HEAT TREATMENT DEFINITIONS

BACKGROUND

1. The Proposed Draft Definitions of Heat Treatments (CX/MMP 96/5) was tabled for consideration at Step 4 by the Second Session of the Codex Committee on Milk and Milk Products. However, The Committee could not consider these proposals because of time restraints. It felt that a number of definitions needed revision and clarification. The Committee agreed to return the document to step 3 and to ask the International Dairy Federation (IDF) to prepare a consolidated document taking into consideration written comments and those made at the Session for consideration at the next Session of the Committee and the subsequent session of the Codex committee on Food Hygiene (ALINORM 97/11, para. 74). To facilitate the process of review, the IDF was specifically requested by the New Zealand Secretariat, in accordance with the direction of the Second Session of the Codex Committee on Milk and Milk Products, to limit this review to the decisions reported in ALINORM 97/11 and to those Government comments available, and not to include any new material at this time.

2. A paper, CX/MMP 98/8, was prepared for consideration by the Committee at its Third Session by the New Zealand Secretariat in collaboration with the Codex Secretariat incorporating the results of the review of comments\(^1\) by IDF. However, due to time constraints, the Third Session of the Committee was unable to consider the paper and agreed to include it on the agenda of the Fourth Session.

3. The Codex Committee on Food Hygiene, at its 29th Session, decided to initiate work on a Code of Hygienic Practice for Milk and Milk Products\(^2\). At its 30th Session, it considered a discussion paper which contained those elements to be included in the Code. It agreed to convert them into a Proposed Draft Code and to discontinue the elaboration of the Code of Hygienic Practice for the Manufacture of Uncured/Unripened and Ripened Soft Cheeses as an independent code. At its 31st Session that Committee considered the Proposed Draft Code of Hygienic Practice for Milk and Milk Products prepared by the drafting group.

4. The Proposed Draft Code was considered by that Committee at its 32nd Session at Step 4.\(^3\)

\(^1\) ALINORM 97/11, para. 74 and CX/MMP 96/5-Add.1 (CRD 5).
\(^2\) ALINORM 97/13A, paragraphs 40-43.
\(^3\) See CX/MMP 99/2.
5. Taking into consideration the above mentioned work by the Codex Committee on Food Hygiene, the Committee is invited to consider referring this issue to the Committee on Food Hygiene for inclusion in the Code of Hygienic Practice for Milk and Milk Products.

**REVIEW OF THE PROPOSED DRAFT DEFINITIONS OF HEAT TREATMENTS BY IDF**

1. **BACKGROUND**

   A. Written government comments were submitted by Canada, Germany, India, Netherlands, Slovak Republic, United States and the European Association for Animal Production (EAAP) (CX/MMP 96/5-Add.1). Further oral comments were made during the Session by the delegates of France, Republic of Korea, New Zealand, United Kingdom and United States, as well as by the observer from the European Community (EC).

   B. These comments have been considered individually in this report. The format and the content of document CX/MMP 96/5 have been revised to take the comments into account and to improve the consistency between the sections. The revised document is provided as Annex 1.

2. **REVIEW OF THE COMMENTS MADE**

   2.1 **General issues**

   The Netherlands requests clarification with regard to the status and the aim of the document and suggests the inclusion of the content in the Code of Principles.

   **Recommendation:** The Committee has decided to submit the document for consideration by the Codex Committee on Food Hygiene. If endorsed by the Committee, the revised document (Appendix 1) should be submitted for consideration by the CCFH. It is further recommended that the definitions themselves are included in the Annex to the Code of Principles (see section 3 of this report).

   2.2 **Definition of Raw Milk**

   Canada suggests that the definition should include the statement “and which has not been submitted to an alternative treatment for the purpose of reducing the microbial population”.

   India proposes that the definition of milk stated in the revised Draft Code of Principles should apply.

   **Comments:** The definition of “milk” stated in the revised Draft Code of Principles is intended for the purpose of the Code, i.e. for the naming and presentation of milk products. It is, however, recognized that this definition actually refers to untreated milk. The definition in the Code reads:

   "milk” is the normal mammary secretion of milking animals obtained from one or more milkings without either addition to it or extraction from it, intended for consumption as liquid milk or for further processing”

   In CX/MMP 96/5, the Draft Definition of “raw milk” serves another purpose, i.e. to distinguish it from heat treated products. The two definitions need not necessarily be the same, however, they should not be contradictory either.

   **Recommendation:** The definition as drafted in CX/MMP 96/5 should remain for this document as it is supplementary and not contradictory to the definition of “milk” in the Code, and as it addresses the generally accepted interpretation of “raw”, meaning not heated or cooked. This definition can also apply even when non-heating alternative treatments are considered, e.g. treatments equivalent to pasteurization.
2.3 Definition of Thermization

Canada advised that Canadian legislation requires a minimum thermization temperature of 63°C for at least 16 seconds and states that temperatures below 63°C should have longer holding times than 16 seconds to qualify for the use of the term “thermized”.

The Netherlands draws attention to an assumed error in note 1, as, normally, an upper limit of 4 microgrammes of phenol per millilitre is accepted for pasteurized milk. It is, therefore, not possible to work with a limit of 2 microgrammes for thermized milk.

In an oral comment, the EC said that the phosphatase limit was incorrect especially in relation to pasteurization. An upper limit was needed to distinguish thermization from pasteurization. Further, the references to two methods were questioned (IDF Standard 63:1971 for thermization and IDF Standard 82:1978 for pasteurization). One method should be selected.

**Comments:** From the literature, thermization conditions in the range between 62 and 65°C are the most commonly used and have been shown to be effective. They are also in accordance with the conditions cited by Cerf (1986) in the Bulletin of IDF no. 200. Heating at 55, 57 and 58°C has been reported to be inadequate or less effective than heating above that range.

It is essential that thermization is defined, that is, it is not sufficient to destroy pathogenic organisms, inactivate the native alkaline phosphatase or cause noticeable chemical changes. An upper limit for the holding time needs to be inserted in the definition to ensure that thermization treatment cannot include (batch) pasteurization conditions.

IDF Standard 63:1971 is a reference method that specifies the determination of phosphatase activity of milk, expressed as the quantity of phenol in microgrammes liberated by 1 ml. According to the Standard, excess of 2 mg of phenol will imply that the milk has not been pasteurized.

IDF Standard 82:1978 has been subject to revision and the revised method has been published as the Provisional IDF Standard 82A:1987. The Standard specifies two alternative routine methods for the qualitative detection of phosphatase activity. This method can detect 0.5% of raw milk in pasteurized milk.

If an upper limit for phenol produced in the phosphatase test for a pasteurized milk is to be included as part of the definitions, then the same (reference) method should be referred to in both the thermization and the pasteurization sections. The IDF Standards do not nominate an upper phenol limit for phosphatase negative milk.

It is not considered essential that a minimum limit for phosphatase activity is included in the document and deletion is, therefore, recommended. It is recommended that the methods specified are labelled as the reference method and routine method, respectively.

**Recommendation:** Adoption of the following definition, which besides editorial amendments including the abandoning of the notes, takes into account the above comments:

“Definition: Thermization is a heat treatment applied to raw milk aimed at reducing the number of organisms in milk and permitting longer storage of the milk prior to further processing. The heating conditions are 62 to 65°C for 15 to 20 seconds. Thermized milk must be phosphatase positive.


2.4 Definition of pasteurization

The EAAP suggests including the following in note no. 2:
“pasteurization destroys neither the spores nor the toxins secreted in the milk by organisms that lived in it prior to its heat treatment”

Comments: It should be noted that the definition in CX/MMP 96/5 has been published by Codex Alimentarius (included in the Code of Hygienic Practice for Spray-dried Milk).

However, in order to improve readability, to provide a more consistent approach in line with literature, and for consistency of format with the other definitions proposed, the definition should be modified including a reference to the heat treatment necessary to inactivate *Mycobacterium tuberculosis* with a reasonable safety margin. This is clearly demonstrated in the diagram given in Bulletin of IDF no. 200 by Burton (1986).

(In some countries *Coxiella burnetii* is used as indicator organism, as it is slightly more heat-stable than *Mycobacterium tuberculosis*.)

Further the definition should not refer to the treated product but to the treatment itself and it would be appropriate to include that the treatment also applies to cream.

The suggested wording provided by the EAAP need not be included in the definition, as the treatment should be defined according to inactivation of *M. tuberculosis* and not to the non-inactivation of certain other microorganisms.

**Recommendation:** Adoption of the following definition, which besides editorial amendments including the abandoning of the notes, takes into account the above comments:

"**Definition:**
Pasteurization is a heat treatment aimed at reducing the number of harmful microorganisms in milk and cream to a level at which they do not constitute a significant health hazard. It is intended to result in an extended shelf life of milk and in only minimal chemical, physical and organoleptic changes. Pasteurization conditions are designed to effectively destroy the organism *Mycobacterium tuberculosis*. Pasteurization of milk and cream results in a negative phosphatase reaction.

**Determination of phosphatase activity:**
According to IDF Standard 63:1971 (under review) or IDF Standard 82A:1978”

2.5 **Examples of minimum temperature/time combinations for pasteurization**

2.5.1 **Pasteurization temperatures:**

**Canada** has advised that the legal requirement for pasteurization is 72°C for 16 seconds, and 63°C for 30 minutes in the case of vat pasteurizers.

**United States** supports the addition of the following time and temperature requirements in addition to the pasteurized milk and skimmed milk requirements:

- **Sweetened milk products and cream:**
  - 66°C for 30 minutes
  - 75°C for 15 seconds

- **High viscosity products (e.g. ice cream mix and eggnog):**
  - 69°C for 30 minutes
  - 80°C for 25 seconds
  - 83°C for 15 seconds

In their oral comments, **New Zealand** and **United States** stated that the time/temperature combinations cited could be misleading. Provisions should be made both for milk and for cream and high viscosity products. **United Kingdom** and **France** said that there was no need for these examples.

**Comments:** Equivalent minimum pasteurization conditions for milk can be determined by plotting the line for the following equation given by Kessler (1985b):

\[ \log t_{p=1} = 14885/T - 41.97 \]

which was derived from equation
\[ \ln \left( \frac{t}{t_o} \right) = \frac{E_a}{R} \left( \frac{1}{T} - \frac{1}{T_o} \right) \]

where:

- \( E_a = 285,000 \text{ J/mol} \) (energy of activation when \( z = 8^\circ C \) and temperature = 72\(^\circ C \))
- \( R = 8.314 \text{ J/mol} \)
- \( t_o = 15 \text{ seconds} \)
- \( T_o = 345 \text{ K} \) (absolute temperature corresponding to 72\(^\circ C \))

\( t \) and \( T \) are the time and temperature in combinations which give the same bactericidal effect \( P^* = 1 \)

The line passes through the points 63\(^\circ C\) for 30 minutes and 72\(^\circ C\) for 15 seconds on the log time versus temperature graph shown below:

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Bøgh-Sørensen (1992) reports temperature/time combinations appropriate for cream.

**Recommendation:** It is found advisable to include examples of time/temperature combinations for milk and cream as the definition relates specifically to the treatment of these products. The inclusion of other specific product examples is not considered advisable as the list will then become too comprehensive. Instead, a general guideline should be inserted addressing the fact that high sugar content and high viscosity require other pasteurization conditions. Consequently, the following guidelines for the application of pasteurization, which takes into account the above comments, is recommended:

“Guidelines for the application of pasteurization

For milk, the minimum pasteurization conditions are those having bactericidal effects equivalent to 72\(^\circ C\) for 15 seconds (continuous flow pasteurization) or 63\(^\circ C\) for 30 minutes (batch pasteurization). Other equivalent conditions can be obtained by plotting the line passing through these points on a log time versus temperature graph.

For cream, the minimum conditions are generally considered to be greater than for milk, for example, 75\(^\circ C\) for 15 seconds (10-20 % fat), 80\(^\circ C\) for 15 seconds (above 20 % fat) and 65\(^\circ C\) for 30 minutes (batch). Formulated milks and creams with high sugar content or high viscosity also require pasteurization conditions in excess of the minimum conditions defined for milk.”

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2.5.2 Cooling temperature:

**Canada** considers that the cooling temperature of “10\(^\circ C\) or below” is far too high and requests, as a minimum, at least 6\(^\circ C\).

**Germany** suggests the following formulation: “*The product is cooled without delay to 6 \(^\circ C\)*”

**United States** supports a revision of the statement as follows: “*Pasteurized product (except for product that will be immediately cultured) is cooled without delay to 10\(^\circ C\) or below*”

**Recommendation:** The temperature to which milk must be cooled after pasteurization is not considered part of the definition nor part of the guidelines for the application of pasteurization and should, therefore, be deleted from the document.
If the CCMMP decides to retain such advice the statement should be that “pasteurized milk and cream (unless it is to be immediately further processed) is cooled to 6°C or lower.”

2.6 Definition of sterilization and the designations “sterilized” and “UHT”

Canada points out an error: the term $F/3$ should be corrected to $F_o = 3$.

Further, Canada informs that the term “sterilized milk” is not used in Canada. Consumers do not recognise a difference in organoleptic properties between sterilized and UHT milks as the latter are aseptically packaged with flavours being identical. “Sterile” and “commercially sterile” are not the same thing. The definitions should be “commercially sterilized” and “UHT” to be more accurate.

The Slovak Republic notes that the term “sterilization” is defined according to the process in regard to its bactericidal effect and covers in-container sterilization as well as UHT treatment regardless of the considerable differences in the extent of heat-induced chemical, nutritional and organoleptic changes. It is suggested that part 4 is rewritten so that it distinguishes the different heat treatments. A formulation is suggested, in which the parameter $F_o$ is avoided as the specified time/temperature combinations are considered sufficient, and in which the principle of equivalent time/temperature combinations is more emphasized.

The EAAP suggests to add at the end of the second line the following: “...or at least to inhibit...” and that the last phrase in note 5 is amended into “in the presence of a large number of spores”.

In their oral comments, the EC and Korea stated that heat treatments that are combinations of sterilization and UHT are already in use. The EC further requested a chemical criterion to distinguish “sterilization” from “UHT treatment”. United Kingdom said that the definition of “UHT treatment” is not clear and the delegates of United Kingdom, France and United States stated that “aseptically processed” is not a heat treatment.

**Comments:** The definition of “sterilization” (section 4) and the subsequent sections concerning the use of the terms “sterilized” and “UHT” should be separated out and redrafted for clarification, as requested.

The definitions should not refer to the treated products but to the processes themselves and it would be appropriate to include that the treatments also apply to cream.

As pointed out by the Slovak Republic, “UHT” and “sterilization” heat treatments have equivalent bactericidal effects but the heat-induced chemical effects in milk and cream are greater during sterilization. Accordingly, the flavour and appearance of “sterilized” milk are different to those of “UHT” milk. For further reading, reference is made to Fox et al. (1995).

A minimum $F_o$ value of 3 min should be retained for the definitions despite some opinions that $F_o$ is not appropriate. The specified minimum heat treatment to ensure public health safety, corresponding to an $F_o$ of 3 min, is the same for both “UHT” and sterilized products. In some circumstances, an $F_o$ of 3 min may be insufficient to ensure microbiological stability at ambient temperatures due to the presence of highly heat-resistant spores from thermophilic bacilli.

The use of $F_o$ assumes that the z value is independent of temperature; this is not strictly correct but the change over the range of temperatures used in UHT is small and insignificant. An alternative definition using the dimensionless index devised by Kessler, B*, at a value of 1, which refers to 9 log reductions of a mixed heat-resistant spore population, corresponds to a heat treatment of similar intensity (equivalent to an $F_o$ of 2.7 min according to Burton (1985) or 3.1 min according to Kessler, (1985a)).

Other equivalent conditions for “UHT” and “sterilization” to give an $F_o$ value of 3 min can be obtained by plotting the line passing through the following temperature/time combinations on a log time versus temperature graph:

- 115°C for 13 minutes,
- 121°C for 3 minutes,
- 140°C for 2.3 seconds.
As pointed out by the EC Commission and Korea, some processes comprise a “UHT” pre-sterilization stage hygienically linked to a final in-container “sterilization”. For the purpose of calculating the $F_0$ value, the effects of the two stages may be considered additive provided they comprise a single continuous process.

It is recognised that the terminology for milks defined here as “sterilized” and “UHT” varies from country to country. Further, in some countries, milk or cream marketed under the designation “sterilized” has been subjected to either a process of “sterilization” in a hermetically sealed container or in a continuous flow “UHT” process followed by aseptic filling in a hermetically sealed container. It should be recognised that it is not possible to reflect all countries’ current legislation and terminology in the Codex definitions.

Some countries use an alternative designation “aseptically processed” for what is defined here as “sterilized” and/or “UHT” milk. As pointed out by several delegates, the term “aseptically processed” does not refer to the heat treatment applied but to the filling process. The document does not hinder the use of such additional terms.

The suggestion to specify chemical criteria for distinguishing “sterilization” from “UHT treatment” should not be followed. The relevant parameters referred to in the literature are the heat-induced formation of lactulose and/or denaturation of β-lactoglobulin. These parameters are technical quality parameters and not relevant for safety purposes. Further, the degree of denaturation of β-lactoglobulin varies to a great extent which makes such a criterion unfit for this purpose. Although the amount of lactulose formed constitutes a better criterion, it cannot be used to distinguish UHT (very short holding time) from dual-stage (long holding time) processes due to extensive overlapping of values.

**Recommendations:** It is found advisable to include examples of time/temperature combinations, emphasizing, however, how equivalent combinations may be found. The definitions and guidelines for their application should be separated out.

Adoption is recommended of the following definitions and guidelines for their application, which besides editorial amendments, including the abandoning of the notes, takes into account the above comments:

**Definition of UHT (Ultra High Temperature) treatment.**
UHT (ultra high temperature) treatment of milk or cream is a high-temperature/short-time heat treatment aimed at producing a commercially sterile product which can be stored at room temperature. The process aims to destroy all microorganisms; any residual microorganisms are unlikely to cause spoilage under normal storage conditions. UHT-treated milk and cream are packaged aseptically into sterilized, hermetically sealed containers*. The total heat treatment is equivalent, in terms of its effectiveness against heat-resistant bacterial spores, to a minimum $F_0$ value of 3 min.

*) A hermetically sealed container is a container that is designed and intended to be secure against the entry of microorganisms.

**Definition of sterilization**
Sterilization of milk or cream is a high-temperature/long-time heat treatment aimed at producing a commercially sterile product which can be stored at room temperature. The process aims to destroy all microorganisms; any residual microorganisms are unlikely to cause spoilage under normal storage conditions. Sterilization is an in-container, batchwise heating process using minimum temperature-time conditions which achieve an $F_0$ value of 3 min.

**Guidelines for the application of UHT treatment and sterilization**
The temperatures for UHT treatment are in the range 135 to 150°C in combination with appropriate holding times such as 140 /C for 2.3 seconds. The temperatures for sterilization are in the range 110 to 125°C in combination with appropriate holding times such as 121°C for 3 minutes or 115°C for 13 minutes.
Other equivalent conditions to give an $F_o$ value of 3 min can be obtained by plotting the line passing through the above temperature/time combinations on a log time versus temperature graph.

The combined effects of two or more treatments may be considered additive provided they comprise a single continuous process.

**Determination of microbiological, chemical and physical stability**

According to IDF Standard 48: 1969 (under review)"

### 3. RECOMMENDATIONS WITH REGARD TO PUBLICATION BY CODEX

It is recommended that the CCMMP considers:

1) that the paper appended is submitted to the Codex Committee on Food Hygiene for inclusion in the Proposed Draft Code of Hygienic Practice for Milk and Milk Products, currently being drafted by the Committee; and

2) that the definitions themselves are inserted in the Annex to the revised Code of Principles concerning Milk and Milk Products4.

**REFERENCES**


**OUTCOMES OF THIS REVIEW**

The proposed revision of the "Proposed Draft Definitions of Heat Treatments of Milk and Cream" is attached to this document as Annex.

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4 Secretariat’s Note: Revised and adopted as the Codex General Standard for the Use of Dairy Terms.
ANNEX

PROPOSED DRAFT DEFINITIONS OF HEAT TREATMENTS OF MILK AND CREAM
(at step 3)

1. SCOPE

The definitions below apply to milk and to cream as defined respectively in Article 2 of the revised Code of Principles concerning Milk and Milk Products and in the revised Standard for Creams (A-9).

2. RAW MILK

2.1 Definition of raw milk:

Raw milk is milk that has not been submitted to any heating, i.e. its temperature has not exceeded that of milk immediately after leaving the udder (that is, not greater than 40°C).

3. THERMIZATION

3.1 Definition of thermization (for industrial purposes only):

Thermization is a heat treatment applied to raw milk aimed at reducing the number of organisms in milk and permitting longer storage of the milk prior to further processing. The heating conditions are 62 to 65°C for 15 to 20 seconds. Thermized milk must be phosphatase positive.

3.2 Determination of phosphatase activity:


4. PASTEURIZATION

4.1 Definition of pasteurization:

Pasteurization is a heat treatment aimed at reducing the number of harmful microorganisms in milk and cream to a level at which they do not constitute a significant health hazard. It is intended to result in extended shelf life of milk and in only minimal chemical, physical and organoleptic changes. Pasteurization conditions are designed to effectively destroy the organism *Mycobacterium tuberculosis*. Pasteurization of milk and cream results in a negative phosphatase reaction.

4.2 Guidelines for the application of pasteurization:

For milk, the minimum pasteurization conditions are those having bactericidal effects equivalent to 72°C for 15 seconds (continuous flow pasteurization) or 63°C for 30 minutes (batch pasteurization). Other equivalent conditions can be obtained by plotting the line passing through these points on a log time versus temperature graph.

For cream, the minimum conditions are generally considered to be greater than for milk, for example, 75°C for 15 seconds (10-20 % fat), 80°C for 15 seconds (above 20 % fat) and 65°C for 30 minutes (batch). Formulated milks and creams with high sugar content or high viscosity also require pasteurization conditions in excess of the minimum conditions defined for milk.”

4.3 Determination of phosphatase activity:

5. **UHT (Ultra High Temperature) Treatment and Sterilization**

5.1 **Definition of UHT (Ultra High Temperature) treatment.**

UHT (ultra high temperature) treatment of milk or cream is a high-temperature/short-time heat treatment aimed at producing a commercially sterile product which can be stored at room temperature. The process aims to destroy all microorganisms; any residual microorganisms are unlikely to cause spoilage under normal storage conditions. UHT-treated milk and cream are packaged aseptically into sterilized, hermetically sealed containers. The total heat treatment is equivalent, in terms of its effectiveness against heat-resistant bacterial spores, to a minimum $F_o$ value of 3 min.

*) A hermetically sealed container is a container that is designed and intended to be secure against the entry of microorganisms.

5.2 **Definition of sterilization**

Sterilization of milk or cream is a high-temperature/long-time heat treatment aimed at producing a commercially sterile product which can be stored at room temperature. The process aims to destroy all microorganisms; any residual microorganisms are unlikely to cause spoilage under normal storage conditions. Sterilization is an in-container, batchwise heating process using minimum temperature-time conditions which achieve an $F_o$ value of 3 min.

5.3 **Guidelines for the application of UHT treatment and sterilization**

The temperatures for UHT treatment are in the range 135 to 150°C in combination with appropriate holding times such as 140°C for 2.3 seconds. The temperatures for sterilization are in the range 110 to 125°C in combination with appropriate holding times such as 121°C for 3 minutes or 115°C for 13 minutes. Other equivalent conditions to give an $F_o$ value of 3 min can be obtained by plotting the line passing through the above temperature/time combinations on a log time versus temperature graph. The combined effects of two or more treatments may be considered additive provided they comprise a single continuous process.

5.4 **Determination of microbiological, chemical and physical stability**