

# codex alimentarius commission

FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS

WORLD HEALTH  
ORGANIZATION

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**Agenda Item 5**

**CX/FH 99/5 - Add. 1**

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FOOD HYGIENE

Thirty-second Session

Washington, DC, November 29 – December 4, 1999

### PROPOSED DRAFT CODE OF HYGIENIC PRACTICE FOR MILK AND MILK PRODUCTS.

#### GOVERNMENT COMMENTS

Following Governments France, Spain, New Zealand, and the United States of America and an International Organisation, International Dairy Federation submitted comments in response to the CX/FH 99/5.

#### GENERAL COMMENTS

##### FRANCE

(a) As it is indicated in the conclusions of the meeting of the drafting group that took place in Brussels on March 1999 (Expansion of scope to include suitability - page 4) and in compliance with the paragraph 2.3 of the present code, the suitability of milk and dairy products is covered in fact by the scope of the present code. The suitability is only one of two components of 'The Food Hygiene' in compliance with the General Principles of the Food hygiene (GPFH). The other component is the notion of food safety. While waiting for debate on how to best define the embodiment of the suitability of the whole food commodity, we must respect the definition of hygiene as it is specified in the GPFH. One must not limit oneself to « safety » and to use, in the setting of the present code, the terms "Hygiene" or "suitability and safety". This correction must be made most of all in the following sections: Introduction, § 1 and 2; 3.4 Regulatory controls; 5.2.2 Food safeties control measures, title (consistent with the title of the section 5.2: Key aspects of hygiene control systems); 8.2 requirements.

(b) It is difficult, generally, to deal favourably on such a document while the annexes, parts that deal with details but nevertheless essential, are missing.

##### NEW ZEALAND

New Zealand strongly supports the redrafting of the code in the format agreed by the Drafting group that met in Brussels on March 22-25, 1999 and recognises that there is much more work to do in fleshing out the draft framework.

In moving towards a code of practice that incorporates outcome-based sanitary measures, New Zealand would like the principles developed for each section to be specifically related to the dairy industry.

These principles should be presented in the hierarchical format agreed by the Drafting Group i.e.:

- Principles
- Objectives and /or explanatory narrative
- Guidelines on application
- Prescriptive material (if necessary)
- Situations/scenarios as examples, (if appropriate)

It is not necessary to repeat principles that are stated in the General Principles of Food Hygiene, but considerable effort will be needed to systematically develop additional principles that are tailor-made for application in the unique setting of the dairy industry.

As an example, general principles in the pre-harvest section are not definitive enough and largely reflect general principles.

The philosophy of the code is moving towards application of outcome-based food controls, However there is no general discussion or explanation of a risk-based approach, appropriate levels of protection, validation etc.

The general hygiene provision for the milk product standards that is quoted in this draft needs to be explained and in this context, additional definitions will be needed.

Principles relating to safety and suitability should be separated (as agreed in Brussels, suitability needs to be addressed as a generic issue).

There still seems to be some confusion as to the role of annexes. If they are an “integral part of the code”, then their contents should be represented (and introduced) with appropriate principles in the body of the code.

## **UNITED STATES OF AMERICA**

The United States supports the current revision of the *Proposed Draft Code of Hygienic Practice for Milk and Milk Products* (CX/FH 99/5) as drafted.

The United States believes that this draft represents significant progress toward accomplishing the objectives that this Committee set out in its last Session. The framework that is proposed in this draft, if endorsed by this Committee, will set the stage for the detailed technical work necessary for rapid progress toward a final document. The issues that have been resolved through the framework document have been vigorously discussed in the Committee and elsewhere for nearly 15 years. We recall the initial breakthrough that set the stage for this progress occurred during the discussion on the hygiene provisions for the CCMMP Dairy Standards, where the CCFH agreed that no specific approach to production or processing should be mandated through Codex and that a country’s level of protection should be respected. We applaud the work of our colleagues in the drafting group.

We encourage the Committee to charge the drafting group to more fully develop the Proposed Draft Code by incorporating guidelines for the application of the principles, incorporating the explanatory information, determining the appropriate organization of the annexes, and incorporating appropriate details in both the main section of the Code and the annexes.

The U.S. believes that the technical level of work that remains can be accomplished through meetings of the drafting group within whatever operating parameters the Committee decides. This would facilitate movement of the document to Step 5.

**INTERNATIONAL DAIRY FEDERATION**

The IDF generally agrees with the **direction** the drafting process has taken. At this stage, the Draft Code is not in an adequate shape nor does it provide sufficient guidance to enable it to progress to Step 5 of the Codex Procedure.

It is recommended that the **drafting group continue** to develop the Draft Code, taking into account the comments made prior to and at the 32<sup>nd</sup> session of the CCFH.

The IDF had earlier recommended to the CCFH Drafting Group to address **suitability** issues that are considered to be fundamental in the Draft Code, such as those referring in particular to general hygienic management measures ("hygienic suitability"). If the CCFH would decide for an inclusion of these issues, we would like to propose the following approach:

Hygiene related measures applied in the manufacture of milk and milk products can be grouped as follows:

- a) Measures intended to provide a good quality (e.g. control of sporeformers, bacterial phages, etc.)
- b) Measures intended to control the general hygiene (e.g. reduction of non-specific microbial contamination)
- c) Food safety measures (e.g. human pathogens)

Quality measures (indent (a)) should not be addressed in the Draft Code but should be left to the industry.

In addition to food safety measures, general hygienic measures should be covered with the understanding that they, for the purpose of this Draft Code, equals hygienic suitability of the foods.

The above approach will ensure that the Draft Code is in conformity with the General Principles for Food Hygiene and the HACCP Guidelines.

The above approach will ensure that the Draft Code is in conformity with the General Principles for Food Hygiene and the HACCP Guidelines.

The term "hygienic suitability" could be defined as follows:

*"For the purpose of this Draft Code, hygienic suitability is the assurance that the food has been handled and/or processed according to the General Principles of Food Hygiene with no loss of hygienic control."*

If the CCFH decides not to address hygienic suitability, the consequences in relation to the TBT Agreement should be investigated. Further, it would be necessary to emphasize this fact in the scope. Otherwise, the reader may get the impression, that the Draft Code addresses all hygienic aspects related to the manufacture of milk products.

With regard to the **format of the Draft Code** the IDF recommends that all sections and sub-sections, in principle, are formatted as follows

- a section addressing Food safety Objectives
- a "principles" section;
- an "guidelines on application" section, including references to relevant annexes, where such are established.

**Validation of control measures** is an area that the drafting group has pointed out as a future work area. IDF finds that guidance in this area is needed, in particular because the Draft Code provides extensive flexibility with respect to choice of adequate control measures.

With regard to the discussion on addressing **shelf life**, it is recommended to provide guidance on how to establish shelf lives as one of the various management tools. It should not be the aim of the Draft Code to state specific duration periods.

## COMMENTS ON SPECIFIC SECTIONS OF THE CODE

### SECTION 2.1. SCOPE

#### INTERNATIONAL DAIRY FEDERATION

We recommend that the application to other foods containing milk ingredients is briefly described, e.g. by inserting the following:

“Individual sections and principles in this Draft Code may, as deemed relevant according to the outcome of risk assessments and/or hazards analyses, also apply to other foods containing milk and milk product ingredients.”

### SECTION 2.2. USE OF THE DOCUMENT:

#### SPAIN

In the third paragraph, second line, where it says: “ ... para quesos de leche cruda, la ...” // “...for raw milk cheeses, the...”, it should say: “... para quesos de leche elaborados con leche cruda, la ...” // “... for raw milk cheeses, the ...”//

In the same paragraph, fifth line, where it says: “ ... tratamientos microcidas ...” // “... microcidal treatments”//, it should say: “... tratamientos bactericidas ...” // “bactericidal treatments”//.

### SECTION 2.4. DEFINITIONS:

#### SPAIN

In this section, some of the definitions should be copied literally, since they are already included in the General Codex Standard for the use of Dairy Terms (Codex Standard Stan 206-1999), such as: “Milk”, “Milk Product” and “Composite Milk Product”.

In the definition for “Hurdle”, where it says: “ ... desarrollo de microbios”//“ ...microbial growth ...”//, it should say: “ ... desarrollo microbiano” //“... microbial growth ...”//

#### INTERNATIONAL DAIRY FEDERATION

Although the definition sections should be subject to constant review during the entire drafting process, we have the following comments at this stage:

- Definitions for “milk”, “milk product”, and “composite milk product” are not needed. Adequate cross-reference to the General Standard for the Use of Dairy Terms has already been made in the Scope.
- Definitions for “hurdle” and “hurdle technology” as follows:

**Hurdle** – A factor or a process that limits, retards or prevents microbial growth, and/or reduces the microbial load, but which by itself cannot keep hazards under complete control.

**Hurdle Technology** - The application of a combination of hurdles, with or without combination with microbiocidal processing steps, which achieves an end product that meets the [Food Safety Objective/level of public health protection].

- An explanation of the use of the term "hygiene" is needed, as it throughout the document only relates to safety (hygienic suitability excluded)
- We recommend that the term "microbiocidal process" is defined, e.g. as follows:

***Microbiocidal process*** – A single processing step that removes, inactivates and/or destroys microorganisms to a level at which they do not constitute a significant health risk.

A definition for "raw milk" is not adequate and will be confusing since the GSUDT defines "milk" as raw milk. What is needed is a definition/explanation for the use of the term "raw" and/or "raw milk product". The term "raw" is used in principally two meanings: (i) to indicate that the milk has not been subject to pasteurization before further processing, and (ii) to designate ingredients before processing in expressions such as "raw material".

### **SECTION 3.2.3.2 VERMIN**

#### **SPAIN**

We propose changing the title of this section from "Vermin" to "Treatment for Pests".

If this proposal is accepted, in the first line, where it says: "Vermin ...", it should say: "Pests ...".

### **SECTION 3.2.3.3 VETERINARY DRUGS:**

#### **SPAIN**

In the second line, we propose changing the expression "withdrawal period" to "waiting period".

## **SECTION 3 PRIMARY PRODUCTION-GENERAL PRINCIPLES**

### **INTERNATIONAL DAIRY FEDERATION**

The Draft Code does not focus on an integrated farm/plant risk based approach. An additional principle referring to the needs for implementing changes/additional requirements at farm level as a consequence of the measures taken at dairy level should be included. However, such principle should state that the primary responsibility for ensuring the safety and hygienic suitability of the milk lies with the primary producer.

The references made to GAP and GHP are highly relevant and should be further referenced in the Draft Code.

### **SECTION 3.3.4. COLLECTION PROCEDURES**

#### **SPAIN**

In the second paragraph, second line, where it says: "... señales obvias de corrupción ..." // "... obvious indications of spoilage..."//, it should say: "... señales obvias de alteración ..." // "... obvious indications of spoilage..."//

### **SECTION 3.3.5 TRANSPORT EQUIPMENT**

#### **SPAIN**

In order to improve the reading of the last paragraph, we propose changing the expression: "... la contaminación por bacteriófagos de cargamentos posteriores de leche cruda." // "... the contamination of subsequent loads of raw milk by bacteriophages..." // to: "... que posteriores cargamentos de leche cruda se contaminen por bacteriófagos."

// "... the contamination of subsequent loads of raw milk by bacteriophages..."//

## **SECTION 3.3.6 TRANSPORT TIME AND TEMPERATURE**

### **SPAIN**

In the second line, where it says “ ... no se deteriore ni estropee.” //“... prevent deterioration or spoilage...”//, it should say: “... no se deteriore ni se altere.” //“... prevent deterioration or spoilage...”//

## **SECTION 3.4 REGULATORY CONTROLS**

### **FRANCE**

While one replaces (cf. general commentaries) the term “safe” by “hygienic”, one must complete the paragraph by: “*Whatever the end uses of the milk, regulatory controls may be necessary to ensure that products are suitable for the intended purpose*”.

## **SECTION 5 CONTROL OF OPERATION**

### **INTERNATIONAL DAIRY FEDERATION**

Hygienic management in a dairy plant comprises the following key aspects, which should be addressed in the Draft Code:

1. Time and temperature control
2. Preventative measures
3. Hurdle technology
4. Microbiocidal processing, where needed
5. Establishment of shelf life (as it relates to product safety and hygienic suitability)

Accordingly, we recommend the following insertions:

### **5.1 CONTROL OF FOOD HAZARDS**

#### **INTERNATIONAL DAIRY FEDERATION**

Insert the following at the end:

”Fundamental prerequisites are the application of adequate hygienic preventative measures in combination with microbiocidal processing steps and/or hurdle technology. These should be in place prior to the establishment of a HACCP based monitoring program.”

#### **5.2.2 FOOD SAFETY CONTROL MEASURES:**

##### **INTERNATIONAL DAIRY FEDERATION**

**Insert the following after the 2<sup>nd</sup> paragraph:**

“The control measures should be selected and combined in accordance with the hazard analysis and be applied effectively. Their accumulated/combined effect should be validated by hazard analysis and verified by the HACCP programme.”

**SECTION 5.2.3.1 RAW MILK****FRANCE**

A simple visual and olfactory control next to the control of the temperature of the raw milk samples “raw material” at the arrival at the dairy plant appear to be dangerously insufficient to judge the quality of this milk, quality that should provide for the security **and** the suitability of the finished products (cf. our general commentaries and section 3 - Principles applicable generally to the primary production of milk, § 1 of the present code). One must also complete the first paragraph by: “This assessment should be done on very specific criteria, notably microbiological or biological. These same samples could be also used for the verification of the physical and chemical criteria pursuant to the point 5.2.5. The raw milk not satisfying to these values should be eliminated from the milk yield.”

The proposed draft is otherwise in more compliance with the conditions towards it aims in the section 5.3 Incoming material requirements of the GPFH.

**INTERNATIONAL DAIRY FEDERATION**

The olfactory etc. checks should also be carried out on samples from individual farms.

**SECTION 5.2.3.2 MICROBIOLOGICAL END PRODUCT SPECIFICATIONS****FRANCE**

The last paragraph lets us suppose that the application of one or several treatments is sufficient to prove that the final product does not present a risk for the consumer's health. Being given the risks of contamination susceptible to be met all along the chain of manufacture, notably the risks of recontamination after a treatment, this hypothesis, that only verifies itself in very particular technologies (sterilization in the final packaging), seems to us dangerous and we propose that this paragraph be suppressed.

**INTERNATIONAL DAIRY FEDERATION**

The second paragraph needs revision.

A criterion does not ensure that the product does not present an unacceptable risk.

Criteria are used to verify that the hazards are under control.

The application of criteria does not depend upon the treatment(s) given, but upon which of the hazards under control that need to be verified (identified by the hazard analysis).

**SECTION 5.2.4 MICROBIOLOGICAL CROSS CONTAMINATION****SPAIN**

In the second paragraph, second line, where it says: “ ... contaminación biológica ...” //“...biological contamination...”//, it should say: “... contaminación microbiológica ...” //“... microbiological contamination ...”//.

**SECTION 5.2.5 PHYSICAL AND CHEMICAL CONTAMINATION****FRANCE**

It is necessary to specify that a plan of surveillance of these contaminations, notably chemical, must be set up to the extent to which findings of a risk analysis would indicate that such residues are susceptible to be found in milk.

**SECTION 5.3 INCOMING MATERIAL REQUIREMENTS****FRANCE**

In conformity with the GPFH, one must include at reception, besides the raw materials, all the ingredients susceptible to enter in the flow chart of milk and dairy products manufacture.

**SECTION 5.4. PACKAGING:****SPAIN**

In order to improve the reading of this section, we propose changing the expression: “con arreglo a las prácticas sanitarias siguientes” //“according to the following sanitary practices”//, to: “siguiendo las prácticas higiénicas” // “following sanitary practices”//

**SECTION 6.1 MAINTANANCE AND CLEANING****INTERNATIONAL DAIRY FEDERATION**

It may not be possible to keep all areas dry. The need also depends on the outcome of the hazard analysis. It should be mentioned that dry cleaning should be the first option to consider, and only where not adequate, replaced by wet cleaning. In such cases, attention should be given to the wet cleaning procedures used.

**SECTIONS 8 AND 9:****SPAIN**

The subsections in sections 8 and 9 should be correctly numbered.

**SECTION 9: PRODUCT INFORMATION AND CONSUMER AWARENESS****SPAIN**

In the first, line where it says: “ ... established in Section 3 of the Code ...,” it should say: “... established in Section

**SECTION 9.3 LABELLING****FRANCE**

The French delegation is not opposed to the possible requirements of an “official agency having jurisdiction”, to the extent to which such an agency has an international statute. The specific requirements of national organisations could not be preserved within the present code that aims exactly to establish some common rules within the international exchanges.

**INTERNATIONAL DAIRY FEDERATION**

Reference to national jurisdiction is not appropriate in an international reference text, as it may undermine the authority of the Codex General Standard for the Labelling of Prepackaged Foods and other related Codex texts.

The term “shelf stable” should be qualified by “at ambient temperatures”. All products are shelf stable, if they are stored at appropriate