The European Margarine Association

IMACE

CODE OF HYGIENE FOR

MARGARINE AND FAT SPREADS

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CHAPTER A – PURPOSE AND SCOPE

The purpose of this Code is to provide guidance for the manufacturing of fat spreads under good hygienic conditions.(GMP). It also offers the opportunity to obtain a complete and accurate picture of a process and its control measures.

The Code applies to fat products, containing not more than 95% fat intended primarily for use as spreads. However it does not apply to fat spreads derived exclusively from milk and/or milk products to which other substances necessary for their manufacture have been added. It only includes margarine and products used for similar purposes (both spreadable and liquid) including cooking and baking and excludes mayonnaise and cheese spreads. The products covered are foods in the form of an emulsion, principally of water and edible fats and oils.

The measures indicated to ensure the safety and wholesomeness of fat products shall apply from raw materials until the sale or supply of the finished product during their shelf life. The Code contains references to a number of general guidelines for hygiene in food manufacturing operations, such as the Council Directive on Hygiene of Foodstuffs 93/43/EEC and the FAO/WHO Codex Alimentarius General Principles of Food Hygiene 1988 (under revision). Definitions of Food hygiene, Code of hygienic practice, Hazard Analysis Critical Control Point (HACCP) can be found in those general guidelines (refer also to Annex III).

The Code covers the specific recommendations for manufacturing plants and processes producing fat products. It should be used in conjunction with legislation and is intended to facilitate its implementation. It will be regularly updated.

The setting-up and management of safe manufacturing operations are ensured by the application of HACCP principles. HACCP is based on the recognition that manufacturers are responsible for determining the critical aspects of producing safe foods. It helps food manufacturers to improve the efficiency of control by providing a disciplined, systematic approach to procedures for assuring food safety.

The HACCP based system described in this Code is a model and should be adapted to each product and each manufacturing process.

The Code has been written by experts of national margarine associations, members of IMACE.

CHAPTER B - PRODUCT AND PROCESS DESIGN PRINCIPLES

1. PRINCIPLES OF PRODUCT AND PROCESS DESIGN

Fat products should be designed to meet all requirements regarding taste, consistency, functionality and appearance. The product design must furthermore ensure that fat products are safe * and do not spoil during their shelf life and intended usage. In this respect, microbiological and chemical hazards as well as foreign body hazards are recognised.

With respect to safety, a preliminary design hazard analysis carried out during product development will provide the basis for the product and process design. The product design will often be based on experience gained with existing products, but due attention should be given to any modification which may result in a product with quite different product characteristics (increased pH, reduced salt, no preservative, large water

droplets or water continuous).
Special attention is necessary when changes in formulation and processing are introduced.

The design hazard analysis may include specifications on the storage conditions that may stop or slow down the growth of any micro-organisms. The type and size of pack must be in line with the intended shelf life of the product once opened.

When the product design is transferred to production, the critical factors must be clearly understood and specified and included in the existing process documentation system. Furthermore, a HACCP study must be carried out.

2. GENERAL PROCESS DESCRIPTION

Production of fat products from raw material to storage consists of the following basic process steps:

1. Purchase and storage of raw materials and packaging materials.
2. Preparation of aqueous phase or stock solution.
3. Preparation and storage of fat phase.
4. Preparation of emulsion.
5. Cooling and crystallisation.
6. Filling.
7 . Storage + Distribution.

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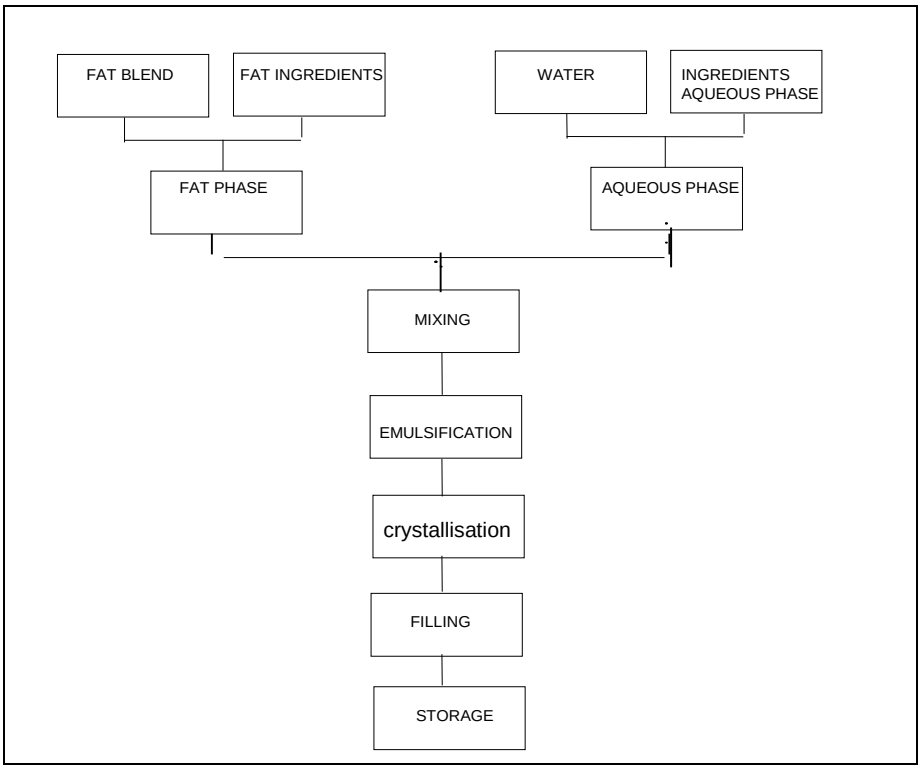
* Requirement for food that is safe and suitable for consumption according to Codex Alimentarius, General Principles of Food Hygiene:

> "formulating design requirements with respect to raw materials, composition, processing, distribution, and consumer use to be met in the manufacture and handling of specific food items".

Fat products manufacture is illustrated in figure 1 below.

Figure 1



3. MICROBIOLOGICAL SAFETY

To achieve a safe design of the product, full attention must be given to the prevention and control of pathogens during the process and shelf life of the product. Relevant pathogens should be evaluated during the product design, e.g. infectious pathogens, such as *Salmonella, Escherichia coli, Listeria monocytogenes and Staphylococcus aureus*. .

Important factors required to achieve a safe product are:
1 The initial microbiological contamination of the raw materials and ingredients
2 The microbiological stability of the product formulation
3 Pasteurisation step(s) during manufacture
4 The shelf life conditions (time, temperature)

3.1. Initial microbiological contamination

Examples of raw materials that are susceptible to contamination with pathogenic micro-organisms are ingredients of dairy origin, soya and gelatin. Raw materials of dairy origin are normally prepasteurised by the supplier. Unless it is ensured that these raw materials are free of pathogens, they must be pasteurised during fat products manufacture.

3.2. Microbiological stability

Microbiological stability may be defined as the degree to which a formulation allows growth of relevant micro-organisms at ambient temperature (both pathogenic and spoilage micro-organisms) if it was exposed to them by contamination. Microbiological stability of a product depends on the chemical composition (e.g. pH, preservative, salt) as well as nutritional (e.g. lactose, whey) and physical factors (water content, emulsion

characteristics: droplet size (average size, total range of sizes). The fact that most spreads are water-in-oil emulsions introduces a very important preservation principle; the aqueous phase is dispersed as droplets in a fat-continuous phase. As these droplets are limited in size, any micro-organism, if it were to contaminate the product, would be restricted in its growth either due to space limitation or due to depletion of the nutrients available in the droplet in which it is present.

A hazard category may be given to a group of products based on their microbiological stability. Hazard categorisation facilitates the provision of hygiene rules and shelf life conditions (Klapwijk, Food Control, 1992).
Alternatively growth of micro-organism in a product can be assessed by a challenge test. More details can be found in " Guidelines for micro-biological testing of reconstituted dried foods. April 1991 - Campden & Chorleywood Food Research Association. Chipping Campden Gloucestershire GL55 6LD, UK. Guidelines for microbiological challenge testing 1987. CFDRA Technical Manual n° 20").
In case of sensitive products and/or very demanding climatic conditions refrigerated distribution should be considered as a worthwhile option to improve the keepability of the product. Appropriate storage conditions and instruction for use must be given on the label where necessary.
Risks associated with consumer handling and usage need attention as well.

3.3. Pasteurisation steps during manufacture

Pasteurisation of raw materials, intermediates and/or the emulsion must be applied where there is a concern about contamination with infectious pathogens. The aim of pasteurisation is to eliminate all infectious pathogens and to reduce the number of spoilage micro-organisms to an acceptable level.

Bacterial spores of toxigenic micro-organisms (e.g. *Bacillus cereus*) cannot be eliminated by pasteurisation, because of their heat resistance. For these micro-organisms it is important that growth in the final product is prevented or controlled to an acceptable level by the product composition and/or emulsion characteristics and/or the shelf life conditions. Although commonly produced fat product formulations do not allow growth of these organisms at the relevant shelf life conditions, in view of new consumer demands (including milder tasting products, absence of preservatives), these micro-organisms may need more consideration in new product development.

4. MICROBIOLOGICAL SPOILAGE

Apart from microbiological safety, microbiological spoilage (moulds, yeasts, sporeforming bacilli, *Enterobacteriaceae*) needs consideration. Growth by spoilage micro-organisms should be controlled since their growth may change key product parameters that are responsible for micro-biological stability thereby creating an environment for growth of pathogenic micro-organisms. Spoilage by moulds is known by the consumer as a defect for fat products. Behaviour of moulds is quite unlike that of bacteria and yeasts and a separate estimation of mould vulnerability may be required as part of product development.

Fat products have a limited shelf life once opened, in particular at ambient temperature, due to the potential for mould spoilage. Preservatives such as sorbates reduce the risk of mould problems if used at the right concentration and pH (< 5.5).

5. GUIDELINES FOR PASTEURISATION

Pasteurisation can take place at a number of steps in the process. At which step in the process pasteurisation is carried out is determined by a number of factors which will be identified during design hazard analysis by the manufacturer With respect to aqueous phase pasteurisation, sensitive liquid raw materials can be pasteurised separately and hygienically mixed at a later stage or pasteurisation of the complete aqueous phase can be done.

The pasteurisation treatments must eliminate the relevant heat-sensitive pathogens and reduce spoilage organisms to an acceptable level. Pasteurisation requirements for raw materials (at the supplier), aqueous solutions and emulsions are outlined below. Actual conditions applied must be based on the outcome of a risk analysis of the particular product. Whenever legislation demands a more stringent condition for pasteurisation this must be adhered to.

5.1. Raw materials

The pasteurisation conditions applied by the supplier should meet as a minimum the conditions required by legislation e.g.EC or recommended by Codex Alimentarius (typically this is 15-20 sec at 72°C). To control storage of liquid milk or whey, pasteurisation may be carried out on site immediately or shortly after arrival of the raw material (typically 15-20 sec at 72°C).

5.2. Aqueous solutions

Pasteurisation condition is typically 15-20 sec at 72°C (this pasteurisation is adequate considering the use of already pasteurised materials and controlled handling of stock solutions and aqueous phases).

It is however important to be aware that a high salt-in-water content (> 8%) may give protection against heat inactivation. Therefore, for these solutions as well as solutions where fermented raw materials are used (which have a high initial level of micro-organisms), a more stringent pasteurisation is recommended (typically, 2 minutes at 70°C or equivalent).

5.3. Emulsions

Pasteurisation conditions of emulsions should be at least 2 min at 70°C or equivalent. This pasteurisation treatment is adequate considering that the main raw materials (fresh and powdered milk and whey) have already undergone some form of pasteurisation either at the supplier or on site. At low microbial load of the raw materials, in practice this treatment will also be sufficient to control spoilage. As has been mentioned for the pasteurisation of aqueous solutions, some special products (e.g. low Aw due to high salt-in-water content >8%, products where fermented raw materials are used) may require a more severe pasteurisation.

6. CHEMICAL AND PHYSICAL HAZARDS

6.1. Chemical contaminants

Chemical contaminants can originate from several sources such as natural sources (e.g. aflatoxin), cleaning agents, transport etc. Appropriate measures should be taken to eliminate or substantially reduce this risk.

Ways of reducing these risks can be selection of supplies and transport and adherence to cleaning instructions.

6.2. Physical hazards

Contamination of raw materials or final product with glass, plastic, string, metal etc presents a hazard. The hazard associated with the manufacturing process is most obvious during open processing. Keeping the environment free of possible foreign objects and keeping open containers covered wherever possible, is a good way to prevent contamination.

7. ALLERGENS

A minority of consumers may be allergic to some ingredients. It is therefore important to protect such consumers by ensuring that potential allergenic substances are not present or by informing the consumer appropriately. Particular caution should be exercised in avoiding the non intentional presence of allergens e.g. due to carry-over or cross-contamination.

CHAPTER C -RAW AND PACKAGING MATERIALS

1. PRINCIPLES

The source and quality assurance of raw materials to be used in fat products is a critical start to all manufacturing processes.

Confidence in the quality of raw materials can be obtained both through knowing both the history of that suppliers' performance against key quality parameters, and by establishing a good communication with the suppliers.

2. OILS / FATS

Incoming oils are of little microbiological threat to yellow fat products if processed and handled properly. Most refinery processes will have heated the oils to a temperature high enough to destroy micro-organisms of concern. Checks should therefore concentrate on risks for subsequent contamination. Such contamination is particularly of concern if the oil contains water. If it is suspected that water is present, oils should be tested for presence of water/and or microbiological contamination (e.g. moulds).

Usually all oils are filtered at the point of entrance to remove foreign material.

Refining of oils and fats does not remove all agrochemicals. These hazards should be covered by the HACCP procedure.

3. INGREDIENTS IN POWDER FORM

Powders e.g. milk, whey, caseinates, bought from approved suppliers normally will meet the agreed specifications. Where this is not assured pasteurisation of the reconstituted ingredients will effectively decontaminate them.

Supplier assurance should provide confidence that supplies are in conformity with legislation relating to veterinary drugs, pesticides and mycotoxins.

4. LIQUID MILK, WHEY AND THE LIKE

These materials must be bought pasteurised. Not only the initial microbial contamination is of concern, but also how the time and temperature of storage might affect the microbial loading. Such liquid materials rely entirely upon chill storage to control microbial growth. A control system is necessary to ensure that time and temperature conditions comply with Council Directive n° 92/46/EEC.

5. ADDITIVES (e.g. FLAVOURS, COLOURS, PRESERVATIVES, EMULSI- FIERS, etc)

Generally these materials have low microbial loads and are of low risk to the product.

6. WATER

All product water must be of potable quality (refer to EU legislation 80/778).

If such water cannot be delivered to the factory, it must be treated before or during use to make it potable .

The microbiological quality of water should be regularly monitored.

The quality of water is related to a number of quality attributes such as hardness. These should be taken into consideration, in particular with respect to taste and flavour impression of finished product. See EU legislation 80/778.

7. GASES

For aerated products gases (e.g. N_2) could be used. These must be food grade and should be filtered, when necessary, to reduce microbiological contamination.

8. PACKAGING MATERIAL (primary and secondary)

Primary packaging is the container in which the final product is marketed.

Secondary packaging material is packaging material that is not in direct contact with the final product.

A number of measures to control the contamination risk of all packaging material can be taken, at least when vulnerable products are produced, such as:

- Minimise contact between primary and secondary packing,
- Carry out filling operation under controlled atmosphere,
- Protect primary packaging material fed to the line.

Personal hygiene to prevent cross-contamination (prim/sec pack).

8.1. Primary Packaging Materials

Primary packaging material should be of high microbiological quality (i.e. low level of micro-organisms, in particular mould spores).

Some high-risk products are very sensitive to any contaminating mould spores, and for these products, microbiological examination of tubs, lids, cover leaves and wrappers should be carried out.

Packaging materials must be handled and managed hygienically, and practices should control the risk of getting extraneous matter into containers.

8.2. Secondary Packaging Materials/Cardboard

Cardboard packaging material can be a source of contamination for spreads, although the outers are not in direct contact with the product. Therefore handling of cardboard in the production areas should be well managed.

9. PROCEDURES AND SPECIFICATIONS

Every particular raw- or packaging material must be described up to the necessary safety standard in writing. These descriptions must be considered as a contract between supplier and customer and can be either a "full specification" [*] or an internal document to define compliance to an "agreed sample". Confirmation of compliance can be necessary.

Suppliers of raw materials, ingredients and packaging material should be approved by the fat products' production management, when appropriate. They should be audited on a regular basis. Reaudit-frequency and sampling plan of incoming materials should be defined based on business criteria, e.g. risk, reliability, volume, monopoly, …

In addition to identifying reliable suppliers, checks on incoming materials should be carried out. Frequency should be defined to assess the suitability of the supplier to provide confidence that sensorial, chemical, microbiological and/or physical specifications are met and that the supplies are in accordance with legal, packaging, hygienic and coding requirements.

Storage should be in the specified way to ensure the quality will not deteriorate during shelf life of production materials. Upon use, normally the first-in, first-out principle has to be applied

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[*] Specifications of materials delivered, whether they refer to raw- or ingredients must therefore:

- cover the limits and tolerances identified with CCPs
- correspond quantitatively to identified (marketing or technical) requirements
- contain target and limits, in order to enable proper trend analysis and process control
- be accompanied by proper monitoring procedures and analytical methods
- be based on proven process capability
- be formally agreed between "supplier" and "customer"

Specifications should be set such that they are met until the end of the declared shelf life of incoming materials.

CHAPTER D – PLANT EQUIPMENT AND PROCESSES

1. GENERAL COMMENTS

Typical equipment used to produce margarine and spreads :

- containers, for storage, mixing or processing. Many containers are equipped with agitators.
- pumps, pipelines, valves and related equipment
- pasteurisers / heat exchangers
- crystallisers (scraped surface heat exchangers), tube or drum system
- filling equipment
- packing and palletising equipment

In margarine and spread plants, heating (e.g. to prevent fats from crystallising), and cooling or chilling (to crystallise) are applied.
Heating media typically are water/steam or electrical heating, cooling medium usually is water whereas ammonia (NH_3) is commonly used for chilling.
Hazards associated with each of the heating, cooling or chilling media must be assessed at their respective process steps in case there should be a leak. Such hazards might include the use of hazardous media or presence of hazardous substances in those media (e.g. to prevent growth of bacteria/algae).
Generally, no specific measurements are required regarding air quality as contamination of the product with pathogens by air is insignificant. For those cases though where air quality is of significant importance, air control systems should be applied (e.g. to control occurrence of mould spores).

1.1. Preventive Maintenance

Production lines should be maintained according to a well-established maintenance and cleaning schedule.
Well-maintained production lines not only assure smooth production, they also prevent unwanted and unexpected breakdowns. As such breakdowns may present a higher risk of introducing foreign bodies into the product (parts of broken equipment), a well-designed maintenance system contributes to safer products.

2. DESCRIPTION OF A TYPICAL PROCESS

For a general process flow, see figure 1, chapter B.

2.1. Fat Blend

Fat blends (mixtures of oils and fats) are either prepared in the production plant or are bought as a blend.
Oils, fats and fat blends are (temporary) stored in containers prior to use. Sometimes, these containers are heated.

2.1. A Typical Hazards

Physical

When oils and fats are delivered with trucks, pipes used for unloading should be free of foreign bodies. Containers should be closed until the oil/fat is required.

2.2. Fat Ingredients / Fat Phase

Some ingredients are fat-soluble. These ingredients are added to the fat blend to form the fat phase. Typical ingredients are emulsifiers, vitamins, and flavours.
Several possibilities exist to add fat-soluble ingredients to the fat blend. The simplest method is to add them directly to the fat blend. Another method consists of preparing one or several premixes of an oil and fat-soluble ingredients and to add these premixes to the fat blend.
Typically, fat blends, premixes and fat phases are prepared or stored in containers, sometimes heated. The containers are then equipped with an agitator. Ingredients are often added manually to the fat phase/premix container whereas the oil or fat is usually pumped to the fat phase or premix container.

2.2. A Typical Hazards

Physical

As ingredients are added to the fat blend, care should be taken not to introduce foreign bodies in the container (e.g. cutting devices, dirty pallets). It is recommended not to use open containers.

2.3. Water

Apart from oils and fats, water is the other main component of margarines and spreads.
Main concern here is to use water of potable quality (see also chapter C).

2.4. Ingredients of the Aqueous Phase / Aqueous Phase

Similar to the fat phase, some ingredients are water-soluble. These ingredients are added to water to form the aqueous phase. Typical ingredients are milk proteins, acids, flavours, salt, preservatives.
A variety of systems exist to add water-soluble ingredients to the aqueous phase.
As with the fat-soluble ingredients, water-soluble ingredients can be added directly to the aqueous phase or through premixes. Premixes are used a lot for water-soluble ingredients and sometimes special processes are needed to make an ingredient appropriate for use.
Typically, aqueous phases and premixes are prepared/stored in containers. The containers are often cooled since the aqueous phase is the most micro-biological sensitive part of a margarine or spread. Some ingredients however must be heated prior to use and are sometimes stored at higher temperatures. The containers are mostly equipped with an agitator.
Ingredients are often added manually to the aqueous phase/premix container whereas other ingredients (e.g. water, milk solution, salt solution,etc) are pumped to the aqueous phase or premix container.
Sometimes it is necessary to pasteurise the aqueous phase or part of it (e.g. a certain premix or raw material). Whether or not to pasteurise depends on the sensitivity of the product to growth of pathogens, the process storage conditions, primary load, vulnerability of the product,... (see chapter B).

2.4. A Typical Hazards

Physical

As ingredients are added to the fat blend, care should be taken not to introduce foreign bodies in the container (e.g. cutting devices, dirty pallets). Vessels should be closed.

Microbiological

Depending on the type of aqueous phase, pasteurisation may be required, for example when presence of pathogens (from raw material) cannot be excluded and no further pasteurisation steps are applied later in the process (see chapter B for details on pasteurisation), storage conditions will also be dictated by microbiological stability of the aqueous phase.

If pasteurisation is needed, it must be done according to the principles described in chapter B and recontamination should be avoided.
Ingredients should be stored in conditions that prevent contamination and/or development of micro-organisms.

2.5. Mixing

In this step, the fat phase and the aqueous phase are put together in the right proportions. Sometimes this step is combined with the emulsification step.

2.6. Emulsification

In this step, the emulsion is formed. Typically this is done in a (heated) container with an agitator. Sometimes the formulation is also done in this container.

2.7. Crystallisation

In its simplest form, margarine processing is turning the liquid emulsion into a solid emulsion (= the margarine or spread) by letting the liquid emulsion crystallise. This crystallisation process is done by chilling the emulsion in a scraped surface heat exchanger. The emulsion is pumped from the emulsification container to the crystalliser.
Temperature of emulsion entering the crystalliser is sometimes controlled by a heat exchanger.
Sometimes, prior to crystallisation, the emulsion may be pasteurised, depending on product sensitivity (see chapter B). Pasteurisation is usually continuous.
Apart from these two basic layouts (with or without pasteurisation), more complex processing may be required, depending on the type of product produced. This should be evaluated on a case by case basis.

2.8. A. Typical Hazards

Physical

Special attention in the preventative maintenance system should be given to the ‘knives’ of the crystalliser that scrape the surface : if these break, sharp foreign objects may get into the product.
When using (open) drum chillers instead of (closed) tube chillers, risk of foreign bodies getting into the product must be carefully assessed.

Microbiological

In case of pasteurisation, it should be applied according to the principles described in chapter B and recontamination should be avoided.

2.9. Filling

At this stage, the solid product is put into a tub, wrapper, bag, box, bottle, container,...
Depending on the packaging form, more or less complex filling machines will be used.
Very simple filling machines consist of a weighing scale and a manually operated valve whereas the more complex filling machines produce the tub, fill it with the product, close it and put it in a secondary packaging.
The secondary packed product is then put onto a pallet.
If products are sensitive to growth of mould spores, special attention should be paid to the microbiological quality of the primary packaging material,.(e.g. disinfection) and control of the air quality in the filling area (e.g. using filtration). In some cases disinfection prior to use is needed to reduce the risk of mould defects of final products.

2.10. A. Typical Hazards

Chemical

When disinfecting the tubs, residues of disinfectants should not exceed safety levels.

Physical

At filling machines, a risk of foreign bodies getting into the product exists. Hence, appropriate measurements should be taken to avoid the occurrence of such incidents.
Tubs should never be used for storing other things (e.g. nuts and bolts).

Microbiological

If, based on a HACCP study, primary packaging (usually tubs) needs to be disinfected, disinfection must be done according to the manufacturer's or generally agreed external recommendations to ensure the safety of the product.
Handling of the primary packaging (e.g. putting tubs/lids in the filling machine) should be done in such a way that the risk of contamination of the primary packaging is minimised.

CHAPTER E - PLANT CLEANING AND SANITATION

The following specific points to the Fat products Industry must be taken into account :

1. An initial water rinse should be carried out to remove as much of the fat and other deposit as possible. Without this the detergents used will not be effective unless used in excessive quantities.

2. Detergents must be carefully selected for their performance in removing the fat and burnt on pasteuriser deposits where appropriate.

3. The different hygiene status post pasteuriser must be taken into account in the cleaning programme.

4. Certain parts of the plant where water is undesirable may be cleaned using vegetable and animal oil.

5. Packing machines are usually very complex machines and cleanability tends to be a problem. Where manual cleaning is used, hygiene program should be followed and properly monitored.

6. Hazardous chemicals must be stored in such a way as to prevent contamination of foodstuffs of food contact surfaces or to present a risk to personnel.

CHAPTER F – PERSONAL HYGIENE

Council Directive 93/43/EEC on the hygiene of foodstuffs lays down the general requirements for personal hygiene in its annex.

The establishment's management should organise training including information in methods of food handling and personal hygiene for all persons responsible for handling food, so that all precautions are taken for the safety and quality of the food products.

Personnel assigned to handling of food should maintain a high level of personal cleanliness during working hours. They should wear protective clothing specific to the area of work.

No person suffering or suspected of suffering from an infectious disease shall be permitted to work in any food handling area.

CHAPTER G – FINISHED PRODUCTS

1. CODING

Each individual consumer unit and secondary packaging must be coded according to legal requirements with respect to shelf life and lot identification. Each consumer pack has to be marked with a best before/durability date.

2. INSTRUCTIONS FOR USE

Appropriate instructions for use of the product should be clearly given on the label. If the product is very vulnerable with respect to microbiological spoilage, an open shelf life indication should be considered, e.g. " after opening keep refrigerated and use within two weeks".

3. STORAGE, DISTRIBUTION AND RETAIL

The shelf life of all products must be clearly defined during product development. At that time full account of temperature in storage, distribution chain and retail must be taken into account. Also consumer handling and usage should be considered. The recommended storage temperature is related to the shelf life of the product. The major factors limiting the product shelf life and which should be considered are temperature and organoleptic changes due to, for example, fat oxidation and microbiological growth. Consequently, storage, distribution and retail temperature used must be appropriate for the product. When specified, chilled conditions should be used.

Also other changes in product quality attributes such as the stability of the emulsion should be taken into account. For this reason the product should be handled in a way that does not deviate from instructions on the

label, e.g. temperature.

It is important to recognise that ambient temperatures can be very variable depending upon season and geographical location.

4. MICROBIOLOGICAL SPECIFICATIONS

The finished product should not exceed any of the limits below during the whole shelf life.

Staphylococcus aureus	max 1000 cfu * per gram	(Method ISO 6888)
Salmonella	absent in 25 g	(Method ISO 6579)

* cfu : colony forming units

5. MICROBIOLOGICAL GUIDANCE

Any presence of Enterobacteriaceae or Coliform bacteria indicates some unsatisfactorily hygienic status concerning raw material, ingredient, packaging material or processing step. This triggers examination and remedial action.

As some growth may occur in the more vulnerable products the microbiological specification at time of filling must be stricter than for more stable products to ensure that the specification during the whole shelf life is not exceeded.

It should be noticed that a low fat product is more vulnerable to microbiological growth at a certain microbiological level than a high fat product.

CHAPTER H - APPENDICES

ANNEX I

EXAMPLES OF TYPICAL HAZARDS TO BE CONSIDERED IN A HACCP STUDY FOR FAT PRODUCTS :

Incoming Material	*Chemical Hazard*	*Microbiological Hazard*	*Physical Hazard (e.g. stones, glass, metal)*
Oils/Fats	**Yes** (e.g. Previous loads, PAH's)	-	**Yes** (*e.g. Pests, damaged coatings*)
Emulsifiers	-	-	**Yes**
Potable Water	**Yes**	**Yes**	-
Minor Ingredients (e.g. Flavours, Vitamins, ...)	**Yes** (*e.g. Solvents*)	-	-
Salt	-	-	**Yes**
Proteins (Dairy or Non-dairy, e.g. Casein, Gelatine)	**Yes** (*e.g. Aflatoxin M1, pesticide residues, veterinary drug residues*)	**Yes**	**Yes**
Preservatives (e.g. Sorbate)	-	-	**Yes**
Acids (e.g. Citric, Lactic)	-	-	**Yes**
Gases (e.g. Nitrogen)	-	**Yes**	-
Packaging	**Yes** (*e.g. Printing inks*)	**Yes**	**Yes**

ANNEX II

1. EXAMPLE OF A HACCP STUDY

This part describes how a HACCP study could be done. Its sole purpose is to provide guidance of doing a HACCP study for a basic margarine and spread product.
It should be noted that all information in this example (process layout, control measurements, critical limits, corrective actions, etc) are suggestions and in no way formal recommendations on how to run a margarine and spread plant.

1.1. HACCP Team

The first step is to assemble a HACCP team. This team should be multi-disciplinary to avoid a one-sided view on food safety : all knowledge on food safety hazards and potential solutions should be combined in this team.
HACCP Team (example) :

- production manager
- quality manager
- maintenance manager
- product development manager

1.2. Description of the Product

In principle, one study must be made for each product or a group of products having the same safety characteristics.
The example is a typical product for the industry :

- 80% fat, water, emulsifier, salt, citric acid, flavouring, and vitamins.
- The product is filled in a tub, the tubs are put into a secondary packaging on pallets.
- Shelf life of the product is 3 months, when stored at ambient temperatures.
- Microbiological assessment was done according Chapter B and product formulation was found to be stable.

1.3. Intended Use

The product can be used for spreading and cooking or frying by all consumer groups (children, adults, and elderly people).
Note : products containing a low fat content usually are unsuited for frying. This should be taken into account when doing the HACCP study.

1.4. Flow Diagram

The company specific flow diagram is shown on page 23.
This company prepares a stock solution of salt. This solution is then added to the aqueous phase. Otherwise, the process flow is analogous to the general process flow of chapter B. After production, the plant is cleaned (typically once a week).

1.5. Hazards and Control Measures for each Step

The HACCP team has identified following Hazards (short list for this example only) :

Physical

- glass (windows, lights)
- knives (used to open bags)

Chemical

- pesticides (raw materials)
- cleaning agents

Micro biological

- no pathogen hazard

The hazards associated with a certain process step are detailed in the table on p 19., columns 1-3. In this example, only the hazards mentioned above are dealt with.

1.6. Identification CCP's

See table on p. 25. The answers to the questions of the decision tree (Control measures in place/Is the step reducing the Hazard/Could contamination occur/Will a subsequent step reduce the Hazard) are given in the subsequent 4 small columns.

1.7. Establishment Critical Limits

If a step has been determined as critical for a certain associated hazard, the critical limits can be found in column 5 of the table.
These limits define the target level and tolerance of a specific parameter related to the CCP. Whenever this parameter is within the defined range, the CCP is well controlled.

1.8. Establish a Monitoring System

Monitoring : scheduled measurement or observation at a CCP of the compliance with the target level(s) and specified tolerance set down for each control measure.
The monitoring system describes the methods by which management is able to confirm that all CCPs are operating within specifications.
See column 5 of the table.

1.9. Establish Corrective Actions

Specifications of the actions to be taken when monitoring results show that a CCP has deviated from its specified tolerance.
See column 5 of the table.

1.10. Establish Verifications Procedures

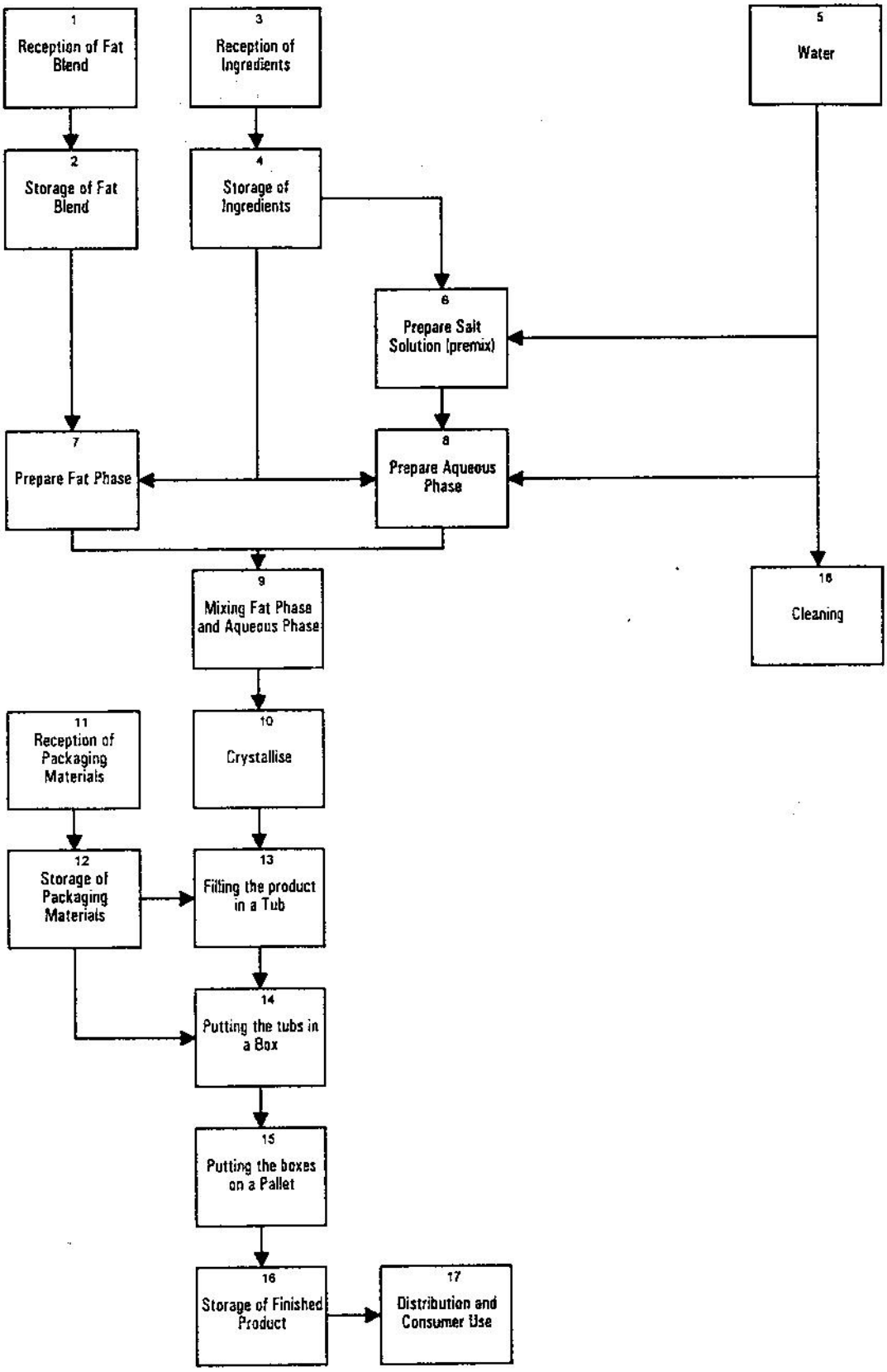
Verification that the HACCP procedures are working properly : verification that the implementation of the HACCP study is properly done.
Apart from verification of the procedures, the HACCP study must be reviewed as well. The HACCP study should be reviewed on a regular basis since changes in product formulation, product processing, factory layout,etc could have an influence on the CCPs and consequently, on the corresponding procedures.
The HACCP team decided to verify the HACCP procedures in the following way :

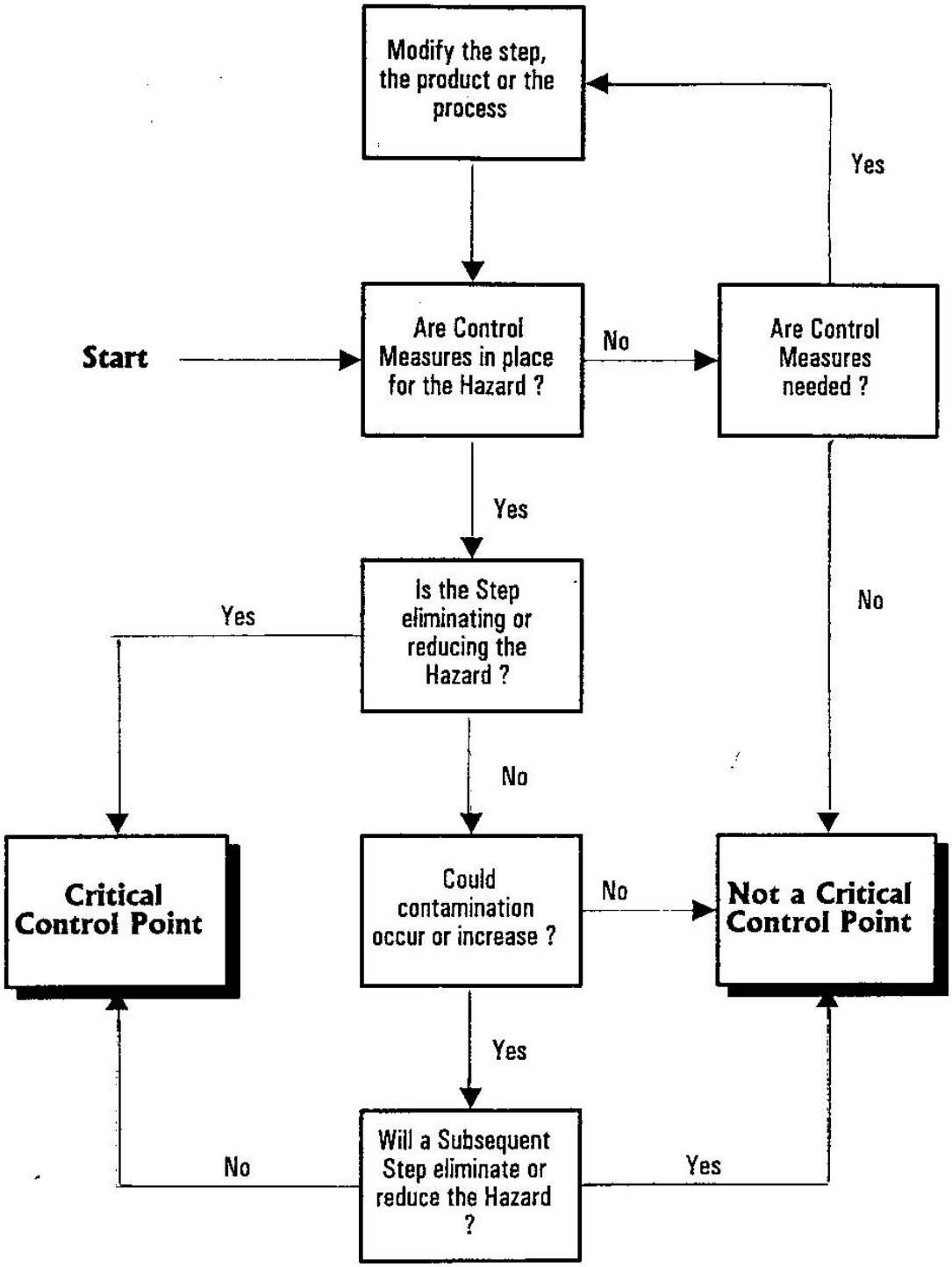
- regular verifications whether instructions and procedures are followed.
- evaluation of the monitoring system regularly
- review of the HACCP study regularly

1.11. Record Keeping and Documentation

As it is important to be able to demonstrate that the HACCP principles have been correctly applied, accurate and complete records must be kept of all HACCP activities.
Examples of those records are :

- quality of raw materials
- processing, cleaning and disinfection records
- deviation files
- verification & review data


1
Reception of Fat Blend
3
Reception of Ingredients
5
Water
2
Storage of Fat Blend
4
Storage of Ingredients
6
Prepare Salt Solution (premix)
7
Prepare Fat Phase
8
Prepare Aqueous Phase
9
Mixing Fat Phase and Aqueous Phase
18
Cleaning
11
Reception of Packaging Materials
10
Crystallise
12
Storage of Packaging Materials
13
Filling the product in a Tub
14
Putting the tubs in a Box
15
Putting the boxes on a Pallet
16
Storage of Finished Product
17
Distribution and Consumer Use


Modify the step, the product or the process
Yes
Start
Are Control Measures in place for the Hazard ?
No
Are Control Measures needed ?
Yes
No
Is the Step eliminating or reducing the Hazard ?
Yes
No
Critical Control Point
Could contamination occur or increase ?
No
Not a Critical Control Point
Yes
No
Will a Subsequent Step eliminate or reduce the Hazard ?
Yes

HOW TO READ THE HACCP TABLE

Column	Explanation
1	Reference to the step of the process flow
2	Hazard evaluated at this process step
3	Description of the control measure associated with this Hazard
4	Small Column : CCP or not. If CCP, column contains **Y**, otherwise **N**.
5	Small Column : contains the answer to the first question of the CCP decision tree.
6	Small Column : contains the answer to the second question of the CCP decision tree.
7	Small Column : contains the answer to the third question of the CCP decision tree.
8	Small Column : contains the answer to the fourth question of the CCP decision tree.
9	Further explanation of the previous columns
4 & 5	Large Columns beneath the small columns 4-8: if the step is a CCP for the Hazard evaluation, the Critical Limits, Monitoring System and Corrective Action are detailed in Column 5.

HACCP TABLE

Step	Hazard	Control Measure	CCP ? Y/N, followed by the answers to Decision Tree Questions. If CCP, further details are provided.					
1	Pesticides	Apart from working with approved suppliers (*see document X *)*, regular tests are done on the raw materials (*see document X **). For each ingredient, product specifications exist.	**Y**	Y	N	Y	N	No subsequent step to reduce the Hazard.
			Critical Limits					See product specification.
			Monitoring System					See document X: Testing of raw materials.
			Corrective Action					Segregation of the finished product unfit for human consumption. If the critical limits are exceeded, the supplier is re-evaluated. Several non-conformances with the same supplier will result in removing this supplier from the approved supplier list. (*see document X * : how to approve suppliers*)
2	Glass	Storage tanks must be closed (no open lids). No windows present in the room, lights are covered with a plastic covering.	**N**	Y	N	N	-	No contamination occurs at this step
3	Pesticides	See step 1.	**Y**	Y	N	Y	N	
4	Glass	No windows present in the room, lights are covered with a plastic covering.	**N**	Y	N	N	-	No contamination occurs at this step
6	Knife	Proper instructions *(see document X *)* : all bags have to be opened first, the knife must be put in its proper place, then the ingredient is added.	**Y**	Y	N	Y	N	Contamination could occur and no subsequent step to reduce the Hazard. Note : should the solution or the ingredient be filtered then the filtering would be the CCP and not this step.
			Critical Limits					-
			Monitoring System					Regular verification that people work according to the instruction.
			Corrective Action					Segregation of the finished product until foreign metal removed. Retraining of people to avoid further incidents.

6	Glass	Lights are covered with a plastic covering. For the windows, a glass register is kept and regular verifications are performed *(see document X *)*.	**Y**	Y	N	Y	N	Contamination could occur and no subsequent step to reduce the Hazard.
			Critical Limits					No broken glass.
			Monitoring System					Glass register and regular verification *(see document X *).*
			Corrective Action					See document X *: Glass Breakage Procedure.
	Cleaning Agents	Appropriate cleaning procedure. This procedure ensures that all cleaning residues are removed (rinsing) (*see also cleaning instruction X **).	**N**	Y	N	N	-	No contamination occurs. Note : the cleaning step will be a CCP since this step must assure that all residues are removed. See step 18.
7	Knife	Proper instructions *(see document X *)* : all bags have to be opened first, the knife must be put in its proper place, then the ingredient is added.	**Y**	Y	N	Y	N	Contamination could occur and no subsequent step to reduce the Hazard. Note : should the solution or the ingredient be filtered then the filtering would be the CCP and not this step.
			Critical Limits					-
			Monitoring System					Regular verification that people work according to the instruction.
			Corrective Action					Segregation of the finished product. Retraining of people to avoid further incidents.
7	Glass	Lights are covered with a plastic covering. For the windows, a glass register is kept and regular verifications are performed *(see document X *)*.	**Y**	Y	N	Y	N	Contamination could occur and no subsequent step to reduce the Hazard.
			Critical Limits					No broken glass.
			Monitoring System					Glass register and regular verification *(see document X *).*
			Corrective Action					See document X *: Glass Breakage Procedure.

8	Knife	Proper instructions *(see document X *)* : all bags have to be opened first, the knife must be put in its proper place, then the ingredient is added.	**Y**	Y	N	Y	N	Contamination could occur and no subsequent step to reduce the Hazard. Note : should the solution or the ingredient be filtered then the filtering would be the CCP and not this step.
			Critical Limits					-
			Monitoring System					Regular verification that people work according to the instruction.
			Corrective Action					Retraining of people to avoid further incidents.
	Glass	Lights are covered with a plastic covering. For the windows, a glass register is kept and regular verifications are performed *(see document X *)*.	**Y**	Y	N	Y	N	Contamination could occur and no subsequent step to reduce the Hazard.
			Critical Limits					No broken glass.
			Monitoring System					Glass register and regular verification *(see document X *).*
			Corrective Action					See document X *: Glass Breakage Procedure.
	Microbiological	Proper instructions to ensure a formulation according to the recipe.	**Y**	Y	N	Y	N	If formulation is not according to recipe, the product might not be as stable as anticipated.
			Critical Limits					X %
			Monitoring System					Registration of ingredients used per shift.
			Corrective Action					Segregation of the finished product. Retraining of people to avoid further incidents.
8	Cleaning Agents	Appropriate cleaning procedure. This procedure ensures that all cleaning residues are removed (rinsing) (*see document X **).	**N**	Y	N	N	-	No contamination occurs. Note : the cleaning step will be a CCP since this step must assure that all residues are removed. See step 18.
9	Cleaning Agents	Appropriate cleaning procedure. This procedure ensures that all cleaning residues are removed (rinsing) (*see document X **).	**N**	Y	N	N	-	No contamination occurs. Note : the cleaning step will be a CCP since this step must assure that all residues are removed. See step 18.

12	Glass	No windows present in the room, lights are covered with a plastic covering.	**N**	Y	N	N	-	No contamination occurs.
13	Glass	Lights are covered with a plastic covering. For the windows, a glass register is kept and regular verifications are performed *(see document X *)*.	**Y**	Y	N	Y	N	Contamination could occur and no subsequent step to reduce the Hazard.
			Critical Limits					No broken glass.
			Monitoring System					Glass register and regular verification *(see document X *).*
			Corrective Action					See document X *: Glass Breakage Procedure.
18	Cleaning Agents	Appropriate cleaning procedure. This procedure ensures that all cleaning residues are removed (rinsing) (*see document X **).	**Y**	Y	Y	-	-	This step reduces the Hazard.
			Critical Limits					Concentration of disinfectant according to manufacturers' recommendation
			Monitoring System					With the cleaning procedure, residues are below the critical limits. As a precaution, the residues are determined once every two year.
			Corrective Action					Segregation of the finished product. When the cleaning procedure has not been properly executed, cleaning is redone.

ANNEX III

DEFINITIONS

Food hygiene is defined in Council directive 93/43/EEC on the hygiene of foodstuffs as :

"All measures necessary to ensure safety and wholesomeness of foodstuffs. The measures shall cover all stages after primary production during preparation, processing, manufacturing, packaging, storing, transportation, handling and offering for sale or supply to the consumer".

Reference should also be made to the Recommended International Code of Practice, General Principles of Food Hygiene CAC/RCP/1/1969/Rev. 3 (1997).

Codes of Hygienic Practice

A document which provides general and specific guidance to manufacturers of similar products outlining the practical requirements of hygienic food manufacture.

. Hazard Analysis Critical Control Point (HACCP) is defined by the Codex Alimentarius Committee on Food Hygiene , Annex to CAC/RCP/1/1969/Rev. 3, (1997).

“A system which identifies specific hazard(s) and preventive measures for their control".

Must

to be implemented immediately, compulsory, mandatory.

Should

recommended for current operations (not necessary to be implemented immediately)
compulsory in the future, to be implemented in all new investments.

Recommend

desirable, optional, preferred practice not necessary to be implemented.

Prevent (*active*)

stop from happening, target zero occurrence.

Water continuous

emulsion where the fat phase droplets are dispersed in a matrix of water.

Fat continuous

emulsion where the aqueous phase droplets are dispersed in a matrix of fat.

Open shelf life

means the period of time following opening of the primary packaging within which the product is suitable for consumption.

Infectious pathogen

pathogenic micro-organisms causing disease after growth (and sometimes toxin formation) in the host. Since the pathogen is able to grow in the host, the infections dose (number of micro-organisms consumed) can be very low. An example of infectious pathogen is Salmonella.

Pasteurisation

Pasteurisation is a heat treatment process applied to a product with the aim of avoiding public health hazards arising from pathogenic micro-organisms. Pasteurisation as a heat treatment process is intended to result in only minimal chemical, physical and organoleptic changes.

Toxigenic pathogen

pathogenic micro-organisms able to produce a microbial substance or substances (toxins) which will induce host damage. The production of the toxin can be either taking place in the host or can take place in a food product that will cause host damage after consumption.