Risk from Listeria monocytogenes in ready to eat smoked fish: Statement of purpose

Vulnerable consumers are defined as those individuals whose immune system is weakened and may be more susceptible to developing infection from *L. monocytogenes (listeriosis)* and likely to suffer more severe symptoms (FSA, 2018). For the purpose of this risk assessment, three groups of vulnerable consumers will be considered (FSA, 2018):

1. Pregnant women, unborn and newly delivered infants
2. Those aged over 65 years
3. Those who are considered clinically vulnerable due to a medical condition or treatment which weakens their immune system. This includes cancer patients, patients undergoing immunosuppressive or cytotoxic treatment, people with diabetes, alcoholics (including those with alcoholic liver disease) and a variety of other conditions.

This risk assessment takes account of the most recent published information, data provided by UKHSA colleagues, and a risk assessment prepared by FSS in spring 2021 in response to a *L. monocytogenes* outbreak linked to smoked salmon. Additionally, to ensure consistency and efficiency, the Hazard Characterisation draws on the recent blue cheese and vulnerable consumers risk assessment (FSA, 2022).

Risk question

What is the risk to vulnerable consumers from *Listeria monocytogenes* in RTE smoked fish?

In scope

- risks from *Listeria monocytogenes*
- risks to the named vulnerable groups above
- risks from all types of smoked fish (for example, cold smoked and hot smoked fish)

Out of scope

- risks from other microorganisms that may be present in smoked fish including non-pathogenic strains of *Listeria*.
- risks from *L. monocytogenes* in smoked fish that is intended to undergo further treatment that would reduce or eliminate the microbiological load (for example cooking).
- risks to other groups, such as the immunocompetent population.
- risks from other smoked foods (for example smoked mussels, smoked cheeses).
- risk from pâté. All UK government guidance pages advise pregnant consumers to avoid all types of pâté (NHS, 2020; NHS 111 Wales, 2022; NHS Inform, 2022; NIDirect, 2022). Pâté is also covered in FSA and FSS guidance for healthcare and social care organisations (FSA, 2018; FSS, 2018).
- risks from other types of RTE fish product that may be hazardous to vulnerable consumers (for example raw unprocessed fish used in sushi-type dishes).

Additional considerations

Risks from salted cured fish, for example gravad

Gravad (also known as gravadlax or gravlax) is a cured fish product popular in Scandinavian countries (Lyhs et al., 2001). The process involves rubbing raw fish fillets with a mixture of sugar and salt and dill is added before a marinating step (Tham et al., 2000). In several outbreaks, cases reported consuming both smoked and gravad fish. Many of the data sets referred to in this risk assessment did not differentiate between smoked and gravad fish. Finally, it is unknown how popular or frequently available this particular product is in the UK market. For these reasons, gravad fish is considered in this risk assessment when the evidence includes it along with smoked fish, but salted and cured fish was considered out of scope. Therefore, data specific to this product was not sought in the preparation of this risk assessment and it is not included in the risk characterisation.

Key assumptions

Any contamination level could lead to illness in vulnerable consumers.

Dose-response models are developed on the assumption that a single organism could lead to infection (Pouillot et al., 2015). The probability of this occurring is incredibly small for healthy individuals but increases for vulnerable groups. As infectious dose would vary depending on the level of immune function in different vulnerable groups and there is little evidence available to calculate these different doses, the decision was made to treat the presence of any *L. monocytogenes* in smoked fish as a risk for vulnerable consumers.

Any strain of *L. monocytogenes* could lead to illness in vulnerable consumers.

There is growing evidence that different strains of *L. monocytogenes* exhibit differing abilities to cause infection (Abdelhamed et al., 2019; Farber et al., 2021), but there is not enough evidence to determine whether any strains pose more of a risk to vulnerable consumer compared to others. Regulation 2073/2005 (footnote 1) and UK Guidelines for Assessing the Microbiological Safety of Ready-to-Eat Foods Placed on the Market do not differentiate on risk of infection based on differences in *L. monocytogenes* strain (Health Protection Agency, 2009). Given this, this risk assessment considered the presence of any strain of *L. monocytogene*s in smoked fish to be capable of causing illness in vulnerable consumers.

Background

Over recent years there have been a number of incidents of listeriosis linked to smoked salmon and other types of smoked fish in the UK. Investigations of some of these incidents have not detected Listeria contamination that is above the legal threshold, however, cases of invasive listeriosis have been reported from people who are vulnerable to L. monocytogenes infection – including pregnant women and people with weakened immune systems – and there have been fatalities (information obtained by FSA and FSS from UKHSA as part of incident investigations).

At the time of writing, there is an ongoing incident of *L. monocytogenes,* with 12 cases reported (footnote 2) (9 England; 3 Scotland), with cases reported from October 2020 – February 2022. Eleven cases reported consumption of smoked fish, ten of which reported smoked salmon specifically. One pregnancy case is associated with this outbreak, and three of the cases are now deceased, with two patients having their death certificates recording *L. monocytogenes* as causative or contributory factors to their deaths.

In order to inform potential changes to advice for vulnerable consumers, FSS and FSA risk assessment teams have been asked to provide an assessment on what the risk to vulnerable

consumers is from *L. monocytogenes* in RTE smoked fish.

Previous Risk Assessments

Several quantitative risk assessments specific to *L. monocytogenes* in smoked fish products have been published. Given the difficulty in determining the infective dose for *L. monocytogenes* (discussed below), most of these risk assessments did not break down the difference in risk for vulnerable groups compared to immunocompetent consumers. Lindqvist and Westöö calculated the probability of illness per serving comparing low-risk and high-risk groups (including children <1 year, pregnant women, those aged over 65 years, and those with HIV/AIDS) using data from Sweden (Lindqvist and Westöö, 2000). The mean probability of illness per serving was 2.0×10^{-3} for the low-risk group compared to 1.6×10^{-2} for the high-risk group (Lindqvist and Westöö, 2000); this equates to the high-risk group having an 8-fold increase in risk of acquiring infection from smoked fish. The authors acknowledge their model for calculating dose-response was conservative, resulting in an overestimation of predicted *L. monocytogenes* case numbers compared to actual numbers recorded in Sweden. They further reflected that since the extent of underreporting of listeriosis is unknown, it is impossible to estimate how closely their predictions might reflect true case numbers (Lindqvist and Westöö, 2000). Pouillot et al. broke down the mean risk of contracting invasive listeriosis per serving of cold-smoked salmon in France (Pouillot et al., 2009); their results are reproduced in

Table 1. Their results also found an increased risk of acquiring listeriosis from consuming smoked fish for vulnerable subpopulations compared to the overall population.

Table 1. The mean risk of contracting invasive Listeriosis per serving of cold-smoked salmon in France (taken from Pouillot et al., 2009)

Subpopulation	Mean risk per serving [95% Credibility Interval]	Increase in risk compared to immunocompetent
Pregnant	1.4 x 10?5 [4.3 x 10?7, 5.5 x 10?4]	x140
Susceptible (immunocompromised)	5.4 x 10?6 [1.7 x 10?7, 2.2 x 10?4]	x54
Over 65 years	1.3 x 10?6 [4.1 x0?8, 5.3 x 10?5]	x13
Reference (immunocompetent)	1.0 x 10?7 [3.3 x 10?9, 4.3 x 10?6]	-
Overall	7.8 x 10?7[2.5 x 0?8, 3.1 x10?5]	-

*Defined as the subpopulation of individuals with one of the following risk factors: cancer (all types), dialysis, transplant, liver cirrhosis, AIDS, and diabetes (all types), regardless of age

Two quantitative risk assessments have been produced to assess the risk from *L. monocytogenes* in several RTE products: one from the FDA/FSIS in 2003 and one from the WHO /FAO in 2004 (FDA, 2003; WHO, 2004). Both considered the risk from smoked seafood specifically amongst other RTE products associated with *L. monocytogenes* infections. Out of 23 RTE products, the FDA risk assessment ranked smoked seafood high risk, (5 out of 23) for risk of infection on a per serving basis. It was ranked number 9 out of 23 (moderate risk) on a predicted median case number per annum basis, taking into account either that a small percentage of consumers regularly consume the product or consumption is infrequent and portions small. The FDA's "smoked seafood" category included both hot- and cold-smoked fish and other seafood like smoked mussels and oysters. In the WHO assessment, cold-smoked fish had the highest estimated cases of listeriosis per serving compared to three other RTE products, at 0.053 cases per 1 million servings. It had the second highest estimated risk per consumer, after pasteurised

milk. The WHO risk characterisation data is summarised in Table 2.

Table 2. WHO risk characterisation data for various ready-to-eat foods (taken from (WHO, 2004)

Food	Cases of listeriosis per 10 million people per year	Cases of listeriosis per 1 million serving
Pasteurised milk	9.1	0.005
Ice cream	0.012	0.000014
Cold-smoked fish	0.46	0.053
Fermented meat products	0.00066	0.0000021

1. Regulation 2073/2005 is used throughout this document as shorthand for Retained EU Regulation (EC) 2073/2005 which applies in England, Wales and Scotland and EU Regulation (EC) 2073/2005 which applies in Northern Ireland.

2. Two further cases within this cluster were identified while the risk assessment was in preparation. The number total of cases as of June 2022 is 14, 11 in England and 3 in Scotland.