Risk from Listeria monocytogenes in ready to eat smoked fish: Risk Characterisation

In determining the risk characterisation consideration was given to whether any differentiation could be made between different vulnerable groups, different smoking techniques or different species of fish. These are detailed below along with a summary on the risk of listeriosis in relation to smoked fish consumption.

Effect on different vulnerable groups

Initially this risk assessment aimed to examine the risk of listeriosis in three separate vulnerable groups: pregnant women and unborn and newly delivered infants, those aged over 65, and those who are considered clinically vulnerable due to a medical condition or treatment which affects their immune system. A number of significant outbreaks (between 4 and 22 cases in each) associated with *L. monocytogenes* contamination of smoked fish were detailed in Table 4. Not all of these provided sufficient detail to ascertain if affected cases came from the vulnerable groups included in this risk assessment, but where this information was provided, vulnerable groups were the majority or all of cases. However, the data available for these outbreaks did not provide enough evidence to differentiate between the risk for different vulnerable groups. It is also noted that only more serious cases of listeriosis are likely to be detected, and that those in vulnerable groups may also suffer from non-invasive listeriosis which is not reported. It should be noted that the risk to pregnant consumers is linked to the risk of miscarriage, stillbirth or premature birth from listeriosis, and that listeriosis may be asymptomatic or associated with mild symptoms in the mother.

Although the increased risk of listeriosis to vulnerable groups was highlighted by all the literature consulted as part of this risk assessment, it was not possible to identify a specific infectious dose for vulnerable consumers more generally, or broken down by the categories outlined above. The risk reported in publications ranged from 10 to 100 times higher than the immunocompetent population, and even up to 1000 times in the case of one specific medical condition.

Non-invasive listeriosis typically occurs in immunocompetent individuals and is not well-studied as clinical presentation is rare. Invasive listeriosis typically occurs in vulnerable or immunocompromised individuals, the symptoms are severe and hospitalisation is required in a high number of cases. For these reasons, the risk characterisation in this risk assessment deals specifically with invasive listeriosis.

In summary, although it is recognised that the risk may differ between these different vulnerable groups, the data presented here supports the conclusion that the risk is higher than for the general population for all of these groups, and that while the immunocompetent population may be able to safely consume food contaminated with *L. monocytogenes* to a level within the legal limit, no level of *L. monocytogenes* contamination can be considered safe for vulnerable groups. Although it is not possible to determine the level of *L. monocytogenes* contamination which can be considered safe for vulnerable groups as a specific infectious dose, there is information

available to show that this level is likely to be significantly lower than the level required to cause illness in immunocompetent groups.

Effect of smoking techniques

The data presented in this risk assessment demonstrates that if adequate protocols are used, cold smoking and the associated processing can significantly reduce levels of *L. monocytogenes* in fish if the initial contamination is in line with anticipated levels of natural contamination. Hot smoking at the necessary temperature can inactivate the pathogen. However, all producers use slightly different procedures and this may affect the efficacy of either hot or cold smoking as a control. Prevalence data suggests that likelihood of contamination in hot smoked fish may be a third to an eighth of that in cold smoked fish. We note that the data available to allow the comparison of hot and cold smoking was incomplete as a number of authors reporting prevalence of *L. monocytogenes* did not define what type of smoking had been used. Additionally, there was not enough data available to compare the reported level of contamination between hot and cold smoked fish products. The further processing that these RTE products are subject to post either hot or cold smoking may introduce or re-introduce *L. monocytogenes* contamination, and the prevalence data presented demonstrates that neither hot nor cold smoked fish can reliably be considered free of L. monocytogenes. The outbreak data presented in section 3.3 does not include any reported incidents attributed to hot smoked salmon.

Although the limited data and uncertainties around the differences in production practices used by different FBOs lead to certain gaps in our understanding of the difference in risk between hot smoked and cold smoked fish, we believe the prevalence and outbreak data support the separate consideration of hot and cold smoked fish in the risk conclusion.

Effect of species of fish

A number of different species of smoked fish are available to UK consumers. The prevalence data presented in this risk assessment suggests that *L. monocytogenes* contamination can be found in any RTE smoked fish product, although reports from different authors implicated different fish species as more likely to be contaminated. For this reason, we do not think there is sufficient data to differentiate between smoked fish of different species. However, it is worth noting, that the most abundantly available evidence used throughout this RA concerns smoked salmon products, which likely to reflect the species preference of UK consumers, with salmon representing 46.6% of the UK chilled seafood species value share in 2021, and smoked salmon making up around a quarter of chilled salmon sales (Chilled Seafood in Multiple Retail, 2021).

Effect of growth within product

Modelling work presented in this risk assessment suggested that typical consumer behaviour could allow low levels of contamination (1 CFU/g) in product with average pH and aw to multiply to above the legal limit of 100 CFU/g by the end of shelf life. However, the model does not take into account the effect of smoke or other inhibitory substances that *L. monocytogenes* may be exposed to, or the effect of other lactic acid bacteria present within the product. Thus modelling alone cannot give a true indication of levels likely to occur at the end of shelf life. Additionally, industry practice may also help to limit the potential for *L. monocytogenes* to be present in a final product. For example, we understand from colleagues in the FSS Incident Investigations and Enforcement Delivery Teams, that it is common industry practice to demonstrate no detection of *L. monocytogenes* in 25 grams at the beginning of shelf life. Where *L. monocytogenes* has been detected in 25 g at the beginning of shelf life, common industry practice is likely to divert this product to alternative route for example, for further downstream processing/cooking into products containing smoked salmon such as pies or quiches. Alternatively, if the product is not diverted,

the FBO must have sufficient evidence to demonstrate that the levels of *L. monocytogenes* will not reach 100 CFU/g at the end of shelf-life. It should, however, be noted that there will be differences between laboratory testing methods used by different FBOs, criteria for release of product at beginning of shelf-life, and for risk management action if *L. monocytogenes* has been detected. These processes will be examined by and agreed with competent Local Authorities. However, no detection of *L. monocytogenes* does not guarantee complete absence of the pathogen. It might be present at a level below the test detection limit or the sampling plan might not be sufficient to detect it and as indicated above, any level of *L. monocytogenes* contamination in RTE smoked fish products may be considered a risk to vulnerable consumers.

Risk to vulnerable consumers

Overall, the number of outbreaks of listeriosis in the UK is very low, even in relation to vulnerable consumers, when examined in the context of the UK consumption data provided in this risk assessment. The over-65 year old population of the UK is 12.5 million (Office for National Statistics), and 6.11% of this would represent over 763,000 over-65s reporting consumption of uncooked smoked fish. The incidence rate of listeriosis per 100,000 population in England and Wales was 0.26 in 2018 and 0.24 in 2019 (most recently available data) which suggests that reported listeriosis infection is rare even amongst more susceptible populations. ACMSF has advised that the qualitative scale can be aligned with an indicative numerical scale for the frequencies of occurrence of risk events and a qualitative low frequency of occurrence has an indicative numerical scale with an assigned frequency of 0.05 - 1.7 cases per 100,000 person years (ACMSF, 2020). However, these groups may not be aware of their increased relative risk of illness following consumption of smoked fish products. Due to the limited information available for milder forms of listeriosis, it has not been possible to understand the level of non-invasive listeriosis experienced by the vulnerable groups considered in this risk assessment.

This risk assessment was produced using a multidimensional model of risk which provides a category for frequency and severity to be taken together as the risk conclusion (see Appendix 2; ACMSF, 2020). On the basis of the evidence presented in this risk assessment, and summarised above, our overall risk conclusion is:

- the frequency of occurrence of invasive listeriosis in the vulnerable population from consumption of cold smoked fish is LOW (for example, rare but does occur)
- the frequency of occurrence of invasive listeriosis in the vulnerable population from consumption of hot smoked fish is VERY LOW for example, very rare but cannot be excluded)

We consider the level of uncertainty for the frequency of occurrence of invasive listeriosis in the vulnerable population from the consumption of hot or cold smoked fish to be MEDIUM. The uncertainty level is largely due to the lack of data on infective doses for *L. monocytogenes* and the variability in susceptibility to infection amongst different vulnerable groups.

- the severity of illness in vulnerable populations from *L. monocytogenes* infection is HIGH (for example, severe illness: causing life-threatening or substantial sequelae or illness of long duration)

We consider the level of uncertainty for the severity of illness of listeriosis in the vulnerable population to be LOW. This uncertainty level reflects the large amount of data on the severity of invasive *L. monocytogenes* infections, particularly within vulnerable groups.

Key uncertainties

The below points contributed to the assignation of a medium uncertainty to the frequency of occurrence of invasive listeriosis:

- there is a lack of data to allow estimation of infectious dose and probability of infection for different vulnerable groups, with dose response models recognised to suffer from uncertainty of the impact of low level exposure on vulnerable populations.
- consumer behaviour around chill storage temperature and use-by date abuse is unknown.
- due to the long incubation period for *L. monocytogenes,* attributing the source of a case or outbreak as smoked fish can be difficult which may result in smoked fish not being identified as the responsible food vehicle.
- the initial contamination level and how it carries through the food chain will affect the level in the final product.
- variations in processing between FBOs and how those specific conditions may affect *L. monocytogenes* presence and levels.
- the level of non-invasive listeriosis experienced by the vulnerable groups identified in this risk assessment. This is compounded by the lack of diagnostic investigations for non-invasive listeriosis.
- the extent of awareness of existing government advice. NHS advice (that smoked fish is a food of most concern, and that care should be taken during pregnancy) was recently added to, acknowledging the current incident and advising pregnant consumers to only eat smoked fish products that have been thoroughly cooked. FSA and FSS advice states, that smoked fish is a high-risk product in terms o*f L. monocytogenes,* with recent updates to the website to highlight the on-going incident and advice to consumers at higher risk of serious infection to always thoroughly cook smoked fish products.
- additionally, we note that some smoked fish products do not indicate on the packaging if the smoking process was hot or cold, meaning that consumers may not be aware of the type of processing the product has undergone.

The other contributing sources of uncertainty are:

- uncertainty around the products and species of fish available on retail in the UK (for example, hot smoked, cold smoked, gravad) and the popularity of different products with UK consumers.
- uncertainties around any other factors influencing consumer behaviour with smoked fish RTE products (for example, dietary preferences, which may lead to consuming bigger amounts of this type of product, practices such as leaving the product to warm up to room temperature before consumption, any further cooking prior to consumption etc).
- uncertainties around the difference in risk if smoked fish is used in salad preparations in deli settings
- uncertainties around the understanding of any specific vulnerabilities and the infectious dose for each group or condition which can increase the risk of infection.

It is recognised that some of the uncertainties highlighted above represent variabilities which are distinct from data gaps. For example, the uncertainty around variability in response to exposure to *L. monocytogenes* experienced by different vulnerable consumers represents both natural variation (for example differing susceptibilities to infection), as well as gaps in data (for example the current lack of understanding as to the different risk relative to the immunocompetent population), and both aspects contribute to the uncertainties which are relevant to the final risk characterisation.