CONFIDENTIAL
R&D REPORT
NO. 172

An Outline Microbiological Risk Assessment for *Listeria monocytogenes* in cooked meats and poultry

2003

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ABSTRACT

The object of this study is to investigate the risk posed by *Listeria monocytogenes* from cooked meat and poultry in the UK. A Microbiological Risk Assessment (MRA) approach is being taken to achieve this goal. The team carrying out this work are drawing heavily on industrial representatives from the meat and poultry manufacturing industry in the UK, so that the outputs of the study are made as relevant to industry and government as possible.

The first part of the MRA – an Outline MRA – is presented here. This gives detail of the purpose and scope of the MRA to be performed. It also identifies the resources available and needed and guides the latter stages of the MRA. The aim is to complete the MRA study early in 2003. The scope has been set after consultation, to cover: healthy adults; pregnant women; perinates and neonates; and otherwise ill persons. The food groups to be covered include: pate; cooked chicken; ham; and fermented sausage. The study will rely solely on existing and accepted knowledge, data and models.

CONTENTS

1. INTRODUCTION

1.1 Microbiological risk assessment activity

Risk analysis is a process which is increasingly being applied to microbiological food safety issues world-wide. The first stage of the process is a formal risk assessment, which seeks to identify the hazards which may arise in a particular food production process or food chain. The second and third stages, risk management and risk communication, are started at the same time as the risk assessment and continued after the risk assessment is completed.

The European Commission has published its 'Opinion on Principles for the Development of Risk Assessment of Microbiological Hazards under the Hygiene of Foodstuffs Directive 93/43/EEC' (European Commission, 1997). Codex has published its 'Principles and Guidelines for the Conduct of Microbiological Risk Assessment' (Codex Alimentarius Commission, 1999). These documents give an introduction to the process of Microbiological Risk Assessment (MRA). Codex has also drafted guidelines giving principles for Risk Management (Codex Alimentarius Commission, 2000). Other bodies such as the World Health Organisation (WHO) and the International Life Sciences Institute (ILSI) have been proactive in formulating procedures and guidelines for performing aspects of Risk Analysis.

Campden & Chorleywood Food Research Association (CCFRA) has also been working in the area of MRA Guideline development (CCFRA, 2000). The target audience on this occasion were food manufacturers rather than governmental or regulatory bodies. The European Commission has conducted, under an EU Directive for Scientific Co-operation (SCOOP), a study to evaluate information requirements to further the development of MRA in Europe. The purpose of this study was to identify sources of data and information that could be utilised in carrying out MRAs. A useful summary of international activity in carrying out MRAs is given on the World Health Organisation MRA website: http://www.who.int/fsf/mbriskassess/index.htm

1.2 The microbiological risk assessment process

There are generally accepted principles for the conduct of an MRA outlined by Codex (Codex Alimentarius Commission, 1999) and the EU Scientific Committee for Food (European Commission, 1997). There is value in an informal outline MRA, before the full, formal MRA, and a formal reporting step can be useful. Consequently the steps that will be followed in this Microbiological Risk Assessment (MRA) study are:

Outline MRA
Statement of Purpose
Hazard Identification
Exposure Assessment

Hazard Characterisation
Risk Characterisation
Production of a Formal Report

1.3 Listeria MRA activity

A microbiological hazard of substantial concern to MRA practitioners is *Listeria monocytogenes*. This bacterium has been the subject of a number of international initiatives especially with respect to ready-to-eat (RTE) foodstuffs.

The European Union took an MRA approach to assessing the risk from *Listeria monocytogenes* in RTE foodstuffs (European Union, 1999). One of the conclusions from their report was that *Listeria monocytogenes* posed a very low risk to consumers at levels of <100 cfu/g. Consequently foods should not contain more than 100 cfu/g throughout their shelf-life. The outputs from this document have now been incorporated into national legislation for countries such as France, Netherlands and Germany. Other countries such as the USA still operate a 'zero tolerance policy' (Ross, *et al*., 2000).

Whilst in general terms, the number of cases of listeriosis has fallen in recent years, *Listeria monocytogenes* remains an important concern for the food chain. The organism has been identified by the United States Food and Drug Administration (FDA) and Department of Agriculture (USDA) as the subject for a major multidisciplinary programme on MRA and the structure and initial data survey for the MRA has been published (FDA and USDA, 1999). A draft of the full MRA on *Listeria monocytogenes* in RTE foods is now available on the internet (FDA and USDA, 2001). This study focuses on the situation in the US, although some comment is made on the situation in other countries.

The Food and Agriculture Organisation of the United Nations (FAO) and the World Health Organisation (WHO) have also been proactive in this area. They have produced draft documents relating to the Hazard Identification and Hazard Characterisation steps of MRA in relation to *Listeria monocytogenes* in RTE foods (Buchanan and Lindqvist, 2000), and to Exposure Assessment (Ross, *et al*., 2000).

There are a number of other *Listeria* exposure assessments that have been developed for specific products, in specific countries. These are reviewed in the FAO/WHO exposure assessment. Although they are not necessarily for cooked meats and poultry, they further illustrate the large amount of interest in modelling this pathogen.

The results of the present study will provide important information to UK governmental departmental agencies in making decisions on risk management and risk communication strategies. For both European and International acceptance of national investigations it is evident that only MRAs formally undertaken in strict accord with the Codex principles will be acceptable. Consequently work here will be carried out along these lines.

2. THE OUTLINE MRA

The purpose of the outline MRA stage is to:

- state the purpose and scope of the MRA to be performed;
- identify the resources available and needed; and
- guide the latter stages of the MRA

These will be re-iterated in the Statement of Purpose and subsequent steps. Consideration is now given to the purpose and scope.

This piece of work has been commissioned by the UK FSA, to give a UK perspective on '*Listeria monocytogenes* in cooked meats and cooked poultry'. These foodstuffs are examples of ready-to-eat foods, on which considerable international effort has been focused over recent years.

3. STATEMENT OF PURPOSE

In the statement of purpose, the specific purpose and scope of the MRA is clearly stated. This includes the form of output from the MRA and output alternatives.

3.1 Purpose

The primary purpose of this research is to identify and quantify the levels of risk to the consumer of *Listeria monocytogenes* infection and illness resulting from the consumption of cooked meats and cooked poultry.

In order to do this, the prevalence and concentration of *L. monocytogenes* in the foodstuff at point of consumption will need to be determined. There will inevitably be a shortage of key data in the meat and chicken processing stages. Consequently it will be necessary to extrapolate information and data, and to use modelling techniques to fill gaps where data are inadequate.

In addition to the 'assessment of the risk', the other main objective is to identify strategies to reduce the risk in the processing scenarios under consideration.

In general, the MRA will be based upon existing and accepted knowledge, data, models, etc., (for example, Hitchens, 1996; Farber, *et al*., 1996; European Commission, 1997; Buchanan, *et al*., 1997; Notermans, *et al*., 1998; and Lindqvist and Westöö, 2000). UK information will be used and supplemented with additional international information when necessary.

An additional objective of the project will be to highlight gaps in knowledge and data that most influence uncertainty.

3.2 Scope

To define the objectives of the MRA, government representatives, manufacturers of cooked meat and cooked poultry products and their trade organisations, as well as public health and epidemiological experts were consulted.

To keep the MRA manageable, the scope has been set to cover the most pertinent aspects of the risk from *Listeria monocytogenes* in cooked meats and cooked poultry with respect to the UK position.

Firstly, the population under consideration needs to be defined. Different groups in the UK population have different responses to *Listeria monocytogenes*. This study will attempt to distinguish between:

- healthy adults;
- pregnant women;
- perinates and neonates (babies soon to be born or just born); and
- otherwise ill persons.

The second consideration is the food groups and processing chains to be included. Table 1 gives a breakdown of products that could be included under the category "cooked meats and cooked poultry", together with an estimation of perceived risk.

For the primary objective of identifying and estimating sources of risk, as many of these foods as possible will be covered. For the second objective, strategies to reduce the risk to the food, however, it was decided that in this study: pate; cooked chicken; ham; and pasteurised (and un-pasteurised) fermented or semi-fermented sausage would be used.

3.3 Forms of output

The principal output of this MRA will be in terms of the likelihood of harm to a member of the population in a time period (a year), as distinct from likelihood of harm on each consumption event of a target food. In ideal circumstances this would be fully quantitative, specifying the numerical probability of a specified degree of harm. However, it is very likely that the quality and quantity of information and data available will impart substantial uncertainty to such a risk estimate. The output, however, ought to allow comparisons of sub-populations, food types and processes, and areas of the "farm to fork" route, in terms of risk. Uncertainties will be taken into account and expressed in the output.

Table 1: Cooked meat and poultry product types considered for *Listeria monocytogenes* risk assessment

Product type	Intrinsic factors	Extrinsic factors	Examples	Relative risk (point of sale)	Relative risk (end of shelf-life)
Pre-cooked, perishable, uncured meats that are ready-to-eat	Low levels of preservatives	Cooked, chilled storage, MAP/vacuum packed	Roast pork (inc. 'honey roast'), cooked beef silverside, cooked chicken portions, roast turkey slices, uncured paté, Pasties/sausage rolls (eaten cold), Chilled meat spreads and cooked uncured sausages	High	High
Pre-cooked, perishable, uncured meats that are ready-to-eat, for sandwiches	Low levels of preservatives	Cook, chilled storage, MAP/vacuum packed	As above, for sandwiches	High	High
Pre-cooked, perishable cured meats that are ready-to eat	Nitrite, NaCl, smoke	Cooked, chilled storage	Some patés, bacon (cooked), cooked ham, frankfurters	High	High
Pre-cooked, perishable cured meats that are ready-to eat, for sandwiches	Nitrite, NaCl, smoke	Cooked, chilled storage	As above, for sandwiches	High	High
Flash-fried/warmed, perishable uncured meats to be cooked before consumption		Warmed, chilled/frozen	Turkey rolls?, skinless sausages (products warmed to set). "Flash fried"/crumbed/ battered poultry products	Medium	Medium /High
Pre-cooked, perishable, uncured meats to be cooked before consumption	Low levels of preservatives, some low A_w	Cooked, chilled/frozen storage	Pasties/sausage rolls (eaten hot), sous-vide, ready meals	Medium	Medium /High

Table 1: Cooked meat and poultry product types considered for *Listeria monocytogenes* risk assessment (continued)

Product type	Intrinsic factors	Extrinsic factors	Examples	Relative risk (point of sale)	Relative risk (end of shelf-life)
Raw, cured, ambient-temperature-stable meats that are ready-to-eat	Nitrite, NaCl, smoke, low pH		Intact salamis, air-dried hams (Parma, Serrano)	Medium	Low/Medium High
Raw, cured, perishable meats that are ready-to-eat, but require chilled storage	NaCl, low pH, nitrite, smoke	Chilled storage	Some spreadable and other salamis, some sliced fermented meats, jelly coated salamis	Medium	High
Raw, dried meats that are ready-to-eat	Low A_w		Beef jerky, biltong	Low	Low
Fully retorted, shelf stable uncured meats		Retorted in-pack	Soups, meats with cereal/vegetables	Low	Low
Pre-cooked, shelf stable, cured meats including canned	NaCl, smoke, nitrite	Cooked in-pack, low heat-treatment if chilled	Canned ham, luncheon meat, sausage (Gelder, some Bologna)	Low	Low

Key risk factors

Conditions (intrinsic and extrinsic) that allow growth of *L. monocytogenes*
Products that are ready-to eat (not cooked before consumption)
Cooked products that are sliced and/or packed after cooking
Cooked products that are ready-to-eat and packed/repacked with lightly preserved ingredients, e.g. coleslaw, or raw salad ingredients, e.g. lettuce
Note: Cooked or pre-cooked means that a minimum temperature of 70^{o}C is delivered at coldest point

4. HAZARD IDENTIFICATION AND HAZARD CHARACTERISATION

Whereas the Hazard Identification step describes the micro-organism under consideration as a hazard, the Hazard Characterisation step is an assessment of the nature of the adverse health effects associated with the hazard as it is present in the food under consideration.

The Hazard Identification and Hazard Characterisation steps in this outline MRA are intentionally brief and cursory, summarising and highlighting important points. Detailed discussion, justification, and supporting information will be included in the final MRA report. Extensive hazard identification and hazard characterisation of *Listeria monocytogenes* in ready-to-eat foods has recently been prepared as part of the Joint FAO/WHO Activities on Risk Assessment of Microbiological Hazards in Foods (Buchanan and Lindqvist, 2000).

4.1 Hazard identification

L. monocytogenes is a Gram-positive, facultatively anaerobic, non-sporeforming rod. The organism is psychrotrophic and grows over a temperature range of around 0°C to 45°C, with an optimum around 37°C. *L. monocytogenes* can grow at pH values between 4.4 and 9.4 and at water activities (A_w) at or above 0.92.

For this MRA study, all strains will be regarded as potentially capable of causing disease. The reasons for reaching this view are as follows:

i) Severe infections have resulted from a wide range of *L. monocytogenes* strains, and there is no firm evidence that the severity of human listeriosis is strain specific.

ii) The majority of listeriosis cases are believed to be foodborne. Hence attempts at aiming to exclude all *L. monocytogenes* strains from the food chain are likely to contribute to the prevention of the disease.

iii) Although a number of techniques are available to subtype *L. monocytogenes*, these are unable, at present, to predict the ability of a specific strain to cause foodborne disease. Epidemiological evidence (McLauchlin, 1993) has shown that certain *L. monocytogenes* types are both more frequently associated with sporadic human disease and are reported more frequently with large foodborne outbreaks of listeriosis; hence it is likely that there are inter-strain differences in the potential to cause disease within this bacterial species. A diverse range of strains of *L. monocytogenes* is, however, involved with sporadic human cases (this is probably the predominant form of the disease) and not all of the large outbreaks have been caused by a restricted group of *L. monocytogenes* types. Hence a wide range of strains have the potential to cause serious disease.

iv) Animal and tissue culture models are available to study the virulence of this bacterium. Although a small proportion of *L. monocytogenes* cultures are non-pathogenic in these models, the majority of cultures are potentially capable of causing human disease. However, these models reflect the natural disease poorly and present difficulty in extrapolating to the entire process of human foodborne disease.

v) There is now a partial understanding of the genetic basis for the pathogenicity and virulence of *L. monocytogenes.* The genetic basis is multifactorial, and at least nine genes and their products are required for these properties. There is limited genetic variation within the virulence genes of wild type *L. monocytogenes* and this variation has not been linked to differences in pathogenicity. The majority of wild-type *L. monocytogenes* cultures appear both to have and express the known virulence genes *in vitro*. A small proportion of wild-type *L. monocytogenes* strains are non-pathogenic using *in vitro* models and in experimental animal infections; however, the genetic basis for this is unlikely to be understood, and the possibility of reversion to pathogenic forms cannot be excluded.

vi) Human feeding experiments to assess the ability of *L. monocytogenes* strains to cause disease have not been attempted. Data collected during foodborne incidents of listeriosis, together with feeding experiments in monkeys, indicate that the attack rate for serious disease is very low in the general population. Therefore, if a population is exposed to a contaminated food vehicle and no cases are recognised, this does not necessarily mean that the contaminating strain is unable to cause disease.

vii) Microbiological criteria for food included in legislation, industry codes of practice and microbiological guidelines in the UK have not distinguished between different *L. monocytogenes* strains and a similar approach has been used in other countries. The WHO Informal Working Group on Foodborne Listeriosis, when considering actions on the recovery of *L. monocytogenes* from foods, did not distinguish between different strains of this bacterium and recommended withdrawal from the market of any foods which have been demonstrated to be causally associated with human cases of listeriosis. The Working Group also recommended to: consider the removal from the market of processed foods in intact packages (e.g. pasteurised milk, dairy products and cooked meats in sealed containers) that are found to be contaminated with *L. monocytogenes.*

4.2 **Hazard characterisation**

4.2.1 Epidemiology

L. monocytogenes is widely distributed in the environment and has been isolated from a variety of sources including soil, vegetation, silage, faecal material, sewage and water. The bacterium is resistant to various environmental conditions such as high salinity or acidity which allows it to survive longer under adverse conditions than most other non-spore-forming bacteria of importance in foodborne disease. *L. monocytogenes* occurs widely in the food processing environment, and can survive for long periods in foods, in processing plants, in households, or in the environment, including at refrigeration or frozen storage temperatures.

4.2.2 Pathology

There is evidence (McLauchlin, 1987) to suggest that *L. monocytogenes* is a transitory resident of the intestinal tract in humans, with 2 to 10 % of the general population being carriers of the organism without any apparent adverse consequences.

L. monocytogenes may cause a relatively mild illness presenting as gastro-enteritis and fever (McLauchlin, 1987). This will be referred to as "febrile listeriosis". It seems likely that this illness is extensively under-reported, but does not usually represent a substantial public health issue. However, febrile listeriosis in pregnant women can result in abortion, premature labour or a critically ill new-born infant.

A more severe form of listeriosis occurs when the organism infects normally sterile sites within the body. This will be referred to as "invasive listeriosis". This is much rarer, of the order of 5 cases per million of population, but much more severe with a fatality rate of 20 to 30% among hospitalised patients. Invasive listeriosis in adults and older children is usually superimposed on another illness. Otherwise healthy older children and adults have a low risk of contracting invasive listeriosis.

This MRA will concentrate on severe listeriosis and the population will be considered as divided into:

i) the low-risk group

ii) the high-risk group, which will be divided into

   a. the perinatal group, including foetuses at risk from febrile listeriosis in the mother
   b. pregnant women (considering risk to the mother rather than the child)
   c. all other high risk people (e.g. transplant patients, elderly, immuno-compromised, and so on).

4.2.3 Dose-Response

Dose-response relationships are often considered under three interrelated headings.

i) The virulence of the organism

As indicated above, there is evidence for variation in virulence among foodborne isolates of *L. monocytogenes*. However, this variation has generally been shown in healthy animals, and it is not clear whether or how this variation can be extrapolated to the high-risk human population groups.

ii) The susceptibility of the host

As indicated above, there are substantial differences in susceptibility between low and high-risk populations. Although research into the mechanisms of *L. monocytogenes* is leading to a better understanding of the differences between these groups, this is not yet adequate to incorporate into a quantitative model.

iii) The influence of the food matrix

There is evidence (McLauchlin, 1987) that the food matrix may influence the infectivity of *L. monocytogenes*. It has been suggested that this may be by influencing the chance that the organism will survive passage through the acid conditions of the stomach. This may be by physico-chemical protection, e.g. by fatty foods, or by induced acid tolerance if the organism has grown in an acid food. Again, this understanding has not reached the stage where it can be incorporated into a quantitative model.

Accordingly, available dose response models do not take variation in any of these factors into account.

There are a number of different mathematical model forms that could be fitted to the available data to produce quantitative, predictive dose-response models. The different model forms differ little in their fit to the available data, but can give substantially different predictions. There is little consensus on the most appropriate form to use.

There are three potential sources of data for the development of quantitative dose-response models.

i) Human volunteer data

This is limited to healthy, adult males and is difficult to extrapolate to the high-risk groups.

ii) Surrogate animal work

While work on animals, usually mice, has elucidated infection mechanisms, extrapolation to humans introduces a great deal of uncertainty, especially in the values of the constants in the models.

iii) Outbreak data

In principle, if detailed data were collected from outbreaks, including estimates of numbers of organisms consumed and details of those who consumed the organism but did not become ill, this could be used to develop quantitative dose response models. However, generally investigations of outbreaks do not provide such data.

Surveillance of listeriosis is carried out in several ways in England and Wales. All cases (both sporadic cases and cases involved in outbreaks) are ascertained from clinical case reports and routine electronic reporting of laboratory isolates to the Public Health Laboratory Service Communicable Disease Surveillance Centre (CDSC) and from isolates submitted for confirmation and typing to the Food Safety Microbiology Laboratory (FSML) (Central Public Health Laboratory). Information from the two sources is later reconciled and collated at CDSC. Further personal, clinical and food consumption information is collected by questionnaires.

Two enhanced surveillance questionnaires are used, according to the two separate categories of risk: the materno-foetal complex and non-pregnancy associated cases. Questions on the forms relate to food information and include where the food was bought and eaten. Other questions capture clinical details and whether or not the case was linked to any others. Identification, including serotyping, antibiogram and phage typing of isolates (both clinical and food), is undertaken by FSML. The concentration of *L. monocytogenes* in contaminated food samples will be estimated and held on record by FSML. If, from the enhanced surveillance dataset, an outbreak is noted, an outbreak surveillance form is sent to the Consultant in Communicable Disease Control dealing with the outbreak. This form captures the mode of transmission, place of outbreak, dates of first and last onset of illness, case details, suspect vehicle of infection, type of incriminating evidence and contributory faults. The completed form is later entered onto the main outbreak database in CDSC. It should be noted that food data in the enhanced surveillance forms is often poor, especially in non-pregnant cases, owing to: a potentially long incubation period (1-70 days); poor memory recall of often elderly patients; and the fact that suspect food items have often long since been discarded. For a suspect food to be properly incriminated, an unopened pack from the same batch as the opened pack must be tested and found to be positive for *L. monocytogenes*. Microbiological results from samples of suspect foods in a patient's fridge may be inconclusive due to the possibility of environmental contamination or the possibility that the patient contaminated the food rather than the other way around.

In summary,

i) available dose response models do not take into account effects of the organism, the host, and the food matrix that are known to be important

ii) there is substantial uncertainty in choice of model form

iii) the limited availability of suitable data introduces substantial uncertainty in the values of the constants in the models.

Accordingly the hazard characterisation step of this MRA will be subject to very large uncertainty. This is in line with the conclusions of FAO/WHO hazard characterisation work (Buchanan and Lindqvist, 2000). In particular, the drafting group concluded that no single dose response model for *L. monocytogenes* could be endorsed, hence indicating large uncertainties.

5. EXPOSURE ASSESSMENT

Listeria monocytogenes can enter the supply chain both with raw materials (e.g. meat, poultry and vegetables) and as a contaminant during processing (e.g. from manufacturing and storage areas). The exposure assessment step needs to identify firstly the locations (e.g. raw material storage, tumbling or massaging prior to cooking, fermentation, smoking or slicing) and the associated process conditions affecting the growth, death and survival of *Listeria monocytogenes.*

Significant growth from the levels found at intake may occur during chilled storage of unpreserved ingredients or during the thawing of frozen ingredients, such as raw meat or liver for pate. The locations where *L. monocytogenes* may re-enter the product (e.g. during cooling, product assembly or slicing) must be identified in carrying out this part of the MRA. Depending on the numbers already in the product and the level of contamination, additional (cross-) contamination may be significant at any stage in the process. There is evidence from investigations of *Listeria monocytogenes* problems in a manufacturing environment, that raw material contamination can be less important than contamination from the factory itself. It is recognised that a manufacturing unit can have 'resident' *Listeria* strains, which are extremely difficult to remove (Bell and Kyriakides, 1998). Consequently the manufacturing process needs to be assessed in terms of its overall design intention and also the effects of its unit operations (e.g. cooking, chilling, slicing, ripening, packaging, garnishing).

Listeria monocytogenes can grow under chilled storage conditions. Consequently, it is essential that the MRA extends descriptively downstream from point of manufacture (e.g. identifying times and temperatures at each stage) to the point of consumption, including retail and domestic storage. For predictions of changes in numbers, bacterial growth, survival and death models are available and those from as many sources as is possible should be used and compared to provide estimates of uncertainty and variability.

Listeria has been associated with meat and poultry products in the UK since 1988 (Kerr, *et al*., 1988). In 1988 an outbreak in England was associated with a food vehicle (Kerr, *et al*., 1988). The first meat/poultry reported case in the USA occurred a year later and was traced to a turkey frankfurter (Wenger, *et al*., 1990). *Listeria* has now been observed in many meat and poultry products.

Some outbreaks of listeriosis associated with cooked meats and poultry are given in Table 2.

The 1987-9 UK paté outbreak can be taken as an example of a process that has caused a problem. In this particular instance, the paté was manufactured by preparing an emulsion of raw meat, fat, spices and other minor ingredients. This unprocessed paté was then put into square-sectioned, hermetically sealed containers and cooked to achieve temperatures in excess of 80°C. The paté was then rapidly cooled, removed from the containers, sliced and

Table 2: Selected foodborne outbreaks of human listeriosis associated with cooked meats and poultry (European Union 1999)

Country	Year	Number of:		Food Implicated
		Cases	Deaths	
USA	1985	1	0	Turkey frankfurter
UK	1987-9	>350	>90	Paté
UK	1988	1	1	Cooked chicken
USA	1988	1	0	Turkey frankfurter
USA	1989	1	0	Sausage
Italy	1989	1	?	Sausage
Australia	1990	9	6	Paté
France	1992	279	85	Pork tongue in aspic
France	1993	33	8	Pork rillettes
Australia	1996	4	1	Cooked chicken
USA	1998-9	100	>10	Hot dogs and deli meats

repackaged for retail sale as pre-packs or distributed for bulk display on delicatessen counters. The paté implicated in the 1987-9 UK outbreak was given a shelf-life of more than 5 weeks, which could allow growth of *Listeria monocytogenes* to high levels. In an investigation of this outbreak, it was concluded that inadequate cooking was unlikely to be the reason for the problem (Bell and Kyriakides, 1998).

Potential contamination from *Listeria* could have arisen from: cooling, when the product was exposed during chilling; contamination from food contact surfaces or containers used to transport the product within the factory; slicing machinery or conveyor belts when the product was sold as pre-packs; and/or garnishing, when the product was decorated post processing.

An effective way to reduce the hazard associated with *Listeria* is to ensure that high standards of environmental hygiene during processing are maintained using regular cleaning and sanitising procedures together with basic standards of good hygienic practice.

The paté illustrates that for most cooked meat operations, the greatest opportunities for contamination arise during slicing and garnishing. Even with high standards of hygienic practice in place, low levels of contamination are likely to occur in up to 5% of sliced meats (Bell and Kyriakides, 1998). The association with public health issues, however, is from contamination with high levels of *Listeria monocytogenes*. It has been suggested that levels of <10 cfu/g (Bell and Kyriakides, 1998) are not unreasonable for paté, and levels of <100 cfu/g have been put forward as acceptable for some RTE foodstuffs (European Union, 1999).

This project is concerned with the risk from *Listeria monocytogenes* in cooked meats and cooked poultry in the food service and domestic environments. Inadequate heating, cross-contamination of treated food from the factory and environment, and prolonged storage (as dictated by time and temperature) are critical areas influencing the extent of the risk. Interaction of the retail, food service and domestic environments can be summarised in Figure 1.

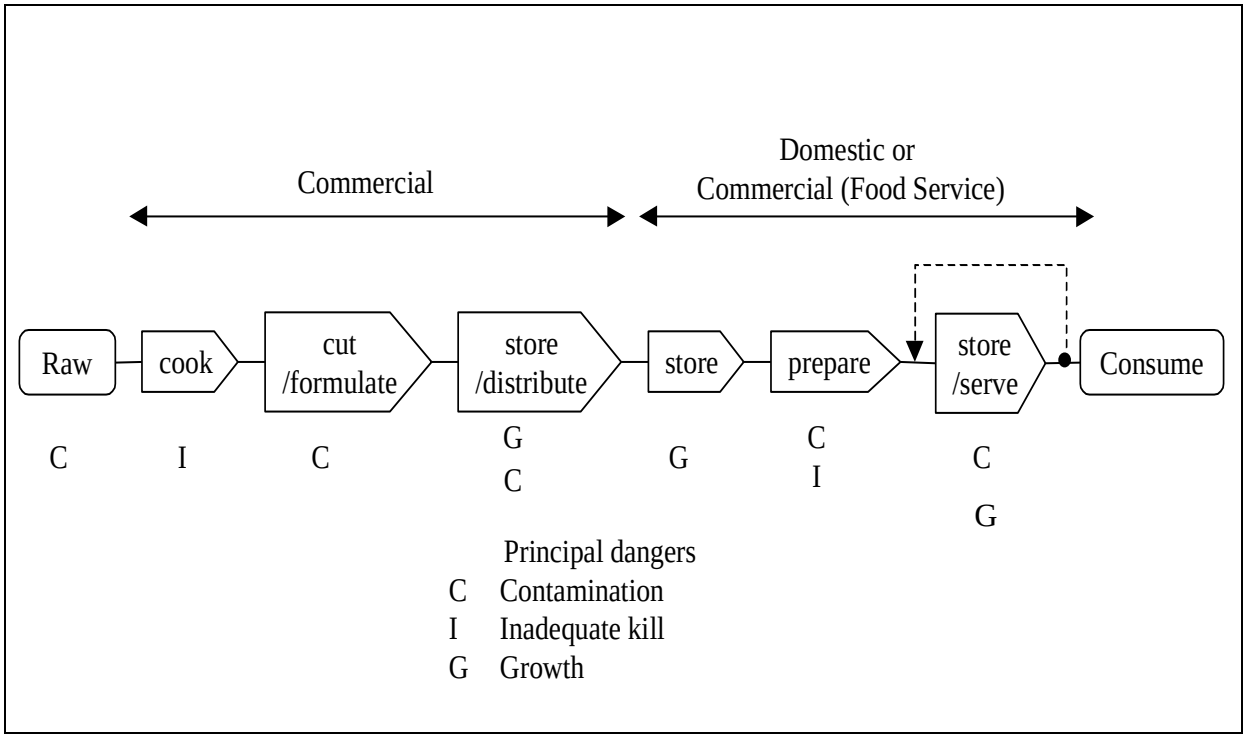

Figure 1: Flow diagram representing critical steps in production, retail, food service and domestic environments, with respect to *Listeria monocytogenes*

5.1 **Resources available**

Exposure assessment involves combining estimates of the prevalence and levels of the pathogen in the food with food consumption data to estimate the numbers of pathogens ingested.

5.1.1 Prevalence and Levels

5.1.1.1 Objective 1: Assessment of current risk

For the objective of assessing current risk, the requirement is to estimate the prevalence and levels of pathogen in the food at the moment of consumption.

There is a substantial amount of published literature on incidence and levels of *L. monocytogenes* in relevant products, most of which relates to retail samples, but with some covering food service situations.

Two substantial and relevant recent draft exposure assessments have been produced (Ross *et al*., 2000, Buchanan and Lindqvist, 2000). However, these principally relate to the USA and most of the literature is concerned with samples taken outside the United Kingdom. Extrapolation to the UK would introduce substantial uncertainty.

In the UK, the Public Health Laboratory Service (PHLS) has carried out a number of surveys over the last decade, resulting in thousands of directly relevant data items. The samples have been taken from retail outlets and food service. These will provide a sound basis for estimating the prevalence and levels in the UK. In addition, the Food Standards Agency (FSA), and previously MAFF, have conducted the National Study of Ready-to-Eat Meats and Meat Products. While not as substantial as the data collected by PHLS, this does amount to several hundred directly relevant data.

Ideally, the estimates of prevalence and levels would be based on samples analysed at the time of consumption. In a food service setting this has usually been the sampling point. In considering the domestic route, the most relevant data comes from retail samples. Extrapolation to the moment of consumption is either by storing the samples before analysis, or by estimating the effects of domestic storage. (For this MRA domestic cooking is not considered. Where this occurs it will reduce the risk.) There is a substantial amount of literature on the growth kinetics of *L. monocytogenes* under a range of appropriate conditions. The major source of uncertainty in modelling the effects of post purchase domestic treatment will be in estimating domestic behaviour. There is a little information available on factors such as domestic refrigerator temperatures. This makes it clear that there is substantial variability and that this can extend beyond recommended ranges, but is not adequate to fully describe that variability. The variability in consumer behaviour will be extended to cover storage times, cross-contamination and cooking.

The uncertainty in consumer treatment will be a major contributor to the uncertainty in exposure assessment by the domestic consumption route. It may be that the most valuable conclusions will be conditional on assumptions of consumer treatment.

5.1.1.2 Objective 2: Assessment of risk reduction strategies

This objective requires that the production, distribution and handling chain be understood and that the contribution of each stage be assessed. This requires models for the effects of those stages. It also requires data on prevalence and levels at those stages, so that the validity and parameters of the models may be assessed.

The requirement to model the chain means that this objective cannot be addressed as generally as the risk assessment described in the previous section. It will be necessary to choose a few products and routes to be studied. This choice will be influenced by the availability of information and by the risk assessment described in the previous section. However, a preliminary choice has been made of:

- paté
- cooked chicken
- ham
- fermented sausage (e.g. salami)

This preliminary MRA has identified these products as being of potential risk, important in the market, representing different processing chains and being representative of a wider range of products.

There is much published literature on the behaviour of *L. monocytogenes* in these products, so models to predict growth, survival and death are generally available. The National Study of Ready-to-Eat Meats and Meat Products (FSA/MAFF 1993-2000) includes some directly relevant UK data on prevalence and levels at different parts of the chain, but otherwise appropriate published data is sparse.

Published data on other products and industrial experience leads to the preliminary conclusion that one of the most important influences on risk is contamination after the commercial cooking step, by *L. monocytogenes* which has colonised the production environment. If this is the case it will be important to model and have good data on incidence and levels in the production environment and the relationship and mechanism between this and product contamination.

Although there is limited published data on *L. monocytogenes* at different stages in the process, both in the product and in the processing environment, there is a substantial amount of data produced by industrial monitoring. Generally this is for presence and does not include counts. In addition, the data has not been produced by a structured survey so that it

will be heavily biased towards more responsible companies and areas where contamination is more likely. Commercial concerns may also limit the extent to which the data, and the important "meta-data" (describing the origin, product and other characteristics of the data itself), can be published. Although such factors will limit the extent to which conclusions can be generalised, the incorporation of industrial monitoring data into the MRA will substantially enhance its value.

5.1.2 Consumption data

Ideally consumption data will relate to the specific products being studied, and will distinguish between the populations being considered - low-risk, high-risk perinatal (pregnant women and new-borns), high-risk non-perinatal (old, ill or otherwise compromised).

The DEFRA National Food Survey is a substantial, well collected body of data which is current and directly relevant to the UK population. Although the published reports do not provide directly relevant breakdowns, the underlying raw data will allow much more relevant analysis. As well as more specific product descriptions, this includes an "Eating Out" survey relevant to the "Food Service" pathway, and information on age and pregnant women which will assist analysis by these high-risk groups. It is unlikely to be possible to extract information directly relevant to other high-risk groups.

The availability of National Food Survey raw data is likely to make the uncertainty due to consumption data small compared to other uncertainties with respect to the old and perinatal high-risk groups. For the ill or otherwise compromised high-risk groups consumption will be taken as that of the general population, introducing additional uncertainty.

5.1.3 Summary

There is substantial information available on the growth, survival and death characteristics of *L. monocytogenes* in relevant conditions. The uncertainty in exposure assessment due to lack of adequate models is likely to be small compared with that arising from lack of information.

Information is lacking in the area of consumer behaviour. There is little data on consumption patterns of some high risk groups. There is little data on the highly variable behaviour of consumers in storing and preparing the foods. There is substantial information on prevalence and levels of *L. monocytogenes* at or close to the point of consumption. This will lead to high quality assessments of current exposure where such assessments are conditional on assumed consumer behaviour, allowing comparisons of exposure between different product groups. The choice of product groups will be dictated by the availability of detailed data and the extent to which product and route (domestic consumption or food service) can be matched between the prevalence and consumption databases.

With respect to the objective of identifying different contributors to exposure and assessing exposure reduction strategies, there is more limited information available. Post-cook contamination is likely to be an important contributor and will be difficult to model in any

mechanistic way. It will be important to have information on the prevalence and levels of *L. monocytogenes* in the environment as well as the product at different stages. Published information in this area is limited and recourse will be made to industrial monitoring data. Although this may limit the transparency of the data and the generality of the conclusions it should lead to conclusions which are of high qualitative value, albeit with a large quantitative uncertainty.

6. RISK CHARACTERISATION

Risk characterisation involves the combination of exposure estimates with hazard characterisation to estimate the frequency and nature of pathological outcomes in the population being considered.

The hazard characterisation of *L. monocytogenes* will include substantial variability and uncertainty that will limit the character of risk estimates based on it.

One of the features distinguishing *L. monocytogenes* from many other foodborne pathogens is the diversity in response between consumers. Most foodborne organisms display broadly similar pathogenicity to most of the population. There are differences in degree of susceptibility so that the very young, very old or those otherwise ill suffer more severely. However, even those outside the high-risk groups suffer similar symptoms, albeit of reduced severity. There is a continuum of response in which the high-risk groups are at the extreme of a distribution.

In contrast *L. monocytogenes* infection displays a discontinuous pathogenicity with either no substantial ill effects at all, or severe illness with a high probability of death. The disparity in response between sub-populations makes it very difficult to draw meaningful conclusions with respect to the overall population. It is not helpful to discuss averages between such extremes of outcomes. Meaningful risk estimates relate to a particular group, the low-risk group or one of the various high-risk groups. The low-risk group is at no substantial risk. Dose-response relationships have been estimated for different high-risk groups, including pregnant women and the immuno-compromised. However, even for these groups the dose-response estimates have substantial uncertainty. Risk estimates in terms of numbers of illnesses or deaths will include all of the uncertainty resulting from the hazard characterisation and will be correspondingly uncertain. Coupled with the unusual pathology of *L. monocytogenes* this will make it difficult to produce useful risk estimates allowing comparison of risk between *L. monocytogenes* and other pathogens.

Comparison of risk from *L. monocytogenes* from different foods or as influenced by different amelioration strategies is less dependent on the hazard characterisation. A lower exposure can be confidently extrapolated to a reduction in pathological outcomes, although the magnitude of that reduction depends on the dose-response relationship. It may be reasonable to draw pragmatically useful conclusions from exposure assessments using the widely accepted rule of thumb that pathogen concentrations below 100 cfu/g do not present a substantial risk.

It should also be possible to make semi-quantitative estimates of differences of risk to different high-risk groups. The information relating to pregnant women is more complete than to other high-risk groups, and this is a clear group to whom risk reduction advice can be targeted.

7. ACKNOWLEDGEMENTS

Funds for this work are gratefully received from the UK Food Standards Agency. The authors also acknowledge assistance and advice given by work colleagues, especially Dr Robert Shaw and the 'Meat Manufacturers Group'.

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