

DECISION

Decision dated 3 December 2007 defining the good practice rules envisaged in paragraph 3 of article L.2323-1 of the public health code

NOR: SJSM0722015S

The Director General of the French health care products safety agency,
Considering the public health code, and especially articles L. 2323-1, L. 5311-1 (8°) and R. 2323-1, 2, 3 and 4,
Decreets:

Article 1

The good practice rules for the collection, preparation, qualification, treatment, storage, distribution and dispensing on medical prescription of human milk by the milk banks are defined in the appendix to this decision.

Article 2

Milk banks have an interval of twelve months starting from the publication of this decision in the Official Gazette of the Republic of France to comply with the decision.

Article 3

The director of the inspection and establishments is responsible for the execution of this decision, which will be published in the Official Gazette of the Republic of France.

APPENDIX

GOOD PRACTICE RULES FOR THE COLLECTION, PREPARATION, QUALIFICATION, TREATMENT, STORAGE, DISTRIBUTION AND DISPENSING ON MEDICAL PRESCRIPTION OF HUMAN MILK BY THE MILK BANKS

INTRODUCTION

The objective of this decision is to define the good practice rules for the collection, preparation, qualification, treatment, storage, distribution and dispensing on medical prescription of human milk in order to guarantee the quality and safety of human milk dispensed or distributed by milk banks.

These provisions are implemented without affecting the compliance with the obligations to be defined in the decree of the minister in charge of health, concerning the conditions of function and organisation of milk banks in application of [article L. 2323-1 of the public health code](#).

The rules described in this decision contribute to the improvement of the services related to the milk bank activities, by integrating a quality approach at all steps.

These rules apply to human milk from anonymous donations and personalised donations.

GLOSSARY

Quality assurance: broad concept that covers anything that may influence the quality of a product, individually or collectively. It represents all the measures taken to ensure that the milk controlled has the quality required for the use for which it is intended.

AUDIT: methodical, independent and documented examination, with the objective of determining whether the procedures and results concerning the quality are such as to allow attaining the objectives set.

CONTROL: set of operations that aim to determine the compliance of the product with specific requirements.

DECONTAMINATION: operation that allows eliminating undesirable micro-organisms. It is the first treatment to be performed on contaminated objects and materials in order to eliminate micro-organisms and facilitate later cleaning and sterilisation.

DISPENSING: the dispensing on medical prescription for administration to a newborn.

DISTRIBUTION: provision to a department of a health care establishment or

to another milk bank.

DONOR: any donation candidate for whom the milk was collected even if the donation was eliminated following serological tests, of a post-donation information or biological tests on the milk.

ANONYMOUS DONATION: donation of milk from a mother to a child other than her own.

PERSONALISED DONATION: milk donation from a mother to her own child.

DONOR RECORD: includes the donor identification elements and all the results of biological tests and the screening tests.

BATCH DOSSIER: includes all the information concerning the preparation, treatment, packaging and control tests on the batch prepared. This dossier includes the batch number.

REGISTRATION: document presenting the results obtained or the proof of the performance of an activity.

COMPUTERISATION: implementation of a computer system including data entry, electronic processing and output of information intended to be used for automatic control, profiles or traceability purposes.

RELEASE: process that allows lifting the quarantine either on milk donations collected for their treatment, or on treated milk batches for their dispensing or distribution, following a decision on their compliance.

BATCH: defined quantity of milk prepared in a single operation or several operations, such that it may be considered as homogeneous. Except in special cases, the size of the batch should be limited to a volume of 4 litres.

LYOPHILISATION: process for transforming a liquid solution into a powder.

MAINTENANCE: set of actions maintaining or re-establishing an entity into a condition that allows it to accomplish an expected function.

QUALITY MANAGEMENT: coordinated activities with the objective of directing and controlling an organisation in terms of quality.

OPERATING PROCEDURE: detailed description of the manner in which an activity must be performed.

NON-COMPLIANCE: defect observed or reported, concerning the activities and the products.

PASTEURISATION: discontinuous heat sterilisation method that allows inhibiting the micro-organisms in a low contamination product.

CERTIFIED PERSON: person with the qualifications required by the law and regulations and recognised by its functional manager, capable of carrying out the tasks he/she has been entrusted with.

PROCEDURE: specific manner in which to perform an activity.

QUALIFICATION: operation intended to demonstrate that an equipment or material functions correctly and gives the expected results. For the personnel, the qualification corresponds to the training acquired and required by the current regulation. It is maintained by the internal or external training in which the personnel are expected to participate.

QUARANTINE: physical, or by other effective means, isolation of the donations collected and the batches of treated milk awaiting a decision on their compliance or non-compliance.

RETURN: return of a milk bottle to the milk bank, irrespective of whether the product presents a preparation defect or not.

SUB-BATCH: mixing of donations from the same donor and intended to enter the composition of a milk batch.

STERILISATION: operation with the objective of eliminating from an object or product any live micro-organisms that contaminate it.

TRACEABILITY: possibility from a recorded identification, to find the history, use or location of milk at all steps of its collection, preparation and distribution. The traceability of a milk batch designates the establishment of a link between the donor, the donation, the batch dispensed or distributed, the path and the final destination.

VALIDATION: operation that allows providing the proof that the expected results were obtained under satisfactory technical conditions.

Chapter I - Personnel

The organisation and maintenance of a satisfactory maternal milk quality management system are based on the entire personnel under the responsibility of the doctor in charge of the milk bank. For this reason, it is necessary to have qualified and sufficient personnel to perform all the tasks attributed.

A nominative organisation chart of the milk bank giving the detail of the different activities must be established. The individual missions and functions must be clearly defined and described in writing. The extent of the functions and missions conferred to a single person must not result in a risk for the proper execution of the former.

The management personnel verify the qualification required and the initial training of the personnel. The personnel receive a theoretical and practical

training appropriate for the job that allows them to be certified for the tasks entrusted. In particular this training must concern the good practice rules, health and safety measures concerning the personnel and the human milk.

Continuous education must be provided to maintain the competence of the personnel and its efficacy. The personnel must be periodically assessed to renew the qualification for the tasks. Documents certifying the training followed by the personnel must be made available.

Chapter II - Premises and equipment

1. Premises

The premises must be situated, conceived, constructed, adapted, maintained and cleaned in a manner appropriate for the operations to be performed.

They must be arranged in the logical order of the milk treatment operations and according to the appropriate cleanliness levels.

The lighting, temperature, humidity and ventilation must be appropriate in order not to affect, directly or indirectly, the product during its packaging and treatment.

2. Equipment

The equipment must be conceived, installed, maintained and cleaned as a function of its use and in order to minimise risks. It complies with safety and personnel protection specifications. Its cleaning must have operating procedures.

Equipment intended for operations essential for the quality or safety of maternal milk (freezer, pasteuriser, lyophiliser, microbiological safety unit, for example) must be subjected to qualification, which is reviewed periodically.

The qualification of the equipment consists in demonstrating that it functions properly and gives the expected results. It is compulsory in case of new equipment, following a repair or displacement.

The regular maintenance and cleaning of the equipment are an essential condition of the quality of the milk dispensed or distributed.

A list of the qualified equipment is established and for each equipment, a log is organised, this log includes the elements concerning the identification, maintenance and the maintenance operations of the equipment. In case of breakdown of critical equipment, the degraded mode function is defined in a procedure.

The pasteurisation temperature is controlled throughout the duration of the pasteurisation and the recording of these controls is signed and kept with the corresponding reference and milk batch number.

The storage units (refrigerators, freezers, cold chambers) must be sufficiently large and designed to allow good storage conditions as well as an orderly storage. They must be clean, cleaned according to written procedures and maintained within the defined temperature limits. A regular temperature and warnings control system must be implemented and verified regularly.

The maternal milk bottles in quarantine are stored in separate clearly identified zones.

Chapter III - Quality management system

The quality management system includes: quality assurance, quality control, compilation and analysis of non-compliance and control of the system via an audit or self-assessment device.

This concept covers anything that may influence the quality of a product, individually or collectively. In particular, quality assurance represents all the measures taken to ensure that the product (distributed or dispensed milk) has the quality required for the use for which it is intended. The basic requirements of the quality system are based on appropriate installations, trained personnel and certified procedures for the collection, preparation and qualification of donations (biological controls), treatment, storage and dispensing or distribution of maternal milk.

The attainment of the quality improvement objective involves the responsibility of the management and that of the doctor in charge of the milk bank. It requires the participation and commitment of the personnel at all levels.

All milk banks must have an appropriate quality management system, under the responsibility of the doctor in charge of the milk bank or a competent person he/she has designated.

The quality system organised must be evaluated during periodic meetings with the management. An annual assessment will allow the assessment of the actions undertaken and to define the new objectives.

1. Documentation

The documentation is an essential element of quality assurance. It is composed of internal documents, mainly: procedures, operating procedures, forms and recordings and external documents (regulator texts and equipment instruction manuals for example).

Clear recordings avoid the errors inherent to verbal communications and

allow retracing the history of the operations. Milk banks must collect and store information that guarantee the traceability of the maternal milk dispensed or distributed.

The documentation must be updated and accessible to the personnel that need it. Any significant documentation of the documents must be controlled, dated and approved by the person authorised to perform this task. Any document with an influence on the quality and safety of maternal milk must be verified, then validated by the doctor in charge of the milk bank prior to implementation.

The operating procedures concern as a minimum the following operations:

- selection of donors;
- collection of maternal milk;
- maternal milk transport conditions;
- pasteurisation of maternal milk;
- biological controls of maternal milk;
- cleaning of premises and equipment;
- maternal milk storage conditions;
- dispensing/distribution of maternal milk;
- collection and analysis of non-compliance;
- maternal milk batch recalls.

2. Computer system

Computerisation allows the automation of information transfer and thus reduces the errors and difficulty of manual entries.

The risks inherent to computer systems concern safety in terms of access and availability of data. The following requirements must be complied with in this context:

- the computer data are only introduced, transferred, modified or destroyed by authorised persons;
- a procedure is established for granting, removing and the authorisation level to introduce, transfer, modify or destroy data, including for the modification of personal passwords;

- the system allows controlling data entry. The system records the identity of operators who introduce, transfer, modify or destroy any data. Any data modification is traced;
- the data are protected against accidental or voluntary damage;
- the system must be capable of restoring in clear all the transfers, entries, modifications and destruction of data;
- the saving and restoration procedures are regularly submitted to a reliability control.

A procedure envisages the function in degraded mode in case of partial or total failure of the computer system.

When computerisation is impossible, specific procedures specify the technical modes for the recording of data.

3. Quality control

The objective of quality control is to verify and guarantee the compliance of the products and methods with pre-established specifications.

Quality control concerns all the products, supplies, reagents, premises and materials that are part of the collection, preparation, qualification, treatment and storage of maternal milk process.

Quality control includes the implementation of control tests, the analysis of results and the acceptance or rejection conclusion for the milk donations. It also includes the control methods and their validation, as well as the implementation of provisions that guarantee that the controls required have been performed.

The controls performed in the preparation or treatment zone must be performed according to the procedures.

The control on reception of supplies and reagents must be documented. The data concerning the product controlled, the performance of control tests, the results obtained and the acceptance or rejection decisions must be recorded.

The results of the control tests must be available rapidly in order to allow the application of appropriate corrective measures or the blockage and withdrawal of the product, if applicable.

4. Management of non-compliance

To guarantee the improvement of the system, the milk bank must compile the non-compliances, assess them and implement the appropriate actions (immediate curative action and/or corrective action after analysis of the

defect observed) and ensure the follow-up.

5. Self-assessment/audit

The self-assessment audit is part of the quality assurance system and must be performed according to a defined periodicity in order to control the implementation and respect of good practice rules and to propose the corrective measures necessary. These practices must be recorded in reports.

Chapter IV - Collection of maternal milk donations

1. Reception of donors

The reception allows establishing between the donor and the team in charge of the human milk collection a reciprocal trusting environment.

A. — Information interview

During the reception, an information interview takes place with the donor, under the responsibility of a doctor, a midwife or a nurse designated by the doctor in charge of the milk bank. The objective of this interview is to make the donation candidate aware of the potential risks of transmissible diseases via maternal milk and of their responsibility, to the importance of the risks related to the taking of medicinal products and hygiene measures to be respected while collecting the milk for the donation. The donor is informed of the regulatory provisions on the compulsory screening tests prior to the donation.

This information is completed by the handing out of clear explanatory documents during the reception of the donor.

After this interview, an identification of the donation candidate is performed.

B. — Identification of the donor

The identification of the donor requires the following information:

- maiden name and marital name for married women;
- first and middle name(s) ;
- date and place of birth (town, department, country) ;
- date and place of childbirth;
- full personal address;

- personal and professional telephone number, if applicable.

This information is controlled and confirmed at each milk collection.

An identification code is attributed to the donor during the first donation. A procedure for assignment of this code is established in order to guarantee its unique and non-reusable character.

C. — Medical-administrative documents

The identification elements are recorded in the donor's dossier where the following is also found:

- pre-donation questionnaire;
- results of biological tests;
- screening tests performed for the first donation;
- any renewal of the biological and screening tests. Given that the information collected from the donors are personal character data, the opinion of the National commission for data processing and civil liberties (CNIL) must be obtained in compliance with the provisions of the [law no. 78-17 of 6 January 1978](#) amended, concerning data processing, files and civil liberties.

The donor's dossier is consulted, verified and completed at each donation under the responsibility of the milk bank doctor, in order to allow the traceability of the donation.

A list of persons certified to consult or modify the information of the donor dossier is established in order to guarantee the confidentiality of the data contained in the dossier. Furthermore, a procedure will be established in order to specify the rules for the use of these data.

2. Qualification of donors

Part IV-2 does not apply to personalised donations.

The objective of the selection of donors is to determine the presence of medical contraindications to the donation of maternal milk in order to protect both the donor and the receiving newborn. This determination takes place via a medical interview and the compulsory screening during the first donation.

A. — Medical interview

The donors are selected after a medical interview that aims to detect risk factors, i.e.:

- intravenous drug use;
- at risk relations of the donor or her partner;
- sexually transmissible infections;
- history of transfusion of labile blood products and surgery that may have required a transfusion;
- history of tissue or organ transplant;
- history of neurosurgery;
- history of artificial insemination without preliminary control of donor;
- renal dialysis;
- history of treatment with extracted pituitary hormones prior to 1986 and personal or family history of neurovegetative disease;
- travel and/or stay in the United Kingdom of more than 1 cumulative year over the period between 1 January 1980 and 31 December 1996.

A pre-donation questionnaire is filled in by the milk donation candidate in order to obtain the information essential for the selection of the donors. It is given by the candidate to the milk donation to the doctor or midwife who evaluates during the medical interview the capacity for the donation and makes sure that it is not likely to harm the health of the donor or of the child.

The transmissible disease screening tests are proposed to the donors during this interview. This interview also takes into account risk factors such as smoking, alcoholism, drug abuse and the use of medicinal products.

The obligation of the serological examinations after informed consent of the interested party applies to mothers who are making a generous donation for other children either during their stay at the maternity or when the donor is at home. In the last case, the donor gives the milk bank collectors a blood sample labelled with her identity, the identity of the person who took the blood sample and the sampling date.

B. — Transmissible diseases screening tests

These tests are performed under medical prescription. The medical prescription is written either by the doctors in charge of the milk bank or by the doctors of the establishment where the woman gave birth, or by the doctors of the establishment where the child is hospitalised, or by the

attending physicians when the donor is at home.

The transmissible disease screening tests are paid by the milk banks. The biological tests to be performed on the blood samples taken for the milk donation are set by the current regulatory texts.

C. — The donor selection criteria

The milk can only be used by the milk bank in the absence of risk factors detected during the medical interview with the donor and if the results of the transmissible diseases screening tests are negative.

The doctor in charge of the milk bank, or a doctor designated by him, makes sure before any use of the donation that the results of the previously mentioned analyses are negative and signs the analysis form. In case of a positive result of a screening, the doctor in charge of the milk bank, contacts the doctor of the establishment where the woman gave birth and compares the results with those from the beginning of the pregnancy. He/she informs the woman and recommends that she consult her attending physician.

The doctor in charge makes sure the donations are destroyed when the screening tests are positive, according to a defined procedure respecting the regulations applicable to the elimination of potentially contaminated waste.

3. Milk collection conditions

The collection is an essential step to guarantee the final quality of the milk.

The milk bank provides written instructions to the donors on the hygiene rules to be followed at the time of collection, on the material to be used for the collection and on the milk storage rules including the cleanliness requirements (cleaning and decontamination) of the refrigerator.

The milk is collected according to the previously mentioned hygiene rules, and kept at the home of the donor under strict temperature and time conditions set by the milk bank.

The donor agrees in writing to respect these hygiene rules before the collection of her milk.

She must report as soon as possible any anomalies likely to harm the quality and safety of the milk donations.

The non-compliances must be analysed and treated by the milk bank, in particular to avoid the incidence on products as of yet unused.

The personnel assigned to the collection must verify the application of the instructions regularly.

Sterile baby bottles are provided by the milk bank with the material for the collection of milk (breast pump). The bottles are pre-labelled or accompanied of stick-on labels. Disposable material should be privileged.

Any material in contact with the skin or the milk is washed and decontaminated systematically according to the conditions set by the milk bank.

Once the milk has been collected, the bottle is closed and placed as soon as possible in the freezer. If the freezing is differed, the time of storage in the refrigerator at a temperature between 0 and + 4°C, must not exceed 48 hours.

A bottle is used for only one collection, the milk that has been collected must never be mixed with already cold milk. Several collections from the same day may be mixed after cooling.

Each bottle includes all the indications that allow identifying the donor, the date of collection of the milk and the indication of any medicines taken by the donor.

Chapter V - Preparation

The preparation includes all the milk sub-batches and batches constitution steps prior to pasteurisation. All the milk donations from the same donor are grouped in a clearly identified sub-batch. The milk batches are composed of a maximum of 6 sub-batches that comply.

The preparation operations must follow well-defined instructions and procedures. At each step of the preparation, the product must be protected from external microbial and any other contaminations.

Prior to the start of the preparation, a verification of the cleanliness of the work zones and material used should be performed.

The milk bank must take measures to avoid any risk of errors for the preparation of personalised milk donations.

Chapter VI - Biological qualification of maternal milk donations

Any milk collected is qualified prior to treatment and pasteurisation.

The biological qualification of milk donations includes bacteriological analyses and authenticity control by immunological analysis. These analyses are performed systematically in order to detect any alteration of the milk quality.

Each milk batch is subject to compulsory systematic biological analyses.

It is recommended to perform the global flora test on each sub-batch constituted for one donor.

The milk biological analyses are performed under the responsibility of a biologist who verifies the validation of the techniques and of the results.

If the samples are transported for the control tests, the biologist also verifies the travel conditions (in particular temperature and delays).

1. Authenticity control

The detection of cow milk proteins is performed on each batch using a validated immunological test, for which the sensitivity threshold must be defined. In case of non-compliance, the milk is destroyed and investigations performed by the milk bank.

2. Bacteriological analyses

A. — Analyses to be performed on the sub-batches and batches

When a sub-batch composed of donations from the same donor, undergoes a systematic bacteriological control, the examination consists in a total aerobic flora count on blood agar after incubation for 24 hours at 37°C; the milk dilution is to be made as a function of the seeding method used by the biologist.

The milk is placed in quarantine at + 4°C while waiting for the results of this control.

The sub-batches are declared non-compliant if the total aerobic flora after 24 hours of incubation at 37°C, is equal to or greater than 10⁶ bacteria per millilitre.

Any non-compliant batch is destroyed by the milk bank which will contact the donor to determine the origin of the contamination.

The sub-batches that comply are grouped in batches and each batch is subjected to the following bacteriological controls prior to being packed in bottles and pasteurised.

- total aerobic flora count on blood agar after 48 hours incubation at 37°C;
- determination and count of *Staphylococcus coagulase positive* microorganisms on Chapman medium 48 hours incubation at 37°C.

The milk dilution is to be made as a function of the seeding method chosen by the biologist in order to detect the threshold defined below.

The batches are declared not to comply if:

- the aerobic flora is equal to or greater than 10⁶ bacteria per millilitre;
- or if the number Staphylococcus coagulase positive microorganisms is equal to or greater than 10⁴ bacteria per millilitre.

B. — Analyses to be performed on the batches only

When the sub-batches are not controlled systematically, the batch undergoes the same bacteriological controls prior to being packed in bottles and pasteurised.

In this case, the batches are declared not to comply if:

- the aerobic flora is equal to or greater than 10⁵ bacteria per millilitre;
- or if the number Staphylococcus coagulase positive microorganisms is equal to or greater than 10⁴ bacteria per millilitre.

In all cases, while waiting for the results of the bacteriology controls, the milk is kept at + 4°C for 48 hours or pasteurised immediately, frozen and kept in quarantine until its compliance has been proved.

The milk batches that do not comply are destroyed by the milk bank.

Chapter VII - Treatment of maternal milk

1. Pasteurisation

The milk batches are treated by pasteurisation at 62.5°C for thirty minutes.

The milk is then cooled at + 4°C as soon as possible, within an interval compatible with the preservation of its quality and then frozen.

2. Control after pasteurisation

A final bacteriological control is performed after pasteurisation, by seeding 0.5 ml of undiluted milk on blood agar and incubation over 48 hours at 37°C.

Any batch for which the control after pasteurisation was positive is destroyed.

The destruction of sub-batches and batches that do not comply is performed in compliance with the regulations applicable to the disposal of potentially contaminated waste.

A documented analysis is performed in order to find the causes of repeated contaminations.

The milk bottles are placed in quarantine after pasteurisation and cooling and while waiting for the results of the control. They can be either stored at +4°C for no more than 48 hours and frozen at -18°C, or frozen immediately at -18°C.

Only milk bottles from batches that have been declared to comply may be released for dispensing and distribution or accepted for lyophilisation.

3. Lyophilisation

The treatment of the milk may include an additional lyophilisation step which will be performed after pasteurisation and obtaining the results of the bacteriological controls. Additional controls will be defined according to the procedure and the packaging used in order to guarantee the quality and safety of the finished product.

4. Labelling

The labelling of the human milk batches must be performed as soon as possible after pasteurisation or lyophilisation; an appropriate procedure must be implemented in order to avoid the risks of errors.

All the bottles must be labelled. The label includes the identification of the milk bank, the date of pasteurisation, the batch number and the use by date.

Chapter VIII - Storage of maternal milk

While awaiting the orders, the frozen milk bottles released for distribution or dispensing are stored in appropriate storage units or in zones of the latter, clearly identified and exclusively reserved for this effect.

The milk bottles from personalised donations are stored in dedicated zones.

The storage duration of the milk batches released for dispensing and distribution must be set in order to guarantee the quality of the milk.

Chapter IX - Distribution, dispensing and transport of maternal milk

The milk may be dispensed on medical prescription in the neonatology departments, paediatrics departments and to children whose condition justifies it.

The milk may be distributed at the request of the previously mentioned hospital departments or another milk bank.

The milk bank must verify that the order form has been validated and must

record the distribution dates, the numbers of the batches distributed and the identification of the receiving department, as well as verifying the proper transport conditions to the receivers irrespective of the responsibility.

The appearance of the product, integrity of the container and the label must be controlled during the distribution or dispensing.

No frozen milk bottle may be returned to the milk-bank after dispensing or distribution.

The lyophilised milk bottles may be placed in stock after control and verification of the integrity of the bottle.

The management of the dispensing must be performed in order to allow the traceability up to the receiver. The duration and storage conditions of the milk must comply for its dispensing.

When the milk is distributed, the management must be carried out up to the receiving department that placed the order. The distribution procedures include: the identification of the demanding department, the date of the order and the quantity of milk desired. A delivery voucher accompanies the products.

The milk transport, from the collection to the distribution or dispensing is carried out in strict compliance with the cold chain.

The milk bank is responsible up to the reception of the product by the receiver who then is responsible for the transport. When the shipping operations are carried out by the receiver or its service provider, they are responsible. It makes sure that the transport conditions comply with regulatory requirements.

Chapter X - Records

All the documents must allow retracing the history of each maternal milk batch dispensed or distributed. All the documents are kept by the milk bank, in compliance with the current regulations.

1. Documents concerning the donor

These documents are composed of the donor dossier (see glossary).

2. Documents concerning the milk dispensed or distributed

Documents concerning the maternal milk dispensed or distributed are composed by the batch record.

This batch record includes:

- – the documents describing the composition and controls of the maternal milk batch;
- – the number and identification of sub-batches composing the batch (identity of donors, dates of donations, results of sub-batches controls);
- – the results of the immunological and bacteriological controls before pasteurisation;
- – the results of bacteriological control after pasteurisation;
- – the recording of the pasteurisation parameters and the lyophilisation diagram;
- – all the documents showing the final destination of the maternal milk, in particular, the medical prescriptions or order forms.

The dossier must be conceived in order to retrace a full history of a milk batch. The documents are written in a clear manner and must be easily accessible. They must include the information concerning the storage, dispensing or distribution to other departments, and any destruction of milk batches.

Issued in Paris, on 3 December 2007.

J. Marimbert