



EUROPEAN CHILLED FOOD FEDERATION
FEDERATION EUROPEENE DES PLATS FRAIS REFRIGERES

RECOMMENDATIONS

FOR

THE PRODUCTION OF PREPACKAGED

CHILLED FOOD

TABLE of CONTENTS

PART 1: PRODUCT AND PROCESS DESIGN OF CHILLED FOOD

Section 1.1	Main hazards	8
Section 1.2	Control measures	11
Section 1.3.	Shelf life	18

PART 2 CLASSIFICATION OF HYGIENE AREAS

Section 2.1.	General hygiene requirements	22
Section 2.2.	Table defining hygiene area requirements	24

PART 3 ADDITIONAL OBLIGATIONS

Section 3.1.	Raw materials and supplier control	43
Section 3.2.	HACCP	45
Section 3.3.	Monitoring, verification and documentation	54
Section 3.4.	Traceability	61
Section 3.5.	Recall	63

APPENDICES

Appendix A	Definitions and abbreviations	68
Appendix B	Case studies using decision tree route to determine minimum status required	74
Appendix C	Air quality	85
Appendix D	Selected reading and other relevant guidelines / codes of practice	88
Appendix E	ECFF aims and membership	91

INTRODUCTION

Chilled foods include a vast range of food products, such as ready-to-eat salads and sandwiches, ready-to-heat meals, pastas and sauces, pizza, desserts, soups, sauces, dressings and doughs. These foods may include both raw and heat-processed ingredients. Further heat processing may or may not be used during the manufacturing process and by the consumer. For these reasons, chilled foods depend on refrigeration as the primary means of preservation.

It is recommended that chilled food manufacturers aim to achieve $<5^{\circ}\text{C}$ in storage and distribution facilities controlled by them. It must however be recognised in the establishment of shelf life that the wider distribution chain, including retail display and consumer refrigerators may operate at higher temperatures. Legislative requirements must also be complied with.

A key criterion for chilled foods is that they must be microbiologically safe at the point of consumption. Pathogens that could result in food-borne illness when consumed must be controlled. Within this context, ensuring the safety and quality of chilled foods is dependent on the integrity of the entire food chain, from production and harvesting of ingredients, through manufacturing and distribution and finally, storage and preparation by the consumer.

Because of the diversity of raw materials, processing conditions and packaging systems that are used in the production of chilled foods, it is not possible to establish a "one size fits all" approach to achieving microbiological safety. Rather, the manufacturer must carefully consider a wide variety of factors and hurdles – raw material quality, hygienic processing, temperature, water activity, acidity, modified atmosphere – in determining ways to control microbiological growth and thus prevent spoilage and/or the development of conditions that can lead to food-borne illness. Via the choice and combination of these elements, the manufacturer is able to determine the optimum shelf life for a product and establish conditions for its use that will ensure safe food products for consumers.

The *ECFF Recommendations* are complementary to European Union (EU) food hygiene legislation, as well as the Codex Alimentarius Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf Life (CAC/RCP 46-(1999)) and the Codex Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3 (1997), Amd. (1999)).

The *European Chilled Food Federation (ECFF) Recommendations for the Hygienic Manufacture of Chilled Foods 2005* (formerly ECFF Guidelines 1996) provide a reference for the production of a wide spectrum of chilled foods, outlining the fundamental principles that should be considered when designing safe manufacturing operations.

The *ECFF Recommendations* provide a resource when developing national guidelines or when working with local enforcement authorities to implement legal requirements at the production stage. In addition, the *ECFF Recommendations* can provide guidance for the producers of chilled foods.

It always remains the responsibility of the Food Business Operator (FBO) to assure the safety of its products (General food law regulation (EC) No 178/2002 – art. 17). It must be recognised that the task of setting up and managing a chilled food operation demands a high level of expertise to ensure that a facility is properly designed and that appropriate procedures are in place to achieve the production of safe foods. These procedures involve application of Good Manufacturing Practices (GMP), Good Hygiene Practices (GHP) and implementation of a Hazard Analysis and Critical Control Points (HACCP)-based system.

SCOPE

The *ECFF Recommendations* provide guidance on process design and hygienic principles related to the manufacture of chilled prepared foods (hereafter referred to as chilled foods), with emphasis on those procedures designed to control the risks associated with bacteria that cause food-borne diseases. However, as guidance, they cannot cover all of the factors that may be applicable to a specific operation.

It is essential that a HACCP-based system is used to identify the specific control requirements for an individual operation.

The *ECFF Recommendations* relate to chilled foods that are capable of supporting the growth of pathogenic organisms.

On-site catering operations must meet the general hygiene requirements (see Section 2.1).

The following foods are considered to be outside the scope of the *Recommendations*:

- cook-chill foods prepared by caterers;
- foods offered for sale at frozen or ambient temperatures;
- fermented foods;
- dairy products;
- foods with pH <4.0 or $a_w \leq 0.85$.

MANAGEMENT RESPONSIBILITIES

FBOs are legally responsible under EU General Principles of Food Law (178/2002/EC) for the safety of food products under their control. Additional national legal obligations may apply.

New products must have been designed to ensure safety before being presented to customers.

FBOs must

- understand the principles of HACCP (see section 3.2) and GMP and ensure that they are applied;
- understand hazards and risks and ensure that they are managed;
- ensure that all personnel understand the importance of maintaining the appropriate hygienic conditions throughout the facility, including appropriate personal hygiene and cleanliness;
- ensure that regular, thorough and planned staff training takes place to reinforce this understanding.

Within the management team an individual with appropriate knowledge and authority should be designated to be responsible for all operations, including review and audit related to all aspects of product safety.

Management must also ensure that there are adequate on- or off-site services, laboratories and equipment to enable informed decisions regarding

- hygiene of the plant and process;
- quality and safety of raw materials, work-in-progress and finished product;
- assessment of finished product over the known shelf life;
- calibration of instrumentation and equipment.

These services must work to a documented quality management system and use competent personnel.

HOW TO USE THESE RECOMMENDATIONS

The *ECFF Recommendations* have been designed to cover a wide range of chilled products of varying shelf lives manufactured under different hygiene conditions. The structure of the *Recommendations* enables easy selection of the relevant information for the category of products covered.

To be effective, the Recommendations must be used in the following way:

- Take into account all essential general information contained in the *Recommendations* (Part 1 and Appendices A to E).
- Use the first Decision Tree (section 1.2.2) to identify the minimum class of area hygiene standards required (i.e. GMP, rHCA or cHCA) – you will need to know the heat process applied and whether or not recontamination is possible. The Decision Tree takes into account only the degree of heat treatment applied and the possibility of recontamination that may present a food safety hazard.
- Refer to section 2.2 for the detailed hygiene requirements applicable to the required area standard.
- If a particular product does not receive the required heat processes set out in the Decision Tree, the manufacturer must apply product processing design conditions such that product safety is demonstrable (see Intrinsic Preservation Factors 'Hurdles', section 1.2.1).
- If a type of product not specifically excluded from the scope of these *Recommendations* is not covered, reference should be made to appropriate national or international codes in conjunction with a HACCP-based system.
- Refer to section 3 for additional obligations relating to systems.
- Where the term “must” is used, this denotes that the conditions referred to are either specifically required by law, or, in cases where a condition is not specifically legally required, the condition is considered necessary by ECFF to implement requirements of general food hygiene legislation to ensure food safety. The term “should” indicates that it desirable to comply with the condition to which reference is made.

While the Recommendations have been drawn up to illustrate good practice, it is the responsibility of the manufacturer to demonstrate that hazards are controlled and to document that risks have been assessed. It is recommended that, where alternative control methods to those given in the *Recommendations* are used, documentation be kept to demonstrate the rationale behind the approach taken.

PART 1

CHILLED FOOD PRODUCT AND PROCESS DESIGN

SECTION 1.1

MAIN HAZARDS

Chilled foods may be manufactured using a wide variety of ingredients, processes and packaging systems. Microbiological, chemical or physical hazards may be very different from one product to another.

To define the hazards that should be controlled, it is necessary to identify these hazards and to assess their occurrence and severity. For example:

- a hazard that is not very frequent but is very serious, such as *Clostridium botulinum*;
- a hazard that is more frequent and serious, particularly for some population categories such as the elderly, infants and young children, pregnant women and immunodeficient people, such as *Listeria monocytogenes*;
- a hazard that is quite frequent and could be serious, such as a bone in a piece of fish.

Control of hazards must be done through application of HACCP systems (see Section 3.2.)

1.1.1 MICROBIOLOGICAL HAZARDS

Chilled foods are very sensitive to microbiological contamination, growth and toxin development. Table 1 lists the pathogenic microorganisms of concern along with their principal growth boundaries. While all of these pathogens need to be taken into consideration, cold growing pathogens such as *Listeria monocytogenes*, psychrotrophic *Clostridium botulinum* and psychrotrophic *Bacillus cereus* are of particular relevance to chilled food.

To control these hazards the following must be taken into account:

- supplier selection, specifications and control of incoming raw material (see Section 3.1);
- appropriate raw material storage and stock rotation (see Section 3.1);
- product/process design and control measures (see Sections 1.2 and 3.2);
- hygienic processing conditions (see Section 2);
- allocation of appropriate product shelf life and instruction of use (see Section 1.3);
- maintenance of the chill chain during distribution and sale (see Section 1.3).

Table 1: Commonly accepted growth boundaries of pathogenic microorganisms¹

Microorganism and growth boundaries ²	Min temp (°C)	Min pH	Min a _w	Aerobic / anaerobic ³
<i>L. monocytogenes</i>	-0.4	4.3	0.92	Facultative
<i>B. cereus</i>	4 ⁴	4.5 ⁵	0.93	Facultative
<i>Campylobacter jejuni</i>	32	4.9	0.99	Microaerophilic
<i>Cl. botulinum</i> Mesophilic/proteolytic	10-12	4.6	0.93	Anaerobic
<i>Cl. botulinum</i> Psychrotrophic/non-proteolytic	3.3	5.0	0.97 (5% NaCl)	Anaerobic
<i>Cl. perfringens</i>	12	5.5-5.8	0.935	Anaerobic
<i>E. coli</i>	7-8	4.4	0.95	Facultative
<i>E. coli</i> O157:H7	6.5	4.5	0.95	Facultative
<i>Salmonella</i>	6	4.0	0.94	Facultative
<i>Staphylococcus aureus</i> ⁶	5.2 ⁷	4.5	0.86	Facultative
<i>V. cholerae</i>	10	5.0	0.97	Facultative
<i>V. parahaemolyticus</i>	5	4.8	0.94	Facultative
<i>Y. enterocolitica</i>	-1.3	4.2	0.96	Facultative

1.1.2 CHEMICAL HAZARDS

Chilled foods, like other food products, are also subject to contamination by environmental contaminants and residues from pesticides or veterinary drugs. Compliance of raw material with the relevant legislation is essential. Supplier selection, evaluation and follow-up are the best control measures.

Chemicals such as cleaning agents, lubricants and pest control materials may also present on-site chemical hazards. The correct use of food-grade chemicals, where appropriate, and application of GMP are the best control measures.

1.1.3 PHYSICAL HAZARDS

¹ References: *Microorganisms in Foods. Vol. 5. Microbiological Specifications of Food Pathogens.* (1995), ICMSF, Blackie Academic & Professional; *ACMSF Report on Verocytotoxin-Producing Escherichia coli* (1995), HMSO, London, ISBN 0-11-321909-1.

² Growth boundaries given under otherwise optimal conditions. Growth criteria will vary according to strain, temperature, and type of acid, solute and other factors and will normally be higher in foods. However, variability in measurement, etc., must be allowed for - a margin of error must be incorporated.

³ It is important to note that even aerobically processed foods may present a risk of growth of anaerobic organisms since they may have an anaerobic internal environment.

⁴ No emetic toxin formation at temperature below 10°C

⁵ Evidence for this limit provided by LL Prokopova (1970) Multiplication and toxigenicity of *Bacillus cereus* contained in food products stored under different thermal conditions. *Voprosy Pitaniia*, **29**, 56-61 (in Russian, English summary) and M Raevuori and C Genigeorgis (1975). Effect of pH and sodium chloride on growth of *Bacillus cereus* in laboratory media and certain foods. *Applied Microbiology*, **29**, 68-73.

⁶ Limits for enterotoxin production, not growth

⁷ Most serotypes fail to grow at <7°C

Physical hazards might include foreign bodies such as metal, glass, wood and bone fragments. Their control is ensured by raw material quality (specifications, supplier evaluation) and provisions applied during processing (e.g. metal detectors after packaging, filters in line).

1.1.4. ALLERGENS

Many foods can be allergenic to some individuals and a very wide range of food and food components have been identified as actual or potential allergens. Common food allergens include cow's milk, fruits, legumes (especially peanuts and soybeans), eggs, crustaceans, tree nuts, fish, vegetables (celery and other foods of the Umbelliferae family), wheat and other cereals as listed in EU labelling legislation (Directive 2000/13/EC).

Control of allergens must be addressed through HACCP systems. This includes the identification of the allergens of concern and the consideration of their presence through direct addition, rework and/or cross contamination. Appropriate labelling must be used.

SECTION 1.2

CONTROL MEASURES

1.2.1. BASIC PRINCIPLES FOR CONTROL

The safety of chilled foods with respect to pathogens must be designed into the product using formulation, processing parameters and preservation factors. This must be validated, taking into account

- any variability in the finished product (e.g. pH, a_w) and processing, considering worst-case possibilities,
- appropriate hygiene during manufacture (see Section 2);
- expected storage conditions;
- usage instructions.

All of these factors must be taken into account for a safe shelf life to be assigned.

Processing Parameters

Heat treatment is customarily used to reduce pathogens and spoilage organisms to an acceptable level. In heat-treated chilled food it is common practice to aim for a Log 6 reduction of either

- *Listeria monocytogenes* (this treatment will also control other vegetative pathogens)
or
- cold growing *Clostridium botulinum* (this treatment will **not** control other spore-forming pathogens such as *Bacillus cereus*).

The choice of heat treatment is part of the product and process design (see Figure 1).

Commonly accepted lethal rates for *Listeria monocytogenes* and cold growing *Clostridium botulinum* are defined in Tables 2 and 3, respectively.

Intrinsic Preservation Factors ('Hurdles')

Individual hurdles, such as reduced water activity, pH, preservatives, and others, or a combination thereof can be used to control pathogen growth, toxin formation and/or spoilage during storage and distribution.

For instance, if a chilled food has not undergone a heat treatment as outlined in Table 3, an individual hurdle can be used to control cold growing *Clostridium botulinum*, such as water activity < 0.97 or pH < 5.0.

The effect of a single hurdle in controlling microorganisms is generally determined under conditions where all other factors are optimal for growth. However, in preserving foods, generally more than one factor is relied upon to prevent spoilage and/or food-borne disease. The combination of several hurdles to control microbial growth may be synergistic. In such cases the overall hurdle effect is stronger than the addition of individual ones.

Individual hurdles or combinations of two or more must be chosen depending on the product composition, processing and storage conditions and must be demonstrated to be sufficiently robust to

consistently assure safety. Demonstration of safety can be by using, for example, predictive modelling and/or challenge testing using the worst-case conditions of expected storage and distribution.

During the evaluation and assessment of their effectiveness it must be ensured that the chosen hurdle system will not cause unwanted side effects. For example, the use of a modified atmosphere to inhibit aerobic microorganisms (in particular moulds) may favour other undesirable anaerobic organisms, resulting in a potentially hazardous product.

Expected Storage Conditions, Shelf life and Usage Instructions

Chilled foods are prepared foods that for reasons of safety and/or quality rely on storage at refrigeration temperatures (generally defined at the national level) throughout their entire life. Having considered product safety the potential for presence and subsequent growth of spoilage organisms must also be taken into account when deciding on the target shelf life and specifying usage instructions. Knowledge of chill chain performance, in terms of temperature and time, as well as reasonable consumer handling, must be taken into account when designing chilled products and establishing their shelf life (see Section 1.3).

Table 2: Lethal rates for *Listeria monocytogenes* (i.e. equivalent heat treatments achieving a Log 6 reduction of *Listeria monocytogenes*)⁸

Temperature (°C)	Time (mins, secs)	Lethal Rate
60	43'29"	0.046
61	31'44"	0.063
62	23'16"	0.086
63	17'06"	0.117
64	12'40"	0.158
65	9'18"	0.215
66	6'49"	0.293
67	5'01"	0.398
68	3'42"	0.541
69	2'43"	0.736
70	2'00"	1.000
71	1'28"	1.359
72	1'05"	1.848
73	0'48"	2.512
74	0'35"	3.415
75	0'26"	4.642
76	0'19"	6.310
77	0'14"	8.577
78	0'10"	11.659
79	0'06"	15.849
80	0'05"	21.544
81	0'04"	29.286
82	0'03"	39.810
83	0'02"	54.116
84	0'02"	73.564
85	0'01"	100.000

Remarks

- These data are supplied as an example of the necessary process to achieve a Log 6 reduction of *Listeria monocytogenes*, the most heat-resistant vegetative pathogen.
- It is important to note that the values have been extrapolated assuming a linear z-value⁹ of 7.5°C and as a reference 70°C.
- *Listeria monocytogenes* is the most heat-resistant vegetative pathogen of significance in chilled foods, and as a consequence, all other vegetative pathogens, such as *Staphylococcus aureus*, *Campylobacter*, *E. coli* and *Salmonella*, will also be heat-inactivated (i.e. at least a Log 6 reduction).
- Typical D values¹⁰ for infectious pathogens at 70°C are:
 - *L. monocytogenes* 0.3
 - *C. jejuni* 0.0001
 - *E. coli* (including O157:H7) 0.001

⁸ References: *Heat Resistance of Listeria monocytogenes in Non-dairy Food Menstrua* (1989), Technical Memorandum No. 523, Campden Food and Drink Research Association, *Heat Resistance of Listeria monocytogenes in Homogenates of Chicken, Beef Steak and Carrot* (1989) JE Gaze, GD Brown, DE Gaskell and JG Banks, *Food Microbiology*, 6, 251-259.

⁹ z value = temperature change required to increase/reduce the D-value by a factor 10

¹⁰ D is the time required to reduce the number of microorganisms by a factor 10 at a certain temperature

- salmonellae 0.01
- *S. aureus* 0.1
- *V. parahaemolyticus* 0.001
- *Y. enterocolitica* 0.01.

Table 3: Lethal rates for *Clostridium botulinum* (i.e. equivalent heat treatments achieving a Log 6 reduction of *Clostridium botulinum*)¹¹

Temperature (°C)	Time (mins)	Lethal rate
80	270.3	0.037
81	192.3	0.052
82	138.9	0.072
83	100.0	0.100
84	71.9	0.139
85	51.8	0.193
86	37.0	0.270
87	27.0	0.370
88	19.2	0.520
89	13.9	0.720
90	10.0	1.000
91	7.9	1.260
92	6.3	1.600
93	5.0	2.000
94	4.0	2.510
95	3.2	3.160
96	2.5	3.980
97	2.0	5.010
98	1.6	6.310
99	1.3	7.940
100	1.0	10.000

Remarks

- These data are supplied as an example of the necessary process to achieve a Log 6 reduction of psychrotrophic *Clostridium botulinum* type B¹²;
- It is important to note that the values have been extrapolated assuming a linear z-value¹³ of 7°C below 90°C and 10°C above 90°C (reference is 90°C)
- Typical *D* value¹⁴ for psychrotrophic *C. botulinum* at 90°C is 1.5. Most bacterial spores, including spores from mesophilic *C. botulinum* and cold growing *B. cereus* are much more heat resistant than those from cold growing *C. botulinum* and will not be inactivated by the pasteurisation treatments presented in this table.

¹¹ Taken from *Code Voor de Productie, Distributie en Verkoop van Gekoelde, Lang Houdbare Gepasteuriseerde Maaltijden*, Belgian, Dutch Working Group.

¹² There is some evidence that products containing lysozyme or enzymes with lysozyme activity may increase heat resistance of *Clostridium botulinum* spores. Additional heat treatments and/or use of other hurdles may be required

¹³ z value = temperature change required to increase/reduce the D-value by a factor 10

¹⁴ *D* is the time required to reduce the number of microorganisms by a factor 10 at a certain temperature

1.2.2 DETERMINATION OF THE MINIMUM HYGIENIC STANDARDS FOR CHILLED PRODUCTS

Minimum hygiene standards based on different levels of heat treatment, if any, can be determined using the Decision Tree in Figure 1. The Decision Tree distinguishes between three hygienic status areas to be applied during manufacturing to eliminate or reduce the risk of any microbiological hazards arising between the heat treatment, if any, and final packaging:

- Good Manufacturing Practices (GMP)
- Raw High Care area (rHCA)
- Cooked High Care area (cHCA)

A detailed description of the requirements in each area (GMP, rHCA, cHCA) is given in Section 2.

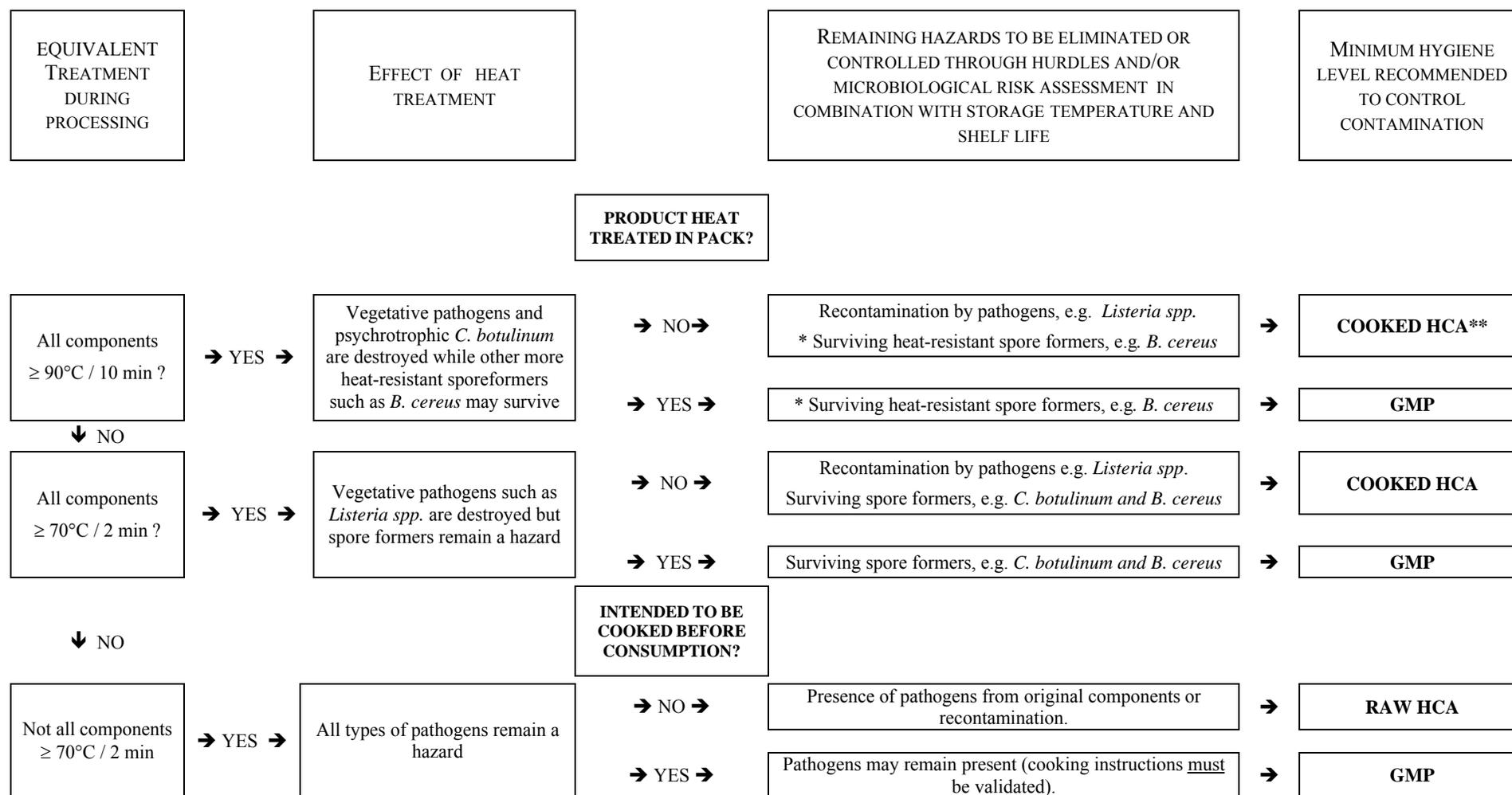
The hygiene status areas highlighted are the **minima** for each type of product.

If there is doubt that the conditions applied might not effectively control the microorganisms of concern, a risk assessment and additional studies must be carried out. If there is still any doubt about the approach to be taken, expert advice should be sought, e.g. from food Research Associations.

Deviations from the Decision Tree approach must be validated (see Section 1.2.3.)

Examples of the use of the Decision Tree are given in Appendix B.

Figure 1: Decision tree to determine the minimum hygienic status required for chilled products



* *B. cereus* is managed in all cases by controlling raw materials, compositional factors (see Table 1), rapid chilling, storage temperature and shelf life

Note: This decision tree does not take into account the use of hurdles other than heat treatment and chilled storage. Refer to section 1.2 and the examples of usage of the Decision Tree in Appendix B.

** GMP conditions are sufficient if the product is mildly pasteurised in pack to inactivate any recontamination that may have occurred

1.2.3. MICROBIOLOGICAL RISK ASSESSMENT

Formal microbiological risk assessment coupled with validation can be used as a tool to evaluate the impact of all of the above on product safety. However, this demands a very high level of scientific and technical expertise as well as significant investment in research and development.

In particular, substantial data are required to carry out microbiological risk assessment, including regarding:

- the microbiological quality (current and historical trends and issues) of the particular raw materials used including in relation to the specific source;
- any pre-treatment to which the raw materials have been subjected and its impact on the survival and growth of any pathogens that may be present and on the potential for toxin development in relation to those materials and;
- recontamination and growth potential during shelf life.

Specialist, expert advice must therefore be sought to use this approach.

Useful References

Interaction of Factors to Control Microbial Spoilage of Refrigerated Foods, VN Scott, J. Food Prot., 1989, 52(6), 431-5.

Mechanism of Action of Food Preservation Procedures 1989, GW Gould (Editor) Elsevier Applied Science London.

Food Preservatives and the Microbiological Consequences of their Reduction or Omission, TA Roberts, PJ McClure, Proc. Nutr. Soc., 1990, 49(1), 1-12.

Growth Predictor, Institute of Food Research, UK. <http://www.ifr.ac.uk/safety/growthpredictor/>

Pathogen Modelling Programme, USDA. <http://www.arserrc.gov/mfs/PATHOGEN.HTM>

ComBase: <http://www.combase.cc/>

Microbiological Risk Assessment for Food Industry Applications, 2000, CCFRA Guideline No. 28.

SECTION 1.3

SHELF LIFE

Shelf life is defined as the period of time for which a product remains safe and meets its quality specifications under expected storage and use conditions. The shelf life determines the durability date (“Use By” or “Best Before”).

The manufacturer is responsible for determining the shelf life and must take into account microbiological safety and stability, physical characteristics (such as texture and colour) and organoleptic quality.

Should the acceptable shelf life for either physical condition or organoleptic quality exceed that for microbiological safety and stability, the assigned shelf life must be that determined for microbiological safety and stability.

However, this section of the *Recommendations* considers only microbiological stability and safety.

Whilst microbiological stability is influenced by the presence or absence of spoilage microorganisms and their growth, microbiological safety depends on the incidental presence of pathogens and their ability to survive, grow or produce toxins in the product during distribution and before appropriate use by the consumer.

Both microbiological safety and spoilage must be considered when assessing microbiological shelf life. The primary requirement is to ensure that products are safe at the time of consumption. Once that is assured, the conditions that may lead to product spoilage must also be addressed.

Systems for shelf life determination may be developed by the FBO, by representative organisations or in cooperation with scientific or regulatory bodies.

1.3.1 SHELF LIFE DETERMINATION

Microbiological safety and suitability of chilled food products are influenced by a variety of factors including raw material quality, hygiene during manufacturing, processing methods and relevant hurdles. To determine shelf life of a product, the food manufacturer must consider all such factors including knowledge of their own and other manufacturers’ comparable products.

In any of the following circumstances review of the HACCP plan is required:

- new product development, modification or extension;
- new packaging development or modification;
- new process development or modification;
- change of production site;
- change or movement of production equipment that could influence the site plan.

Reassessment of the shelf life may be required including microbiological studies and storage trials.

Assessment of Safe Shelf Life

Pathogens must be accounted for by safe product and process design (see Section 1.2). Identification of the relevant pathogens is critical for the successful assessment of safe shelf life.

Determination of safe shelf life may involve, for example:

- a review of relevant scientific information, e.g. characteristics of microorganisms;
- use of predictive modelling programs, some of which are publicly available such as ComBase, USDA Pathogen Modelling Program or Growth Predictor;
- challenge testing with the relevant pathogens where predictive modelling does not give sufficient confidence to set a safe shelf life on its own;
- historical data for similar products;
- storage trials (see below).

It is important to recognise that, for many chilled foods, it may be necessary to identify a combination of factors to assure safety. This will include the heat treatment applied, the intrinsic properties of the food (e.g. presence or not of lysozyme), or mild preservatives that may be added and/or consideration of shelf life (time and temperature). The assessment of shelf life must take into account storage conditions, the performance of the chill chain, in terms of temperature and time, as well as reasonable consumer handling in the market or country of concern. These aspects must be taken into account as part of HACCP.

For example, psychrotrophic *C. botulinum* can be controlled through heat treatment (90°C, 10 min or equivalent, see Table 3). If the heat treatment is different the possibility of growth of *C. botulinum* depends, among others, on:

- composition of products (presence or not of lysozyme, salt content, pH, a_w , for example. See Table 1);
- conditions of packaging (modified atmosphere, for example);
- chill chain

The shelf life must be defined taking into account all of these factors.

In any case, the shelf life that is defined must have been assessed to deliver product safety with respect to the microorganisms of concern (see Section 1.2).

Storage Trials

Storage trials are not appropriate to determine the safety of chilled foods for those pathogens that are not frequently found, but which still present a hazard in the product of concern. Storage trials are generally restricted to indicator and spoilage organisms as well as common pathogens. These trials consist of:

- storing a product at one or more predetermined temperatures during specific time periods, that take into account knowledge of actual chill chain performance (transportation, intermediate storage, display and sale), in terms of temperature and time, as well as reasonable consumer handling. These aspects must be taken into account as part of HACCP.

and

- testing the product at minimum three time points for the relevant indicator and spoilage microorganisms as well as pathogens as identified by HACCP, and which may be present in the finished product;

1.3.2 “USE BY” AND “BEST BEFORE”

As chilled foods are highly perishable products, in general the date of minimum durability should be indicated with “Use By”.

The “Use By” date is fixed taking into account

- the result of shelf life determination test;
- safety margins.

A documented shelf life determination protocol must be used.

Exceptions justifying the use of “best before” may exist but these should be validated through HACCP plans and must be in accordance with national legislation.

1.3.3 SHELF LIFE VERIFICATION

Shelf life must be regularly verified within the context of HACCP under the realistic storage conditions reflecting the performance of the chill chain. See Section 3.3.

PART 2

CLASSIFICATION OF HYGIENE AREAS

SECTION 2.1

GENERAL HYGIENE REQUIREMENTS

2.1.1 BASIC PRINCIPLES OF HYGIENIC MANUFACTURING

In manufacturing it is critical that the whole production-delivery chain from raw material production to the retail sale operates to guarantee the safety and quality of the final product. Chilled prepared foods and their raw materials often have limited shelf lives. They cannot rely on product testing prior to delivery and/or processing.

For these reasons, each operator in the chain must work according to GHP/GMP and HACCP principles.

The operations of the suppliers of raw materials must be monitored by the manufacturer to ensure that the suppliers work as agreed and that the raw materials meet the specifications set.

For the chilled food manufacturer, hygienic processing can be summarised in a simple “3 C principle”:

- keep **C**lean;
- keep **C**old;
- avoid **C**ross contamination.

If these principles cannot be followed, there will be a risk of contamination or pathogen growth, which must then be controlled by other means.

2.1.2 GENERAL HYGIENE REQUIREMENTS

Basic legislation and guidance exist at the EU and Codex Alimentarius level. The *ECFF Recommendations* are complementary to the legal text, providing additional detail to assist the operator.

Ensuring hygienic manufacture requires the management of:

- raw materials and packaging materials;
- premises and facilities;
- equipment;
- personnel and training;
- operational and hygiene controls.

Depending on the type of product that is produced, different requirements apply. A Table distinguishing between the hygiene levels required in these three areas is provided in Section 2.2.

The manufacturing area is separated into three categories according to hygiene requirements: Good Manufacturing Practice Area, Raw High Care Area and Cooked High Care Area. Premises layout is designed in this way to control risks of cross contamination.

- A **Good Manufacturing Practice** (GMP) standard is used throughout the plant.
- A **High Care Area** (HCA) is an area where only ready to eat foods are handled, designed to a high standard of hygiene, where practices relating to personnel, ingredients, equipment and environment are managed to minimise contamination by microorganisms.
 - o Raw HCA (rHCA) – any prepared ready to eat materials can be brought into this area
 - o Cooked HCA (cHCA) - only materials that have been decontaminated (i.e. equivalent to a 6-log reduction of *Listeria monocytogenes*) are allowed to be brought into this area

Areas should be designed to minimise the potential for build-up of contamination and to maximise the ease of cleaning and disinfection.

To keep raw materials, in-process products and final products in optimal condition and protected from cross-contamination, storage and processing facilities should also follow the principles of "one-way-flow" and "first in, first out" and be equipped to maintain temperature, humidity and ventilation.

The different areas (GMP, rHCA, cHCA) must be strictly separated.

SECTION 2.2

TABLE FOR GENERAL HYGIENE REQUIREMENTS

The following is intended to serve as a useful check-list for standards required for the manufacture of chilled prepared food. The list begins with Good Manufacturing Practices (GMP), which constitute the minimum for hygienic manufacturing practices. A reference to additional requirements for raw and cooked High Care Areas (HCA) are indicated, where appropriate.

GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS	RAW HIGH CARE AREA (rHCA) REQUIREMENTS	COOKED HIGH CARE AREA (cHCA) REQUIREMENTS
2.2.1 RAW MATERIALS AND PACKAGING MATERIALS		
Raw materials and packaging materials <u>must</u> be purchased to agreed specifications and from suppliers who comply with Good Manufacturing Practice and HACCP, and who can demonstrate compliance with all relevant legislation.		
<u>Specifications</u>		
Raw material specifications, including specification for the packaging materials, <u>should</u> be determined through application of HACCP principles and validated during the design phase. The operator <u>should</u> prepare a specifications manual covering: <ul style="list-style-type: none"> – details of the supplier and manufacturing/supply site; – description of the raw material and its functionality; – ingredients breakdown; – labelling requirements; 		

<p style="text-align: center;">GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS</p>	<p style="text-align: center;">RAW HIGH CARE AREA (rHCA) REQUIREMENTS</p>	<p style="text-align: center;">COOKED HIGH CARE AREA (cHCA) REQUIREMENTS</p>
<ul style="list-style-type: none"> – microbiological, chemical, physical and organoleptic characteristics of the delivered products; – target values and critical acceptance limits; – packaging materials, description of pack type, size and quantity; – storage and distribution conditions; – safe handling and use instructions; <p>In addition, procedures <u>should</u> be available to identify monitoring actions at reception, provisions to be taken in case of non-conformity and the responsibilities of the supplier and the processor in case of dispute.</p>		
<p><u>Supplier Evaluation</u></p>		
<p>Suppliers <u>should</u> be selected in order to obtain raw materials of required quality and safety. The supplier evaluation <u>should</u> focus especially on:</p> <ul style="list-style-type: none"> – their ability to comply with the specifications manual; – the existence or not of a quality management system and of monitoring procedures at the supplier’s; – the supplier technical assistance, etc. <p>To evaluate the suppliers, the processor may use several means, such as sample analysis and/or auditing (see section 3.1 for assessment of supplier quality management systems).</p>		
<p><u>Monitoring at Reception</u></p>		
<p>Raw materials <u>must</u> be checked against appropriate critical acceptance limits (see section 3.3.1.1).</p>		

<p style="text-align: center;">GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS</p>	<p style="text-align: center;">RAW HIGH CARE AREA (rHCA) REQUIREMENTS</p>	<p style="text-align: center;">COOKED HIGH CARE AREA (cHCA) REQUIREMENTS</p>
<p><u>Storage</u></p>		
<p>Raw materials <u>must</u> be stored as quickly as possible after delivery in adequate, specifically designated areas and under hygienic conditions that prevent contamination by microorganisms, insects, rodents, foreign bodies and chemicals and to avoid adverse physical conditions.</p> <p>Storage areas <u>must</u> be designed to be easily cleaned, to provide ready access to the stored items and good circulation of air around the stored items.</p> <p>All batches of raw material <u>must</u> be coded and an appropriate stock control procedure used (see section 3.4).</p>		
<p>2.2.2 PREMISES AND FACILITIES</p>		
<p><u>Surfaces (Floors, Walls and Ceilings)</u></p>		
<p>All surfaces of rooms, i.e. walls, ceilings and floors, <u>should</u> be sealed and impervious to water and <u>must</u> be capable of being cleaned and being kept in a dry condition.</p>	<p>All surfaces of rooms, e.g. walls, ceilings and floors, <u>must</u> be sealed and impervious to water and <u>must</u> be capable of being cleaned and being kept in a dry condition.</p>	
<p>Floors <u>should</u> be sloped to gullies and drains so that pools of water do not collect. All wall/floor, wall/wall and wall/ceiling junctions <u>should</u> be covered where possible to facilitate easier cleaning.</p>		
<p>Floor drains and gullies <u>must</u> be designed and maintained to prevent back-ups, to be cleanable and properly trapped. Drainage flow <u>should</u> be away from the final product preparation areas.</p>	<p>Floor drains and gullies <u>must</u> drain away from the High Care Area.</p>	

<p style="text-align: center;">GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS</p>	<p style="text-align: center;">RAW HIGH CARE AREA (rHCA) REQUIREMENTS</p>	<p style="text-align: center;">COOKED HIGH CARE AREA (cHCA) REQUIREMENTS</p>
<p><u>Entrances (Doors and Windows)</u></p>		
<p>Internal doors <u>should</u> and external doors <u>must</u> be tightly fitting.</p>	<p>Doors <u>must</u> be tightly fitting.</p>	
<p>Windows <u>should</u> be unopenable, otherwise they <u>must</u> be appropriately screened.</p>	<p>Windows <u>must</u> be unopenable.</p>	
<p><u>Lighting</u></p>		
<p>All lighting <u>should</u> be of a suitable intensity and <u>must</u> be appropriately guarded.</p>		
<p><u>Services</u></p>		
<p>Services <u>must</u> be installed in such a manner as to minimise their potential as dust traps. Service pipes (e.g. steam, water) <u>should</u> be hygienically lagged to prevent condensation from forming on their surfaces.</p>	<p>Services <u>must</u> be installed in such a manner as to minimise their potential as dust traps. Service pipes <u>must</u> be hygienically lagged to prevent condensation from forming on their surfaces.</p>	
<p>Water, steam and ice that is in direct contact with food <u>must</u> be potable, in compliance with the applicable legislation.</p>		
<p>Non-potable water used for the generation of steam, refrigeration, fire control and other similar purposes not relating to food <u>must</u> be conducted in separate</p>		

<p style="text-align: center;">GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS</p>	<p style="text-align: center;">RAW HIGH CARE AREA (rHCA) REQUIREMENTS</p>	<p style="text-align: center;">COOKED HIGH CARE AREA (cHCA) REQUIREMENTS</p>
<p>systems, readily identifiable and having no connection with or any possibility of reflux into the potable water systems.</p>		
<p>Waste water from refrigeration equipment, hand and equipment wash facilities etc. <u>should</u> be trapped to drain in such a way as to prevent any risk of product contamination.</p>	<p>Waste water from refrigeration equipment, hand and equipment wash facilities etc. <u>must</u> be trapped to drain in such a way as to prevent any risk of product contamination.</p>	
<p>Particular attention <u>must</u> be paid to the risk of back-siphoning of condensate water from refrigeration equipment drain systems.</p>		
<p><u>Temperature Control and Recording</u></p>		
<p>The temperature and humidity of the storage and production areas <u>must</u> be controlled such that product safety and shelf life are assured, e.g. for chilled products it may be helpful to maintain production areas at 12°C or less.</p>		
<p>All temperature and humidity controlled areas <u>must</u> have sufficient capacity to maintain product temperatures during anticipated high ambient temperatures and peak loads. They <u>should</u> be fitted with monitoring and recording devices and a reliable system (e.g. alarm) designed to signal loss of control.</p>		
<p><u>Staff Facilities</u></p>		
<p>Adequate hand washing facilities <u>must</u> be appropriately sited. Taps <u>must</u> not be hand operable.</p>		
<p>Hand drying facilities <u>must</u> be provided and disposable towels <u>should</u> be used.</p>	<p>Hand drying facilities <u>must</u> be provided and disposable towels <u>must</u> be used.</p>	

<p style="text-align: center;">GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS</p>	<p style="text-align: center;">RAW HIGH CARE AREA (rHCA) REQUIREMENTS</p>	<p style="text-align: center;">COOKED HIGH CARE AREA (cHCA) REQUIREMENTS</p>
<p>Cloakroom and toilets <u>must</u> not open directly into any food handling areas.</p>		
<p><u>Air Quality</u></p>		
<p>Ventilation and air-handling systems <u>must</u> be hygienically designed. Regard <u>must</u> be made to the location of the plant and any environmental factors that might present a significant risk of product contamination</p>		
<p>No specific GMP requirements</p>	<p>Air supplies to the rooms <u>should</u> be filtered or otherwise treated to remove particles (see Appendix J).</p>	<p>Air supplies to the rooms <u>must</u> be filtered or otherwise treated to remove particles (see Appendix J).</p>
<p>No specific GMP requirements</p>	<p>Air systems <u>must</u> be designed and operated such that condensation and dust are avoided.</p>	
<p>No specific GMP requirements</p>	<p>Air systems <u>must</u> be managed efficiently by means of frequent inspection of the equipment, including filters, environmental monitoring of microbial loads in the assembly room air, and corrective action procedures.</p>	
<p>No specific GMP requirements</p>	<p>The balance of filtered air flow <u>must</u> maintain the area at a positive pressure with respect to the raw materials and tray wash areas and away from areas where finished products are assembled. The number of air changes and conditioning of the air <u>must</u> minimise condensation.</p>	

GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS	RAW HIGH CARE AREA (rHCA) REQUIREMENTS	COOKED HIGH CARE AREA (cHCA) REQUIREMENTS
2.2.3 EQUIPMENT		
<u>Design and Location of Equipment</u>		
Equipment including fillers, conveyors, transfer belts and packaging equipment <u>must</u> be designed to be cleanable and capable of being decontaminated.		
Such equipment <u>must</u> be installed and operated such that product assembly can be conducted under consistently good conditions minimising the potential for contamination.		
<u>Equipment for Handling Products in HCA</u>		
Not applicable	All equipment and utensils used for handling products after heating <u>must</u> be cleaned and decontaminated at appropriate intervals	
Not applicable	All equipment used for handling products <u>must</u> be dedicated to the High Care Area and be kept separate from that used in other areas.	
Not applicable	If reusable trays are used, special washing and decontaminating equipment <u>must</u> be provided for use in a dedicated area with appropriate transfer to the High Care Area side of the manufacturing operation. All containers <u>must</u> be covered to minimise recontamination.	

<p align="center">GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS</p>	<p align="center">RAW HIGH CARE AREA (rHCA) REQUIREMENTS</p>	<p align="center">COOKED HIGH CARE AREA (cHCA) REQUIREMENTS</p>
<p>Cleaned and decontaminated utensils, equipment and containers <u>must</u> not pass unprotected through areas where recontamination could occur.</p>		
<p><u>Equipment to Monitor CCPs</u></p>		
<p>Performance of all instrumentation monitoring critical control points <u>must</u> be regularly checked, and re-calibrated if necessary, according to a documented procedure.</p>		
<p>Hand washing regimes <u>must</u> be rigorously enforced.</p>		
<p>Visitors <u>must</u> be informed in advance that they <u>must</u> comply with the same rules and procedures as employees. They <u>must</u> also be instructed not to handle equipment, work-in-progress or finished products.</p>		
<p>2.2.4 PERSONNEL AND TRAINING</p>		
<p><u>Management Responsibility</u></p>		
<p>All personnel including management <u>must</u> understand the importance of maintaining the appropriate hygienic conditions throughout the facility. The management <u>must</u> ensure that staff handling chilled foods are given thorough and planned training in all relevant aspects of chilled food production, storage and distribution, as well as personal hygiene and cleanliness. Management <u>must</u> set a good example at all times.</p>		
<p>An individual having knowledge and authority <u>must</u> be designated within the management team to be responsible for all operations, including review and audit relating to all aspects of product safety.</p>		
<p>Records of training <u>must</u> be maintained for current staff. Detailed job descriptions <u>must</u> be provided for staff carrying out specific jobs.</p>		
<p>All employees <u>must</u> be issued with and work to documented company rules with regard to hygiene policy.</p>		

GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS	RAW HIGH CARE AREA (rHCA) REQUIREMENTS	COOKED HIGH CARE AREA (cHCA) REQUIREMENTS
Personnel (including cleaners and service staff) <u>must</u> be medically screened, trained and instructed in personal hygiene and health requirements.		
No specific requirements	Specific additional health screening may be necessary, e.g. stool testing.	
<u>Protective Clothing</u>		
Appropriate factory wear including hair covering <u>must</u> be provided and worn as directed.		
Beards and moustaches <u>should</u> be covered when any food product is exposed.	Beards and moustaches <u>must</u> be covered when any food product is exposed.	
No specific GMP requirements	All staff working in the High Care Areas <u>must</u> enter through a specially designated area and follow specified procedures for changing into visually distinctive clean protective clothing covering personal clothing (but not a one-piece overall) and footwear.	
No specific GMP requirements	High Care Area clothing <u>must</u> only be worn in this area and <u>must</u> be removed in the designated area before leaving the High Care Area.	
No specific GMP requirements	Protective clothing <u>must</u> be changed at the end of every shift and footwear properly cleaned and decontaminated.	
No specific GMP requirements	It is important to be aware that the use of gloves does not reduce the need for hand washing. If gloves are used hands <u>must</u> be washed before the gloves are put on. Gloves <u>must</u> be changed every break period or, where sterile disposable gloves are used, they <u>must</u> be changed at least every two hours or when damaged or when personnel leave the production line for any reason.	
If reusable gloves or aprons are used they <u>must</u> be maintained in a satisfactory, hygienic condition.		

<p style="text-align: center;">GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS</p>	<p style="text-align: center;">RAW HIGH CARE AREA (rHCA) REQUIREMENTS</p>	<p style="text-align: center;">COOKED HIGH CARE AREA (cHCA) REQUIREMENTS</p>
<p>2.2.5 – OPERATIONAL AND HYGIENE CONTROLS</p>		
<p>In all steps of processing, including delays in manufacture, critical temperatures for multiplication of microorganisms (10°C to 60°C) <u>must</u> be avoided. Total exposure within this temperature range <u>must</u> be limited to 2 hours, unless justified under HACCP principles.</p> <p>Application of HACCP principles may result in a number of control measures, such as:</p> <ul style="list-style-type: none"> – heating to maintain temperature above 60°C during a delay in manufacture, e.g. hot vegetables awaiting further processing or a sauce that is being hot filled; – active cooling to below 10°C during a delay in manufacture, e.g. raw meat awaiting further processing or cooked pasta that has been chilled prior to processing; <p>Remember to consider batch size with respect to the heating or cooling of in-process products, especially during a delay in production.</p>		
<p><u>Raw Material Preparation</u></p>		
<p>The raw materials preparation area <u>must</u> be designed to hold and handle the range of raw material types to be prepared in a hygienic manner, minimising contamination.</p>		
<p>Raw material <u>must</u> be handled and prepared in a manner that minimises contamination and microbiological growth.</p>		

<p style="text-align: center;">GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS</p>	<p style="text-align: center;">RAW HIGH CARE AREA (rHCA) REQUIREMENTS</p>	<p style="text-align: center;">COOKED HIGH CARE AREA (cHCA) REQUIREMENTS</p>
<p>Thawing is a critical process and must be considered within a HACCP plan.</p> <ul style="list-style-type: none"> – The time and temperature parameters <u>must</u> be selected so as to minimise microbiological growth. – The risks of contamination from condensation and/or product drip <u>must</u> be considered. 		
<p>Prepared raw materials, including those that have been thawed, <u>should</u> be processed immediately. If not, they <u>must</u> be held at specified conditions of time and temperature.</p>		
<p>No specific GMP requirements</p>	<p>All materials <u>must</u> be subjected to an appropriate decontamination step at the point of entry into the High Care Area. For example, heat treatment, disinfection or removal of outer packaging, washing.</p>	
<p><u>Heating</u></p>		
<p>All heating equipment <u>should</u> be hygienically designed and, where appropriate, <u>must</u> be properly instrumented. Vapour and moisture extract systems <u>should</u> be efficient, hygienically designed and well maintained to minimise the risk of contamination of heated product by condensate or other residue</p>		
<p>As a minimum, heating equipment <u>must</u> be fitted with both direct reading measuring thermometers and continuous recording equipment. The temperature measuring and recording equipment <u>must</u> be independently calibrated at regular intervals against a nationally recognised standard.</p>		
<p>Heat processes <u>must</u> be validated and critical parameters controlled and recorded where appropriate. The heat processes <u>must</u> take account of the worst conditions likely to occur with respect to heat transfer (for instance, the use of frozen raw materials or the use of large pieces of meat). All parts of the product <u>must</u> receive a minimum heat process appropriate to the target organism to be controlled and to achieve the projected shelf life. For some raw materials the required heat process may be detrimental to the nutritional and sensory characteristics of the food and lower temperatures may be used, provided heat processes of equivalent lethality are applied (see section 1.2). Achieving designated target temperatures <u>must</u> be monitored by instrumentation of the heating vessel or by use of a calibrated measuring thermometer with an accuracy of $\pm 0.5^{\circ}\text{C}$ or as appropriate to the critical limit.</p>		

<p style="text-align: center;">GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS</p>	<p style="text-align: center;">RAW HIGH CARE AREA (rHCA) REQUIREMENTS</p>	<p style="text-align: center;">COOKED HIGH CARE AREA (cHCA) REQUIREMENTS</p>
<p>Personnel responsible for heat treatment <u>must</u> be specifically trained and fully competent.</p>		
<p>It is essential to protect heated ingredients from recontamination.</p>	<p>It is essential to protect heated ingredients from recontamination.</p>	
<p>When the product is heated in pack, strict precautions <u>must</u> be taken to ensure that only packs that have been heated and cooled according to the specified criteria are dispatched.</p>	<p>Not applicable</p>	
<p>No specific GMP requirements</p>	<p>Where there is a heat process at the point of entry into the HCA from the GMP area, the heating equipment <u>must</u> be designed and located so that it can be readily loaded with raw materials from the GMP area and hygienically unloaded into the HCA.</p>	
<p><u>Chilling</u></p>		
<p>Chilling of the product <u>must</u> commence as soon as it is practicable after heating, assembly or air drying has been completed. The cooling rate <u>must</u> be such that significant growth of surviving microorganisms is prevented. Appropriate measures <u>must</u> be used to ensure that the product will not be contaminated, e.g. chlorination of water, regular cleaning of chiller units.</p>		
<p>Finished product <u>must</u> be placed in dedicated chillers designed for the type and amounts of product to be chilled. Product <u>must</u> be chilled to the temperature required by current food hygiene regulations or below.</p>		
<p>Where relevant, packs <u>must</u> be dried as quickly as possible under hygienic conditions.</p>		
<p>Manual handling whilst wet <u>should</u> be avoided. Where this is essential, precautions <u>must</u> be taken to ensure that it is done in a hygienic manner.</p>		
<p>Documented procedures <u>must</u> specify necessary action to be taken in case of failure.</p>		

<p style="text-align: center;">GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS</p>	<p style="text-align: center;">RAW HIGH CARE AREA (rHCA) REQUIREMENTS</p>	<p style="text-align: center;">COOKED HIGH CARE AREA (cHCA) REQUIREMENTS</p>
<p><u>Assembly and Packing</u></p>		
<p>No specific GMP requirements</p>	<p>If sealed containers are to be transferred into the HCA:</p> <ul style="list-style-type: none"> – They <u>must</u> be inspected outside the HCA for evidence of spoilage or physical damage (e.g. blown cans, torn packs). – They <u>must</u> be adequately cleaned at the point of transfer, and only after that <u>must</u> the seal be broken and the product removed in the HCA. <p>Documented procedures <u>must</u> be available that <u>must</u> specify action required if any spoilage is noted.</p>	
<p>For products cooked in pack, after the packs have been assembled and filled, they <u>must</u> be sealed and heated and stored under time and temperature conditions that prevent significant microbial growth and outgrowth of spores.</p>	<p>Not applicable</p>	
<p>Packs <u>must</u> be checked at regular intervals to verify that they are hermetically sealed. Immediate action <u>must</u> be taken to correct any fault in the packaging machinery or packaging ingredient and appropriate checks made on product produced since the previous satisfactory check.</p>	<p>Not applicable</p>	

<p style="text-align: center;">GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS</p>	<p style="text-align: center;">RAW HIGH CARE AREA (rHCA) REQUIREMENTS</p>	<p style="text-align: center;">COOKED HIGH CARE AREA (cHCA) REQUIREMENTS</p>
<p><u>Coding and Labelling</u></p>		
<p>Finished products <u>must</u> be properly labelled in accordance with legislative requirements and <u>must</u> include the Use By date, temperature and storage conditions, and if necessary, cooking instructions.</p>		
<p><u>Handling of Finished Product</u></p>		
<p>The storage and distribution temperature <u>must</u> be that which will maintain product safety for the intended shelf life of the product. If the temperature of the product is the principal means of preservation, that product <u>must</u> be kept at a temperature as low as possible.</p> <p>The product <u>must</u> be stored so as not to render it injurious to health.</p> <p>Performance of the proposed distribution chain <u>should</u> be assessed and evaluated.</p> <p>Regular and effective monitoring of temperatures of storage areas, transport vehicles and store display cases <u>should</u> be carried out. This monitoring <u>should</u> take place, in particular, when the transport vehicle is loaded or unloaded.</p> <p>Particular attention <u>should</u> be paid throughout storage and distribution to:</p> <ul style="list-style-type: none"> – periods of defrosting of refrigeration units; – temperature abuse; – overloading the cold storage facility; and <p>anything that could damage the containers and/or packaging material.</p>		

<p style="text-align: center;">GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS</p>	<p style="text-align: center;">RAW HIGH CARE AREA (rHCA) REQUIREMENTS</p>	<p style="text-align: center;">COOKED HIGH CARE AREA (cHCA) REQUIREMENTS</p>
<p><u>Cleaning and Disinfection</u></p>		
<p>Adequate separate equipment washing facilities <u>must</u> be installed.</p>	<p>Dedicated equipment washing facilities <u>must</u> be installed.</p>	
<p>Consideration <u>should</u> be given to adequate extraction from equipment washing facilities, thus reducing potential condensation problems and ensuring that aerosols do not contaminate the product.</p>	<p>Equipment washing facilities <u>should</u> be placed in a segregated room within the HCA. Alternatively cleaning <u>should</u> be carried out after production has finished.</p>	
<p>Properly evaluated hygiene schedules for all equipment and the environment <u>must</u> be established and documented. Their effectiveness <u>should</u> be regularly reviewed and confirmed.</p>		
<p>Clean-as-you-go <u>should</u> be the policy. It is important to keep the area as dry as possible.</p>	<p>Clean-as-you-go <u>must</u> be the policy wherever possible. It is important to keep the area as dry as possible.</p>	
<p>Staff <u>must</u> be trained in the correct operation of hygiene schedules and the correct use of cleaning and decontamination equipment and ingredients, including chemicals.</p>		
<p>Mops, squeegees, cloths, condensation removal equipment and hoses are recognised as particular sources of contamination with <i>Listeria</i> and wherever possible these <u>should not</u> be used, or if essential, they <u>must</u> be dedicated to Area of use (e.g. rHCA, cHCA) and be frequently cleaned and decontaminated.</p>		
<p>High-pressure hoses <u>should</u> preferably <u>not</u> be used, but, if necessary <u>should</u> be used only by designated trained personnel between production periods. They <u>should not</u> be used to clean drains without subsequent decontamination of the whole area.</p>	<p>All hoses can produce aerosols; therefore high-pressure hoses <u>must</u> be used only by designated trained personnel and only between production periods. They <u>must not</u> be used to clean drains without subsequent decontamination of the whole area. Low pressure hoses <u>should</u> be used only between production periods.</p>	

<p style="text-align: center;">GOOD MANUFACTURING PRACTICE (GMP) REQUIREMENTS</p>	<p style="text-align: center;">RAW HIGH CARE AREA (rHCA) REQUIREMENTS</p>	<p style="text-align: center;">COOKED HIGH CARE AREA (cHCA) REQUIREMENTS</p>
<p>Regular monitoring of the cleanliness of food contact surfaces <u>should</u> be carried out immediately before production commences (see section 3.3.2.1).</p>	<p>Monitoring the cleanliness of food contact surfaces <u>must</u> be carried out immediately before production commences. This <u>must</u> be supported by regular microbiological validation. Environmental monitoring for <i>Listeria</i> spp. is strongly recommended. (See section 3.3.2.1)</p>	
<p>Standards of cleaning, including laundering of protective clothing <u>should</u> be determined using HACCP principles and be compatible with the hygiene standards needed for the particular area.</p>		
<p><u>Pest Control</u></p>		
<p>Effective pest control <u>must</u> be in place throughout the plant.</p>		
<p><u>Waste Management</u></p>		
<p>Food waste and other refuse <u>should</u> be disposed of as quickly as possible and <u>must</u> not accumulate in food rooms except when unavoidable for the proper functioning of the business.</p>		
<p>Food waste and other refuse <u>must</u> be deposited in containers specially designed and marked for this use. These containers <u>must</u> be of an appropriate construction, kept in sound condition and be easy to clean and disinfect.</p>		
<p>Refuse stores <u>must</u> be designed and managed in such a way as to enable them to be kept clean and minimise pest access.</p>		

PART 3

ADDITIONAL OBLIGATIONS

SECTION 3.1

RAW MATERIALS AND SUPPLIER CONTROL

One important aspect in the assurance of the safety and quality of chilled foods is the use of good quality raw materials that conform to previously defined specifications.

Raw material quality is critical for chilled foods since they are often delivered from the supplier in the condition in which they will be used in the final product, e.g. cooked chicken and pre-cut fresh vegetables.

To ensure that raw materials meet requirements regarding quality and safety, the following aspects need attention:

- a system ensuring consistent supplier selection and ongoing supplier performance;
- specifications containing all parameters that are relevant for quality and safety;
- transport, storage and traceability of raw materials;
- verification of these points. See section 3.3.

3.1.1 SUPPLIER SELECTION

A consistent supplier selection system is needed to ensure that raw materials are purchased from reliable suppliers that have an implemented quality system based on GMP, GAP (where relevant) and HACCP principles. When new ingredients are purchased from an already approved supplier or when existing ingredients are intended for a new application, it is essential to re-evaluate the supplier to ensure that the ingredient is able to meet its required quality and safety parameters.

On-going supplier performance is critical. It depends on the type of ingredients to what extent performance must be verified, including frequency of auditing.

Testing of raw materials may be required in addition to identifying an approved supplier. For packaging materials, this testing can be restricted to visual controls on compliance of the supply, machinery run, damaged pallets, etc. For raw materials and ingredients, it may also include organoleptic, chemical, microbiological and/or physical tests. The frequency of this testing will depend upon the reliability of the supplier (e.g. number of complaints) and the type of raw materials, the supplier's own quality system and the products in which the material is to be used. See also section 3.3.

A risk categorisation of raw materials may help to identify testing needs of raw materials with regard to microbiology

- Low-risk raw materials: raw materials in which the presence of pathogens is not to be expected, e.g. salt. When bought from an approved supplier, these ingredients rarely require microbiological analysis as their microbial load will be limited.
- Medium-risk raw materials: raw materials that might present a microbiological hazard such as contamination with salmonellae or staphylococci, e.g. pasteurised egg yolk. Control of these hazards is managed through the use of approved suppliers with implemented HACCP and QA programmes. Analysis of these raw materials according to a pre-defined sampling plan will have to verify that the raw materials meet their specifications. Regular supplier auditing should be done to ensure ongoing satisfactory supplier performance.

- High-risk raw materials: raw materials that are known from previous history to be susceptible to microbiological contamination with or presence of hazardous microorganisms, e.g. spices. These could be very sensitive raw materials even when supplied by an approved supplier. More frequent monitoring of microbiological quality of these raw materials may give an indication of the level of control.

3.1.2 SPECIFICATIONS

All raw and packaging materials must have written specifications that detail critical parameters.

The supplier must formally agree to the specifications before actual supply of raw materials (based on test supplies).

The microbiological specification defined for the various raw materials depends on their intended use. If ingredients have been pre-treated at the supplier (e.g. blanched, frozen vegetables) this should be reflected in a tighter microbiological specification compared with fresh vegetables. For fresh-cut vegetables and herbs, intended to be eaten raw, management of hazards is based on minimisation of microbial and other contamination during growing and harvesting of fresh produce. This is assured through GAP (Good Agricultural Practice) as well as management systems that limit contamination and growth of (pathogenic) microorganisms from farm to consumption (e.g. Eurep GAP).

The microbiological specification should consist of the following components: relevant microorganisms or their toxins/metabolites, the analytical methods, the sampling plan and the microbiological limits.

3.1.3. INTAKE, STORAGE AND TRACEABILITY OF RAW MATERIALS

Raw material must be transported at the specified temperature and according to the agreed specification.

All incoming raw materials must be inspected prior to unloading to prevent the intake of out-of-specification material and introduction of contaminants to the plant. If a Certificate of Analysis (COA) is sent together with the delivery, it must be verified that this is in agreement with the specification.

Each delivery must be registered, and a coding system must be in place to ensure traceability (see Section 3.4).

Appropriate storage conditions must be specified and applied for all types of raw materials. Perishable raw materials must be stored at chill temperatures. Special care must be taken to prevent cross contamination of raw materials used raw in ready-to-eat products by other raw materials. Allergen cross-contamination hazards must also be assessed and controlled during storage. See section 1.1.4.

Thawing of frozen ingredients must be done under conditions that minimise microbial growth. Thawing at ambient temperature can lead to uncontrolled and unrecognised growth of pathogens and can only be applied when risks have been properly assessed.

The “first in first out” principle of stock rotation should be applied, taking account of raw material shelf life.

SECTION 3.2

HACCP

HACCP systems manage and control food safety but cannot make a fundamentally unsafe product safe.

Food safety must be designed into a product at the development stage. See section 3.2.4

This section is adapted from the Codex “*Recommended International Code of Practice – General Principles of Food Hygiene*” (CAC/RCP 1-1969, Rev. 4-2003).

3.2.1 INTRODUCTION

The HACCP system, which is science-based and systematic, identifies specific hazards and control measures to assure the safe production of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

HACCP can be applied throughout the food chain from primary production to final consumption and its implementation should be guided by scientific evidence of risks to human health. As well as enhancing food safety, implementation of HACCP can provide other significant benefits. In addition, the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

The successful application of HACCP requires the full commitment and involvement of management and the work force. It also requires a multidisciplinary approach; this multidisciplinary approach should include, when appropriate, expertise in agronomy, veterinary health, production, microbiology, medicine, public health, food technology, environmental health, chemistry and engineering, according to the particular study. The application of HACCP is compatible with the implementation of quality management systems, such as ISO 9001, and is the system of choice in the management of food safety within such systems.

While the application of HACCP to food safety is considered here, the concept can be applied to other aspects of food quality.

For definitions concerning HACCP, refer to Appendix A.

For a full explanation of HACCP principles and the latest HACCP updates refer to CODEX General Principles of Food Hygiene: http://www.codexalimentarius.net/web/standard_list.do

For chilled foods, consideration of HACCP most often involves the identification and control of microbiological hazards, particularly:

- presence (and growth) of infectious pathogens in ready- to-eat raw foods, e.g. *Listeria monocytogenes*, salmonellae;
- survival and growth of vegetative and spore forming pathogens in heat treated foods, e.g. psychrotrophic *Clostridium botulinum*, *Bacillus cereus*.

Control of these organisms is reflected in the Decision Tree in Figure 1.

3.2.2 PRINCIPLES

This section sets out the principles of the Hazard Analysis and Critical Control Points (HACCP) system adopted by the Codex Alimentarius Commission. The second section provides general guidance for the application of the system while recognising that the details of application may vary depending on the circumstances of the food operation.¹⁵

The HACCP system consists of the following seven principles:

- Principle 1: conduct a hazard analysis.
- Principle 2: determine the Critical Control Points (CCPs).
- Principle 3: establish critical limit(s).
- Principle 4: establish a system to monitor control of the CCPs.
- Principle 5: establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.
- Principle 6: establish procedures for verification to confirm that the HACCP system is working effectively.
- Principle 7: establish documentation concerning all procedures and records appropriate to these principles and their application.

3.2.3 GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

The application of the HACCP principles is the responsibility of each individual business.

Management awareness and commitment is necessary for implementation of an effective HACCP system. The effectiveness will also rely upon personnel having the appropriate HACCP knowledge, skills, training and commitment.

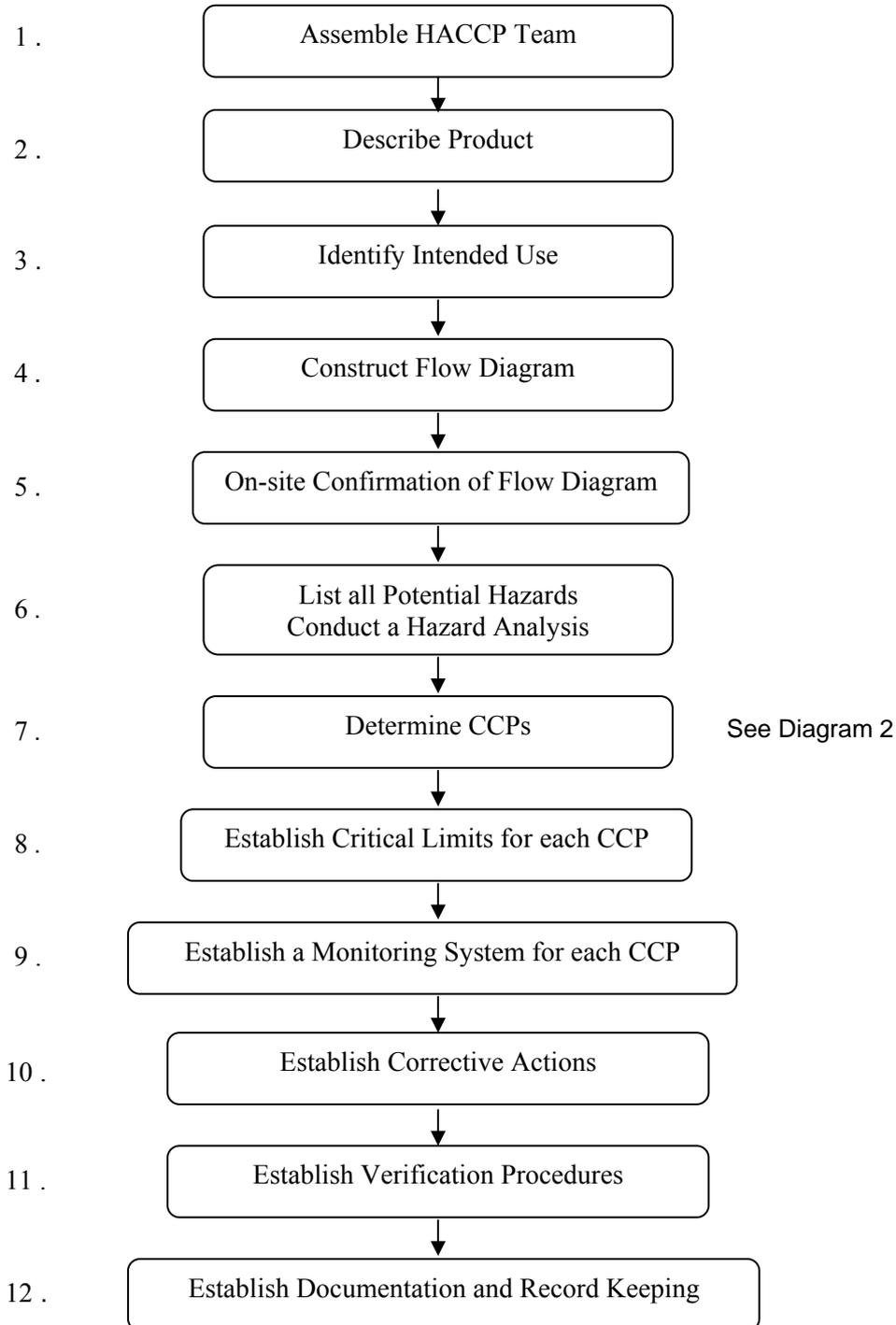
In order to facilitate the successful application and implementation of the HACCP system the FBO must have in place prerequisite programs such as good hygienic practices according to the Codex General Principles of Food Hygiene, the appropriate Codex Codes of Practice, and appropriate food safety requirements as set out in these ECFF Recommendations.

The HACCP plan must be validated prior to implementation. It must be reviewed and revalidated when any modification is made in the product, process, or any step.

The application of HACCP principles consists of the following tasks as identified in the Logic Sequence for Application of HACCP (Diagram 1).

¹⁵ The Principles of the HACCP System set the basis for the requirements for the application of HACCP, while the Guidelines for the Application provide general guidance for practical application.

DIAGRAM 1
LOGIC SEQUENCE FOR THE APPLICATION OF HACCP



Step 1: Assemble HACCP team

The food operation should assure that the appropriate product specific knowledge and expertise are available for the development of an effective HACCP-plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice

should be obtained from other sources. The scope of the HACCP plan should be identified. The scope should describe which segment of the food chain is involved and the general classes of hazards to be addressed (e.g. does it cover all classes of hazards or only selected classes).

Step 2: Describe the product

A full description of the product should be drawn up, including relevant safety information such as:

- composition (such as formulation, pH, a_w , preservatives, recipe);
- structure (such as multi-layer emulsion type);
- process details (such as mixing method, heat treatment, working method);
- packaging details (such as MAP, VP, aseptic fill or exposed to environment);
- expected performance of chill chain;
- target shelf-life (such as total life, customer use);
- instructions for use (such as storage temperature, cooking instructions);
- intended use (such as: target population group [children, the elderly], single or multiple use pack, ready-to-eat or requires heating or cooking by the consumer);
- sensory attributes/requirements.

Step: 3 Identify intended use

The intended use should be based on the expected uses including preparation of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. those receiving institutional feeding, may have to be considered.

Step 4: Construct flow diagram

The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the operation. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

The flow diagram should include as much information as possible about the intended production process, including any potential alternatives under consideration and any potential rework routes.

Examples of types of information required on the flow diagram are:

- lists of raw materials/ingredients/packaging;
- ingredients preparations (debagging, chopping, dipping, pre-mixing etc);
- correct sequence of proposed process steps;
- time/temperature conditions proposed for each step, to include potential for delay;
- possibility of rework/recycling (and likely routes, storage times, etc);
- equipment proposed;
- relevant analytical data for formulation and at process stages if parameters vary through the proposed process (e.g. pH, a_w , salt).

Step 5: On-site confirmation of flow diagram

The HACCP team for the intended manufacturing site must confirm that the process defined in the flow diagram is feasible in routine production and amend the flow diagram where appropriate.

Step 6: List all potential hazards and conduct a hazard analysis

The HACCP team should list all the hazards that may be reasonably expected to occur at each step from primary production, processing, manufacture, and distribution until the point of consumption.

The HACCP team should next conduct a hazard analysis to identify for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of a safe food.

In conducting the hazard analysis, wherever possible the following should be included:

- the likely occurrence of hazards and severity of their adverse health effects;
- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of microorganisms of concern;
- production or persistence in foods of toxins, chemicals or physical agents;
- conditions leading to the above.

The HACCP team must then consider what control measures, if any, exist that can be applied for each hazard.

More than one control measure may be required to control a specific hazard and more than one hazard may be controlled by a specified control measure.

Step 7: Determine Critical Control Points

There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a HACCP Decision Tree (e.g. Diagram 2), which indicates a logical reasoning approach. Training in the application of the Decision Tree is recommended.

All control options should be identified and evaluated to determine whether one or any combination of them would be appropriate for the hazard in question. With a product under development the control options identified may be different for alternative production processes.

If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

Step 8: Establish critical limits for each CCP

Critical limits must be specified and validated if possible for each Critical Control Point. In some cases more than one critical limit will be elaborated at a particular step. Criteria often used include

measurements of temperature, time, moisture level, pH, a_w , available chlorine, and sensory parameters such as visual appearance and texture.

Step 9: Establish a monitoring system for each CCP

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. A designated person with knowledge and authority to carry out corrective actions when indicated must evaluate data derived from monitoring. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee that the CCP is in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are often preferred to microbiological testing because they may be done rapidly and can often indicate the microbiological control of the product. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by the responsible reviewing official(s) of the company. See section 3.3.1.

Step 10: Establish corrective actions

Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur.

The actions must ensure that the CCP has been brought under control. Actions taken must also include proper disposition of the affected product. Deviation and product disposition procedures must be documented in the HACCP record keeping.

Step 11: Establish verification procedures

Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Examples of verification activities include:

- Review of the HACCP system and its records;
- Review of deviations and product dispositions;
- Confirmation that CCPs are kept under control.

See section 3.3.

Step 12: Establish documentation and record keeping

Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation.

Documentation examples are:

- hazard analysis;
- CCP determination;
- critical limit determination.

Record examples are:

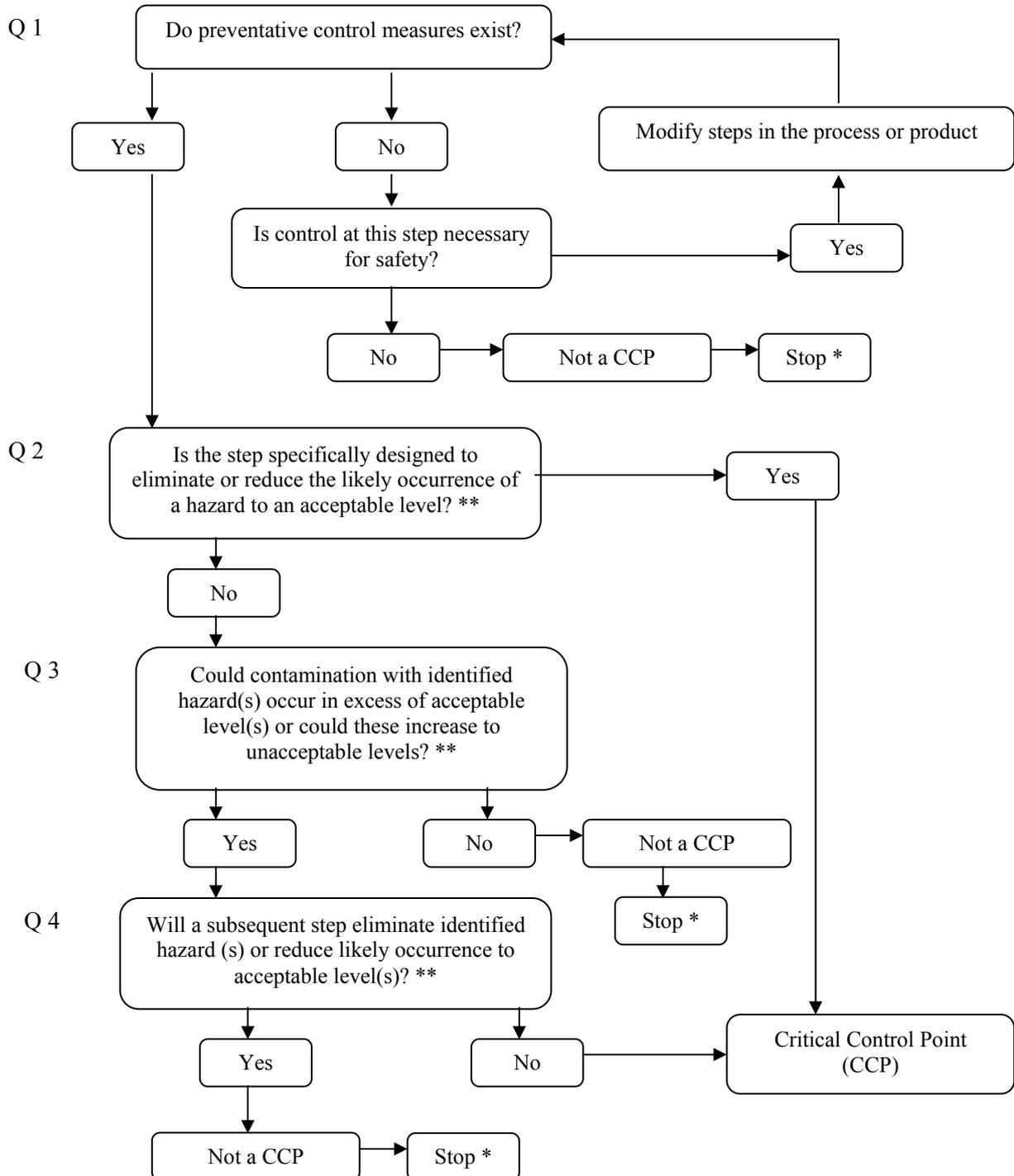
- CCP monitoring activities;
- deviations and associated corrective actions;
- modifications to the HACCP system.

An example of a HACCP worksheet is attached as Diagram 3.

DIAGRAM 2

EXAMPLE OF DECISION TREE TO IDENTIFY CCPS

(answer questions in sequence)



* Proceed to the next identified hazard in the described process

** Acceptable and unacceptable levels need to be determined within the overall objectives in identifying the CCPs of the HACCP plans

**DIAGRAM 3
EXAMPLE OF A HACCP WORKSHEET**

1.

Product Description

2.

Process Flow Diagram

3.

List							
Step	Hazard(s)	Control Measure(s)	CCP	Critical Limits	Monitoring Procedures	Corrective Actions	Records

4.

Verification Plan

SECTION 3.3

MONITORING, VERIFICATION AND DOCUMENTATION

End product specifications must reflect legal requirements for food safety.

Confidence in meeting these requirements, as well as in the appropriate application of these Recommendations, is ensured by:

- monitoring actions (measurements, observations) which are implemented, in particular at each CCP (see also Section 3.2);
- verification of the correct implementation of the HACCP plan;
- management of nonconformities;
- records and document management.

3.3.1 MONITORING

To ensure the correct implementation of GMP requirements and control measures defined in the HACCP plans (Section 3.2), a monitoring plan must be set up, documented and carried out. The plan should indicate for each point to be monitored:

- the criteria to be monitored;
- the persons in charge of the monitoring;
- the monitoring frequency;
- the sampling procedure;
- the monitoring method to be used;
- the target level, tolerances and critical limit;
- the recording of monitoring results;
- the measures to be taken in case of non-conformity.

Monitoring methods can comprise actions such as measuring process parameters, checking process records, analysing samples, visual inspection or auditing.

Analytical methods used must be validated against the appropriate reference method.

Each monitoring activity must be recorded. The record should include:

- the product identification information such as product name, product number or batch code;
- the time of monitoring;
- the relevant sampling conditions such as product temperature;
- the person who was in charge of the monitoring;
- the result, preferably quantified;
- proof that measures were taken in case of nonconformity.

3.3.1.1 Monitoring at Reception

Monitoring at reception allows verification of compliance of raw material with specifications.

Monitoring frequency of raw materials takes into account the confidence that the user has in the supplier, based on elements such as supplier auditing, previous test results, certificates of analyses, or product complaints (see Section 3.1).

Raw material monitoring should be done before use. Where this is not possible, the corrective action plan must include handling and disposal of any affected raw material, work in progress or finished product.

The personnel in charge of the monitoring at reception must be appropriately trained and qualified. Specific training in organoleptic assessment may be required.

Monitoring of incoming materials may include, for example:

- vehicle cleanliness, vehicle temperature, product temperature;
- integrity of the raw material packaging;
- raw material labelling;
- visual inspection;
- absence of foreign bodies;
- organoleptic characteristics: appearance, odour, taste;
- microbiological analysis of raw material and packaging;
- physical and chemical analysis.

Unacceptable raw material must be identified and stored separately for appropriate disposal.

3.3.1.2 Monitoring During Processing

Monitoring during processing may include, for example:

- checking process temperatures and times (such as heating, cooling or thawing);
- checking the packaging integrity (such as film resistance to the different treatments, seal integrity, absence of leaks, gas composition);
- monitoring compliance with cleaning and disinfection requirements (e.g. contact times, disinfectant strengths, temperatures);
- inspecting the condition of process equipment (e.g. presence of filters, absence of leakages).

Unacceptable product or in-process material must be identified and stored separately for appropriate disposal.

3.3.1.3 Monitoring of Finished Products

On the condition that all CCPs on raw material and products during processing are monitored correctly and there are no non-compliances no particular monitoring of finished products will be required (see Section 1.6.2 verification).

3.3.1.4 Monitoring Personnel Hygiene

Monitoring the hygiene of personnel in production may include, for example:

- visual inspection of cleanliness;
- correct wearing of the factory clothing;
- respect of hygiene rules and working procedures;
- observation of hand washing requirements;
- medical screening.

3.3.2 VERIFICATION

In addition to monitoring, verification must be regularly performed to a planned schedule to demonstrate compliance with specifications, Good Manufacturing Practice and HACCP-based systems. Verification activities include, at the minimum:

- environmental testing to verify efficiency of cleaning and disinfection;
- audits such as on hygiene, HACCP, suppliers, quality systems, management of non-conformities;
- verification of the efficacy of processes to meet the limits stated in the HACCP plan;
- relevant microbiological and chemical analyses at the stage of raw materials, in-process products or finished product up to the end of shelf life according to a predetermined sampling plan.

3.3.2.1 Environmental Testing

Environmental testing is used to verify the efficiency of cleaning and disinfection. It will involve sampling of both product contact and non-contact surfaces after cleaning and disinfection and may use microbiological samples such as swabs or contact plates and/or non-microbiological indicator systems such as ATP swabs or rinses.

- **Rapid Hygiene Monitoring** ATP swabbing and similar rapid hygiene monitoring systems give a result that can be interpreted before start-up. This is then a means of monitoring rather than verification. As such testing is relatively expensive, it is best used to monitor specific CCPs (e.g. cutting knives for cooked meat in a sandwich plant). Manufacturers of systems will advise on the setting of standards.
- **Microbiological Testing** The results of environmental microbiological tests are not available soon enough to be used for CCP monitoring, but can be used to verify cleaning and disinfection, to monitor trends and for investigation purposes.

During commissioning of new plant, equipment or processes, including cleaning and disinfection systems, extensive environmental sampling is an effective means of confirming that the intended cleaning and disinfection methods are effective (can be by rapid and/or microbiological testing).

When to Sample

Environmental monitoring should be done after cleaning and disinfection and immediately before start-up of production. Any surfaces that are not visibly clean at this point must be re-cleaned before swabbing (swab results do not add any value in such cases).

The operator should decide on the points to be swabbed, selecting items that are particularly difficult to clean and/or have been shown to cause problems in the past. During commissioning, a large

number of items may be tested, the number being reduced once confidence in cleaning methods is established.

It is good practice to rotate sample points and lines tested as well as the shift, time and day of sampling.

What to Test For

Microbiological testing will usually be for indicator organisms only (ACC (aerobic colony count), Enterobacteriaceae, yeasts and moulds).

Specific pathogen testing can also be useful in some circumstances, e.g. testing of environmental swabs from a Raw or Cooked High Care area for *Listeria spp.* on a regular basis can be used to confirm that this organism is not building up in the environment, and is therefore strongly recommended.

Interpretation of Results

Standards to be applied will vary according to the type of equipment, its material of manufacture, its age and its use (e.g., stainless steel surfaces used for cooked meat may achieve a total aerobic count of < 1000 cfu per 625 cm² whereas a similar surface used for raw meat may be acceptable at < 2500 cfu per 625 cm²). In most cases, product contact surfaces should achieve <10 cfu Enterobacteriaceae per 625 cm². The operator should decide on standards based on knowledge of product, equipment and cleaning method.

Listeria spp. should not (or only rarely) be detected in a Raw or Cooked High Care Area, even in floor/drain swabs, if cleaning is effective. Action must be taken if positives are found. This should include, e.g.

- review of cleaning methods;
- reswabbing (after re-cleaning);
- review of product results.

3.3.2.2 Audits

Quality audits are conducted to assess the effectiveness of an organisation's management to assure the safety and quality of products.

A formal audit (e.g. ISO, BRC, IFS certification) is carried out by an independent team of trained qualified auditors. These audits are performed by accredited inspection bodies. The frequency of audits is defined by the accredited inspection body and may also be set in (national) legislation.

In addition to these formal audits, FBOs are recommended to carry out internal audits to verify conformance of systems and processes against pre-set requirements. Furthermore, a food manufacturer must audit their raw material suppliers (see section 3.1).

An audit process consists of the following steps:

- *Organisation of the audit*
Audit organisation (agreement of date, scope, etc) is done by the auditor in consultation with the site or department that will be audited. The auditor is responsible for obtaining all information necessary for audit preparation including for example previous audit reports, a HACCP plan, process descriptions, etc. Often a questionnaire can be used to gather this information.

- *The audit*
An audit will take from a few hours up to several days, depending on the scope of the audit and the size/complexity of the site or department. Usually, a check list is used to make sure that all elements have been addressed. All findings/observations must be discussed during the audit. If necessary, a follow up audit will be arranged. Main findings and actions requested must be communicated to the auditee during the summary session.
- *Audit report*
A full audit report must be issued within an agreed timescale.
- *Follow up*
The necessary audit follow-up measures depend on the audit findings and results. The auditee must prepare an action plan based on the recommendations given, also within an agreed timescale. Implementation of recommendations should be assessed by the auditor and will normally be evaluated during the next regular audit.

Internal audits may focus on one department, system or process. It is recommended that an internal audit of all departments, processes and systems is carried out once a year.

3.3.2.3 Verification of Processes

Process verification comprises

- the control of processes within specified limits and tolerances, and
- the calibration of critical measuring devices and control equipment.

3.3.2.4 Microbiological Analyses

Particular attention should be paid to HACCP verification using microbiological analysis. Examination of a material for indicator or spoilage organisms can provide simple, reliable and rapid information about processing failure, post-processing contamination, contamination from the environment and the general level of hygiene. Methods normally involve estimation of numbers of organisms in the food.

Testing of end products alone will not guarantee their safety and cannot therefore be used as a control measure but for verification purposes only. The safety of the products must be assured by the proper application of Good Hygiene Practices and HACCP (see Section 3.2).

It is important to recognise that microorganisms are rarely distributed homogeneously in a product or a batch. In addition, pathogens, if present, are usually at low levels. A sampling plan is therefore used, which is based on risk assessment, taking into account the hygiene status of the product (raw or cooked, for example) and its intended use (ready-to-eat or to be cooked). The plan includes the sampling procedure, the criteria to be complied with, the prescribed number and size of sample units and the test methods to be used.

Methods should be reference methods or validated alternative methods or other documented and scientifically justified methods. The use of kits for screening using indicator organisms is acceptable when suspect results are then followed up using standard laboratory methods. Analyses should be performed by a competent laboratory. End product analyses may be performed by an independent accredited laboratory to meet local requirements by authorities.

Legally defined microbiological criteria, including defined sampling plans, are applicable to end products. Raw material/ingredient and in-process test results must be reviewed against knowledge of the product components and the production process.

It is important to test only for relevant microorganisms. For example:

- It is not relevant to include ACC testing of products that are not in-pack pasteurised and which contain ingredients such as cheese or salami, as these ingredients will contain lactic acid bacteria, contributing to the ACC.
- When sampling fresh fruit and vegetables or products containing them, it is important to note that testing for Enterobacteriaceae will not provide useful information since these materials often carry high levels of these organisms as part of their normal flora.

When a count is found that is above specifications or criteria, investigations must be carried out to determine the cause of the non-conformance (see Section 1.6.3).

In addition to individual results being interpreted, trend data should be generated. Rolling averages can be on a weekly, monthly or quarterly basis, as most appropriate. An assigned warning level should be associated with each rolling average and appropriate actions to be taken in case of these levels being exceeded.

3.3.3 MANAGEMENT OF NON-CONFORMITIES

Non-conformity occurs when the results of monitoring do not comply with pre-determined standards defined in product specifications (raw material, in-process products, finished products) or process specifications.

The management of non-conformities consists of the following elements:

- Identification of the non-conformity that may be classified into one of three categories:
 - critical: non-conformity that presents a safety hazard for the consumer; the result is outside the critical limit in the HACCP plan.
 - major: non-conformity unacceptable for the product quality.
 - minor: non-conformity that does not affect the consumer safety or the essential product quality characteristics.
- Containment of the problem, such as segregation of affected product, stopping the production, or isolation of damaged equipment.
- Remedial actions in order to prevent a reoccurrence of the non-conformity, such as adjusting the process, repairing equipment, retraining personnel or changing work instructions.
- Disposal of any affected product, if relevant, such as its safe reprocessing, reworking, or destroying.
- Reviewing HACCP and GHP.
- Recording of all the above-mentioned elements.

Non-conformities must be managed by appropriately trained, qualified and authorised personnel. Responsibilities must be clearly defined by management (see page 6).

3.3.4 DOCUMENTATION

Sufficient information must be available to demonstrate control, in particular at the CCPs. Such information must be filed and may include:

- procedures, data and calculations used to elaborate and validate the processes (such as scheduled heat or other preservation treatments, cooling methods);
- if applicable, procedures, data and records establishing the efficacy of hurdles used;

- procedures, data and records relevant to the establishment and validation of the product shelf life;
- any changes made to the product, processes or other factors used in establishing the scheduled heat or other treatments;
- documents and records linked with the HACCP plan (including the hazard analysis).

3.3.5 RECORDS

Records provide evidence to show that the required hygienic quality has been achieved and that the measures have been implemented according to the HACCP plan.

Records can also be used for product traceability.

Records may comprise:

- purchase orders, delivery orders from the supplier;
- stock cards, consignment documents;
- delivery orders to the client;
- monitoring information, such as:
 - all CCP records;
 - personnel hygiene monitoring, microbiological testing results, personnel certificates, evaluation / qualification files;
 - monitoring records at reception (compliance with the specifications);
 - temperature records (of products, premises, transport vehicles, equipment),
 - results of microbiological, chemical and physical testing (such as products, packaging, fluids, packaging gas);
 - cleaning and disinfection monitoring, check-list, results of microbiological testing, results of visual inspection.

Adequate documentation and records must be readily available to demonstrate compliance with these *Recommendations* and should be retained according to legal requirements or, if not specified, for a minimum of six months past the shelf life of the product.

All documents concerning hygiene control, all records, all procedures and instructions, other documents such as raw material specifications, processing and monitoring data sheets should be identified, distributed as needed, filed and kept up to date.

SECTION 3.4

TRACEABILITY

Traceability has for a long time been used as a logistics tool. More recently, traceability appeared as a quality management tool for crisis management and product recall. Traceability as such does not improve food safety but establishes the transparency needed for efficient control measures.

The purpose of this section is to provide recommendations for implementing traceability and good practices in view of its use with respect to Article 18 of Regulation (EU) 178/2002¹⁶ laying down the general principles and requirements of food law and procedures in matters of food safety.

In terms of practical application, traceability allows tracking of the history, application and location of products under consideration. Traceability can relate to

- the origin of ingredients and packaging materials;
- the processing history;
- the distribution and location of the product after delivery.

Traceability should be based on the principles of HACCP. It requires documented procedures aiming at product identification, from purchasing of the starting materials throughout the whole production process and shipment.

All measures of traceability should be part of the quality system of the food producer and not handled separately.

Traceability throughout the food chain is possible only if each operator establishes traceability within his/her operation. Food operators must therefore respect the following principles:

- request documentation and/or labelling accompanying supplies of foods, of food contact materials and other products purchased;
- define and identify the lots of products manufactured;
- define and establish a clear link between goods coming in and products going out;
- records the names and addresses of their suppliers and customers, and the commercial names and grades of products, identify transport, define and identify the lots of raw materials as well as of goods delivered;
- document this information, especially all relevant safety information based on risk assessment (HACCP) pertaining to the lots of raw materials received or to the manufactured goods;
- guarantee that all documented information is reliable and readily available.

This cascade approach must be used in the whole food chain. This means that all the operators in a given (part of the) food chain need to use the same principles of traceability. Customers must require the application of these principles from their suppliers. Therefore, if traceability in the food chain is to be achieved, each single part of the chain must respect the rules of

¹⁶ OJ L 31, 1.2.2002, p. 1.

identification enabling traceability back to the suppliers of each ingredient and component of the finished product and *vice versa*.

The scope and the limits of traceability must be clearly defined as part of the food operator's quality system. In particular, it should be clear

- whether the above-mentioned principles of traceability also apply to rework, co-products and waste;
- how continuous production fits in the concept of traceability;
- how batches or lots of products are defined and to what extent they are separated during production or distribution;
- what performance in degree of precision and delay is to be expected from the traceability system and to what extent the system is regularly tested.

To facilitate the transparency of the food chain, especially when applied to multi-component products, it may be useful to define and certify common standards, including traceability, for well-defined parts of the chain.

Traceability also applies to primary producers, e.g. farmers, who must therefore apply these rules accordingly, e.g. keep details of feed supplied, spray plans, veterinary treatment of animals. This covers not only primary producers based in the EU but also those in third countries. However, it will be difficult to ensure that similar traceability standards are applied in developing countries and the necessary measures should be undertaken to make them aware of, and to assist them in meeting EU requirements.

For products originating from outside the EU, the operator importing these goods is responsible for documenting all relevant parameters, including the origin, needed to establish traceability downstream the food chain.

A FBO must not accept raw materials or other products that are of uncertain origin or which are not batch coded.

Internationally accepted standards and systems such as the EAN/UCC standards and Best Before/Use By date should be used to identify products.

Traceability should not be confused with identity preservation (e.g. material that is certified as being organic or GM-free). Traceability is only one of the tools to achieve the objective of identity preservation. This means that customer and supplier will have made an agreement on the value and also on the additional costs of implementing an identity preservation system.

SECTION 3.5

RECALL¹⁷

A product recall is conducted to protect public health and safety. It may be initiated as a result of findings from the food business itself or information obtained from suppliers, retailers, wholesalers, governmental health authorities or consumers.

All FBOs engaged in the wholesale supply, manufacture or importation of food must be capable of rapidly and effectively managing product recalls. This applies in particular to chilled food where products move rapidly from production to consumption.

A recall action removes from sale, distribution and consumption foods that may pose a safety or health risk to consumers¹⁸. In general two levels of recall may be considered:

- *trade recall (withdrawal)*: the recovery of the product from distribution centres and wholesalers. It may also involve recovery of product from hospitals, restaurants, other major catering establishments, as well as other food processors;
- *consumer (public) recall*: in addition to a trade recall, the recovery of any affected product in the possession of consumers.

For short shelf life chilled foods recall may present practical difficulties, however a detailed written recall plan should be prepared describing, step-by-step the procedure to be followed.

While this section is limited to product recall for food safety reasons, a FBO may consider managing a market withdrawal or stock recovery in the same way as a recall.

3.5.1. DEVELOPING A RECALL PLAN

Establishing a recall plan requires consideration of:

- people involved, their responsibilities and contact details;
- information to be gathered;
- incident classification and action to be taken;
- communication;
- corrective actions (See section 3.3.3);
- recall closure and evaluation

¹⁷ Regulation (EC) 178/2000 of the European Parliament and the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L31 p.1).

¹⁸ Guidance on the Implementation of Articles 11, 12, 16, 17, 18, 19 and 20 of Regulation (EC) No 178/2002 on General Food Law, December 2004: http://europa.eu.int/comm/food/food/foodlaw/guidance/guidance_rev_7_en.pdf

3.5.1.1 People Involved

Recall coordinator

One person should be identified as the recall coordinator to prepare for and coordinate all activities related to a recall. Preferably this should be the FBO's senior quality manager. The recall coordinator should be knowledgeable about every aspect of the operation, including purchasing, processing, quality assurance, distribution, and consumer complaints. The recall coordinator is responsible for preparing and updating a recall plan and reporting to top management at regular intervals about its readiness and effectiveness.

Incident Management Team

In particular for short shelf life products speed is critical, therefore the initial team should be small and with decision making authority to enable rapid decisions to be made.

Senior management personnel should be nominated to represent the principal areas involved in a recall. The incident management team must be authorised to make decisions in carrying out a recall and to communicate to all stakeholders involved.

Typically, an incident management team should consist of the recall coordinator and the managing director. Other representatives may be required from, for example:

- quality;
- manufacturing;
- warehousing and distribution;
- purchasing;
- sales and/or marketing;
- legal;
- public relations;
- other resources as required

In small business operations, the committee may consist of just one or two people, each having a number of the above responsibilities.

The responsibilities of each team member in regard to a recall must be clearly defined in the product recall plan. For example, the recall coordinator is responsible for maintaining the incident contact list, notifying the health authorities and the head of public relations for preparing a media statement if necessary.

3.5.1.2 Information Gathering

Prior to making a recall decision, gather information on the affected product, such as:

- product name and description, including package size and type;
- lot identification;
- the remaining shelf life of the affected product and whether it may have been frozen by the consumer in accordance with labelled instructions - this will indicate the timescale and feasibility of any recall and the type of communication required;

- batch size, date and amount released;
- distribution and amounts of the product in each part of the chain: within the business, wholesale, foodservice, retail, consumer, nationally, within the EU, exported outside the EU;
- production records of the batch(es) concerned;
- potential for the same problem or type of contamination occurring in other products;
- name and contact information of the person reporting the incident, and the date of the report;
- date of the incident;
- nature of the incident;
- number of similar reports received (for example, from customer complaint records);
- results of tests and other investigations on suspect or other samples.

3.5.1.3 Incident Classification and Action to be Taken

The identification and characterisation of hazards related to the reported incident, assessment of exposure to these hazards and the risks involved will determine the level of action required including the decision whether or not to notify the authorities and/or recall the affected product. External expert advice may be needed to determine the seriousness of the hazard and the risks involved.

Depending on the nature of the hazard and the possible risks, incidents may be classified according to:

- ***Class I incident*** where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death.
- ***Class II incident*** where there is a remote probability of adverse health consequences from the use of the product.
- ***Class III incident*** where the use of the product will not cause adverse health consequences.

Based on the information from the incident classification, decisions are taken on whether or not to recall the affected products, as indicated below.

Class	Product has not left the immediate control of the FBO	Product on the market
I	Withdrawal	Recall and notification
II	Withdrawal	Withdrawal or recall in consultation with the authorities
III	Withdrawal at the discretion of the FBO	Withdrawal or recall at the discretion of the FBO

The decision must be justified, documented and communicated appropriately.

The means of controlling and disposing of, or correcting the defect in the stock returned during a recall should be specified in the recall plan. This may include actions such as destroying, relabelling or reworking products. All actions must be documented.

3.5.1.4 Communication

The recalling company is responsible for promptly notifying each of its affected consignees about the details of the recall in line with national legislation and/or customer requirements.

If it is decided to carry out a public recall, the authorities must be notified in a co-ordinated way, preferably by the brand owner.

3.5.1.5 Recall Closure and Evaluation

A recall will be terminated by a recall status report summarising and documenting the facts and the actions taken. If possible, the report details the effectiveness of the recall in terms of recovered product.

The report should be communicated to the incident management team and other relevant personnel to ensure that all issues, including the design of the recall process are addressed.

3.5.2. RECALL SIMULATIONS -TRAINING AND REVISION

In order to evaluate its recall process, a company must conduct periodic, documented recall simulations. A simulated recall should involve the selection, without prior notice to personnel involved in the simulated recall, of at least one lot of product that has been placed on the market. A hypothetical reason for recalling the product should be specified and the recall plan followed to establish a strategy for recalling the product. The simulation should proceed at least to the point at which communication is to be made beyond the firm's organisational limit. However, even if the simulation is stopped at this point, full details of who will be contacted at that point and how contact will be established should be specified.

If problems are identified during a recall simulation, the recall plan and procedures must be revised accordingly.

APPENDICES

APPENDIX A

DEFINITIONS AND ABBREVIATIONS

Challenge testing: deliberate inoculation of relevant microorganisms into a food product to determine the product's ability to support survival, growth or inactivation of the organism during storage at defined temperature(s). (6)

Chilled food: foods that for reasons of safety and/or quality rely on storage at refrigeration temperatures throughout their entire shelf life. (6)

'Clean-as-you-go': maintenance of work areas in a clean and tidy manner at all times

Cleaning: the removal of soil, food residue, dirt, grease or other objectionable matter. (2)

Container (i.e., primary package): any box, tin, plastic or other receptacle, or wrapper in direct contact with the food product. (1)

Contaminant: any biological or chemical agent, foreign matter, or other substance not intentionally added to food which may compromise food safety or suitability. (2)

Contamination: the introduction or occurrence of a contaminant in a food or food environment. (2)

Cook-chill foods: UNPACKED foods produced by a catering system based on cooking followed by chilling, storage in controlled low temperature conditions (0°C to 3°C) and subsequent reheating immediately before consumption. (5)

Cooking: heating by the consumer so that all parts of a food or food ingredient reach a minimum time/temperature equivalent of 70°C for 2 minutes, i.e. 6-log reduction of *Listeria monocytogenes*. Validation of preparation instructions should assure that these time and temperature requirements are met. (5)

Cooling equipment: equipment to reduce a product's temperature. (1)

Control (verb): to take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan. (2 Annex)

Control (noun): the state wherein correct procedures are being followed and criteria are being met. (2 Annex)

Control measure: any action or activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level. (2 Annex)

Corrective action: any action to be taken when the results of monitoring at the CCP indicate a loss of control. (2 Annex)

Critical Control Point (CCP): a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level. (2 Annex)

Critical limit: a criterion that separates acceptability from unacceptability. (2 Annex)

Decontamination: destruction of *Listeria monocytogenes* in a product by heat and/or chemicals or other validated means equivalent to at least a 6-log reduction. (6)

Deviation: failure to meet a critical limit. (2 Annex)

Disinfection: the reduction, by means of chemical agents and/or physical methods, or the number of microorganisms in the environment, to a level that does not compromise food safety or suitability. (2)

Establishment: any building or area in which food is handled and the surroundings under the control of the same management. (2)

Filling and sealing: operation consisting of placing a food product in a container and closing it. (1)

Flow diagram: a systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item. (2 Annex)

Food or foodstuff (as defined by EU Regulation): any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. Includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance. It does not include feed, live animals unless they are prepared for placing on the markets for human consumption, plants prior to harvesting, medicinal products, cosmetics, tobacco and tobacco products, narcotic or psychotropic substances, residues and contaminants. (3)

Food business: any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food. (3)

Food Business Operator (FBO): the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control. (3)

Food handler: any person who directly handles packaged or unpackaged food, food equipment and utensils, or food contact surfaces and is therefore expected to comply with food hygiene requirements. (2)

Food hygiene: all conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain. (2)

Food safety: assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.(2)

Food suitability: assurance that food is acceptable for human consumption according to its intended use. (2)

Good Manufacturing Practice (GMP): The requirements set out within section III. (ECFF)

Hazard: a biological, chemical or physical agent in, or condition of, food (or feed) with the potential to cause an adverse health effect. (2, 3)

Hazard analysis: the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan. (2 Annex)

Hazard Analysis Critical Control Point (HACCP): a system that identifies, evaluates, and controls hazards which are significant for food safety. (2)

HACCP plan: a document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food safety in the segment of the food chain (e.g. refrigerated foods) under consideration. (2 Annex)

Heating: heating by the manufacturer so that all parts of a food or food ingredient reach the correct target time/temperature conditions or their equivalents appropriate to microorganisms to be controlled for the projected shelf life. These time/temperature conditions should take into account the 1996 Report of the ECFF Botulinum Working Party. (5)

Hermetically sealed container: containers that are designed and intended to protect the contents against the entry of viable microorganisms after closing. (1)

High Care Area:

Cooked High Care Area (cHCA): a chilled area designed to a high standard of hygiene where practices relating to personnel, ingredients, equipment and environment are managed to minimise microbiological contamination of a ready to eat product comprising only cooked ingredients.

Raw High Care Area (rHCA): a chilled area designed to a high standard of hygiene where practices relating to personnel, ingredients, equipment and environment are managed to minimise microbiological contamination of a ready to eat product containing uncooked ingredients.

Hurdle: microbial growth limiting, retarding or preventative factor. (1)

Hurdle technology: the use of a combination of factors to effect control of microbial growth. (1)

Hygiene schedule: documentation of procedures appropriate for dismantling or clean-in-place, cleaning and decontaminating (including methods, dosages and chemicals), the frequency of use of equipment and the monitoring procedures to assure compliance with hygiene requirements. The schedule includes in-plant environmental screening and also documentation for personnel hygiene systems. (5)

Lethal rate: lethal rate is an expression of the rate at which a target organism is killed at any given temperature, relative to the rate at which it is killed at a reference temperature. (5)

Microbiological criterion: defines the acceptability of a product or a food lot, based on the absence or presence, or number of microorganisms, including parasites, and/or quantity of their toxins/metabolites, per unit(s) of mass, volume, area or lot. (4)

Modified atmosphere: atmosphere in a packaged product (vacuum or gas) that differs from the ambient atmosphere. (1)

Monitor: the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control. (2 Annex)

On-site catering operations: operations producing food and/or drink for consumption on-site. (6)

Packaging: any operation consisting of placing the food in containers (i.e. primary packaging) or placing the food containers in further packaging materials. (1)

Packaging materials: materials such as cardboard, paper, glass, plastic film, metal, etc., used to manufacture containers or packaging for refrigerated packaged food.(1)

Pasteurisation value: the length of time at a given temperature required to obtain a specified level of destruction of a microorganism whose heat resistance characteristics are known.

The heat resistance of a microorganism is characterised by D and z values defined as follows:

- D = time (in minutes) to achieve a 90% or one log reduction of a microbiological population at a given temperature;
- z = the number of degrees required for the thermal destruction curve to transverse one log cycle (expressed in degrees Celsius or Fahrenheit). (1)

Pasteurised food ingredient: where a legal standard is applied to pasteurisation, e.g. milk, cream and eggs, such ingredients may be considered as heated for the purpose of these Recommendations. (5)

Placing on the market: the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves. (3)

Pre-distribution storage: storage on site under conditions controlled by the manufacturer. (5)

Pre-packaged: any single item for presentation as such to the ultimate consumer and to mass caterers, consisting of a foodstuff and the packaging into which it was put before being offered for sale, whether such packaging encloses the foodstuff completely or only partially, but in any case in such a way that the contents cannot be altered without opening or changing the packaging.

Primary preparation: cleaning and trimming of raw materials. (5)

Primary production: those steps in the food chain up to and including, for example, harvesting, slaughter, milking, fishing. (2)

Rapid cooling: lowering the temperature of the food in a way such that the critical zone for microbiological proliferation (60°C-10°C) is passed through as rapidly as possible and the specified temperature is attained. (1)

Raw material: individual components as received at the factory, used in the preparation of a final product.

Ready-to-eat food (RTE): food intended by the producer or the manufacturer for direct human consumption without the need for cooking or other processing, effective to eliminate or reduce to an acceptable level microorganisms of concern. (7)

Recall: the action taken to remove from sale, distribution and consumption foods that may pose a safety or health hazard to consumers. In general two levels of recall may be considered:

- **Trade recall:** the recovery of the product from distribution centres and wholesalers. It may also involve recovery of product from hospitals, restaurants, other major catering establishments, as well as other food processors;
- **Consumer recall:** in addition to a trade recall, the recovery of any affected product in the possession of consumers.

Refrigerated storage facility: facility designed to keep refrigerated foods at the intended temperature. (1)

Reheating: heating by the consumer to a temperature suitable for organoleptic purposes, where its application is not required to assure safety of the product. (5)

Retail: the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar foodservice operations, shops supermarkets distribution centres and wholesale outlets. (3)

Secondary preparation: size reduction of raw materials following primary preparation. (5)

Shelf life: the period during which the product maintains its microbiological safety and sensory qualities at a specific storage temperature. It is based on identified hazards for the product, heat or other preservation treatments, packaging method and other hurdles or inhibiting factors that may be used. (1)

Shelf life testing: assessment of shelf life using storage trials and/or challenge testing.

Step: a point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption. (2 Annex)

Stock recovery: a company's removal or correction of product that has not been marketed or that has not left the direct control of the firm. For example, product located on premises owned by, or under the control of, the firm, and no portion of its lot(s) has been released for sale or use. (6)

Storage trial: storing a product at predetermined times and temperatures as part of shelf life determination. (6)

Traceability: the ability to trace and follow a food, feed, food-producing animal or substance intended to be, or expected to be incorporated into a food or feed, through all stages of production, processing and distribution. (3)

Use By date: the date after which the product should not be consumed. It is determined from the date of production, utilising the product shelf life, building in a margin of safety as determined by the manufacturer. (1)

Validation: obtaining evidence that the elements of the HACCP plan are effective. (2 Annex)

Verification: the application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine compliance with the HACCP plan. (2 Annex)

Withdrawal: a company's removal or correction by its own volition of a distributed product that involves no health hazard, and that is initiated for two reasons:

- the product has a quality defect (e.g. colour or texture) or is underweight or has labelling irregularities that do not pose a potential risk to public health and safety;
- as a precaution pending further investigation and – if a risk to public health or safety is established – leading to recall.

Sources:

1. Codex Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf Life, CAC/RCP 46-(1999)

2. Codex Recommended International Code of Practice - General Principles of Food Hygiene, CAC/RCP 1-1969, Rev. 3 (1997), Amd. (1999).
3. EU Regulation Laying Down the General Principles of Food Law, Establishing the European Food Safety Authority and Laying Down Procedures in Matters of Food Safety, Regulation (EC) No 178/2002.
4. Codex Principles for the Establishment and Application of Microbiological Criteria for Foods, CAC/GL 21.1997.
5. ECFF: As contained in 1996 Guidelines.
6. ECFF 2005
7. Microbiological Criteria for Foodstuffs EU Regulation 2073/2005

APPENDIX B

**CASE STUDIES USING DECISION TREE ROUTE TO DETERMINE
MINIMUM HYGIENE STATUS REQUIRED**

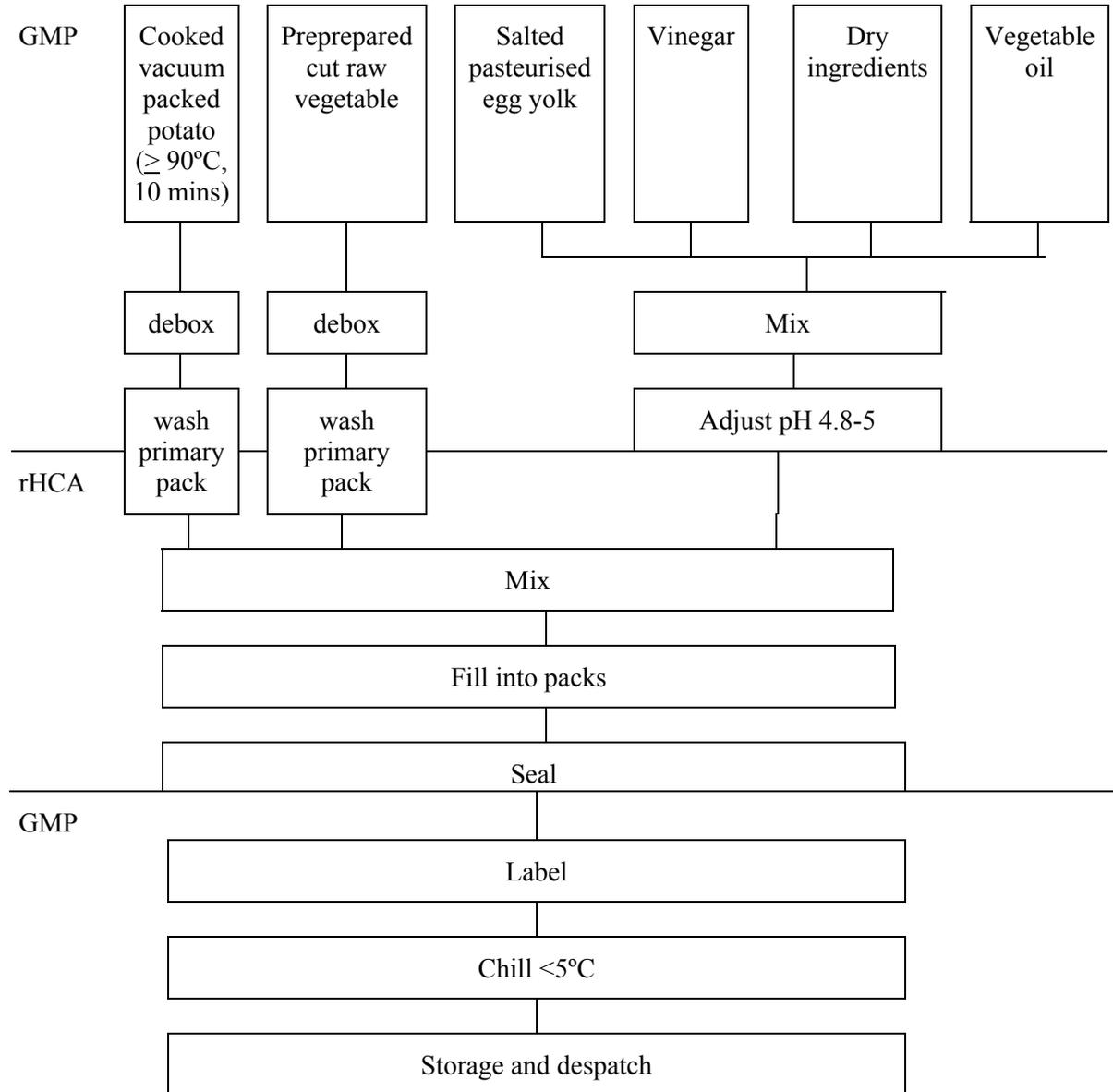
CASE 1: POTATO SALAD

PROCESS FLOW DIAGRAM

CATEGORY OF FOOD: RAW AND COOKED PREPARED READY TO EAT PRODUCT

PART 1

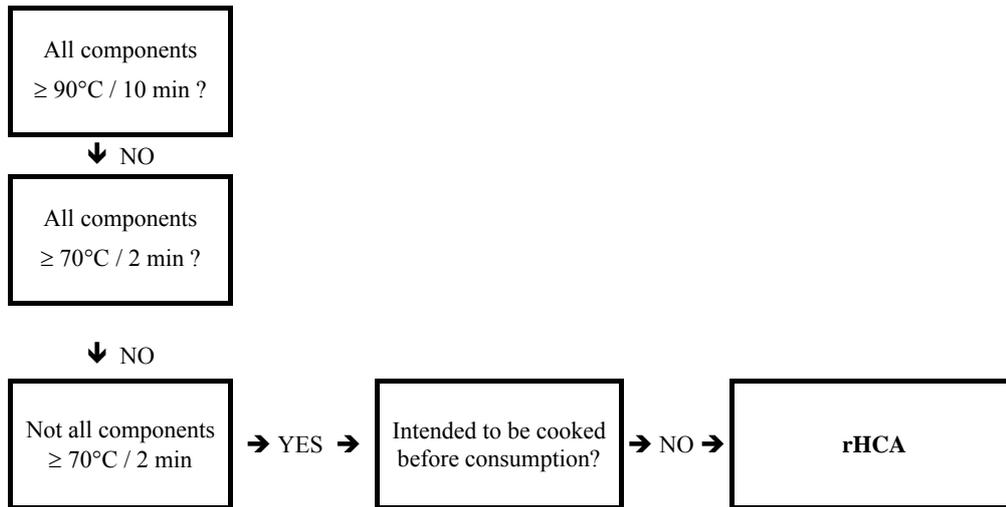
SUMMARY / PROCESS FLOW



CASE 1: POTATO SALAD

DECISION TREE ROUTE TO DETERMINE MINIMUM HYGIENE STATUS REQUIRED

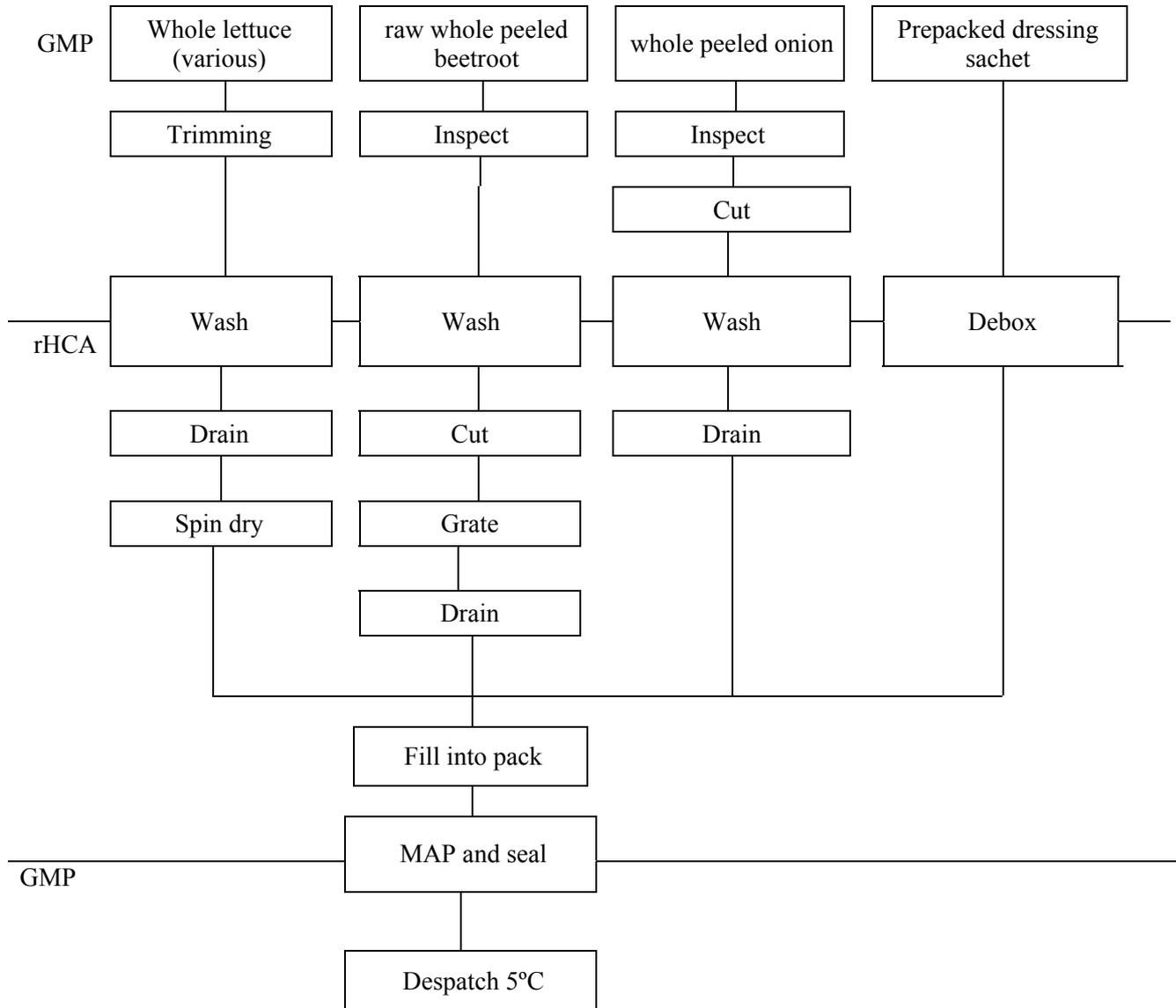
What is the treatment applied?



<p>Minimum Hygiene Status Required:</p> <p>Finished Product Main Pathogen Hazards:</p> <p>Finished Product Pathogen Control Measures:</p>	<p>rHCA</p> <p><i>Listeria</i> spp from potential recontamination. <i>Listeria monocytogenes</i> can grow in the final product owing to the pH. If Lm growth potential is eliminated by (e.g. acetic acid concentration in addition to pH control) it may be acceptable to pack in a GMP environment</p> <p>Surviving PSYCHROTROPIC spore formers, e.g. <i>C. botulinum</i> and <i>B. cereus</i></p> <p>rHCA</p> <p>Pasteurisation $\geq 70^{\circ}\text{C}$ for 2 mins</p> <p>Shelf life limitation (see section 1.3.1)</p> <p>Chilled Storage</p>
---	--

CASE 2: MIXED LEAF SALAD
PROCESS FLOW DIAGRAM

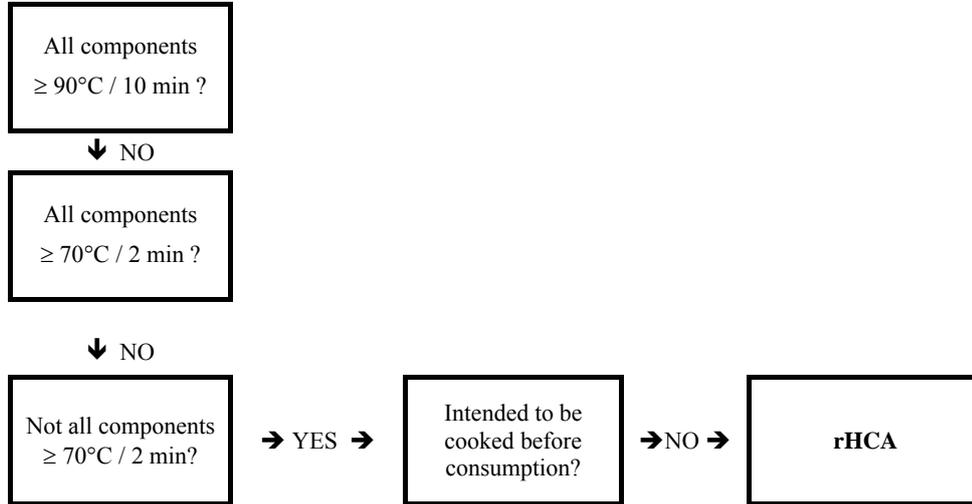
CATEGORY OF FOOD: RAW PREPARED READY TO EAT PRODUCT



CASE 2: MIXED LEAF SALAD

DECISION TREE ROUTE TO DETERMINE MINIMUM HYGIENE STATUS REQUIRED

What is the treatment applied?



<p>Minimum Hygiene Status Required:</p> <p>Finished Product Main Pathogen Hazards:</p> <p>Finished Product Pathogen Control Measures:</p>	<p>rHCA</p> <p>Listeria spp from potential recontamination</p> <p>Surviving spore formers, e.g. <i>C. botulinum</i> and <i>B. cereus</i></p> <p>Washing prior to packing</p> <p>rHCA</p> <p>Shelf life limitation (see section 1.3.1)</p> <p>Chilled storage</p>
---	--

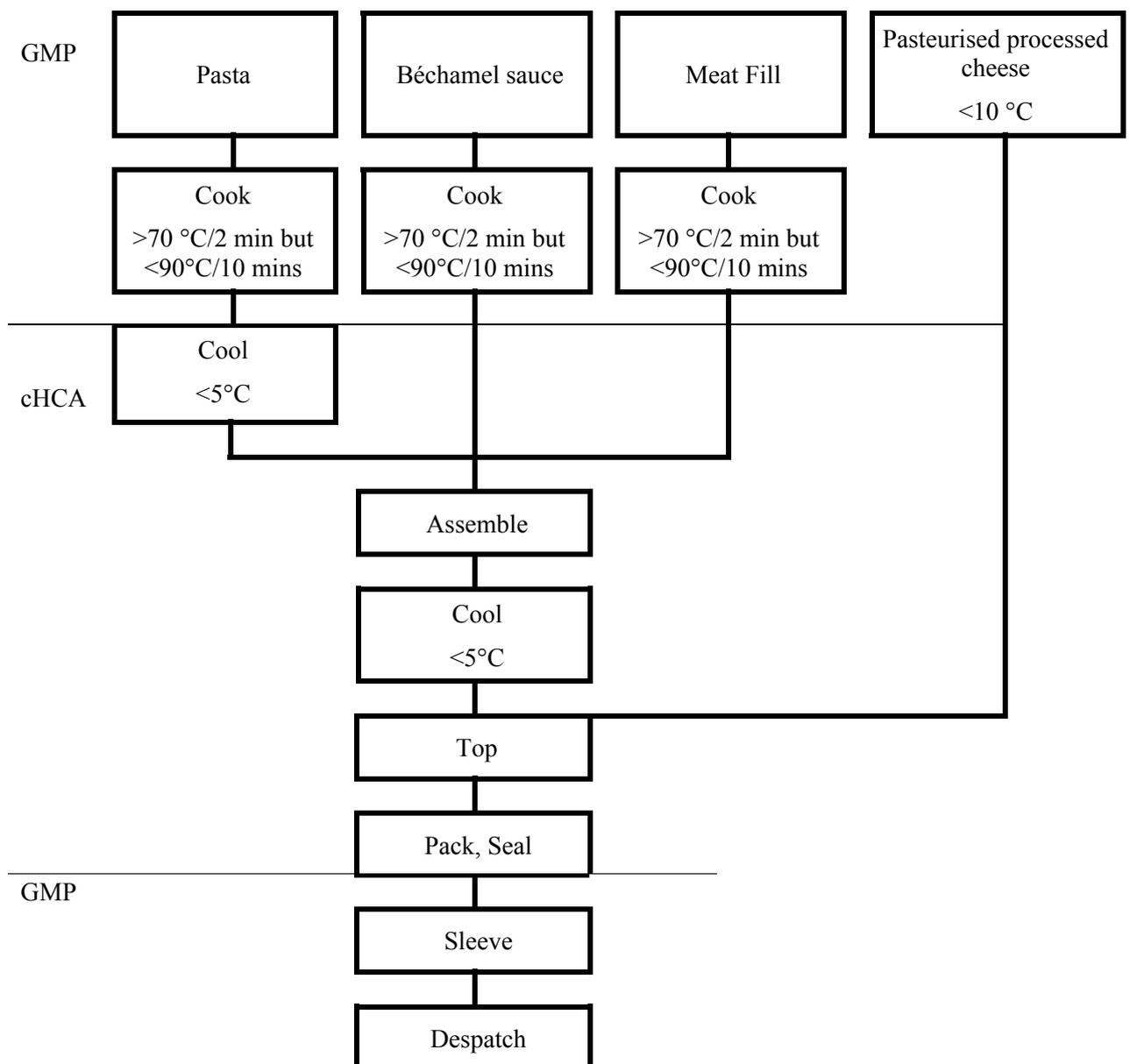
CASE 3: CHEESE-TOPPED LASAGNE

PROCESS FLOW DIAGRAM

CATEGORY OF FOOD: CHILLED COOKED PRODUCT REQUIRING REHEATING ONLY PRIOR TO CONSUMPTION

PART 1

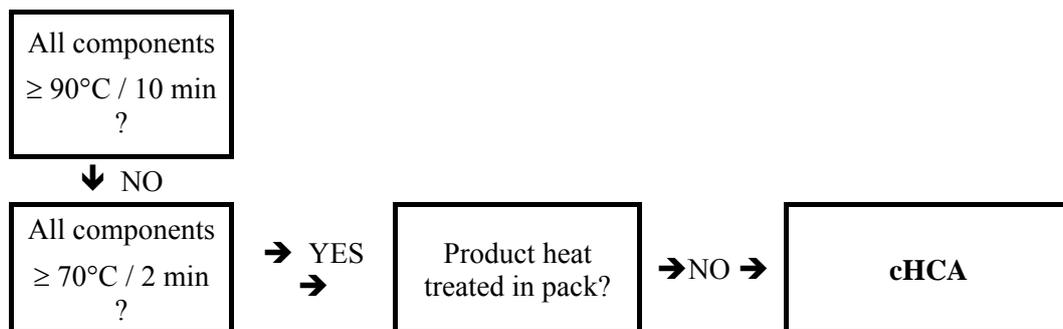
SUMMARY/PROCESS FLOW



CASE 3: CHEESE-TOPPED LASAGNE

DECISION TREE ROUTE TO DETERMINE MINIMUM HYGIENE STATUS REQUIRED

What is the treatment applied?



Minimum Hygiene Status Required:	cHCA
Finished Product Main Pathogen Hazards:	Listeria spp from potential recontamination Surviving spore formers, e.g. <i>C. botulinum</i> and <i>B. cereus</i>
Finished Product Pathogen Control Measures:	cHCA Pasteurisation $\geq 70^{\circ}\text{C}$ for 2 mins Shelf life limitation (see section 1.3.1) Chilled storage

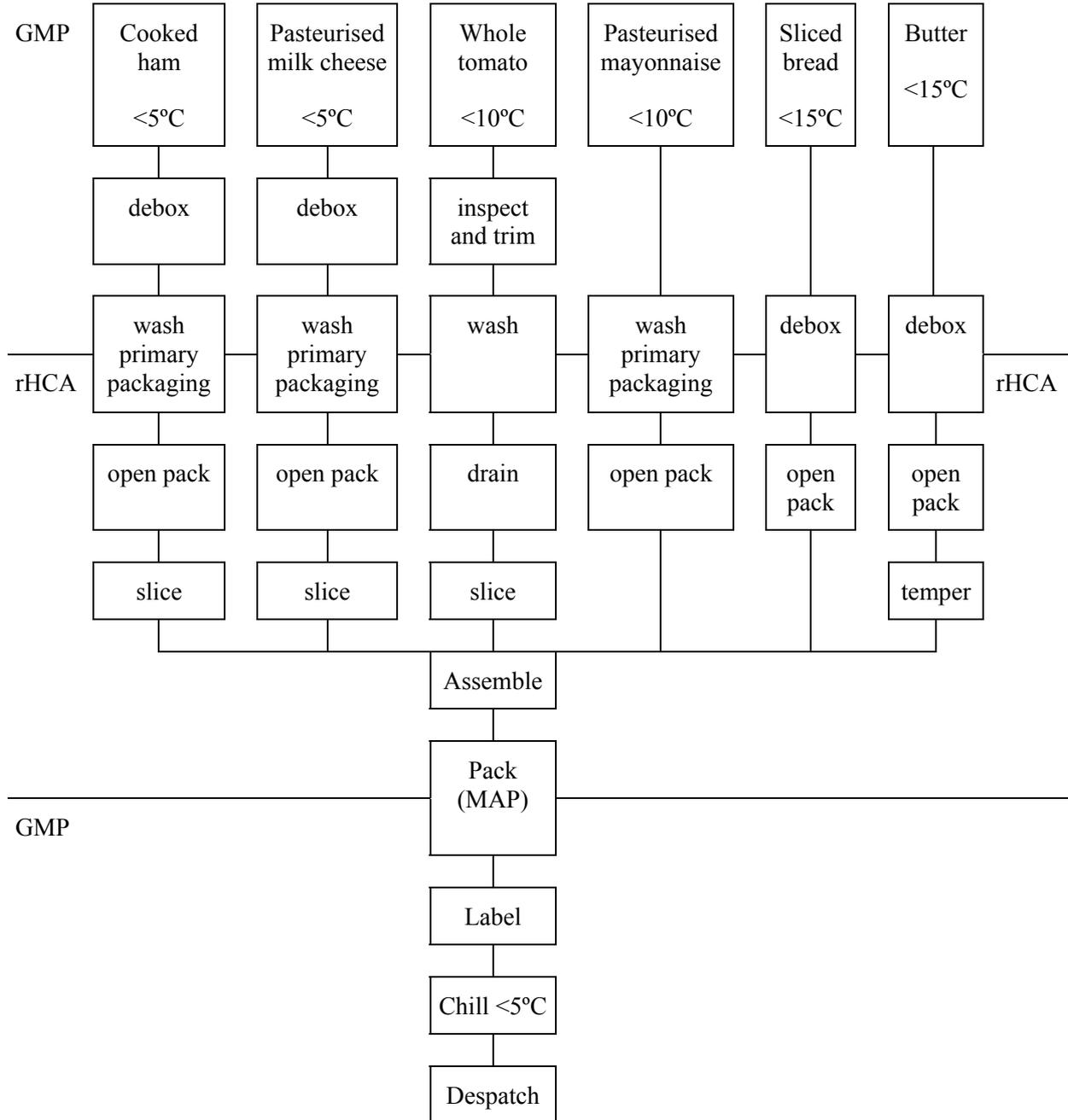
CASE 4: HAM, CHEESE AND TOMATO SANDWICHES

PROCESS FLOW DIAGRAM

CATEGORY OF FOOD: READY TO EAT PRODUCT WITH COOKED AND RAW INGREDIENTS

PART 1

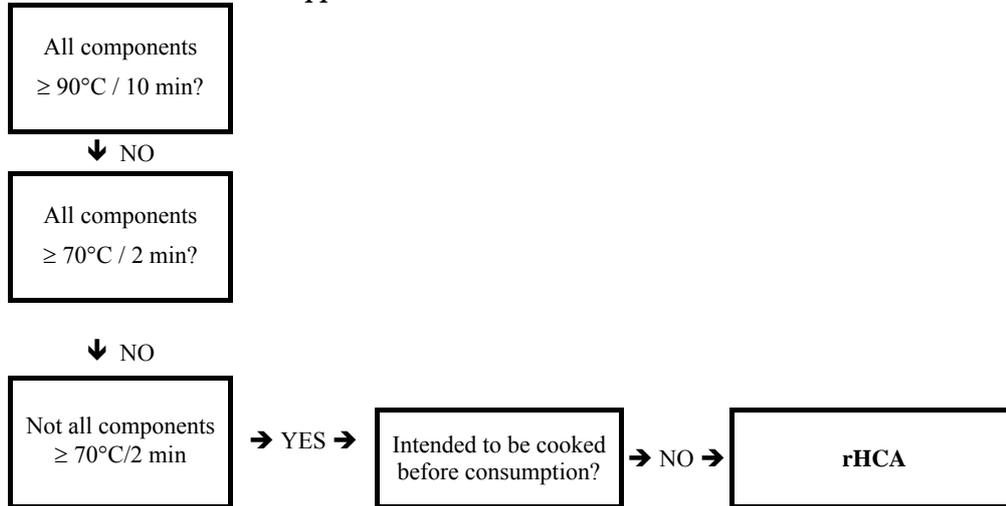
SUMMARY / PROCESS FLOW



CASE 4: HAM, CHEESE AND TOMATO SANDWICHES

DECISION TREE ROUTE TO DETERMINE MINIMUM HYGIENE STATUS REQUIRED

What is the treatment applied?



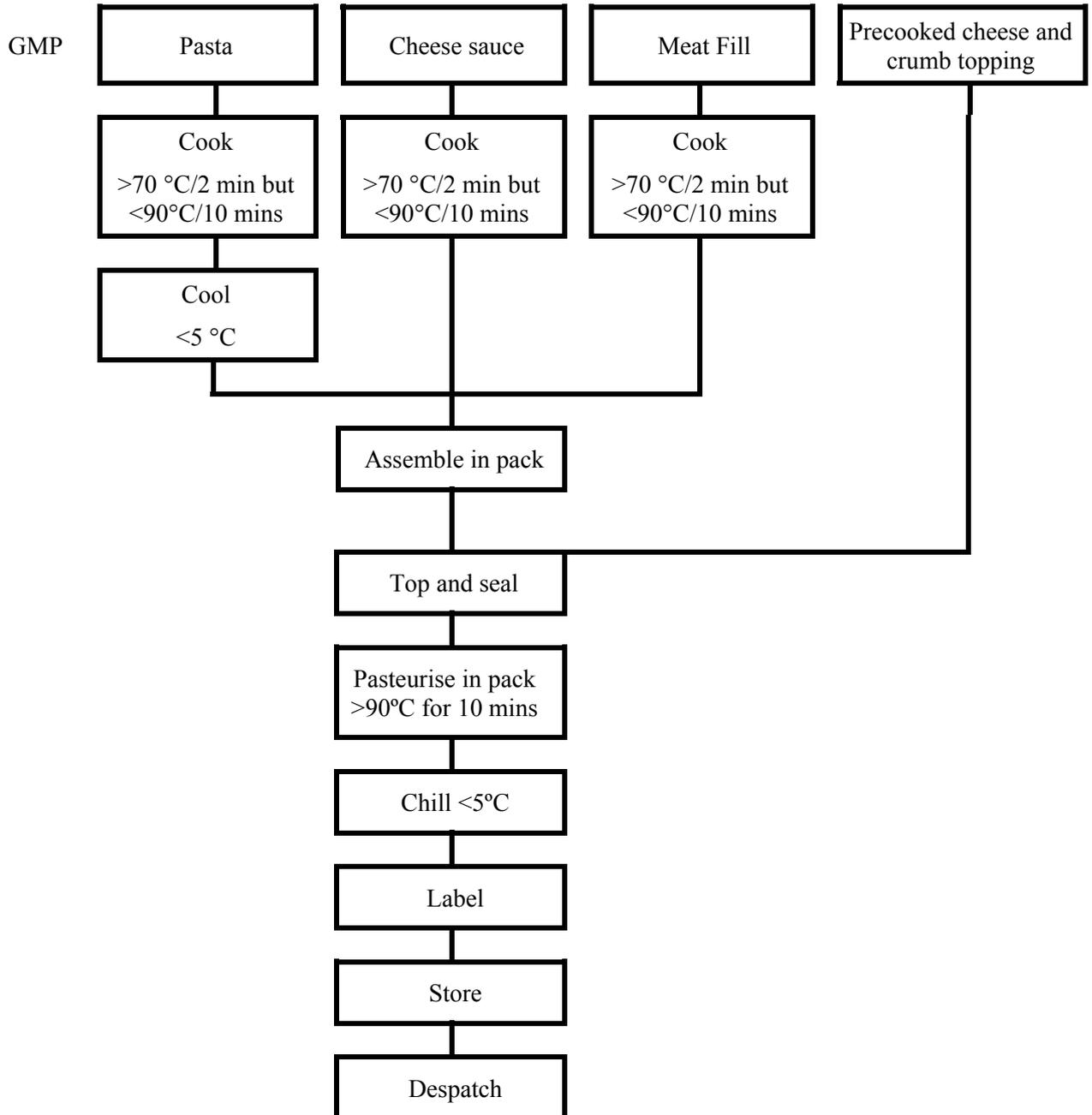
Minimum Hygiene Status Required	High Care Area
Finished Product Main Pathogen Hazards	Refer to Decision Tree p16
Finished Product Pathogen Control Measures	rHCA
	Ingredients specification
	Shelf life limitation (see section 1.3.1)
	Chilled storage

CASE 5: IN PACK PASTEURISED PASTA MEAL

CATEGORY OF FOOD: READY TO REHEAT PRODUCT

PART 1

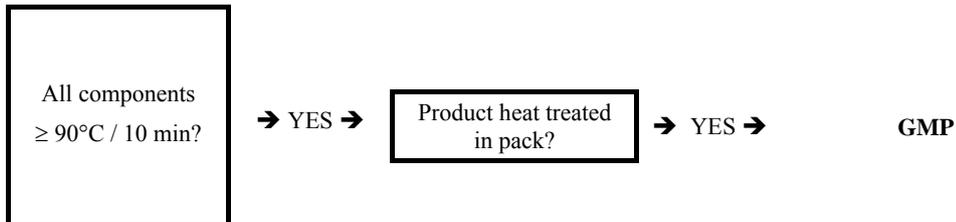
SUMMARY / PROCESS FLOW



CASE 5: IN PACK PASTEURISED PASTA MEAL

DECISION TREE ROUTE TO DETERMINE MINIMUM HYGIENE STATUS REQUIRED

What is the treatment applied?



Minimum Hygiene Status Required	Good Manufacturing Practice
Finished Product Main Pathogen Hazards	Refer to Decision Tree p16
Finished Product Pathogen Control Measures	In-pack pasteurisation $\geq 90^{\circ}\text{C} / 10 \text{ min}$
	Shelf life limitation (see section 1.3.1)
	Chilled storage

APPENDIX C

AIR QUALITY

It is not possible to eliminate completely the risk of microbial contamination of a prepared foodstuff. However, High Care Area operations and systems must be designed and managed with the aim of preventing contamination.

Many factors can contribute to food contamination by microorganisms during production, such as: raw materials, equipment, personnel and the air in the production environment. Air can act as a source of contamination from outside the processing area, or as a transport medium, moving contamination from other sources within the processing area, such as personnel, drains and overhead structures. Control of airborne microbiological contamination can be achieved by well-designed hygienic air handling systems provided that the production process and the nature of the associated risks are fully understood.

Air quality control systems are primarily designed to prevent product contamination by spoilage organisms or particles that may act as a transport vehicle for microbiological contamination; however, other considerations may also need to be taken into account, for example, the requirement for temperature and relative humidity control, prevention of air turbulence and maintenance of personnel comfort. Directional air flow to ensure that air moves to aerosol generating areas and such locations as personnel entry zones should be considered.

The specification of requirements for individual air handling systems depends to some extent on the risk category of the food product, the target microorganisms to be controlled, and the environment surrounding the higher risk (High Care) Area. Hazard analysis must be carried out to determine the standards required for each circumstance. For example, high efficiency air filtration is not essential where the supply air is not a significant factor in dispersing contamination, or where the level and type of contamination on the materials handled are such that any contribution from the air is relatively insignificant. Similarly, air filtration alone cannot guarantee room cleanliness - air movement, room design and activity within the controlled environment are of great importance. However, in all cases, air quality must be controlled so that it does not become a factor limiting product hygiene, and procedures must be established to manage and service the air handling system. A minimum standard of air filtration is essential to ensure that a clean and hygienic condition is maintained within the air handling systems, and F5 grade is recommended as a minimum level of air quality.

The air handling system must be designed so that it does not become contaminated, either during operation or by any cleaning operations within the production area. Condensation within the ductwork must be prevented and the ingress of other forms of water vapour during the normal operation or cleaning of the controlled space must not be allowed, as this may promote microbial growth in the system. Compliance with the requirements for the control of Legionnaires' Disease must be implicit in any system design.

It is vital to avoid drawing in contaminated air such as aerosols from cooling equipment, combustion gases, etc., and exhaust fumes. Air intakes must therefore be sited to avoid such sources.

To prevent air from lower-risk areas entering and contaminating the higher-risk (High Care) Area, continuous room pressurisation is essential to ensure correct air flows. **Air flow must be from higher- to lower-risk operations.** The degree of pressurisation will depend on the nature of the operation and the number of openings that need to be protected. Openings and access should be kept to a minimum to control air loss to an acceptable level whilst maintaining air flow, air change rate and a positive differential pressure.

A restricted High Care Area or enclosure can be achieved by air filtration and air flow to surround the product when it is not practical or necessary to have the complete room as a High Care Area. This design is known as a ‘mini-environment.’

It must be emphasised that the important feature of room pressurisation is that air must flow **at all times** from higher to lower risk, not the room pressurisation itself. Only a small amount of overpressure, measured in Pascals, is sufficient. The influence of access to ambient air from GMP areas such as dispatch should be controlled. Outside weather conditions such as wind can pressurise GMP areas and influence corridor and even High Care areas; thus access control is critical.

As air quality may be an essential element in food safety and must be taken into account in the risk assessment, specialist expert advice should be taken.

Further Reading

Guidelines on air quality standards for the food industry (second edition) (2005). CCFRA Guideline No. 12. Campden & Chorleywood Food Research Association, UK.

The Minimisation of Microbic Pollution Risk in the Food Industry, Dr F Mariani, Swiss Contam. Control, 1990, 3(4a), 355-7

Ventilation and air conditioning, Chartered Institute of Building Services Engineers (CIBSE), 2001, ISBN: 1 903287 16 2. www.cibse.org

Useful Technical Information

A level of 19-20 litres of outside air per second, per person, should be allowed. The minimum standard is 8 l / s / person. (CIBSE).

A minimum of 10-12 air changes per hour is recommended to help control relative humidity and temperature but will depend on the nature of the process.

The amount of outside air make-up required will depend on the level of room overpressure required.

A suggested maximum air velocity of 2.5 m/s should not be exceeded across the air handling unit cooling coils (if installed) in order to prevent condensate droplets from being carried over into the system and hence supporting microbial growth within the unit. If this is considered to be a risk, then design steps must be taken to eliminate it.

Where a mini “High Care” environment is installed, a minimum target air velocity (in the absence of turbulence) of 0.3 m/s over the product is recommended.

Heating, Ventilation and Air Conditioning (HVAC) type filters are used to remove particulates from the air. Refer to the following table for filter classifications (EN 779 and EN 1822).

For High Care Areas, if there is a hazard of microbiological contamination from the air supply to the areas, filtration standards of F7 to H 11 are recommended; however, the exact specification required will depend upon the analysis of risk. It is essential that such filters be installed with suitable pre-filtration for maximum filter life and that the filter system is leakproof.

AIR FILTER TEST REFERENCE CHART

General Filter Type	Filter Test Reference and Classification				Filter Test Type and application for the food industry
Primary filters to collect coarse dust	PREVIOUS Eurovent 4/5 arrestance		Current <u>EN779</u> arrestance		Average value for collection of large particles using synthetic test dust. Filter used to prevent mechanical system fouling and as pre-filters to secondary and semi-HEPA range.
	EU1	<65	G1	<65	
	EU2	65<80	G2	65<80	
	EU3	80>90	G3	80>90	
	EU4	>90	G4	>90	
Secondary filters to collect and retain small particulate dust	Eurovent 4/5 efficiency %		EN779 efficiency %		Average percentage value test using atmospheric air. Filters installed to keep general food processing areas clean and free from airborne pollution. Some high care use according to risk assessment.
	EU5	40<60	F5	40<60	
	EU6	60<80	F6	60<80	
	EU7	80<90	F7	80<90	
	EU8	90<95	F8	90<95	
Very small particulate air filters of the semi HEPA & HEPA type for specific particulate control.	Eurovent 4/4 initial efficiency		EN1822 minimum MPPS %		Filters installed for high care/high risk good process applications. Was Eurovent 4/4 sodium chloride test - now EN 1822 aerosol MPPS.
			H10	85	
	EU10	95<99.9	H11	95	
	EU11	99.9<99.97	H12	99.5	
	EU12	99.97>99.99	H13	99.95	
Highly efficient air filters ULPA type			H14	99.995	Filters used for laboratory work, in cabinets and some mini environments. EN 1822 aerosol MPPS
			U15	99.9995	
			U16	99.99995	
		U17	99.999995		

MPPS - Most Penetrating Particle Size

HEPA - High Efficiency Particulate Air (filters)

ULPA - Ultra Low Penetration Air (filters)

Eurovent 4/5/ EN779 arrestance and efficiency test references are based on average percentage values. Primary and secondary filters are at their lowest efficiency when they are new, and at their most efficient at the end of their useful life. EN 1822 tested filters offer a guarantee of minimum performance when newly installed as stated above.

APPENDIX D

SELECTED READING

OTHER RELEVANT GUIDELINES/CODES OF PRACTICE

Chilled Food

Best Practice Guidelines for the Production of Chilled Food. (2006). 4th Edition. Chilled Food Association, UK. Published by The Stationery Office, ISBN-13 978-1-901798-11-1

Guide de bonnes pratiques d'hygiène et d'application des principes HACCP - Produits traiteurs. (2006 - in draft). SYNAFAP, France.

Code of Hygienic Practice for Refrigerated Packaged Foods with Extended Shelf Life (CAC/RCP 46- (1999)), Codex Alimentarius Commission.

General Hygiene

Recommended International Code of Practice – General Principles of Food Hygiene (CAC/RCP 1-1969, Rev. 3 (1997), Amd. (1999)), Codex Alimentarius Commission.

Guidelines on the Application of the Principles of Risk Assessment and Risk Management to Food Hygiene Including Strategies for their Application. (1995) Codex Committee on Food Hygiene, CX/FH 95/8

Guidelines on air quality standards for the food industry (second edition) (2005). CCFRA Guideline No. 12. Campden & Chorleywood Food Research Association, UK.

Hygienic Design Guidelines. (2002). 1st edition. Chilled Food Association, UK. ISBN 1 901798 07 0.

Packaging Hygiene Guidelines for Suppliers to the Chilled Food Industry. (1999). 1st edition. Chilled Food Association, UK. ISBN 1 901798 05 4.

Temperature

A Guide to the International Carriage of Perishable Foodstuffs (ATP). (1988). Department of Transport, UK.

Recommendations for the Chilled Storage of Perishable Produce. (1979). International Institute of Refrigeration.

Quality Management Systems

ISO 22000:2005 - Food Safety Management System. International Standards Organization

ISO 9000 series. International Standards Organization.

Laboratory Practice

A Code of Practice for Microbiology Laboratories Handling Food, Drink and Associated Samples (third edition) (2004). CCFRA Guideline No.9. Campden & Chorleywood Food Research Association, UK.

Effective microbiological sampling of food processing environments (1999). CCFRA Guideline No. 20. Campden & Chorleywood Food Research Association, UK.

Medical Screening

Health Surveillance and Management Procedures for Food-Handling Personnel. (1989). World Health Organisation Technical Report Series 785, WHO, Geneva.

Notes on the Control of Gastrointestinal Infections, Infestations and Bacterial Intoxications in the UK. (1990). Communicable Disease Report Supplement 1, PHLS, UK.

Food Handlers: Fitness to Work, Aug. 1994, Department of Health, London. UK

Miscellaneous⁴

Food and Drink - Good Manufacturing Practice: A Guide To Its Responsible Management. (5th edition) (2007). IFST (Institute of Food Science and Technology), UK.

General Guidelines for Microwaveable Products. (1991). Food and Drink Federation (available via Chilled Food Association, UK).

Due Diligence Guidance on the Agricultural Use of Pesticides for Suppliers to Chilled Food Manufacturers. (2002). Chilled Food Association, UK. ISBN 1 901798 02 X

Microbiological Guidance for Produce Suppliers to Chilled Food Manufacturers. (2002). Chilled Food Association, UK. ISBN 1 901798 03 8.

Water Quality Management: Guidance for the Chilled Food Industry. (1999). Chilled Food Association, UK. ISBN 1 901798 01 1.

⁴ = Various relevant CODEX documents are currently under discussion and are not listed specifically.

APPENDIX E
ECFF AIMS AND MEMBERSHIP

Aims of the Federation

1. To develop a common European approach to safety and quality standards in the production and distribution of chilled prepared foods.
2. To represent the key interests of European manufacturers of chilled prepared foods in their formal dealings on major issues with European decision makers, regulatory bodies and with other relevant groups.
3. To provide a co-ordinating link for national associations where this is required and to offer support and endorsement on occasions when this is judged helpful.
4. To liaise with other industry associations, regulatory authorities, research organisations, retailer and consumer groups.
5. To promote a favourable environment for the marketing of chilled prepared foods in the long term.

For current membership, see ECFF website: www.ecff.net

List of Working Group Members

ORGANISATION	REPRESENTATIVE
BReMA (Belgian Ready Meals Association)	Dr Guido Bresseleers
CFA (Chilled Food Association (UK))	Miss Kaarin Goodburn
Chilled Food Industries Association (Finland)	Mrs Hillevi Latvalahti
Nestlé (Switzerland)	Mrs Helen Falco
SYNAFAP: Syndicat National des Fabricants de Plats Préparés Frais (France)	Mrs Sonia Litman
Unilever Foods (The Netherlands)	Dr Geke Naaktgeboren
Uniq/CFA (UK))	Dr Sheila Benson