4.03.2024

Imported food risk statement

Enoki (enokitake) mushrooms and *Listeria monocytogenes*

Scope: Enoki (enokitake) mushrooms, or golden needle mushrooms - fresh packaged (including vacuum packed, but not canned, dried or frozen enoki mushrooms)

Recommendation and rationale
Does *Listeria monocytogenes* in imported enoki mushrooms present a potential medium or high risk to public health: ☑ *Yes* ☐ *No* **Rationale**: • *L. monocytogenes* is a moderately infectious pathogen that can cause severe disease in susceptible populations, with a case fatality rate of 15–30%. • There is strong evidence that *L. monocytogenes* can be present in enoki mushrooms and foodborne illness outbreaks have been associated with the consumption of enoki mushrooms, including in Australia. • The method of production and processing can introduce microbial contamination. There is also the potential for post-processing contamination to occur. • Growth of *L. monocytogenes* can occur on enoki mushrooms, including when stored at refrigeration temperatures. • A cooking step such as boiling enoki mushroom should eliminate the hazard. However, there is evidence of enoki mushrooms being consumed raw or without adequate cooking. • Available evidence indicates that the prevalence and level of *L. monocytogenes* in enoki mushrooms is sufficient to be a public health risk.

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Nature of the microorganism: *Listeria monocytogenes* is a Gram-positive, non-spore forming rod-shaped, facultative anaerobic bacterium that is found throughout the environment. *L. monocytogenes* has been isolated from domestic and wild animals, birds, soil, vegetation, fodder and water; and from the floors, drains and wet areas of food processing factories (FSANZ 2013). *L. monocytogenes* is a hardy organism. The temperature range for growth is between –1.5 and 45°C, with the optimal growth temperature being 30–37°C (FSANZ 2013). Temperatures above 50°C are lethal to *Listeria*, but it can survive for long periods at refrigeration temperatures and below freezing. *L. monocytogenes* is relatively tolerant to acidic conditions and can grow in a broad pH range (4.0–9.6). *L. monocytogenes* can grow at a water activity (a_w) as low as 0.90 and survive for extended periods of time at an a_w of 0.81. It is reasonably salt-tolerant; reported to grow in 13–14% sodium chloride (Farber et al. 1992; Lado and Yousef 2007). *Listeria* can grow well under both aerobic and anaerobic conditions (Sutherland et al. 2003).
Adverse health effects: For susceptible populations, *L. monocytogenes* can cause severe disease that is potentially life threatening. People at risk of invasive listeriosis include pregnant women and their foetuses, neonates, the elderly and immunocompromised individuals (such as cancer, transplant and HIV/AIDS patients). Patients with diabetes, asthma, cirrhosis and ulcerative colitis are also at a greater risk (FSANZ 2013). In pregnant women, invasive listeriosis can cause spontaneous abortion, stillbirth or neonatal infection. Influenza-like symptoms, fever, and gastrointestinal symptoms can also occur in the mother. In immunocompromised individuals and the elderly, invasive listeriosis can cause potentially fatal bacterial meningitis, with symptoms of fever, malaise, ataxia and altered

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mental status. The onset of illness of invasive listeriosis generally ranges from 3 days to 3 months after infection. Invasive listeriosis has a fatality rate of 15–30% (FDA 2012; FSANZ 2013).

Published data indicate that contaminated foods responsible for foodborne listeriosis usually contain levels of *L. monocytogenes* >100 cfu/g (Ryser and Buchanan 2013).

Exposure to *L. monocytogenes* usually has minimal impact on the general healthy population. If infection does occur, it can be asymptomatic or present as a mild febrile gastrointestinal illness that can be mistaken for a viral infection (FSANZ 2013).

Consumption patterns:

Data from 2011–12 Australian National Nutrition and Physical Activity Survey (ABS, 2014) is used to determine consumption patterns for specific foods. Enoki mushrooms are not listed as a specific food, so it is not possible to separate out that consumption data from the collective "All mushrooms" data set.

Approximately 43% of adults (aged over 17 years) reported consuming mushrooms either raw or cooked while 33% of children (16 years and younger) reported eating mushrooms. In both groups, the majority of respondents consumed cooked or heat-treated mushrooms.

Less than 0.1% of respondents specifically reported consuming "oriental mushrooms", a food classification that included shiitake, enoki, oyster, chestnut, shimeji and wood ear mushrooms.

Imports of enoki mushrooms have been steadily increasing year-on-year (2010: 169,000 kg; 2022: 2.23 million kg) strongly indicating that consumption of enoki mushrooms has increased over this time.

Enoki mushrooms have been cultivated for hundreds of years and are often used in Chinese, Japanese, and Korean cuisine. Individuals of Asian heritage are more likely to consume enoki mushrooms and more often than other sectors of the population. Those unfamiliar with enoki mushrooms may consume them occasionally and may consume them raw.

Risk factors and risk mitigation:

Enoki mushrooms, *Flammulina filiformis,* (formerly known as *Flammulina velutipes*) is a member of the gilled mushroom family, Physalacriaceae. These mushrooms, also known as golden needle or enokitake, are commonly used in East Asian cuisine including from China, Japan, Korea and Vietnam. *Flammulina filiformis*, when grown naturally are golden brown, loosely clustered with a relatively short stipe, unlike those produced commercially which are white capped (pileus), with a long slender stipe which are harvested clumped together on a single root stock.

Commercial production of enoki uses open topped jars (e.g. mason jars) with a lignin-cellulose based medium (hard wood, sawdust or wheat straw) with the addition of a wheat or rice bran (or similar) nitrogen supplement. Both the jars and the medium including the supplement should be sterilised prior to use to remove any microorganisms that would compete with enoki spawn. Water and spawn (spore seeding) are added to the medium in the jars which are capped to retain the high humidity (50-80% moisture content with a slightly acidic pH) and a higher concentration of CO_2 which is required for spore germination and initial stipe development. Once the stipe and pileus is close to the top of the jar, a disposable collar is placed around the neck of the jar to promote long straight stipe growth. Harvest occurs once growth has reached the top of the collar, which is then removed and the enoki mushrooms are pulled out of the jar, including the "root stock" and packaged into polypropylene (PP) or similar bags with either a partial or full vacuum applied. Although some parts of this process are mechanised, (mainly the racking of jars to trays, stacking of the trays and movement to and from culture rooms; packaging) collaring and harvesting are still performed by hand.

Production of enoki mushrooms requires high humidity (50-80%), water added to the growth matrix, relatively high CO_2 concentrations of 0.3-0.5% during initial mycelial growth reducing to 0.1-0.2% during stipe elongation and pileus formation and ambient temperatures (18-25°C) to ensure rapid growth (reviewed in Dowom et al, 2019). This also creates an ideal environment for pathogenic *Listeria* spp. to grow and persist. If *L. monocytogenes* becomes established in the production environment (e.g. entry to the facility via equipment, people, ingredients), given the nature of the enoki growth requirements, it will be difficult to eliminate and may remain a potential source for ongoing contamination of the enoki mushrooms during growth and harvest. Any additional handling (e.g. collaring) of enoki mushrooms during the growth phase will increase the risk of product contamination. To minimise contamination of enoki mushrooms with *L. monocytogenes*, effective control measures should be in place during primary production and processing, e.g. through application of Good Manufacturing Practices (GMP) on-farm and Good Hygienic Practices (GHP) at critical points in the supply chain (Codex 2017).

L. monocytogenes is able to grow on enoki mushrooms, both whole and cut, with elevated growth rates associated with increasing temperatures. For example, Fay et al. 2023 reported growth rates at 5°C: -0.02±0.03; 10°C: 0.28±0.03; 25°C:

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1.32±0.12 log CFU/g per day during for storage of up to 7 days. Kim et al (2020) reported growth of *L. monocytogenes* on enoki mushrooms stored at 5°C for 30 days with increasing growth rates at higher temperatures. Thus, if *L. monocytogenes* is present on enoki mushrooms when packaged and the product has an extended shelf-life (> 14 days), it has the potential to grow to high numbers before consumption, even if refrigerated. Application of a partial vacuum and continued respiration by enoki mushrooms may slow the growth rate of *L. monocytogenes* slightly. However, depending upon the initial contamination level, combined with longer storage times at temperatures of 5°C to ambient for both transport and storage, it is likely that the concentration of *Listeria* could increase to levels of 10^5-10^7 cells/g. This would constitute a public health and safety risk, particularly for vulnerable populations (FSANZ unpublished). Cooler storage temperatures (less than or equal to 1°C) have been shown to control growth - Kim et al (2020), with no increase in *L. monocytogenes* numbers occurring over one month. Consumer advice varies on the suitability of enoki mushrooms to be consumed raw. The Australian Mushroom Growers Association recommends enoki not be consumed raw but instead undergo light cooking (AMGA 2023). The US Mushroom Council states enoki mushrooms can be consumed either eaten raw in salads or as part of a sandwich or can be used as an ingredient in soups and stocks (US Mushroom Council 2021). Traditional preparation of enoki mushrooms involves boiling or thorough heating before consumption. As there is evidence enoki mushrooms are consumed in non-traditional ways (e.g. salads, stir fries), they present an increased risk for listeriosis. To reduce any *L. monocytogenes* present to safe levels, the mushrooms need to be heated to at least 70°C for at least two minutes. There are no specific measures reported for the control of *L. monocytogenes* in enoki mushrooms during production, although a number of wash water additives have been proposed that could be applied either at food service or in the home (Chung et al 2023). However, it is unclear if these would be effective at reducing the level of *Listeria* contamination sufficiently to minimise the risk to consumers, particularly if the enoki was at the end of its shelf life. **Risk assessment by FSANZ to inform risk management** A semi-quantitative risk assessment was undertaken by FSANZ to determine if a significant public health and safety risk is posed by *L. monocytogenes* on imported raw enoki mushrooms, and to provide scientific justification for risk management measures that can be applied to provide an appropriate level of risk for consumers. This also included consideration of applying a performance objective at the Australian border to achieve an appropriate level of risk. A performance objective is defined as the maximum frequency and/or concentration of a hazard in a food at a specified step in the food chain before the time of consumption that provides or contributes to an appropriate level of risk. The risk assessment estimated risk of illness to Australian consumers across a range of scenarios based on assumptions that all imported enoki mushrooms: • are refrigerated at 5°C post border • have a storage time before consumption of between 14 and 55 days post border entry • are cooked before consumption, and • where cooking is 99% effectiveness (i.e. 'usually eliminates the hazard'). Best case scenario (i.e., with a shorter storage time and effective cooking before consumption) estimated a medium to high risk of illness if 10% of imported enoki was contaminated at levels of 1,000 CFU/g where the serving size was 100g. A higher risk was estimated if 15% of imported enoki was assumed to be consumed raw between 14 and 35 days post border entry. The outcomes of the risk assessment showed that: • labelling for storage conditions and directions for use is required to reduce risk but alone is insufficient to reduce the public health and safety risk posed by imported enoki under reasonably foreseeable conditions of use; • enoki must be refrigerated through-chain once packaged, and must be labelled to be refrigerated and cooked thoroughly to reduce the risk of illness from this product; • risk increases with a longer shelf-life; and • applying a performance objective of *L. monocytogenes* not detected in five 25g samples of enoki from a lot contributes to reducing risk to an appropriate level. Enoki mushrooms can be considered a potentially hazardous food due to the potential presence of *L. monocytogenes* that can grow on this product during storage. Cooking time/temperatures required to achieve a 6D reduction of *L. monocytogenes* are 65°C for 9.3 minutes, 70°C for 2 minutes and 80°C and 85°C for 0.09 and 0.02 minutes respectively (FDA Guidelines). As such, it is also recommended instructions on the labels of enoki mushrooms in relation to storage and cooking be clear. For example, labelling with "Must be refrigerated below 5°C" and "Cook thoroughly at 70°C for at least 2 min".

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Surveillance information:

Listeriosis is a notifiable disease in all Australian states and territories. In 2022 the reported incidence rate was 0.3 cases per 100,000 population (88 cases), this includes both foodborne and non-foodborne cases[1]. The foodborne rate is estimated to be 98% (90% Crl 90-100%) for *L. monocytogenes* cases in Australia (Kirk et al. 2014). The previous five year mean reported incidence rate was 0.3 cases per 100,000 population per year (ranging from 0.2–0.4 cases per 100,000 population per year). It is not anticipated that the global coronavirus disease pandemic had a significant impact on the number of listeriosis cases reported in 2021, as listeriosis is not generally a travel-associated illness and people would still seek medical care due to the severity of the illness.

Enoki mushroom recalls due to detection of *Listeria monocytogenes* (no known illnesses reported)

Canada (2021-2023):

- 16 September 2023: Golden Mushroom. Golden Mushroom brand Enoki Mushroom recalled due to Listeria monocytogenes - Canada.ca
- 16th October 2023 Lian Teng. Lian Teng brand "Champignon Énoki" (Enoki Mushrooms) recalled due to Listeria monocytogenes - Canada.ca
- 19th September 2023: Super brand. Super brand Enoki Mushroom recalled due to Listeria monocytogenes - Canada.ca
- 28th July 2023: SSS brand. SSS brand Mushroom (enoki) recalled due to Listeria monocytogenes - Canada.ca
- 15 May 2021: Ravine Mushroom Farms. Certain Enoki Mushrooms may be unsafe due to Listeria monocytogenes - Canada.ca
- 7 May 2021: Goldenway International Trade Co. Certain Enoki Mushrooms may be unsafe due to Listeria monocytogenes - Canada.ca

Australia (2023):

- 28th June 2023: Concordia Traders (Aust) Pty LTD. Current food recalls (foodstandards.gov.au)
- 27th June 2023: Natural Mushroom. Current food recalls (foodstandards.gov.au)
- 7th June 2023: KO Food Australia Pty LTD. Current food recalls (foodstandards.gov.au)
- 2nd June 2023: Fruit Perfection Pty LTD. Current food recalls (foodstandards.gov.au)
- 9th May 2023: Korea Connections. Current food recalls (foodstandards.gov.au)
- 6th April 2023: K-mama https://www.foodstandards.gov.au/industry/foodrecalls/recalls/Pages/K-mama-Enoki-Mushrooms-300g.aspx
- 10th March 2023: K-mama https://www.foodstandards.gov.au/consumer/generalissues/Pages/Listeria-Monocytogenes-linked-to-fresh-enoki-mushrooms-imported-from-South-Korea.aspx

US (2022-2023):

- 24th February 2023: Jan Fruits Inc.
- 17th November 2022: Green Day Produce Ltd
- 13th December 2022**:** Utopia Foods

Note: FDA surveillance found many samples of enoki mushrooms were contaminated with various strains of *Listeria* most of which were not the same as the outbreak strains.

Europe (2022):

- 13 May 2022: Ireland,: RASFF notification (2022.2633) Green Box Ltd Cendawan https://www.fsai.ie/news_centre/food_alerts/recall_cendawan_enoki_mushroom.html
- 5 May 2022: Slovenia: RASFF notification (2022.2633) Green Box Ltd Cendawan Quantitative sampling detected levels of 2.6x 10^5 CFU/g (allowable maximum limit is <100 CFU/g). https://webgate.ec.europa.eu/rasff-window/screen/notification/547886 ; https://www.gov.si/novice/2022-05-05-odpoklic-enoki-gob-zaradi-ugotovljene-prisotnosti-bakterije-listeria-monocytogenes/
- 25th March 2022: Netherlands: RASFF notification (2022.1779) Quantitative sampling detected levels of 1.4 x 10^2 - <20 CFU/g and 7.6 x 10^3 - 1.3 x 10^3 CFU/g (allowable maximum limit is <100 CFU/g). RASFF Window - Notification detail (europa.eu)

[1] Data on the number of listeriosis cases provided by the National Interoperable Notifiable Disease Surveillance System with population data from the Australian Bureau of Statistics (accessed 11 January 2023)

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- 15th February 2022: Netherlands: RASFF notification (2022.1776). Quantitative sampling detected levels of 1.6 x 10^4 - 1.2 x 10^2 CFU/g and 3.2 x 10^2 - 5.0 x 10^5 CFU/g. RASFF Window - Notification detail (europa.eu)

Illness associated with consumption of enoki mushrooms contaminated with *Listeria monocytogenes*

A search of the scientific literature from 2000 to 2023 via EBSCO; the US CDC National Outbreak Reporting System; and other publications identified 5 listeriosis outbreaks associated with consumption of enokitake mushrooms.

USA (2016-2022):

- 2022: A recall of Utopia Foods Inc. of Glendale NY, November 2022 and expanded on 13 December 2022. As of 7 April 2023, 5 people infected and hospitalised were reported from 4 states, 2 persons from California, and 1 each from New Jersey, Michigan and Nevada.
- 2020: As of 9 June 2020, 36 people were infected by *L. monocytogenes* from 17 states. 31 were hospitalised, 4 died and 2 foetal losses in 6 pregnancy-associated cases. Source identified as enokitake mushrooms supplied by Green Co. LTD.
- 2017: *L. monocytogenes* in enokitake mushrooms resulted a multi-state outbreak with 5 ill patients, one died.
- 2016: multi-state outbreak caused by *L. monocytogenes* in enoki mushrooms led to 36 reported illnesses; 4 died.

Australia (2017-2020):

- 6 cases were notified between October 2017 and March 2020. Product was recalled on 10 April 2020. The strains were shown to be related to the USA outbreak strain via whole genome sequencing.

Data on the prevalence of *Listeria monocytogenes* in enoki mushrooms

In 2023, FSANZ coordinated an Australian national survey of imported and domestic enoki. The results indicate that 34/299 (11%) imported enoki samples were contaminated with *L. monocytogenes* at concentrations up to 11,000 CFU/g. The mean contamination level was 1,250 CFU/g. No detections of *L. monocytogenes* were observed in the 36 domestic samples.

Food Standards Agency and Food Standards Scotland issued an advisory notice in 2023 to vulnerable consumers to thoroughly cook enoki mushrooms following sampling data found the presence of *L. monocytogenes* in 13 of 40 (32.5%) samples tested. Contaminated mushrooms were imported from China, Korea, Thailand and other Asian countries. (FSS and the FSA advise on Listeria monocytogenes in imported Enoki mushrooms | Food Standards Scotland)

The US FDA's (2023) national testing of *L. monocytogenes* on imported enoki mushrooms from the Republic of Korea and the People's Republic of China, showed 43% and 15% of the samples respectively were positive for *L. monocytogenes*.

A search of scientific literature from 2000 to 2023 via EBSCO and other publications only identified 4 surveys for *L. monocytogenes* in enoki mushrooms; 3 from China and one from Spain. They indicated a prevalence of *L. monocytogenes* ranging from 0-100% on fresh whole enoki mushrooms, noting the study by Chen et al (2014) was based on a small sample collection post-processing from 4 different facilities, while the remaining 3 studies were at retailer level. An overall estimation of prevalence at 46.9% (95% Confidence Interval 9.3-88.4%) was determined using a random effect meta-analysis.

Standards or guidelines

Australia does not currently have microbiological criteria that applies to *L. monocytogenes* and enoki mushrooms in the Australia New Zealand Food Standards Code. Food Safety Standards in Chapter 3 apply to food businesses including food importers, to sell safe and suitable food including during transport and packing activities and to ensure products are traceable. Standard 1.2.6 requires that labels on food include appropriate directions for use and storage to maintain the safety of the food.

In response to international recalls and alerts in relation to enoki mushrooms, the Department of Agriculture, Fisheries and Forestry (DAFF) issued an Imported Food Notice (IFN 01-23 - Listeria monocytogenes in enoki mushrooms - DAFF (agriculture.gov.au) in March 2023 to raise awareness of the risk of *L. monocytogenes* contamination in enoki mushrooms.

General guidance for mushroom producers in Australia is available from the Australian Mushroom Growers Association, however, these do not specifically cover enoki mushroom production (AMGA 2020).

Codex general principles of food hygiene *CAC/RCP 1 – 1969* follows the food chain from primary production through to final consumption, highlighting the key hygiene controls at each stage (Codex 2020).

Standards or guidelines
Codex code of hygienic practice for fresh fruit and vegetables *CXC 53-2003* addresses Good Agricultural Practices and Good Hygienic Practices that help control microbial, chemical and physical hazards associated with all stages of the production of fresh fruits and vegetables, from primary production to consumption (Codex 2017). There are industry developed schemes to manage food safety in horticulture. These are audited by a third party against specific requirements. Some of these schemes are internationally benchmarked to the Global Food Safety Initiative (GFSI) (FSANZ 2020). Production of safe and suitable enoki mushroom is best managed with a through-chain approach starting at primary production, including environmental monitoring of *Listeria* spp.
Management approaches used by overseas countries
The European Food Safety Authority (EFSA) recommends good hygiene, manufacturing and agricultural practices in food producing countries. The *European Commission Regulation (EC) No 852/2004 – Annex 1 Part A: General hygiene provisions for primary production and associated operations* outlines general provisions for the hygienic production of food, including fresh produce. This includes requirements on water use; health and hygiene of food handlers; cleaning and sanitising of facilities, equipment and vehicles; animal and pest exclusion; storage of waste; and the use of biocides (EU 2004). Fresh fruit or vegetables imported into Canada must meet Canadian requirements as set out in the Safe Food for Canadian Regulations as well as the Food and Drug Regulations. Under Section 8 of the Safe Food for Canadian Regulations food that is imported, exported or inter-provincially traded must not be contaminated; must be edible; must not consist in whole or in part of any filthy, putrid, disgusting, rotten, decomposed or diseased animal or vegetable substance; and must have been manufactured, prepared, stored, packaged and labelled under sanitary conditions (CFIA 2019b). Additionally, shipments of fresh enoki mushrooms arriving in Canada on or after March 15, 2023 from the Republic of Korea and/or the People's Republic of China must be held and tested (CFIA 2023). Currently, enoki is held until tests confirm *L. monocytogenes* is not detected in a lot. In the US, the Produce Safety Rule of the Food Safety Modernization Act established science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. This includes requirements for water quality; biological soil amendments; sprouts; domesticated and wild animals; worker training and health and hygiene; and equipment, tools and buildings (FDA 2019b). The USDA has aligned the Harmonized Good Agricultural Practices Audit Program (USDA H-GAP) with the requirements of the FDA Food Safety Modernization Act's Produce Safety Rule. While the requirements of both programs are not identical, the relevant technical components in the FDA Produce Safety Rule are covered in the USDA H-GAP Audit Program. However, the USDA audits are not regarded as a substitute for FDA or state regulatory inspections (FDA 2019a). The FDA has issued an Import Alert (IA) for enoki mushrooms from Republic of South Korea (July 2022) which was extended to China (March 2023) (FDA 2023). Currently, to secure release of an individual shipment subject to detention without physical examination under this import alert, the owner, consignee, and/or other responsible party for the affected goods would provide evidence that the product does not bear or contain *L. monocytogenes*. The FDA issues these alerts to help prevent potentially violative products from being distributed in the US. After the 2020 outbreak, the FDA implemented an Imported Specialty Mushroom Prevention Strategy, with a focus on enoki mushrooms, to protect public health and prevent future *L. monocytogenes* outbreaks in specialty imported mushrooms. "The FDA's prevention strategies are affirmative, deliberate approaches undertaken by the agency to limit or prevent the recurrence of a root cause that led to an outbreak or adverse incident" (FDA, 2023).

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