. //”It has been shown that improper procurement, manufacturing and handling of animal feed can result in the introduction of pathogens, spoilage organisms and dangerous chemical agents, such as pesticide residues, mycotoxins and other potentially hazardous agents which can affect the safety and suitability of milk and milk products”//.

In point 5.1.1 Hazard Identification, the word “Alérgica” //”allergic”// is used twice, where the word should be “alergénicas” //”allergenic”//.

In point 6.1, the principle should read: “Las áreas de procesamiento deberán mantenerse tan secas como sea posible” //”The processing areas should be kept as dry as possible”//.

In the 3rd paragraph of point 9.3 Labeling, the word “figurarse” //”appear” (reflexive)// should be changed to “figurar” //”appear”//.

Annex 1:

In the section on “Use of Annex 1” in the 5th paragraph, the following wording is suggested: “Hay una gran variedad en los productos a base de leche cruda, la mayor parte son productos adicionados con cultivos, como por ejemplo, quesos” //”There is a great variance in raw milk products, most of which are products that have cultures added, for example, cheeses...”//. This adjustment should be made wherever the term is used.

In the 9th paragraph of the same section and other parts of the text where used, we suggest adding the word “recipientes” //containers// to the word “cántaras” //cans//, to read “cántaras o recipientes” //cans or containers//.

In the 4th bullet in point 3.2.1.2, we suggest changing the text to the following: “Una separación eficaz de toda fuente de contaminación, tales como sanitarios, en su caso, y montones de estiércol; y” //”effective separation from all sources of contamination, such as lavatories, if applicable, and manure heaps; and”//.

Point 3.3 should read: “El control del tiempo y la temperatura es importante durante el almacenamiento y transporte de la leche y depende mucho de la clase y eficacia de las medidas de control aplicadas durante y después del procesamiento. Por eso, las necesidades de control del tiempo y temperatura al nivel de la granja deberán comunicarse claramente por el fabricante de los productos lácteos” . //” The control of time and temperature is important during the storage and transport of milk and depends greatly on the type and effectiveness of the control measures applied during and after processing. For this reason, the need for time and temperature control at the farm level should be clearly communicated by the manufacturer of milk products”//.

The sub-headings “Milking Equipment” and “Storage Equipment” should be numbered.

Appendix A:

On page 49 of the Spanish version of the document, it says: “Sistema Lactoperoxidasa” //”Lactoperoxidase System”//, but it should say: “Sistema Lactoperoxidasa” //”Lactoperoxidase System”//.

Appendix B:

On page 51 of the Spanish version of the document, Competitive Microflora, the documents in parenthesis say: “peróxido de hidrato” //”peroxide hydrate”//, but it should say: “peróxido de hidrógeno” //”hydrogen peroxide”//.