

Report of the

**FAO EXPERT CONSULTATION ON THE TRADE IMPACT OF
LISTERIA IN FISH PRODUCTS**

Amherst, MA, USA, 17-20 May 1999



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Fish Utilization and Marketing Service
Fishery Industries Division
Food and Agriculture Organization
of the United Nations
Viale delle Terme di Caracalla
00100 Rome
Italy
<http://www.fao.org/WAICENT/FAOINFO/FISHERY/FISHERY.HTM>

Food Quality and Standards Service
Food and Nutrition Division
Food and Agriculture Organization
of the United Nations
Viale delle Terme di Caracalla
00100 Rome
Italy
<http://www.fao.org/WAICENT/FAOINFO/ECONOMICS/ESN/NUTRI.HTM>

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PREPARATION OF THIS DOCUMENT

This document contains the report of the FAO Expert Consultation on the Trade Impact of *Listeria* in Fish Products. The Consultation which brought together 21 experts from 14 countries was held in Amherst, MA, USA, from 17 to 20 May 1999 to review the data available, assess the risk associated with the contamination of fish products with *Listeria*, and evaluate its impact on international trade of fish products. The Consultation was organized jointly by the Fishery Industries Division and the Food and Nutrition Division of FAO, and hosted by the Department of Food Science of the University of Massachusetts in Amherst, MA, USA. The Consultation was funded by the Regular Programme of FAO (Fishery Industries Division and the Food and Nutrition Division) and by the FAO/DANIDA Inter-regional Training Project on Fish Technology and Quality Assurance GCP/INT/609/DEN.

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ABSTRACT

The globalization and growth of international trade in fish and fishery products in recent years has made these products one of the most important items traded in terms of value. Concerns regarding the safety of these products has prompted the emergence of a number of new regulations such as a zero-tolerance policy for *Listeria monocytogenes* in fishery products or the use of a risk based approach to establish maximum limits for *Listeria* in these products. The paper describes the findings of the FAO Expert Consultation on the Trade Impact of *Listeria* in Fish Products, held in the University of Massachusetts, Amherst, USA from 17 to 20 May 1999. It documents the current scientific knowledge regarding the risks of listeriosis in relation to fishery products, discusses current regulations and their impact on trade and provides guidelines for the prevention and control of *Listeria* in these products.

CONTENTS

	<i>Page</i>
1. INTRODUCTION	1
2. BACKGROUND	2
3. OBJECTIVES	3
4. RISK ASSESSMENT	3
4.1 Statement of purpose	3
4.2 Hazard identification	3
4.3 Exposure assessment	4
4.3.1 Geographical distribution	4
4.3.2 Prevalence of <i>L. monocytogenes</i> in fish and fishery products.....	4
4.3.3 Growth and survival of <i>L. monocytogenes</i>	5
4.4 Hazard characterization	7
4.4.1 Epidemiological patterns of listeriosis	7
4.4.2 Dose response	7
4.5 Risk characterization	8
5. REGULATION AND TRADE	9
5.1 Introduction	9
5.2 Impact of <i>L. monocytogenes</i> on trade	10
5.3 Microbiological criteria	12
5.4 Recommendations for establishing criteria	13
6. PREVENTION AND CONTROL OF <i>L. MONOCYTOGENES</i> IN FISHERY PRODUCTS	14
6.1 Introduction	14
6.2 Control measures to reduce or eliminate <i>L. monocytogenes</i> from the processing environment	16
6.2.1 Risk factors and hot spots of contamination	16
6.2.2 The effects of various processing parameters on the survival of <i>L. monocytogenes</i>	17

6.3	Control strategies	17
6.3.1	Raw materials	17
6.3.2	Processing environment	18
6.3.3	Retail trade	18
7.	GAPS IN CURRENT KNOWLEDGE ON THE INCIDENCE OF <i>L. MONOCYTOGENES</i> IN FISHERY PRODUCTS	18
8.	RECOMMENDATIONS	19
ANNEX I	- List of Participants	21
ANNEX II	- List of Background Papers	23
ANNEX III	- Control Guidelines	24

1. INTRODUCTION

The Food and Agriculture Organization of the United Nations (FAO) convened an Expert Consultation on the Trade Impact of *Listeria* in Fish Products through the joint efforts of its Fishery Industries Division and Food and Nutrition Division and the Department of Food Science of the University of Massachusetts. The Consultation was held at the Lincoln Campus Centre, University of Massachusetts, Amherst, USA from 17 to 20 May 1999. The list of participants is presented in Annex I.

Ms. Maria de Lourdes Costarrica, Senior Officer, Food Quality Liaison Group, Food and Nutrition Division, FAO opened the Expert Consultation and welcomed the participants. Prof. Fergus Clydesdale, Head, Department of Food Science, University of Massachusetts welcomed the participants to the University and to Amherst and wished them success in the week ahead.

Dr. Grimur Valdimarsson, Director, Fishery Industries Division, FAO thanked the participants on behalf of the Director-General of FAO for accepting the invitation to attend the consultation and for placing their valuable time and expertise at the disposal of FAO. He also thanked Prof. Clydesdale and his staff at the University of Massachusetts for hosting the Consultation.

Dr. Valdimarsson stated that there has been a dramatic increase in world trade of fish and fishery products over the last 10 years, particularly in developing countries. These countries have increased their net income for fish and fishery products from about US\$ 3 billion to some US\$ 18 billion over this period. This amounts to more than their combined income from exports of tea, coffee, meat and bananas. Currently developing countries provide about 50% of all fish and fishery products entering the global market. In recent years the global community has also been seeking a common approach for maximizing the quality and safety of all food products. This includes the use of the Hazard Analysis and Critical Control Point (HACCP) approach as a means of assuring proper food handling, processing and marketing and minimizing the risk to the consumer from foodborne infections and intoxications.

The Uruguay Round of Multilateral Negotiations included a number of Agreements which have direct implications for trade in fish and fishery products and apply to Members of the World Trade Organization (WTO). These include the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement). Article 5 of the SPS Agreement requires that WTO Members ensure that their sanitary and phytosanitary measures are based on an assessment of the risks to human, animal or plant life or health, and in doing so to take into account risk assessment techniques developed by the relevant international organizations. The development of risk assessment techniques as a means of evaluating the risks associated with microbiological hazards is viewed as a priority by the Codex Alimentarius Commission (CAC) and by FAO. In recent years FAO has convened a series of international meetings on risk assessment, risk management, risk communication and risk analysis. The "Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment" have been advanced to Step 8 by the Codex Committee on Food Hygiene for adoption by the Codex Alimentarius Commission in June 1999.

Dr. Valdimarsson pointed out that there is always some risk associated with the consumption of food. These risks vary from one food to another and from one processing method to another. He also indicated that it is important that the experts in this area convey this message to the policy-makers and the public. This is of particular importance in the case of *Listeria monocytogenes*, a ubiquitous microorganism that may cause serious illness. Applying a strict zero-tolerance policy for this organism would effectively put a number of products out of the market, such as pre-cooked shrimp and smoked fish. He further pointed out that this meeting would discuss how these important issues could be dealt with.

In closing Dr. Valdimarsson reminded the experts that their participation in this consultation was to be in their personal capacities as international experts in the subject area and not as representatives of their governments, institutes or other organizations. He acknowledged that the participants had already done a great deal of preparation prior to the consultation and would be asked to work many additional hours in the days ahead in order to produce a report of their discussions prior to their departure from Amherst.

The consultation elected Prof. Herbert O. Hultin, Department of Food Science and Director of the Gloucester Marine Station, University of Massachusetts as Chairperson. Dr. Jeffrey Farber, Research Scientist and Head of Microbiology Research Division, Health Canada agreed to serve as Vice-Chairperson and Mr. Alan Reilly, Director, Operations Division, Food Safety Authority of Ireland agreed to serve as Rapporteur. The deliberations of the consultation were based on a number of background papers (listed in Annex II).

2. BACKGROUND

The rules that govern international trade are those agreed on during the Uruguay Round of Multilateral Trade negotiations and apply to Members of the WTO. With respect to food safety matters, those rules are set out in the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The overall objective of the SPS Agreement is to permit countries to take legitimate measures to protect the life and health of their consumers while prohibiting them from using measures in a way that unjustifiably restrict trade. Thus, the primary role of the SPS Agreement is to limit the use of any measures that may restrict trade to those that are justified and necessary to provide the appropriate level of health protection.

In the case of human health, the standards, guidelines and other recommendations of the Codex Alimentarius Commission (CAC) are considered by the WTO to reflect the international consensus regarding the requirements for protecting human health. When there are no specific international standards, sanitary and phytosanitary measures may be introduced provided there is a scientific justification based on a risk assessment appropriate to the circumstances and transparency and consistency are maintained. The same provisions apply if Members introduce measures to protect human health that provide a higher level of protection than would be achieved by international standards, guidelines and recommendations. As for most other foodborne pathogenic bacteria, no international specific standards or recommendations exist for *L. monocytogenes*.

The globalization and growth of international trade in fish and fishery products in recent years has made these products one of the most important items traded in terms of value. This situation has prompted the emergence of a number of new regulations based on perceived or real concerns about the possible distribution of microorganisms or their toxins that could affect the health of consumers.

L. monocytogenes, and other *Listeria* species, have been isolated from fishery products on a regular basis since the late nineteen eighties. However, the available data indicates wide differences in the geographic distribution or prevalence in different types of products. Its relatively high incidence in ready-to-eat and heat-treated fishery products has raised concerns about the survival and growth potential of the organism in such products, as they are not processed further before consumption. *L. monocytogenes* has not been associated with a large outbreak of listeriosis due to the consumption of contaminated fishery products. However, at least three sporadic documented cases have been reported in the early nineteen nineties and more recently, “gravad” trout and smoked trout have been linked to a small outbreak of listeriosis.

Several countries have a zero-tolerance policy for *L. monocytogenes* in foods, including fishery products. This can be applied to all foods or only high-risk food items that support growth of the organism. It can also be applied to foods with a history of being implicated in listeriosis outbreaks. Following several product recalls it appears that the presence of *L. monocytogenes* in fish and fishery products may have severe economic consequences for producers. Considering the current knowledge

of *Listeria* and listeriosis, a zero-tolerance policy for all ready-to-eat fishery products may be overly conservative relative to providing an adequate level of public health protection. Zero-tolerance policies for products that do not undergo any listericidal process steps seem to be in contradiction with new modern regulations for fishery products. These regulations are all based on the use of HACCP principles which recommend the use of risk assessment in identifying and controlling hazards, thus establishing maximum limits rather than zero-tolerance. In recent years, other countries have acknowledged this and have introduced regulations allowing maximum limits on the content of *L. monocytogenes* in foods. The range of these limits varies between 10 colony forming units (cfu)g⁻¹, to 100 cfu g⁻¹ or 1000 cfu g⁻¹ depending on the products, their risk category and time of consumption. However, in the case of *Listeria* contamination of fish, there is still need for a more complete assessment of the risk and the implications on international fish trade. The present consultation addressed these points.

3. OBJECTIVES

The objectives of the consultation were:

- To contribute to the development and application of risk assessment:
 - Examine the current scientific knowledge concerning *L. monocytogenes* in fish and fishery products;
 - Identify incidence, survival and growth patterns concerning *L. monocytogenes* in different fishery products and its geographical distribution.
- To discuss the impact and suitability of existing regulations relating to *Listeria* in fish and fishery products and to make recommendations for the development of risk-based policies;
- To discuss the impact *Listeria* contamination of fish and fishery products has on trade and to recommend measures to prevent/control contamination;
- To identify gaps in the current knowledge relating to *L. monocytogenes* in fish and fishery products

4. RISK ASSESSMENT

4.1 Statement of purpose

The purpose of this section is to document current scientific knowledge concerning the risks of listeriosis in relation to fishery products, in order to enable identification of risk contributing and risk mitigating factors for facilitating risk management decisions. While the risk assessment includes some quantitative information, the time frame of the Consultation did not permit a quantification of the risks of listeriosis associated with fishery products.

4.2 Hazard identification

L. monocytogenes is the sole hazard of interest in this assessment.

L. monocytogenes is a bacterial pathogen causing serious human illness such as perinatal infections, septicaemia and meningitis. More recently, a new form of disease caused by *L. monocytogenes* has been recognized involving mild gastrointestinal symptoms. Although listeriosis occurs infrequently, at an annual incidence rate of 2 to 10 cases per million, the fatality rate is high, usually in the range of 20-30%. Highly susceptible individuals include pregnant women, neonates, elderly people and immunocompromised individuals. This last group includes, in decreasing order of risk, organ-transplant recipients, patients with AIDS, HIV-infected patients and patients with cancer. We are likely to see an increase in the incidence of listeriosis as the numbers of susceptible individuals and vulnerable groups increase over the next decades.

Although other routes of transmission have been described, indistinguishable strains have been isolated from epidemic cases and from the food implicated, clearly identifying the role of food in the epidemiology of listeriosis. Foods associated with transmission are characteristically highly processed, have extended shelf lives at refrigeration temperatures, are capable of supporting the growth of *L. monocytogenes* and are consumed without further cooking. Although some strains of *L. monocytogenes* are more frequently associated with human diseases, at this time, all strains must be considered to be potentially pathogenic.

4.3 Exposure assessment

4.3.1 Geographical distribution

Listeriosis is mainly reported in industrialized countries with few or no reports from Africa, Asia and Latin America. It is not known whether this reflects different exposure rates, consumption patterns, dietary habits, host susceptibility, or lack of testing facilities in different regions.

4.3.2 Prevalence of *L. monocytogenes* in fish and fishery products

4.3.2.1 Water and raw fish

Unpolluted seawater and ground waters used in aquaculture are generally free from this organism, and fish from these environments are uncontaminated. In temperate regions, the organism has been isolated from surface waters and lakes, and in coastal waters subject to pollution or contamination from industrial, human or animal sources. When *L. monocytogenes* is present in fish from these environments it is usually present in very low numbers. In tropical regions, the reported incidence of *L. monocytogenes* is very low and freshly harvested fish from these environments are generally free of this pathogen.

Different strains of *L. monocytogenes* may be isolated from fish raw material and from final products suggesting that fish can be contaminated at any point between harvest and consumption. In particular, *L. monocytogenes* can colonize the processing environment and this has been established as a primary mechanism of contamination for some products.

4.3.2.2 Cold smoked fish

Cold smoked fish is produced by filleting raw fish which is subsequently salted (3.0-3.5% NaCl in water phase), dried and smoked at a temperature < 30°C. The fish is then usually sliced and vacuum packaged. It should be stored at a temperature ≤ 5°C, and under these conditions has a recommended shelf-life of 3 to 6 weeks. Several surveys reveal that 10-60% of freshly processed cold smoked salmon is contaminated with *L. monocytogenes*. The contamination level is usually ≤ 100 cfu g⁻¹. A similar contamination rate has also been observed on other lightly preserved fish and fishery products that are processed without a listericidal step. During storage for 2 to 3 weeks at 5°C *L. monocytogenes* may increase in numbers but it is difficult to predict the magnitude of increase. Uncontrollable factors including the physiological state of the organism and the presence and type of microflora on the product will affect the potential for growth of *L. monocytogenes*.

The processing environment contributes to the presence of *L. monocytogenes* in cold smoked fish. *L. monocytogenes* can become established on processing surfaces and may be very difficult to detect and to remove. After production, time and temperature of storage are the most important factors that determine outgrowth. Survey data suggest that levels rarely exceed 10³ cfu g⁻¹ at the time of consumption.

4.3.2.3 Cooked fishery products

L. monocytogenes has been recovered from a range of ready-to-eat fishery products, such as cooked shrimps and cooked crabmeat. The rate of contamination of cooked ready-to-eat products varies. For example, less than 1% of ready-to-eat fishery products imported into Canada during 1996/98 were contaminated with *L. monocytogenes* while pooled data from 6 other published reports (involving 6

countries, 498 samples) on ready-to-eat cooked shrimp indicated a contamination rate of about 4.8%. This indicates post-process contamination, as *L. monocytogenes* should be reduced to undetectable levels by cooking. When cooked products are stored at chill temperatures (i.e. < 5°C) for extended periods, the potential for growth of *L. monocytogenes* will be less restricted because of the absence of competitive flora.

4.3.3 Growth and survival of *L. monocytogenes*

4.3.3.1 Growth potential

The major factors controlling the fate of microbial populations in fish and fishery products are temperature, water activity and pH. Specific organic acids, and many preservative compounds, may also play an important role in reducing microbial growth in fishery products. Thus, the potential for growth of *Listeria* in fishery products is related to the product composition, type and intended end use. Some examples are shown below.

Products with the potential to contain high levels of *L. monocytogenes* at the time of consumption

Lightly preserved fish products (pH >5.0, NaCl < 8.0%), including:

- lightly salted
- cold smoked
- “gravad”
- marinated
- fermented
- caviar

Heat-treated, before packaging:

- hot smoked fish
- cooked shrimp
- reconstituted fish protein products

Products unlikely to contain high levels of *L. monocytogenes* at the time of consumption

- products receiving a listericidal treatment
 - products cooked before consumption (fresh, frozen fish)
 - sterilized canned products
- short shelf-life products to be eaten raw
- semi-preserved products not supporting *Listeria* growth (pH ≤ 5.0 and/or NaCl ≥ 8%)

The growth limits of *L. monocytogenes* are summarized in Table 1.

The tolerance to a particular environmental constraint is greatest when all other conditions are optimal for growth. For *L. monocytogenes*, growth is maximal when temperature is in the range 20 – 25°C, although the growth rate is fastest at ~37°C. When several factors are sub-optimal for growth, the growth permitting ranges of each of those factors will be reduced. Thus, growth at the lowest pH or water activity will only occur when all other conditions are optimal. This behaviour has been embodied in the “Hurdle Concept¹” and is reflected in the product categories presented earlier in this section.

¹ Hurdle concept: term employed when foods are preserved by a combination of parameters (e.g. temperature, pH, water activity, etc.) that often have a synergistic effect.

There are exceptions to this general trend, e.g. while slightly elevated salt concentration may inhibit growth rate, it may at the same time increase tolerance to high temperature of many bacterial species.

Table 1: Growth limits for *L. monocytogenes*

Environmental Factor	Lower Limit	Upper Limit
Temperature (°C)	-0.3 to + 3	~ 45
Salt (% NaCl, water phase)	< 0.5	12-13
Water activity (a _w)*	0.91 – 0.93	> 0.997
pH (HCl as acidulant)	4.2 – 4.3	9.4 – 9.5
Lactic acid (water phase)	0	3.8 – 4.6 mM, MIC of undissociated acid (800 – 1000 mM, MIC of sodium lactate)

* values for NaCl as the humectant

4.3.3.2 Growth rates

The physico-chemical attributes of many fish and fishery products will permit the growth of *L. monocytogenes*. Some representative growth rates for conditions relevant to these products are shown in Table 2.

Table 2: Representative maximum growth rates of *L. monocytogenes* predicted by a mathematical model

Generation time (hours)			
Temperature (°C)	pH 7.0, a _w 0.990	90 mM total lactate, pH 6.2, a _w : 0.990	90 mM total lactate, pH 6.2, a _w : 0.965
25	0.8	1.0	1.6
10	6	7	11
7	13	15	24
5	29	33	53
0	620	730	1150

As discussed earlier, it is recognized that other factors may affect potential for growth of *L. monocytogenes* in foods. Also, *L. monocytogenes* is known to be sensitive to quaternary ammonium compounds, chlorine and sanitizers containing peracetic acid and peroctanoic acid. Irradiation can effectively reduce *L. monocytogenes* to undetectable levels in products. Due to all these factors, the presently available predictive models for growth are unable to make accurate predictions. Accurate prediction of growth is a necessary tool for a proper risk assessment.

4.4 Hazard characterization

4.4.1 Epidemiological patterns of listeriosis

The epidemiological pattern of human listeriosis is a background of sporadic cases with occasional outbreaks. A decrease in the number of sporadic cases has been observed during the last ten years in the UK, USA and France. While several reports indicate that fish and fishery products can be frequently contaminated with *L. monocytogenes*, no major outbreaks associated with these products have been reported. This may be due to inadequate surveillance systems in several countries or because not all factors contributing to both sporadic cases and outbreaks associated with fisheries products have been identified. A low number of cases (Table 3) have been linked to fish associated listeriosis outbreaks when compared to listeriosis outbreaks associated with other foods.

Invasive listeriosis includes perinatal infections, central nervous system infections and bacteremia. Neurologic sequelae have been observed in 30% of patients with central nervous system infections. Ninety per cent of cases occur in populations with impaired immunity. The incubation period ranges from 1 to 90 days, with a mean of 3 to 4 weeks. This variability may reflect variation in the number of cells ingested, differences in host susceptibility, or differences in virulence of the strains. Excepting nosocomial infections, person-to-person transmission has not yet been firmly documented during food-borne community acquired outbreaks. The role of healthy carriers (4 - 6% of the healthy population) in the epidemiology of listeriosis warrants further studies.

Table 3: Main documented cases of foodborne listeriosis associated with fish and fishery products

Location / year	No. cases	Clinical forms ¹	No. deaths	Food	No. cfu g ⁻¹	Strain serovar
USA- 1989	2 ²	2 ²	0	Shrimp	NK	4b
Italy – 1989	1	0/1	0	Fish	NK	4b
Australia – 1991	2	0/2	0	Smoked mussels	1 x 10 ⁷	NK
New-Zealand 1992	4	4/0	0	Smoked mussels	NK	1/2b
Canada – 1996	2	0/2	NK	Imitation crab meat	2 x 10 ⁹	1/2b
Sweden – 1994/95	8	3/8	2	“gravad”/cold smoked rainbow trout	<100-6200	4b

¹: no. of pregnancy related cases / no. of non-pregnancy related cases;

²: not known if this was the total number of cases

NK: not known

4.4.2 Dose response

The dose response relationship of *L. monocytogenes* for humans is not known. In general, the infectious dose of a foodborne pathogen depends on a number of variables including the condition of the host, the virulence of the strain, the type and amount of food consumed, and the concentration of the pathogen in the food. Animal studies suggest that reducing levels of exposure will reduce clinical disease. From the reported numbers of *Listeria* in contaminated food responsible for epidemic and sporadic foodborne cases, there is little evidence that a very low number of *L. monocytogenes* in food causes listeriosis. In a number of outbreaks, enumeration of units of implicated foods indicated both high (> 1,000 cfu g⁻¹) and low levels (< 100 cfu g⁻¹) of contamination. Some of these data related to fish and fishery products are summarized in Table 3. High levels of *L. monocytogenes*

(10^3 – 10^7 cfu gr¹) have been detected in soft cheeses involved in 5 outbreaks. These facts, together with data on the recovery of the organism from implicated foods suggest the likelihood that high infective doses are involved in most cases.

4.5 Risk characterization

From the foregoing discussion, it is clear that ready-to-eat fishery products frequently contain *L. monocytogenes*. The level of contamination at the time of consumption cannot be calculated with confidence. Usually low levels are found and it is known that levels of ~10 – 100 cfu g⁻¹ may occur infrequently at the time of manufacture of cold smoked salmon. In cooked products, lower levels of contamination occur. Growth of *L. monocytogenes* on these products can be demonstrated, although growth is slow under proper storage conditions. Calculations suggest that *per capita* human exposure to doses of *L. monocytogenes* exceeding 1,000 cfu (total ingested dose) is likely to occur several times each year. Despite this exposure, the total incidence of invasive listeriosis is estimated to be 2-10 per million population per annum in countries where data are available.

Listeriosis outbreaks may extend over many months or years, and with low attack rates. The incubation period is usually of the order of 3–4 weeks, but may extend to over three months. These factors combine to make outbreaks difficult to recognize and to investigate. The severity of consequences of listeriosis is high, with 20 - 30% case-fatality rates.

Recognizing the potential for fishery products to be a vehicle for large outbreaks of listeriosis, it is prudent to seek appropriate strategies to minimize human exposure to infectious doses of the organism. Currently, however, there is insufficient data for the dose-response relationship to be determined, but there is growing consensus that the majority of the healthy population is highly resistant to doses in the order of 1,000 to 10,000 cfu *L. monocytogenes*. There is no consensus on the dose required to cause illness in susceptible individuals. However, using the available epidemiological data, and consumption patterns, crude estimates of the risk of listeriosis from fishery products can be made.

Regarding fish and fishery products, the dose-response has been estimated elsewhere combining data on the incidence of listeriosis in Germany with data on the levels of *L. monocytogenes* in smoked-fish in that country. It was necessary to make many assumptions, but all were chosen to result in conservative estimates. Epidemiological and food survey data were combined, using a predictive modelling approach, to estimate a dose-response relationship for *L. monocytogenes* levels and incidence of listeriosis. Two methods were used to model and calculate the dose-response relationship. Both methods gave a similar result. Using that approach, for the estimated immunocompromised sub-population of Germany (20% of the population), the model predicts a 1 in 59 million chance of infection from consumption of a 50g serving of fish containing 100 bacteria per gram.

It must be emphasized that this estimate rests on many assumptions. Nevertheless, when extrapolated across the population and the number of salmon meals consumed per year, the estimate reflects the low incidence of listeriosis in those nations where epidemiological data are available. The above estimate, is of the same order of magnitude as the reported per annum incidence of listeriosis.

Thus, despite the fact that there is considerable potential for fish and fishery products to cause listeriosis, the available data indicate that this potential has not been observed. There is little epidemiological evidence to implicate fishery products in large outbreaks. The reasons for this are unknown.

5. REGULATION AND TRADE

5.1 Introduction

The rules that govern international trade are those agreed on during the Uruguay Round of Multilateral Trade negotiations and apply to Members of the WTO. With respect to food safety matters, those rules are set out in the SPS Agreement. The overall objective of the SPS Agreement is to permit Member Countries to take legitimate measures to protect the life and health of their consumers. Sanitary and phytosanitary measures shall not be applied in a manner that would constitute a disguised restriction on international trade.

The SPS Agreement establishes a two-tier test of whether a country's regulation of a food safety issue, such as *L. monocytogenes* contamination of fishery products, is legitimate or is an illegitimate non-tariff trade barrier. The sequence of evaluation for an SPS regulatory measure under the WTO progresses from a science to a policy level test. The questions asked are:

Is the SPS measure based on an internationally accepted standard?

Failing this, has the country supplied a valid risk assessment to defend its selection of the regulatory measure?

Finally, are there alternative methods of implementation that have a lesser trade effect while achieving the same level of protection ?

The ordering of the two levels is important, as a risk assessment (science level) needs to lead any policy discussion and selection among risk management and communication strategies. The SPS Agreement encourages harmonization through adoption by countries of internationally recognized standards. In addition, the agreement requires that a country accepts the sanitary and phytosanitary measures of another country as equivalent, even when they differ from their own, if the exporting country objectively demonstrates that its measures achieves the importing countries appropriate level of protection.

International trade of fishery products undergoes verification of a safety assurance system and/or port-of-entry inspection. In the case of listeriosis prevention, like for other food safety hazards, it is well recognized that implementation of safety assurance such as Good Hygiene Practices (GHP) and HACCP systems are the most efficient and reliable approaches to ensure safety. However, if records demonstrating the application of HACCP-based safety systems are not available, the alternative is inspection at the port-of-entry.

Differences in criteria and policies among countries stress the urgent need for harmonization of the criteria, including sampling plans, sample size, and methodology. In this respect, the CAC encourages harmonization of food standards based on risk assessment. For example, the "Recommended International Code of Practice-General Principles of Food Hygiene", includes provisions for GHP and for the incorporation of HACCP or other equivalent food safety assurance systems based on risk assessment principles. There is also a need for the harmonization of guidelines for inspection and certification procedures in international trade. The Codex "Principles for Food Import and Export Inspection and Certification" recommends government to government assurance that basic quality standards, including those for food safety, are met. The Codex Committee on Food Import and Export Inspection and Certification Systems has developed "Guidelines for the Design, Operation and Assessment and Accreditation of Food Import and Export Inspection and Certification Systems" which were adopted by the twenty-second Session of the Codex Alimentarius Commission in 1997. "Draft Guidelines for the Development of Equivalence Agreements regarding Food Import and Export Inspection and Certification Systems" have been advanced to Step 8 of the Codex elaboration procedure.

5.2 Impact of *L. monocytogenes* on trade

A comprehensive assessment of the impact of different standards for *L. monocytogenes* on trade of fish and fishery products is not available. However, preliminary studies provide some evidence of trade impact because of rejections or detentions of imported products. Published data suggest that some of these cases would not have occurred if standards were harmonized. Further analysis is needed before the impact of this pathogen on trade of fish and fishery products can be quantified.

Table 4 presents data on fishery products recalled from the market by some European Union countries because of contamination by *L. monocytogenes* between January 1998 and March 1999.

Table 4: Fish products removed from the EU market between January 1998 and March 1999 because of contamination by *L. monocytogenes*

Date	Product Description	Country of Origin	Notified by	Message
29 Jan 1998	Pollack	Germany	Austria	Consignments confiscated and press release issued. Presence in 25g.
29 Jan 1998	Salmon and Pollack	Germany	Austria	German Authorities confiscated consignment and issued press release. Presence in 25g.
23 Feb 1998	Smoked Coalfish in oil	Germany	Austria	Consignments detained.
11 Mar 1998	Chilled smoked Salmon morsels	Denmark	Austria	Best before 23/07/98.
09 Apr 1998	Frozen cod fillets	China	France	Consignment has been detained.
09 Apr 1998	Smoked salmon	Norway	Austria	Best before 22/07/98.
09 Apr 1998	Smoked salmon and Coalfish	Germany	Austria	Consignment has been detained.
11 Jun 1998	Smoked salmon	Scotland	Italy	The volume of product that was still with the importer was seized.
29 Jan 1999	Salmon and Pollack	Germany/ Denmark	Austria	*
29 Jan 1999	Smoked salmon and Pollack	Germany	Austria	*
29 Jan 1999	Salmon and Pollack	Germany	Austria	*
05 Feb 1999	Smoked salmon	Germany/ Denmark	Austria	*
05 Feb 1999	Smoked salmon and salmon	Germany/ Denmark	Austria	*
12 Feb 1999	Salmon and Pollack	Germany	Austria	*
12 Feb 1999	Smoked salmon	Germany	Austria	*
29 Mar 1999	Smoked salmon	Germany/ Denmark	Austria	*

* The Austrian authorities seized the distributed product. The press was informed. *Listeria* present in 25g
Source: Food Alerts in the EU January 1998-March 1999

The USFDA has taken strong action against many processors due to the presence of *L. monocytogenes*. Since 1985, Class I recalls have been imposed on ready-to-eat foods contaminated with *L. monocytogenes*, including cheeses, ice-cream, milk, fish, prepared salads, sandwiches, crab meat, smoked fish, and bakery products. From 1987 to 1992, there were recalls on 970 ready-to-eat products from 109 firms because of contamination with this organism. Between 1987 and August 1998 there were 112 Class I recalls for domestic or imported ready-to-eat seafood products (Table 5).

Table 5: US Class I recalls issued in the United States for domestic and domestic/imported ready-to-eat seafood products contaminated with *L. monocytogenes* since 1987

Product	No. of Class I recalls since 1987	Pounds affected	Location of manufacturer
Crustacean			
Crab	46	>141,197	USA (Alabama, Florida, Georgia, Maine, North Carolina, Oregon, Texas, Virginia, Washington), Chile, Mexico
Shrimp	7	>31,332	USA (Florida, Georgia, Massachusetts, New York, Washington)
Lobster	2	>264	Canada
Shellfish			
Mussels (marinated)	1	Unknown	USA (Massachusetts)
Mussels (smoked)	2	Unknown	New Zealand
Snails	1	1455	USA (Colorado, Florida, Georgia, Illinois, Louisiana, New Hampshire, New Jersey, New York, Oregon, Pennsylvania, Texas, Washington)
Fin Fish			
Hot smoked	6	>253	USA (Kentucky, Maryland, Maine, New York, Washington, California)
Cold smoked	22	>93,722	USA (Massachusetts, Maine, New Jersey, New York, Oregon, Washington), United Kingdom
Smoked*	16	>9,292	USA (California, Florida, Illinois, Maryland, Maine, North Carolina, New York, South Carolina, Tennessee, Virginia, Washington)
Salted	1	Unknown	Canada
Other			
Imitation seafood	5	>1773	USA (Idaho, Nevada, Oregon, Utah, Virginia, Wyoming), Japan, Korea
Seafood salad or spread	3	>42	USA (Florida, Maine, Washington)

* Hot or cold smoking process not identified.

Data compiled from FDA Enforcement Reports

Source: Adapted from Jinneman, K.C., Wekell, W.W. and Eklund, M.W. 1999. Incidence and behaviour of *Listeria monocytogenes* in Fish and Seafood, p 601-630. In Ryser, E.T. and Marth, E.H., eds., *Listeria, Listeriosis and Food Safety*, 2nd edition, Marcel Dekker, Inc. New York.

Out of 323 samples of imported products analyzed by the Canadian Food Inspection Agency in 1997 and 1998, one sample of cooked shrimp was rejected due to the presence of *Listeria* (Table 6).

In addition to the direct costs of rejections and detentions, there are additional economic costs that result from inspection/re-inspection at port-of-entry, delays in distribution, transportation, expiry of shelf-life, and the opportunity cost of holding products.

Table 6: Imported fishery products inspected in Canada for the presence of *L. monocytogenes* in 1997-98

	Chile	China	Korea	India	Japan	France	Thailand	USA	Other	Total
Kamboko					2		1	153	2	158
Shrimp Cooked	2			2			40	30 ^a	5	79
Crab Cooked	1		5					29	2	37
Salmon Smoked								6	2	8
Pâté								2		2
Eel Cooked		2								2
Clam Cooked		3								3
Mussels Smoked								1		1
FISH					1			1		2
Cod Smoked		1								1
Trout Smoked								2		2
OTHER	2	1	9		2	1			13	28
TOTAL	5	7	14	2	5	1	41	224	24	323 ^b

^a One of these samples contained *L. monocytogenes*.

^b The incidence of *L. monocytogenes* contamination in imported fishery products was 0.3% (1 positive out of 323 products tested).

Source: Data supplied by the Canadian Food Inspection Agency (CFIA) in Ottawa

5.3 Microbiological criteria

Currently there is no international agreement on ‘acceptable levels’ of *L. monocytogenes* in foods, including fishery products. In several countries, criteria or recommendations for tolerable levels of *L. monocytogenes* in ready-to-eat foods, have been established. Some countries like USA, Austria, Australia, New Zealand and Italy require absence of *L. monocytogenes* in 25 g of foods (referred to as zero-tolerance). Other European countries (e.g. Germany, Netherlands and France) have a tolerance of less than 100 cfu g⁻¹ at the point of consumption. Others (e.g. Canada and Denmark) have a tolerance of less than 100 cfu g⁻¹ for some foods and a zero-tolerance for other foods, especially those with extended shelf-lives that can support the growth of *L. monocytogenes*. In addition to differences in criteria for *L. monocytogenes*, several countries use different sampling plans and methodologies, which make matters more complex. Therefore, there is a need to harmonize microbiological criteria for *L. monocytogenes* in foods at international level, based on the principles of risk assessment.

While details on the policy on *L. monocytogenes* in all countries is not available, examples from some countries are discussed here.

The detectable presence of *L. monocytogenes* in ready-to-eat food is considered to be a hazard to health under current US FDA policy. The limit of sensitivity of the analytical method is actually 1 cfu per 25 g (0.04 cfu g⁻¹).

In Canada, foods have been placed into 3 categories, based upon health risk. Products in Category 1 have been causally linked to outbreaks of listeriosis and receive the highest priority in inspection and compliance activities. Currently, there are no fishery products included in this category. Category 2 contains all other ready-to-eat foods which are capable of supporting growth of *L. monocytogenes* and have a shelf-life exceeding 10 days (in this category the action level is absence in 25 g). Category 3 contains two types of ready-to-eat food products; those supporting growth with a < 10 day shelf-life and those not supporting growth. These products receive the lowest priority in terms of inspection and compliance action. For Category 3 ready-to-eat foods, factors such as the presence or absence of Good Manufacturing Practice (GMP), levels of *L. monocytogenes* in the food (action level of 100 cfu g⁻¹) and/or a health hazard evaluation are all considered in the compliance action taken.

In Denmark, ready-to-eat foods have been placed into six categories where absence of *L. monocytogenes* in 25 g is required in heat treated foods and in otherwise preserved, not heat treated foods that are capable of supporting growth within the shelf-life. This level is necessary in foods capable of supporting growth, in order not to exceed 100 *L. monocytogenes* per gram at the point of consumption. In heat treated and preserved foods that do not support growth within the shelf-life and for raw, ready-to-eat foods, a level below 10 *L. monocytogenes* g⁻¹ is regarded as acceptable, a level between 10 and 100 g⁻¹ is not satisfactory and a level above 100 g⁻¹ is not acceptable.

The International Commission for Microbiological Specifications for Foods (ICMSF) states that sampling of food for microbiological testing and the use of criteria are insufficient to ensure food safety. However, these tools are useful as part of the verification programme to ensure that the HACCP-plan is working. Thus, according to ICMSF, for:

- in-pack, heat-treated products – no testing is necessary (documentation for the heat-treatment process);
- raw products and/or products which are to be heat-treated before consumption – no testing is necessary;
- ready-to-eat products, unable to support growth of *L. monocytogenes* – 10 samples should be taken and the lot should be rejected if any sample contain > 100 *L. monocytogenes* g⁻¹;
- ready-to-eat products, able to support growth of *L. monocytogenes* – 20 samples should be taken and the lot rejected if any sample contains > 100 *L. monocytogenes* g⁻¹.

More recently, international criteria for *L. monocytogenes* have been discussed by a Working Group of the Codex Committee for Food Hygiene. This Working Group agreed to propose to the Codex Committee on Food Hygiene to recognize that numbers of *L. monocytogenes* not exceeding 100 g⁻¹ in food at the time of consumption is of low risk to the consumer. Furthermore, with respect to imported foods, it agreed to recommend that lower levels may need to be applied at the port-of-entry for foods that support the growth of *L. monocytogenes*, in order not to exceed 100 cfu g⁻¹ at the point of consumption.

5.4 Recommendations for establishing criteria

Microbiological testing of products does not ensure food safety. Food safety is only improved through efficient implementation of GMP and HACCP systems, including prerequisite programmes. Microbiological criteria may be used to help producers in applying HACCP. Microbiological criteria may also be applied when the history of a food product is unknown or when documentation for efficient and adequate application of HACCP is not available. Sampling plans should be developed taking into account the risk level of each product.

The regulatory policy for *L. monocytogenes* in foods should be based on principles of HACCP and those measures necessary to achieve an appropriate level of public health protection as determined by risk assessment approaches. The criteria for *L. monocytogenes* in foods should be applicable to ready-to-eat foods at all points during the product shelf-life. A risk assessment approach using current scientific knowledge was used to develop a proposal for a decision tree to assist the establishment of criteria for *L. monocytogenes* to be used in international trade (Figure 1).

Factors including freezing, pH, water activity, lactate and organic acids may be used to reduce the growth of *L. monocytogenes*, but in some cases it will be difficult to assess whether a food can support the growth of this bacterium within the stated shelf-life. In such cases, a conservative approach may be taken and growth regarded as possible, unless it can be documented that the product does not support growth. It is a responsibility of the manufacturer to provide the necessary documentation to show that the product can not support the growth of the organism. Such documentation might include challenge tests and/or shelf-life studies.

In order to be able to assess whether a product can support growth of *L. monocytogenes* within the stated shelf-life information about the actual length of shelf-life must be given by the manufacturer. Therefore, it is strongly recommended that the length of the shelf-life together with either the production date or the “use-by-date”, as well as recommended conditions for storage be stated on the package.

With the current technology used in the food industry it is possible that low numbers of *L. monocytogenes* can occur sporadically in a number of different fishery products, including cold smoked salmon. Therefore, it is recommended that these products should have a “use-by-date” such that at the end of product shelf-life *L. monocytogenes* numbers will be less than 100 cfu g⁻¹. Furthermore, health authorities should ensure that the stated shelf-life for ready-to-eat products that support the growth of *L. monocytogenes* are within safe limits and that highly susceptible individuals are informed and provided with guidelines about safe handling of food.

6. PREVENTION AND CONTROL OF *L. MONOCYTOGENES* IN FISHERY PRODUCTS

6.1 Introduction

Providing effective control of *L. monocytogenes* is challenging. The effective control of *L. monocytogenes* will be product, process and plant specific, therefore, these recommendations are presented as guidance. Not all the items listed below will apply to any particular operation, however, some will be useful in most situations.

Plant management should be committed to expending those resources that are necessary to address the problem. Employees must be trained to understand the problem, the potential sources of the organism, and the specific controls the plant is employing for *L. monocytogenes*. This may go far beyond normal training in GHP.

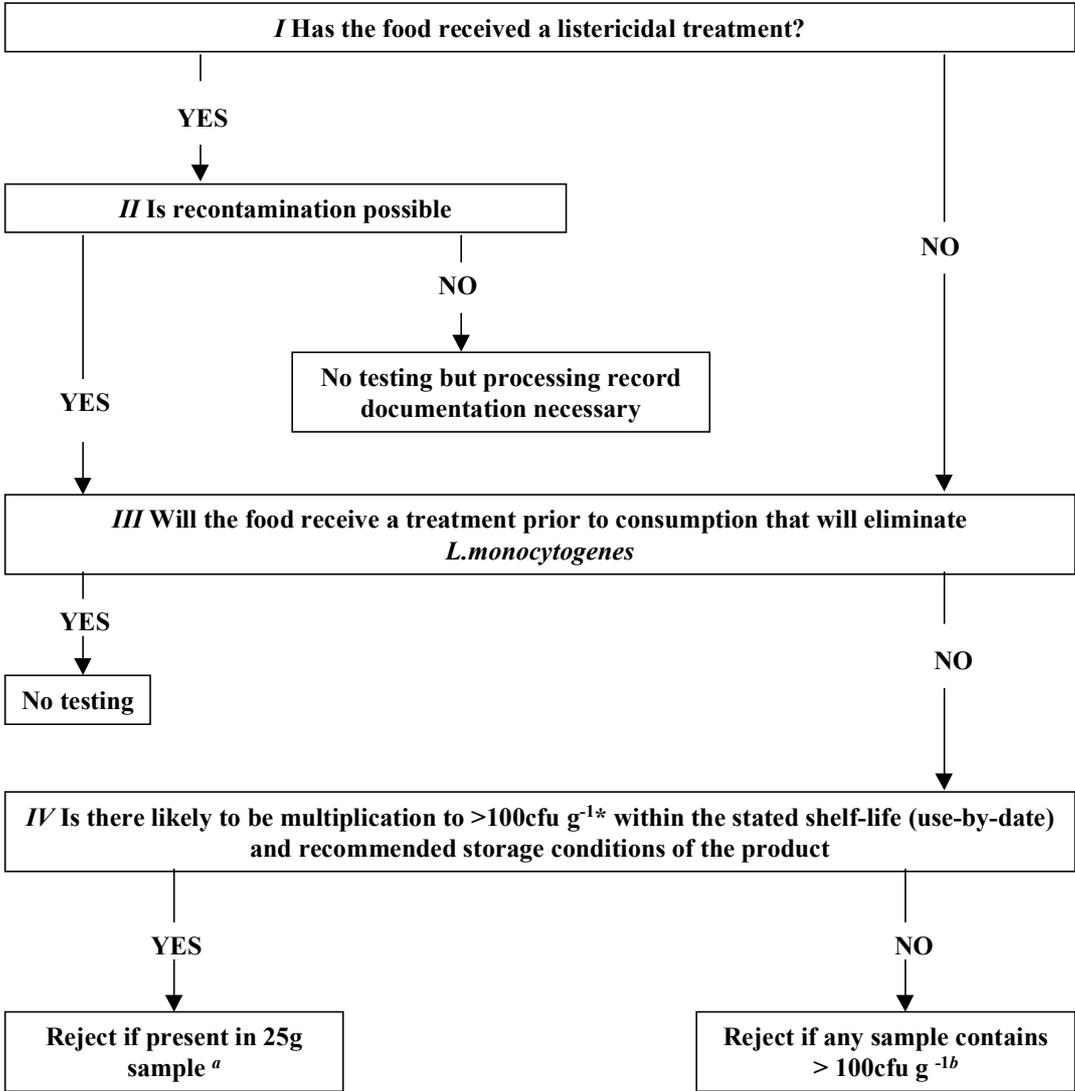
While most raw fishery products do not appear to be a significant source for *L. monocytogenes*, under certain conditions, these may become contaminated with the organism. In addition, the environment within processing plants will often contribute to the potential for contamination with *L. monocytogenes*. For cooked products, the plant should validate that the heat treatment is adequate to destroy *L. monocytogenes*. Once a cook step has been applied, the focus of a *Listeria* control programme will be on preventing recontamination of products that are subsequently handled or subjected to further processing, such as slicing or re-packaging. For those raw fishery products that have a low potential for contamination from the marine environment, most of the potential for contamination with *L. monocytogenes* occurs during product handling. Thus, minimization of contamination is recommended for these items as well as for cooked products.

These recommendations can also be applied to operations where there is no heat treatment to inactivate *L. monocytogenes*, but there is a need to minimize contamination of the product. These operations may include steps, for example washing, to remove the organism from the product. Control must focus, not only on reducing the numbers of *L. monocytogenes* on products by physical means, but also on preventing the establishment and growth of *L. monocytogenes* in the environment.

Because *L. monocytogenes* contamination can come from multiple sources, a comprehensive control programme may involve a combination of strategies that are compatible with HACCP and GHP.

To verify *L. monocytogenes* control, plants should implement an environmental monitoring programme for *Listeria* species. This programme, specific to the plant, should detail the areas to be sampled for *Listeria* species, the frequency of sampling, and the action to be taken when *Listeria* species is detected.

Figure 1: Proposed decision tree for the establishment of *L. monocytogenes* criteria in foods



^a Establish a new shelf-life considering storage conditions i.e. time/temp or a new process formulation

^b This numerical value should be revised based on further risk assessment

6.2. Control measures to reduce or eliminate *L. monocytogenes* from the processing environment

GHP and HACCP are essential in producing a safe food, and education and training can help producers and consumers apply safe handling practices. Inspection may provide evidence that the operations and practices used can consistently give a safe food while microbial testing can be used to indicate that GHP and HACCP have been effectively applied but it is recognized that sampling and testing of foods cannot guarantee their safety.

The ways in which *L. monocytogenes* may be introduced into fishery processing plants are numerous due to the ubiquitous nature of this bacterium. Raw marine fish does not appear to be a primary source for *L. monocytogenes* although slaughtered fish from colonized slaughterhouses may introduce the bacteria to a plant. Whatever the initial source of *L. monocytogenes* might be in each case, the main issue for the producer is to avoid colonization of the processing environment and subsequent spread to the product. This should be done by the systematic implementation of GHP and an effective HACCP programme.

Studies of smoked salmon production have identified control points for contamination with *L. monocytogenes*. By paying special attention to these points, including cleaning of in-process products, cleaning food-contact surfaces, separation of staff functions, personal hygiene and restriction on entry of visitors, the prevalence of *L. monocytogenes* in products and the processing environment was reduced in a number of plants. Including a heat treatment (hot steam, hot air, hot water at 80°C) in cleaning and sanitizing procedures at various control points (skinning-, slicing- and brining equipment) has been shown to be effective in controlling *L. monocytogenes* in fishery processing plants.

6.2.1 Risk factors and hot spots of contamination

Research has demonstrated that sanitation and clean-up procedures appear to eliminate *L. monocytogenes* from the processing line and equipment, but recontamination can occur soon after resumption of processing. It has been demonstrated that reservoirs of *L. monocytogenes* can easily be established in the processing plant. For example, in processing of smoked salmon, the brining process and the post-brining areas have been identified as the most contaminated sites. Using pulsed-field gel electrophoresis (PFGE) for typing the isolates, it has been demonstrated that the *L. monocytogenes* types on the final product were similar to those associated with brining and slicing but different from the types found on the raw material.

When production facilities were in a good state of repair, research has shown that high levels of job rotation is associated with the frequency of *L. monocytogenes* contamination. Also, cleaning of the production line once or more during daily production may be of benefit in lowering the risk for *L. monocytogenes* contamination. However, there is still some debate on this latter subject, as evidence gleaned from the meat and dairy industries suggest that mid-shift clean-ups can increase the level of contamination in the plant.

While research has assisted in understanding how and where products become contaminated with *L. monocytogenes*, a number of issues remain unsolved. For example, more understanding of the mechanisms by which *L. monocytogenes* adheres to product and processing equipment and how best to kill/remove adhered cells is required. By the application of good manufacturing and cleaning practices and by the appropriate selection of disinfectants for work surfaces or sterilization by heat of critical areas, a low level of initial contamination can be maintained. At present, it may be unrealistic to expect *Listeria*-free products even after application of the most stringent hygienic processing.

6.2.2 The effects of various processing parameters on the survival of *L. monocytogenes*

6.2.2.1 Smoking

Smoking is one of the oldest methods used to preserve fish. In most cases, salting or brining precedes the smoking process. Smoking impregnates the fish with volatile smoke compounds, which impart flavour and colour, as well as bacteriostatic and antioxidant characteristics. Smoking can either be carried out at relatively low temperatures, in which case the main effect of the smoking is to deposit flavours and preservative compounds onto the fish, or at higher temperatures leading to cooking or partial cooking and drying of the product.

Under natural cold-smoking conditions (< 30°C), the frequency and levels of *L. monocytogenes* seem to decrease, and smoking may thus help to reduce *L. monocytogenes*. Hot smoking (> 65°C), seems to eliminate *L. monocytogenes* when smoke is applied during the whole heating process. Because smoking conditions are not standardized, the effect of smoking on bacteria, and the inhibitory effect during storage, may vary for cold-smoked and hot-smoked fish from different producers. The prevention of recontamination of both cold-smoked and hot-smoked fish is therefore of great importance.

6.2.2.2 Chlorine/Organic acids

Elimination or reduction of *L. monocytogenes* on products has been attempted using washing with hyper-chlorinated water (200 ppm free chlorine). However, this method could not ensure a *L. monocytogenes* free product. Similarly, it has been shown that depending on dose and time of exposure, dipping or spraying foods with organic acids can reduce the levels of *L. monocytogenes*, but its complete elimination could not be obtained. In summary, in most cases, only a 1-2 log reduction in numbers of *L. monocytogenes* on fish can be obtained using these techniques.

6.2.2.3 Heat

The heat resistance of *L. monocytogenes* varies considerably with the intrinsic properties of the heating medium. D_{60} values of 1.95 - 1.98 min for cod fillets and 4.23 - 4.48 min for salmon fillets have been observed. This difference may be due to the higher lipid content in salmon compared to that of cod. It is well known that the heat resistance may also be influenced by factors such as pH, acidulant, NaCl content, growth temperature history and heat shock.

It is generally agreed that *L. monocytogenes* will be inactivated by proper pasteurization. Minimal heat-processing of foods, to no less than 70°C for 2 min at the coldest spot, would ensure the destruction (ca. 6 logs) of *L. monocytogenes*. In Australia, it is recommended that the heat applied to cook-chill products should be designed to achieve a 6-log reduction in the levels of *L. monocytogenes* based on a D_{70} value of 0.3 minutes and a z-value of 6°C. However, it is unclear at the present time as to what should be the target decimal reduction value for *L. monocytogenes* in fishery products.

6.2.2.4 Other parameters

New preservation techniques such as the development of protective bacterial cultures targeted to inhibit the growth of *L. monocytogenes* in fishery products are presently being developed. Other control measures that are being used on an experimental basis include irradiation either alone or in combination with modified-atmosphere packaging and high intensity UV light.

6.3 Control strategies

6.3.1 Raw materials

In general, *L. monocytogenes* is not usually found on fish captured from open waters, although contamination may take place long before the fish raw material reaches processing factories. Potential sources of *L. monocytogenes* on fishing vessels include contamination from water and ice, soiled surfaces and boxes, as well as contamination from human and avian sources. Since *L. monocytogenes* is commonly found in surface waters of lakes and in coastal waters, fish captured or cultivated in these

waters may possibly carry this organism. In addition, fish produced through aquaculture may come into contact with *L. monocytogenes* through contaminated feed, exposure to agricultural run-off or contaminated sediment in farming pens. However, there are strong indications that raw material is not currently a primary source for contamination of the final product with *L. monocytogenes*.

6.3.2 Processing environment

The emphasis of a control programme for *L. monocytogenes* should be on the more common sources of direct product contamination. The greatest risk for product contamination occurs when a product contact surface is contaminated. This risk is highest between the point where a food is cooked, pasteurized, or decontaminated and where the food is packaged. Annex III outlines several measures that can be applied to minimize the potential for contamination of fishery products with *L. monocytogenes* within the processing environment. Many of these should be considered for inclusion in a prerequisite programme. Some may also be useful in a HACCP programme. It is unlikely that any establishment will find utility in all of the items listed, however some of these suggestions should be useful in most operations.

6.3.3 Retail trade

Little is known of the potential for *Listeria* contamination of fish and fish products at the retail level. Products that are purchased in bulk and re-packaged prior to sale may be vulnerable to *L. monocytogenes* contamination. Establishments should consider that contamination may occur from any food contact surface as well as from secondary contamination sites such as floors, drains, ceilings, walls or equipment support structures (See Annex III). Retailers should be made aware of the risks that can arise from contamination of foods with *L. monocytogenes* so that appropriate measures can be instituted. Environmental sampling would not be practical or cost effective at the retail level, but diligent enforcement of sanitary conditions of food contact surfaces and handling areas, and personal hygiene practices should reduce the potential of contamination of fishery products by *L. monocytogenes* at the retail level.

If *L. monocytogenes* is present in a ready-to-eat fish product, the safety, as well as the quality is dependent upon the time and conditions of storage and display for sale. If storage temperatures fluctuate significantly, the quality will deteriorate and the risk to consumers will be increased. Thus retailers should pay strict attention to the temperature of storage. In addition, monitoring of "use-by-dates" may be one mechanism for control at retail level.

Control options for *L. monocytogenes* during processing is primarily a matter of having a proper cleaning and sanitation programme. Special attention needs to be paid to the presence of *L. monocytogenes* in plants producing ready-to-eat fishery products. A specific hygiene and sanitation programme needs to be developed in order to keep the contamination with *L. monocytogenes* at a low level. A total elimination of *L. monocytogenes* from the processing environment is impractical and may be impossible, as reintroduction of the organism is likely to occur. However, through the use of such programmes, a plant can reduce the number of *L. monocytogenes* contaminated products that it produces.

7. GAPS IN CURRENT KNOWLEDGE ON THE INCIDENCE OF *L. MONOCYTOGENES* IN FISHERY PRODUCTS

- There is a need to estimate accurately the risk of listeriosis due to fishery products, and to identify appropriate risk-mitigation and control strategies.
- There is a need for epidemiological data on the role of fishery products in listeriosis to assess the validity of any risk assessments undertaken.

- New data are required on the dose-response relationship for *L. monocytogenes*. A better understanding of the role of host susceptibility factors and virulence factors of the organism is also required to complement the dose-response information.
- There is a need to investigate the use of *Listeria* species as an indicator of the presence of *L. monocytogenes* for in-plant environmental monitoring programmes.
- Predictive models are able to generate data on the growth rates of *L. monocytogenes* inoculated onto products. Information on the ecology of *L. monocytogenes* on naturally contaminated products is required to determine the amount of growth likely within their recommended 'use-by-date' and at the recommended storage temperatures. Specifically, data concerning the influence of cell injury and competitive flora are required.
- For exposure assessment, more data concerning contamination levels on products and frequency of contamination, geographical distribution and information on the integrity of the chill-chain for fishery products are required. Consumption pattern data, and data concerning production volumes should also be collated and integrated with the risk assessment. In particular, there is a lack of data for tropical regions and their fishery products.
- Information is required on how the organism becomes established in the fish processing environment and methods for its prevention/elimination.
- Information is required on the trade impacts of *L. monocytogenes* in fishery products and the benefits and costs of different criteria and sanitary and phytosanitary measures.

8. RECOMMENDATIONS

The Consultation made the following recommendations:

- Microbiological criteria for *L. monocytogenes* in foods should be harmonized, risk based and only used on ready-to-eat high risk products which can support growth of the bacterium.
- For the purpose of setting standards it should be accepted that it is not possible to produce certain fishery products consistently free of *L. monocytogenes*.
- Food quality and safety assurance systems based on GHP/HACCP principles should be developed and implemented to reduce the potential for *L. monocytogenes* colonization of the processing environment. Research should be undertaken to understand the mechanisms by which *L. monocytogenes* adheres to product and processing equipment and how best to inactivate/remove adhered cells.
- Uniform sampling plans and a standard method for the enumeration of *L. monocytogenes* in fishery products should be developed. This should be considered in the work programme of Codex or some other international body.
- Consensus should be sought on acceptable probabilities of contamination of fishery products with *L. monocytogenes*, from which decimal reduction values appropriate to specific commodities can be developed.
- The potential for *L. monocytogenes* growth should be considered in setting the shelf-life of products such as cold smoked fish.

- Labels on fishery products should include recommended specific storage temperatures and a “use-by-date”.
- Laboratory-based surveillance systems should be developed to determine the incidence of listeriosis in populations at risk, to detect and investigate outbreaks of the disease, and to study its foodborne transmission.
- The role of healthy carriers, approximately 4–6% of the healthy population, in the epidemiology of listeriosis should be studied.
- Risk communication to vulnerable groups, and consumer education, should be implemented as part of a risk management strategy. As a priority, this should include advice to vulnerable groups on avoidance of certain types of foods as well as on safe food handling practices.

Annex I

LIST OF PARTICIPANTS

Prof. Lahsen Ababouch, Département de Microbiologie et Biotechnologie Alimentaire, Institut Agronomique et Vétérinaire Hassan II, PO Box 6202, Rabat, Morocco

Dr. Dane Bernard, Vice President for Food Safety Programs, National Food Processors Association, 1350 I St., Suite 300, Washington, DC, 20005, USA

Prof. Julie A. Caswell, Food Marketing Economics, Department of Resource Economics, 235 Draper Hall - Box 32040, University of Massachusetts, Amherst, MA 01003, USA

Prof. Fergus M. Clydesdale, Head, Department of Food Science, Room 230, Chenoweth Laboratory, University of Massachusetts, Amherst, MA 01003, USA

Prof. Maria Teresa Destro, Department of Food and Experimental Nutrition, Faculty of Pharmaceutical Sciences, University of Sao Paulo, Av. Prof. Lineu Prestos, 580, 05508-900 Sao Paulo, Brazil

Dr. Jeffrey M. Farber, Research Scientist and Head of Microbiology Research Division, Food Directorate, Health Canada, Sir Frederick G. Banting Research Centre, Tunney's Pasture, Postal Locator 2204A2, Ottawa, Ontario K1A 0L2, Canada (*Vice Chairperson*)

Prof. Herbert O. Hultin, Director of the Marine Station, Marine Foods and Food Biochemistry Department of Food Science, Box 7128 Marine Station, Gloucester, MA 01930, USA (*Chairperson*)

Prof. Hans Henrik Huss, Chief, Microbiology Section, Department of Seafood Research Danish Institute for Fisheries Research, Ministry of Food Agriculture and Fisheries, Technical University of Denmark, Building 221, DK-2800 Lyngby, Denmark

Prof. I. Karunasagar, Head, Department of Fishery Microbiology, College of Fisheries University of Agricultural Sciences, PB No. 527, Mangalore 575-002, Karnataka, India

Dr. John E. Kvenberg, Division Director of HACCP Programs, Centre for Food Safety and Applied Nutrition, United States Food and Drug Administration, 200 C Street, SW, Washington, DC, USA

Prof. Robert E. Levin, Room 346, Chenoweth Laboratory, Department of Food Science, University of Massachusetts, Amherst, MA 01003, USA

Dr. Lynne A. McLandsborough, Room 344, Chenoweth Laboratory, Department of Food Science, University of Massachusetts, Amherst, MA 01003, USA

Prof. Amaury Martinez, Instituto de Ciencia y Tecnología de Alimentos, Facultad de Ciencias, Universidad Central de Venezuela, Calle Suapure - Lomas de Bello Monte, Apartado 47097, Caracas 1041 A, Venezuela

Dr. Birgit Nørrung, Senior Scientist, Institute of Food Safety and Toxicology, Danish Veterinary and Food Administration, Mørkhøj Bygade 19-DK 2860 Søborg, Denmark

Dr. Servé H. Notermans, Principal Scientist, TNO Nutrition and Food Research Institute, PO Box 360, 3700 AJ Zeist, The Netherlands

Mr. Alan Reilly, Director, Operations Division, Food Safety Authority of Ireland, Abbey Court Lower Abbey Street, Dublin 1, Ireland (*Rapporteur*)

Dr. Jocelyne Rocourt, Chef de Laboratoire, Département de Bactériologie et Mycologie
Centre National de Référence de *Listeria* et Centre Collaborateur de l'Organisation Mondiale de la
Santé pour la Listériose d'Origine Alimentaire, Institut Pasteur, 25/28 Rue du Dr. Roux,
F-75724 Paris Cedex 15, France

Dr. Liv Marit Rørvik, Senior Lecturer, The Norwegian School of Veterinary Science
PO Box 8146 Dep., Oslo 0033, Norway

Dr. Tom Ross, Scientific Researcher, School of Agricultural Science, University of Tasmania, GPO
Box 252-54, Hobart, Tasmania 7001, Australia

Ms. Sirilak Suwanrangsri, Director, Fish Inspection Centre (Bangkok), Fish Inspection and Quality
Control Division, Department of Fisheries, Kaset-Klang, Chatuchak, Paholyothin Road, Bangkok
10900, Thailand

Dr. Wilhelm Tham, Lecturer and Scientific Researcher, Department of Food Hygiene, Faculty of
Veterinary Medicine, Swedish University of Agricultural Sciences, PO Box 7009, S-750 07 Uppsala,
Sweden

FAO Secretariat

Dr. Peter Karim Ben Embarek, Fishery Industries Officer, Fish Utilization and Marketing Service,
Fishery Industries Division, Fisheries Department, Food and Agriculture Organization of the United
Nations, Viale delle Terme di Caracalla, 00100 Rome, Italy

Dr. Sarah Cahill, Associate Professional Officer, Food Quality and Standards Service, Food and
Nutrition Division, Food and Agriculture Organization of the United Nations, Viale delle Terme di
Caracalla, 00100 Rome, Italy

Ms. Maria de Lourdes Costarrica, Senior Officer, Food Quality Liaison Group, Food Quality and
Standards Service, Food and Nutrition Division, Food and Agriculture Organization of the United
Nations, Viale delle Terme di Caracalla, 00100 Rome, Italy

Dr. Grimur Valdimarsson, Director, Fishery Industries Division, Fishery Department, Food and
Agriculture Organization of the United Nations, Viale delle Terme di Caracalla, 00100 Rome, Italy

Dr. Shawky Dagher (FAO Consultant), Biology Department, American University of Beirut, PO Box
11-0236, Beirut, Lebanon

Annex II

LIST OF BACKGROUND PAPERS

Background paper no.	Title	Author
1	Lessons from an outbreak of listeriosis related to vacuum-packed "gravad" and cold-smoked fish	Wilhelm Tham
2	<i>Listeria</i> in tropical fish and fishery products	I Karunasagar and Indrani Karunasagar
3	Incidence of <i>Listeria monocytogenes</i> and <i>Listeria</i> spp. in fish and vegetables	Amaury Martinez
4	<i>Listeria monocytogenes</i> in the smoked salmon industry	Liv Marit Rørvik
5	Incidence and significance of <i>Listeria</i> in fish and fish products from Latin America	Maria Teresa Destro
6	<i>Listeria</i> in international trade in tropical fish products	Sirilak Suwanrangi
7	Epidemiology of human listeriosis and seafood	Jocelyne Rocourt and Alan Reilly
8	Potential of <i>Listeria</i> hazard in African fishery products and possible control measures	Lahsen Ababouch
9	Microbiological criteria for <i>Listeria monocytogenes</i> in foods under special consideration of risk assessment approaches	Birgit Nørrung
10	Risk assessment of <i>Listeria monocytogenes</i> in fish products: Some general principles, mechanism of infection and the use of performance standards to control human exposure	Servé Notermans
11	Predictive modelling of the growth and survival of <i>Listeria</i> in fishery products	Tom Ross
12	The Canadian position on <i>Listeria monocytogenes</i> in ready-to-eat foods	Jeffrey M. Farber
13	Risk assessment used to evaluate the US position on <i>Listeria monocytogenes</i> in seafood	John E. Kvenberg
14	Economic approaches to measuring the significance of food safety in international trade	Julie A. Caswell
15	Control options for <i>Listeria</i> in seafood	Hans Henrik Huss
16	Guidelines to prevent post-processing contamination from <i>Listeria monocytogenes</i>	Dane Bernard, R. Bruce Tompkin, Virginia N. Scott, William H. Sveum, Kathy Sullivan Gombas

Annex III

CONTROL GUIDELINES

General Considerations

To effectively manage the risk of product contamination it is necessary to assess where along the product flow the exposed food is more likely to become contaminated. This is generally wherever something has direct contact with the unpackaged product. Examples of some primary sites leading to product contamination include:

- Brining solutions and injection equipment;
- Slicing equipment;
- Packaging equipment;
- Conveyors;
- Water or ice used in processing/storage;
- Racks for transporting finished product;
- Hand tools, gloves, aprons, etc. that contact exposed finished product;
- Spiral freezers/blast freezers;
- Containers such as bins, tubs, or baskets used for holding a food while it is waiting to be further processed or packaged.

Other areas of the environment can also serve as secondary sources of *L. monocytogenes*. These areas may harbour the organism and under certain conditions lead to contamination of the above product contact surfaces or the food. By controlling the presence of *L. monocytogenes* in the environment it is possible to reduce the risk that product or a product contact surface will become contaminated. The significance of these areas will vary depending upon the facility, the process(es), the temperature and humidity of the room, and the food. Examples of such secondary sources include:

- Equipment framework and other equipment in the area;
- Floors;
- Drains;
- Walls, especially if there are cracks that retain moisture;
- Ceilings, overhead structures, catwalks;
- Condensate;
- Insulation in walls or around pipes and cooling units that has become wet;
- Trolleys, forklifts, walk-alongs;
- Cleaning tools such as sponges, brushes, floor scrubbers;
- Maintenance tools.

Consideration should also be given to the potential for *L. monocytogenes* to be brought back into the clean environment. This may be the result of traffic in the processing and packaging areas (people and equipment, such as trolleys and forklifts, that enter from more contaminated points in the operation) or unscheduled equipment maintenance.

It should be recognized that in a plant with an effective control programme *L. monocytogenes* contamination, when it occurs, is line or equipment specific. While it is possible to have random isolated contamination with *L. monocytogenes* in a controlled environment, contamination more likely will occur after the organism has become established in a niche. When this happens, routine cleaning and sanitizing become less effective in controlling the organism. As the equipment is operated, the bacteria work their way out of the niche and become deposited onto the outer surfaces of the equipment. As product moves over or through the equipment, the contamination is spread downstream to other areas along the product flow. This situation can be corrected only by identifying the source or niche of

L. monocytogenes growth and eliminating it. Among the sites found to be potential harbourages are the following:

- Hollow rollers for conveyors;
- On/off switches;
- Rubber seals around doors;
- Damp insulation;
- Conveyor scrapers, especially if frayed and in poor condition;
- Open bearings within equipment;
- Hollow implements, including box cutters;
- Trash cans and other such ancillary items;
- Standing water in production areas;
- Cleaning tools, including mops and sponges;
- Poorly maintained in-line air filters through which compressed air must pass;
- Wet rusting or hollow framework;
- Motor housings;
- Walls/crevices of spiral freezers;
- Ice makers.
- Condensate traps in vacuum pumps

In addition to the possible establishment of *L. monocytogenes* in a niche, consideration must be given to certain conditions or situations that present an extra risk for contamination of finished products with *Listeria* contamination. When such events occur, processors may need to take extra precautions to guard against contamination. Examples of such situations include:

- a) Moving or significantly modifying a packaging line.
- b) Installing used equipment or equipment that has been in storage or used in another plant.
- c) Equipment breakdowns.
- d) Construction or major modifications in the product handling and packaging area (e.g., replacing refrigeration units or floors, replacing or building walls, modifications to sewer lines).
- e) Using employees that are not familiar with the operation, the *L. monocytogenes* control procedures in use, or the procedures for cleaning equipment in the production area where ready-to-eat (RTE) foods may be exposed to contamination.
- f) Personnel who handle RTE product contact surfaces or equipment that are likely to be contaminated (e.g., floor, trash cans) and not changing gloves or following other required procedures before handling product.
- g) Difficulty in meeting scheduled cleaning of the floors of holding coolers due to heavy production schedules.
- h) A drain backing up.
- i) Product being caught or hung-up on equipment. Stagnant product in a system can be a major site of microbial growth during production. The equipment should be modified to eliminate areas where product stops moving along or through a processing line.
- j) Raw or under-processed product being detected in a cooked product area. If this occurs, the process must be stopped, the unacceptable product removed, and the equipment re-cleaned and sanitized.
- k) Frequent changing of packaging film, labels, line speeds, etc. due to frequent changes of product being packaged.
- l) Personnel being used interchangeably for packaging raw and cooked products.
- m) Increased production requiring wet cleaning of down lines in the same room as lines running product.
- n) Cleaning of equipment parts, tubs, screens, etc. on the floor.
- o) Waste bins in the ready-to-eat area not being properly maintained, cleaned and sanitized. Personnel handling product may come into contact with these items and then contaminate product and/or product contact surfaces.

Specific Considerations: Processing Area

As noted before, certain types of raw fishery products as well as other ingredients used in processing may contain *L. monocytogenes*, although the presence of the organism and the levels of contamination vary widely. Because of this potential, steps should be taken to minimize the potential for cross-contamination from raw ingredients to products that have been treated to eliminate or reduce the contamination.

Separating raw products from semi-finished and finished products is a key factor in preventing cross-contamination.

1. Wherever possible, there should be linear flow of product through the operation from the raw ingredients to the finished product.
 - a) Plants should be rearranged, where necessary, to improve the flow of product, equipment, and people to facilitate separation of raw from cooked or treated product.
 - b) It is desirable to establish positive airflow on the “clean” side of the operation relative to the “dirty” side (e.g., maintain negative air pressures in raw product areas and positive pressures on the clean or finished product side).

2. Compartmentalize operations as needed to enhance the separation of raw ingredients and processed products.
 - a) Provide separate, dedicated washing areas and clean-in-place systems for cooked or treated product equipment and raw processing equipment.
 - b) Rework and trash barrels for cooked or treated product areas should be labelled or colour coded and not used elsewhere in the plant. They must be cleaned and sanitized daily or more frequently if microbiological testing data indicate this is necessary.
 - c) Remove hoses from the manufacturing areas where ready-to-eat products are exposed before start of operation each day so that line workers are not tempted to use these for spot cleaning during production.
 - d) Consider having separate utensils, carts, racks, totes, equipment, cleaning utensils, etc., colour coded where practical, for the ready-to-eat product area.
 - e) Where possible, eliminate overhead fixtures in the ready-to-eat area.
 - f) Where possible, isolate wet process areas from other production areas; at a minimum, remove standing water as soon as possible.

3. Control traffic flow patterns between the raw ingredients and the processed products sides of the operation to prevent transfer of *L. monocytogenes* from the “dirty” or “raw” side of the operation to the “clean” or “cooked” side.
 - a) Equipment, utensils and people in raw and cooked areas should not be interchanged during the working day.
 - b) Drains from the “dirty” or “raw” side should not be connected to those in the “clean” or “cooked” side.
 - c) If footbaths are installed, they must be properly maintained, or they can become a source of contamination. Maintaining clean dry floors is preferred to the use of footbaths, unless there is a specific need that cannot be addressed otherwise. Footbaths should contain stronger concentrations of sanitizer than would normally be used on equipment (e.g., 200 ppm iodophor, 400-800 ppm quaternary ammonium compound); a depth of 2 inches is recommended. Chlorine is not recommended for this use as it becomes too quickly inactivated. If chlorine is used, strict attention must be given to maintaining its strength. Footbaths will be ineffective if cleaved boots are carrying large particles of dirt/plant waste.
 - d) Another option is to spray a foam disinfectant on the floor as people or rolling stock (carts, forklifts, etc.) enter the room.

Water used in processing operations that will come in contact with product should contain an antimicrobial known to be effective against *L. monocytogenes* and approved for the specific application at the levels used.

Specific Considerations: Packaging and Storage

Pallets entering the packaging room must be clean, dry and in good condition and preferably not made of wood.

Store and package exposed products in a clean, dry environment.

- a) Bacteria cannot multiply without water. If the environment is clean and dry, *L. monocytogenes* remains dormant or, perhaps, dies.
- b) There is less transfer of bacteria from surfaces if the surfaces are clean and dry.
- c) The spread of contamination by vehicular and pedestrian traffic is reduced considerably if the floors are clean and dry.
- d) The cooling units in packaging rooms and coolers for exposed product should have dehumidifying capability. To facilitate the removal of humid air and to dry floors after cleaning, it may be necessary to exhaust air outside the plant. Heating air within a room can also be effective for removing moisture at the end of the cleaning/sanitizing process.

Specific Considerations: Equipment

Equipment should be properly designed and maintained.

- a) Equipment must be designed to facilitate cleaning and to minimize sites where microbial multiplication can occur. The acceptability of the design of new or replacement equipment should be reviewed to determine its cleanability and its potential to minimize microbial contamination.
- b) Even though visually clean, previously used equipment may harbour pathogens. Plan accordingly, prior to putting such equipment into production.
- c) Properly maintain equipment to minimize breakdowns and the risk of contamination during repair.
- d) Equipment that is damaged, pitted, corroded, or cracked should be repaired or replaced.
- e) Equipment or catwalk framework should not be hollow such that water can collect and harbour *L. monocytogenes*.
- f) Lubricants can become contaminated with product residue and become a centre for growth of *L. monocytogenes*. Use lubricants that contain listericidal additives (e.g., sodium benzoate).
- g) Avoid conveyor designs and locations that are difficult to clean and sanitize. Conveyors for product prior to packaging should not contain hollow rollers. Do not locate conveyors or other processing equipment in which product is exposed near the floor, as this is a likely source of *L. monocytogenes*. Avoid overhead conveyors, if possible, as they are more difficult to clean, sanitize and inspect. Either provide a safety ladder or design the conveyor so it can be lowered for cleaning.
- h) Racks used for transporting exposed cooked product should have cover guards over the wheels to prevent spray from the wheels falling onto the rack and product as the racks are moved.
- i) Racks used in operations after products are cooked can be a significant source of contamination if not properly cleaned and sanitized before use. The most reliable method of sanitizing racks is with heat. Heat can be applied by (1) a hot water (82.2°C/180°F) rinse in a rack washer so the racks will reach a temperature of 71.1°C/160°F or higher, (2) steam applied in a cabinet after cleaning in a rack washer, or (3) placing the racks into an oven and applying moist heat to raise the temperature of the racks to 71.1°C/160°F or higher. When using heat to sanitize, it is essential that the equipment be thoroughly cleaned so the heat does not bake the soil on, making it more difficult to remove, resulting in more contamination problems in the future.
- j) Regular maintenance schedules should be adopted and followed to minimize the potential for harbourages and to reduce the potential for contamination of equipment due to unscheduled repair operations.

- k) For maintenance of equipment in the cooked, RTE area it may be necessary to use tools dedicated to this area or to sanitize tools prior to use in this area. Maintenance personnel should wear clean smocks that are not used in raw material areas. Equipment should be re-sanitized after maintenance work.

Specific considerations: Plant Sanitation

- a) Use sanitation procedures designed to control *L. monocytogenes*. The frequency of cleaning and sanitizing the equipment and environment of a plant depends upon experience and microbiological data. Routine microbiological testing allows the plant to develop a baseline for comparison purposes, observe trends, and detect a developing sanitation problem.
- b) Successful control of *L. monocytogenes* requires consistency and attention to detail. The steps include (1) dry clean, (2) pre-rinse the equipment, (3) visually inspect the equipment, (4) foam and scrub the equipment, (5) rinse the equipment, (6) visually inspect the equipment, (7) clean the floors, (8) sanitize the equipment and floors, (9) conduct post-sanitation verification, (10) dry the floors, (11) clean and put away supplies. Some equipment may require disassembling prior to cleaning and sanitizing, and may need to be re-sanitized after re-assembling.
- c) Quaternary ammonium compounds (quats) have been found to be effective against *L. monocytogenes*, and leave a residual germicidal effect on surfaces. In addition, sanitizers containing peracetic acid and peroctanoic acid have been shown to be effective against biofilm containing *L. monocytogenes*. Areas that should be sanitized with such compounds and a suggested frequency are as follows:

AREA	FREQUENCY
Drains	Daily
Floors	Daily
Waste containers & storage	Daily
Walls	Weekly/monthly
Condensate drip pans	Weekly/monthly
Heating ventilating air conditioning (HVAC)	Weekly/monthly
Coolers	Weekly/monthly
Spiral freezers	Semi-annually

- d) The cleanup crew should receive special training in proper procedures to control *L. monocytogenes*. Close monitoring and correction is essential to improve and maintain a high level of performance.
- e) Priority must be given to rooms and equipment used for holding and packaging exposed ready-to-eat product. Consideration should be given to assigning reliable personnel to areas where ready-to-eat products are handled and packaged.
- f) It is very desirable, even necessary in some cases, to have a person on the staff whose primary responsibility is to monitor the cleaning and sanitizing process at night to be certain it is being done correctly. Concerns over having the plant ready on time for start-up must be secondary to having the plant correctly cleaned and sanitized. Extensive experience indicates that, if the equipment is properly cleaned and sanitized before start-up, the risk of contamination from equipment during production is minimal.
- g) The utility of mid-shift cleanups is not entirely clear. In certain situations, they may be counter-productive by increasing the risk of *L. monocytogenes* contamination. There may be instances

however when this is necessary to reduce contamination. Microbiological testing should be conducted to determine the utility of this practice in each circumstance.

- h) Some plants have found the following sanitizing procedure to be helpful each night. After cleaning the equipment, apply a high level of sanitizer (e.g., 800 ppm quat), allow it to stand for about 20 minutes, rinse thoroughly, and then apply the normal level of sanitizer (e.g., 200 ppm quat or chlorine). At the end of the production week the high level of sanitizer can be left on the equipment until before start-up. The sanitizer is then rinsed, the normal level is applied, and the room is prepared for start-up. Under certain circumstances, it may be beneficial to spray an aerosol of 200 ppm quat into a room as a final step in the process of cleaning and sanitizing; weekly or monthly fogging may be useful.
- i) Rotating other sanitizers (e.g., chlorine, acid-anionic, peracid and iodophors) into the sanitation programme may provide for greater effectiveness. Consider using new peracid-based sanitizers such as Matrixx, Vortexx and others where they have been demonstrated to be effective against *L. monocytogenes*.
- j) Modify equipment so it is simple in design, easy to clean, and has fewer maintenance problems. Breakdowns during production increase the risk of *L. monocytogenes* contamination.
- k) Sanitizing with high temperatures, if manufacturers' instructions permit such application, may be particularly useful for biofilm removal.
- l) Hot water/steam sanitation is an alternative to chemical sanitation that is especially effective where equipment is difficult to clean. Wherever possible, apply steam as a final step for equipment that is difficult to clean. One method is to place a metal cover over the equipment and then inject steam. In some cases, equipment can be steamed in a cook oven. The objective is to heat the equipment so it will reach at least 71.1°C/160°F throughout. A holding period of one hour or more is desirable. For equipment that may be more sensitive to heating it may be necessary to use a lower temperature (e.g., 62.8°C/145°F) and a longer holding time. (See earlier cautions about thorough cleaning prior to application of heat.)
- m) Plastic tubs which can be stacked may be a problem unless they are cleaned and sanitized daily. They must not be placed directly on the floor, unless placed on a clean plastic mat.
- n) Infrequent cleaning of coolers used for holding finished unpackaged product is a common cause for increased *L. monocytogenes* problems, particularly during peak periods. These coolers should be emptied and cleaned at least once per week. Maintaining dry floors in these coolers is also important.
- o) Infrequent defrosting, cleaning, and maintenance of spiral freezers used for freezing unpackaged product is a potential source of *L. monocytogenes*. These freezers should be cleaned twice a year.
- p) Condensate that accumulates in drip pans of refrigeration units should be directed to a drain via a hose. Care must be taken to ensure that the hose does not become blocked. Solid forms of sanitizers (e.g., blocks or donuts of quats) can be placed in the drip pan to control microbial growth. In addition to the routine use of sanitizers, drip pans should be cleaned regularly.
- q) Using compressed air to remove debris from equipment during production can increase the risk of contamination. Compressed air can be a source of *L. monocytogenes* when in-line filters are not maintained or replaced with regularity. Thus, when compressed air must be used directly on product or product contact surfaces, the air should be filtered at the point of use and the filters maintained. This practice should be restricted, preferably, to cleaning certain equipment (e.g., packaging machines) at the end of production before cleaning begins.

- r) Never clean coolers or other rooms when exposed, ready-to-eat product is present. Do not rely on covering the product with plastic or paper. Remove all unpackaged product from the room before beginning to clean.
- s) Do not dismantle and wash equipment on the floor.
- t) The best method for cleaning floors is to use a powdered caustic cleaner, apply water as needed, use a dedicated, colour-coded brush to clean the floor, and then thoroughly rinse, using a low volume hose, and sanitize the floor. Newer cleaners and sanitizers may be more effective for controlling *L. monocytogenes* on the floor. Floor scrubbers can be helpful, particularly for cleaning large open spaces such as hallways. The equipment used for cleaning must be maintained and properly cleaned so it does not become a source of contamination. Application of powdered citric acid to certain areas of the floor may be effective for controlling *L. monocytogenes*, provided the floor has been properly cleaned and dried before applying the citric acid. For maximum effectiveness, the surface of the floor should be maintained at pH 5.0 or below. Litmus paper can be used to check the pH. While this may help control *L. monocytogenes*, the condition of the floor should be monitored, as the acid condition will cause deterioration that eventually will necessitate replacing the floor.
- u) Floor drains must be designed and maintained to prevent backups. If a backup occurs, production must cease, the drain cleared, and the area carefully cleaned with caustic, rinsed, and sanitized. Avoid splashing equipment during the process. The floor should then be dried. Never use a high-pressure hose to clear a drain. An aerosol will be created that will spread contamination throughout the room.
- v) Whenever possible, eliminate trench drains.
- w) Bactericidal drain rings are recommended.
- x) Floor drains should be cleaned and sanitized in a manner that prevents contamination of other surfaces in the room. Floor drain brushes must be at least 5 mm ($\frac{1}{4}$ inch) smaller than the diameter of the drain opening or a splashguard must be used to prevent splashing during cleaning. Utensils for cleaning drains should be dedicated to that purpose to minimize the potential for contamination. If floor drains are cleaned first, it may be necessary to clean and sanitize them again at the end of the process.
- y) Cleaning tools should be sanitized using 600-1000 ppm quat solutions and either stored dry or in quat solutions maintained at 1000 ppm.

Specific Considerations: Personnel Hygiene

Establish personal hygiene practices with *L. monocytogenes* control as a major objective. The following information should become part of employee training for *L. monocytogenes* control.

- a) Clean gloves, smocks, and aprons are essential to protect against product contamination. Ideally there should be one colour smock for the raw side of the operation and one for the processed side. Disposable gloves and aprons should be used wherever possible in cooked product areas. Disposable paper sleeves (arm covers) can provide another barrier for those who handle exposed product. Disposable items should be discarded when leaving the work area and replaced with new when returning. Some garments (e.g., smocks) may be left in the department and re-used, provided they are still clean. Gloves should be replaced if damaged. The use of gloves does not preclude the need for employees to wash hands regularly.

- b) Everyone working in areas where ready-to-eat products are exposed must clearly understand that the purpose of wearing clean garments and disposable gloves is to protect the product from contamination, not protect themselves from getting dirty.
- c) If an unclean surface is touched, then hands should be washed and gloves changed.
- d) Equipment and soiled clothing must not be stored in lockers.
- e) If possible, assign a person in the packaging room to pick up material from the floor, remove trash, and perform other housekeeping tasks. This person must not work on a packaging line or handle product that will be packaged or replaced on the line.
- f) Rubber boots that are non-porous and easily cleaned are better for *L. monocytogenes* control than other footwear. Boots are necessary where footbaths are used.

ENVIRONMENTAL MONITORING PROGRAMME TO VERIFY CONTROL

An environmental monitoring programme is recommended to assess the need for additional control measures for products that may be recontaminated by *L. monocytogenes*. Industry experience has shown that an ongoing monitoring and control programme that uses *Listeria* species (*Listeria* spp. or "generic *Listeria*") as an indicator of potential *L. monocytogenes* contamination not only reduces the possibility of finding *L. monocytogenes* in finished product but other pathogens as well. Industry experience also shows that re-entry of *Listeria* spp. into the production environment cannot be reliably prevented. Thus, ongoing monitoring to detect the organism in the environment is necessary.

Each company should establish its own *L. monocytogenes* monitoring programme considering the guidelines outlined below.

General Principles for Verification of Environmental Monitoring

Environmental monitoring (microbiological testing) should focus on a non-pathogenic indicator such as *Listeria* spp. or *Listeria*-like organisms, since these indicators will be found more frequently in the environment than *L. monocytogenes* and because test results are available sooner. Monitoring results should alert the plant to potential problem areas, prompting further investigation and focusing of additional control efforts, as necessary. Goals for reduction of positives should be established in order to encourage continuous improvement. A detailed set of action plans should be developed to control the risk of *L. monocytogenes* in the event that the goals are not met.

Each plant, product, and process must be evaluated to determine the appropriate monitoring points. Each packaging line should be regarded as an independent unit for *L. monocytogenes* monitoring and control. It is recommended that both food contact surfaces and non-food contact surfaces that pose the potential to contaminate product be tested. One approach might be to separate testing into environmental sites, product contact sites, and product itself. Keep in mind that since *L. monocytogenes* will not be frequently found in products in operations following these control guidelines and because it will not be uniformly distributed, product testing will not be a reliable indicator that *L. monocytogenes* contamination has not occurred. Thus, the emphasis of the programme discussed here is on testing for *Listeria*-like organisms in the environment to verify control. There can be many variations on how this is done. Some guidelines are presented below.

Environmental testing

- Plants should determine the points to sample and the frequency of sampling based on knowledge of their specific operation and the controls that have been put into place, as well as any microbiological data available. Suggested areas include support structures, overhead areas or structures, walls, floors, drains, and room air. Weekly sampling is recommended initially for most wet areas where *L. monocytogenes* can grow; in dry-cleaned areas sampling may be less frequent.
- The number of sampling points and the frequency of sampling may be adjusted based on results over time. For example, repeated negative findings may suggest elimination of a sampling site or a reduced frequency of sampling for a particular area.
- Statistical Process Control (SPC) may be used to track results and identify the need to take action.
- Plants should determine the action to be taken in the event that *Listeria* spp. is detected at frequencies exceeding the upper control limit, target, or “trigger” that the plant has set (although some attention should be given to cleaning and sanitizing an area when any positive is found). Because the reasons for a positive finding are likely to be plant-specific, corrective actions will vary. Consider the following points in determining corrective actions for environmental positives:
 - Detection of *Listeria* spp. in an environmental monitoring sample does not necessarily indicate a microbiological control problem; it does indicate that additional investigation should be undertaken.
 - When environmental monitoring results indicate a trend toward an increased incidence of *Listeria* spp., plants should investigate to determine the reason(s) for the increase and should take action to reduce the level again.
 - If a positive sample is detected, and the sample was a composite sample, the individual samples should be tested to pinpoint the location of the positive.
 - Additional samples should be taken from the environmental area where the positive was detected. These samples may indicate that additional corrective actions are needed in this area.
 - If, after corrective actions have been applied, additional samples are positive, the environment should be intensively cleaned and re-tested.
 - Consider the need to sample (additional) food contact surfaces in the areas where environmental positives are detected.

Food Contact Surface Testing

- Food contact surfaces may be sampled routinely for *Listeria*-like organisms as verification that environmental controls are preventing *L. monocytogenes* contamination of surfaces; or they may be sampled only when environmental monitoring suggests there may be a problem.
- As with environmental sampling, plants should determine the points to sample, the time of day for sampling, and the frequency of sampling based on knowledge of their specific operation and the controls that have been put into place, as well as any microbiological data available.
- Plants should investigate to determine the reason(s) for all positives on food contact surfaces. Investigative sampling must be capable of identifying equipment that contains niches where *L. monocytogenes* has become established. Until these sites are located, it is not always possible to correct an ongoing problem.
- Corrective actions should be taken for all food contact surface positives based on a pre-determined plan of action and the actions should be documented. Contamination of some product contact surfaces is of greater concern than others. Examples of corrective action include modifying cleaning and sanitizing procedures, re-design of equipment, improved GHPs, etc.
- Plants should consider whether finding *Listeria*-like organisms on food contact surfaces should result in the need for product testing.

Product testing

- Plants may decide to test product as a result of positive food contact surfaces.
- In addition, random product testing may be used to verify that the *L. monocytogenes* control/monitoring programme is effective in preventing product contamination. All sampled lots should be held until the laboratory results are available.
- Plants must determine the action to be taken in the event that *L. monocytogenes* is detected in a product sample.

Environmental Sampling Guidelines

- When taking swab or sponge samples, use a scientifically acceptable method.
- Samples may be composited where scientifically appropriate; where possible, the remaining portion of individual samples should be retained until composite results are obtained, in case additional testing of the individual samples is necessary.
- Packaging line samples (product contact surfaces) should be from areas as large as practical. Environmental samples should represent a constant area (e.g., 45cm x 45cm (1.5 ft x 1.5 ft.), 61 cm x 91 cm (2 ft. x 3 ft.), etc.)
- Floor drains represent an almost constant problem area; a corporate decision should be made on whether or not to include drains in the environmental sampling program. A separate goal for drains may be appropriate.

Problem Solving

When an effective control programme for *L. monocytogenes* is in place, the primary source of contamination is often a niche where *L. monocytogenes* has become established and is multiplying. When *L. monocytogenes* finds a niche, the contamination will be line-specific. In general, the contamination will flow downstream along a packaging line. When seeking the source of a niche, collect and analyze sponge samples individually, not as composites. Sample additional sites along the line and sample more frequently throughout the day. Tear down suspected pieces of equipment, collecting samples of suspicious sites and materials. Clean and sanitize the equipment as it is being reassembled. If cleaning and sanitizing are unsuccessful, remove sensitive electronics, oil and grease and apply heat to 71.1°C/160°F. Small parts can be placed in an oven; larger equipment can be shrouded and steam applied under the tarp. Lower temperatures for longer times may also be effective. Also consider the possibility that employee practices may be involved in the contamination. Refresher training in the controls necessary to prevent *L. monocytogenes* contamination may be indicated.

For further information please contact:

Dr. Grimur Valdimarsson

Director
Fishery Industries Division
Fishery Department
Food and Agriculture Organization
of the United Nations
Viale delle Terme di Caracalla
00100 Rome
Italy
Tel: + 39 06 57056519
Fax: + 39 06 57055188
email: grimur.valdimarsson@fao.org

Dr. Peter Karim Ben Embarek

Fishery Industries Officer
Fish Utilization and Marketing Service Fishery
Industries Division
Fisheries Department
Food and Agriculture Organization
of the United Nations
Viale delle Terme di Caracalla
00100 Rome
Italy
Tel: + 39 06 57055034
Fax: + 39 06 57055188
email: peter.benembarek@fao.org

Ms. Maria de Lourdes Costarrica

Senior Officer
Food Quality Liaison Group
Food Quality and Standards Service
Food and Nutrition Division
Food and Agriculture Organization
of the United Nations
Viale delle Terme di Caracalla
00100 Rome
Italy
Tel: + 39 06 57056060
Fax: + 39 06 57054593
email: lourdes.costarrica@fao.org

Dr. Sarah Cahill

Associate Professional Officer
Food Quality and Standards Service
Food and Nutrition Division
Food and Agriculture Organization
of the United Nations
Viale delle Terme di Caracalla
00100 Rome
Italy
Tel: + 39 06 57053614
Fax: + 39 06 57054593
email: sarah.cahill@fao.org