Food Safety Information Note for

Cold-Smoked Salmon Producers

SEA-FISHERIES PROTECTION AUTHORITY

SAFE SUSTAINABLE SEAFOOD

The document has been produced by the Sea-Fisheries Protection Authority (SFPA) in consultation with the Food Safety Authority of Ireland (FSAI) and Bord Iascaigh Mhara (BIM).

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Food Safety Information Note for

Cold-smoked Salmon Producers

This information note highlights some specific food safety legal requirements and recommendations for producers of ready-to-eat cold-smoked salmon.

Cold-smoked salmon production involves a specialised process whereby raw salmon is filleted, possibly skinned, dry salted or immersed in brine, dried and smoked at temperatures of typically 18 to 28°C. The smoked salmon is then cooled, possibly sliced, vacuum packed and labelled prior to storage and distribution. Typically, it is sold to customers as a ready-to-eat food. In contrast to hot smoking, the cold smoking process does not cook the salmon.

Contents

1. POTENTIAL HAZARDS

The survival and growth of micro-organisms can present a potential biological food safety hazard in cold-smoked salmon. *Listeria monocytogenes* and *Clostridium botulinum* contamination can cause serious illnesses called listeriosis and botulism, respectively. Numerous other micro-organisms such as *Staphylococcus aureus* can cause food-poisoning.

Listeriosis is a disease that affects primarily the elderly, people with weakened immune systems, pregnant women and their unborn children and newborns. It can cause septicaemia (blood poisoning), meningitis, miscarriages and stillbirths. Although listeriosis is rare, it can be extremely serious with high hospitalisation and mortality rates. Listeriosis can be contracted by eating food contaminated with *Listeria monocytogenes*. *Listeria* is widespread in the environment, including in the marine environment. It is found in soil, plants and water. It can also be carried by animals and can be present in raw fish. Furthermore, *Listeria* can survive and persist in food processing establishments. The cold smoking process will not necessarily eliminate *Listeria*. It can grow, albeit slowly, at refrigeration temperatures. For further information see FSAI Microbial Factsheet Series *Listeria monocytogenes*.

Clostridium botulinum is a hazard associated with vacuum packed or modified atmosphere packed foods. While *C. botulinum* doesn't grow under normal atmospheric conditions, it can survive as a spore. When exposed to conditions without oxygen (or with very low oxygen), for example in vacuum packed (or modified atmosphere packed) foods, spores can germinate, leading to *C. botulinum* growth and the production of a toxin that causes botulism. Botulism is a rare but serious and potentially fatal illness. Symptoms can include blurred vision, muscle weakness and paralysis. For further information see FSAI Foodborne *Botulism* webpage.

Staphylococcus aureus produces a toxin that can cause food poisoning. Symptoms can include nausea, vomiting, abdominal cramps and diarrhoea with recovery usually within a few days. Humans can frequently be asymptomatic carriers of *S. aureus* and food handlers can contaminate food if good hygiene practices aren't followed. For further information see FSAI Microbial Factsheet Series *Staphylococcus aureus*.

There are also potential chemical hazards associated with cold-smoked salmon. Polycyclic aromatic hydrocarbons (PAHs) can be formed and released during the burning of organic matter such as wood. Some PAHs have been found to have toxicological effects and the PAH Benzo[a]pyrene is carcinogenic to humans. European legislation (Commission Regulation (EC) No 1881/2006 as amended) sets limits for PAHs in food.

Chemical contamination can also arise from the use of unsuitable wood (e.g. painted / treated wood) in smoking. Antibiotic residues are potential chemical hazards of relevance to farmed salmon.

Potential physical hazards can include metal, glass, plastics, bones and hair.

2. CONTROLLING THE HAZARDS

Food Safety Management Systems based on HACCP (Hazard Analysis and Critical Control Point) principles and prerequisite programmes are necessary to control potential food safety hazards. Regulation (EC) 852/2004 requires Food Business Operators (FBOs) to implement procedures based on HACCP. It is important that FBOs carry out a thorough Hazard Analysis on each step in the process and put appropriate control measures in place.

Some specific food safety requirements (set out in Regulation (EC) No 852/2004, Regulation (EC) No 853/2004 and associated legislation) and recommendations for cold-smoked salmon producers are outlined here.

2.1 Be Selective When Sourcing Raw Materials

All raw materials (e.g. raw salmon, salt, wood) should be of the highest quality possible and should be sourced in accordance with in-house supplier approval procedures. Where relevant, certificates of analysis/conformance should be requested from the supplier.

To minimise the risk of purchasing salmon that is contaminated by *L. monocytogenes* or other harmful micro-organisms, cold-smoked salmon producers should be satisfied that good hygienic practices and correct temperature control have been applied from the salmon harvesting or catching stage up to the point of receipt into the smoking establishment. FBOs can also undertake organoleptic checks to assess raw salmon quality. For example, the following are indicators of good quality in a gutted raw salmon:

- eyes bright and clear;
- red gills;
- odourless or sea-fresh smell;
- good skin condition (bright, shiny, clear mucus, no damage);
- a firm body;
- guts completely removed with no damage to the cavity wall.

The proper selection of wood used to produce smoke is also very important as certain woods, such as off-cuts, recycled wood or painted / treated wood, could potentially contain chemical contaminants and should never be used for smoking food products. Wood should be purchased from a reputable supplier. The use of kiln dried wood chip certified for smoking food is recommended as it is free from harmful chemicals and has a consistent moisture and burn rate.

Salt must be food grade.

2.2 Take Steps to Prevent Cross-Contamination

Micro-organisms can spread through contact from one area (e.g. work surface, equipment, hands, food) onto another. To minimise the risk of cross-contamination, the following should be considered:

- Product flow – Raw product should be separated from smoked products within the processing establishment. Product flow should be from raw to finished product.
- Employee actions – Poor hygiene practices could potentially spread micro-organisms around a processing establishment leading to contamination of food (see *2.8 Ensure that Staff Members are Adequately Trained and Implement Good Hygiene Practices* below).
- Cleaning and disinfection procedures (see *2.6 Implement Effective Cleaning and Disinfection Procedures* on page 10).

2. CONTROLLING THE HAZARDS (CONTINUED)

2.3 Implement Temperature Control (and Where Applicable, Time Control)

Proper temperature control is one of the most effective ways of controlling the growth of micro-organisms. In general, micro-organisms multiply slowly at refrigeration temperatures and don't multiply during frozen storage. In particular, the following should be considered:

- **Raw salmon temperature at in-take** – Raw salmon can be received packed in ice or refrigerated at a temperature approaching that of melting ice (as close as possible to 0°C) or, if frozen, at a temperature of not more than -18°C.
- **Raw salmon storage temperature** – i.e. storage at refrigeration or freezing temperatures as per the above point.
- **Thawing** – if frozen, raw salmon for smoking must be defrosted before use. Defrosting should be carried out under controlled temperature and time conditions.

- **Salting temperatures** – Salting should be done under controlled time / temperature conditions (see *2.4 Control the Salting Step* below).
- **Drying temperature** – In some processes, a drying step is carried out before cold smoking to aid pellicle formation and to provide a surface for the smoke to adhere to. Ideally, drying should be done under controlled time / temperature conditions.
- **Smoking temperatures** – Micro-organisms can potentially grow at cold-smoking temperatures (typically 18 to 28°C). Consequently, smoking time and temperature must be monitored (see *2.5 Standardise the Cold Smoking Step* below).

- **Cooling temperature** – Smoked salmon is usually cooled before packing to prevent moisture/condensation in vacuum packs. After smoking, cold-smoked salmon should be cooled to refrigeration temperatures rapidly (i.e. within 2 or 3 hours). While refrigeration temperatures are typically 0 to 5°C, a refrigeration temperature of less than 3°C is recommended for vacuum packed smoked salmon while still under FBO control to prevent non-proteolytic *C. botulinum growth*[1].

- **Storage and distribution temperatures** – All final products should be kept at refrigerated temperatures during storage and distribution (i.e. less than 3°C recommended while smoked salmon is still under FBO control, otherwise 0 to 5°C). If selling to the final consumer via online or telephone sales, the FBO must ensure that the delivery system will keep the food at a safe temperature. See FSAI publication Selling or Advertising Food Online.
- **Exposure to ambient temperatures** – Time exposed to ambient temperatures (e.g. during cutting and slicing) should be minimised.

[1] See FSAI Guidance Note No. 18 Validation of Product Shelf-Life Appendix 2 Safety and Shelf-Life of Foods with Respect to *Clostridium botulinum*.

2. CONTROLLING THE HAZARDS (CONTINUED)

2.4 Control the Salting Step

Salting is a critical step for controlling the growth of micro-organisms as it reduces water activity (a_w), making it difficult for micro-organisms to grow. There are two types of salting: dry salting and brining. In general, dry salting is more commonly used for large fish such as salmon.

To ensure consistency, validated in-house procedures should be followed and monitored for each production cycle. Important parameters include the thickness or weight of the salmon portions, the amount of salt/volume of brine used, salting duration and the temperature during the process.

The percentage of fat can affect the rate of salt uptake in the fillet; higher fat content results in less moisture loss and slower salt absorption. In the case of brine, a hydrometer / brineometer can be used to determine the percentage saturated solution of brine. Such equipment must be calibrated and used according to manufacturer's instructions. The reuse of brine or salt for subsequent batches is not recommended.

The final product should have a minimum water phase salt (WPS) (the amount of salt compared to amount of moisture (water) in the flesh) of 3.5%, to inhibit / slow micro-organism growth. Specifically, 3.5% WPS prevents growth and toxin production by non-proteolytic *C. botulinum* in vacuum or modified atmosphere packed chilled foods with a shelf-life of greater than 10 days.

The percentage of salt (sodium chloride, NaCl) in the water (aqueous) phase of a product can be calculated from the salt content (grams of sodium chloride present in 100g product) and the moisture content (grams of water per 100g of product) using the following calculation:

$$\frac{\text{(Salt content)}}{\text{(Salt content + moisture content)}} \times \frac{100}{1} = \textbf{\% Water Phase Salt (WPS)}$$

For example, if a sample of smoked salmon was analysed by lab and found to have a salt content of 3g NaCl/100g and a moisture content of 60 g H_2O/100g, the %WPS is:

$$\frac{\text{(3g NaCl/100g)}}{\text{(3g NaCl/100g + 60g } H_2O\text{/100g)}} \times \frac{100}{1} = \textbf{4.8\% Water Phase Salt (WPS)}$$

It is recommended that cold-smoked salmon producers undertake testing of the final product for moisture and salt content and calculate % WPS when initially validating the process and routinely verifying the salting step during production.

See FSAI Guidance Note No. 18 Validation of Product Shelf-Life and the UK Food Standards Agency Guidance The safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum* for further information on *C. botulinum* including other control factors, e.g. water activity (a_w). Different control factors can act together as hurdles to *C. botulinum* growth and toxin production.

2. CONTROLLING THE HAZARDS (CONTINUED)

2.5 Standardise the Cold Smoking Step

Smoke can be generated from wood chips, friction smokers or a combination of both. Smoke compounds permeate the salmon. In addition to adding flavour, smoke compounds can reduce the growth of some micro-organisms. Scientific studies, however, show varying results (see Thomas *et al.*, 2012) and the cold smoking step will not necessarily eliminate *Listeria*.

Cold smoking steps vary significantly from smoker to smoker and from establishment to establishment (typically from 18 to 28°C and for 6 to 24 hours). The cold smoking step for a particular smoking process should be standardised in so far as possible.

Factors to be considered include:

- The thickness or weight of the salmon portions (also see *2.4 Control the Salting Step* above).
- The time and temperature for each smoking cycle (also see *2.3 Implement Temperature Control (and Where Applicable, Time Control)* above).

It is recommended that cold-smoked salmon producers undertake some testing of final product for PAH especially when validating the smoking step. PAH limits are set in Commission Regulation (EC) No 1881/2006 as amended.

See Codex Alimentarius Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes for further guidance on controlling PAH.

2.6 Implement Effective Cleaning and Disinfection Procedures

Effective cleaning and disinfection are required to reduce the levels of micro-organisms in the processing environment and, consequently, the risk of microbial contamination of food. Persistent *L. monocytogenes* can be difficult to eradicate from processing environments. *L. monocytogenes* bacteria can accumulate together to form biofilms on surfaces. *L. monocytogenes* can, however, be reduced, eliminated or prevented from becoming established in the processing environment by strictly adhering to cleaning and disinfection procedures and by targeting areas where the organism has been found to persist.

Special attention must be paid to drains and difficult to clean equipment such as skinning machines, brining injection needles and slicing equipment. Cleaning and maintenance records of equipment should be maintained. See Appendix 2 of the FSAI publication The Control and Management of *Listeria monocytogenes* Contamination of Food for further information.

2.7 Include a Freezing Step to Kill Parasites, Where Necessary

If not previously frozen, wild salmon must be subjected to a freezing step of at least (a) – 20°C for not less than 24 hours; or (b) – 35°C for not less than 15 hours to kill viable parasites. This is a legal requirement under Regulation (EC) No 853/2004 as amended. A freezing step is not required for farmed salmon if the parasite risk is considered to be negligible. Such a freezing exemption automatically applies to farmed Atlantic salmon reared in Ireland. See FSAI Fish Parasites webpage. A freezing exemption applies to farmed salmon from some other countries.

2.8 Ensure that Staff Members are Adequately Trained and Implement Good Hygiene Practices

All food handlers must be supervised and instructed / trained in food hygiene matters commensurate with their work activity. This is a legal requirement under Regulation (EC) No 852/2004 and is essential for food safety. Staff involved in developing and maintaining the Food Safety Management System must have received training on the application of HACCP principles.

2.9 Monitor the Processing Environment for *Listeria monocytogenes*

Environmental sampling is a legal requirement in establishments manufacturing ready-to-eat foods, which may pose a *L. monocytogenes* risk for public health under Commission Regulation (EC) No 2073/2005.

Producers of cold-smoked salmon must sample the processing areas and equipment for *L. monocytogenes*. If detected, action must be taken to prevent a risk to public health.

The European Union Reference Laboratory for *Listeria monocytogenes* (EURL *Lm*) has published Guidelines on Sampling the Food Processing Area and Equipment for the Detection of *Listeria monocytogenes*[2]. These guidelines can be used to design environmental monitoring procedures. They include a list of suggested areas for sampling.

The sampled area should be as large as possible to increase the probability of any *L. monocytogenes* present being detected. Where possible, it is recommended that an area of 1000 cm^2 to 3000 cm^2 (i.e. 0.1 m^2 to 0.3 m^2) is swabbed). For example, swabbing 20 cm by 50 cm equals 1000 cm^2 (or 0.1 m^2).

[2] This EURL *Lm* guidance is currently being updated. It is expected that the new guidance will direct FBOs to ISO 18593:2018 Microbiology of the food chain – Horizontal methods for surface sampling.

2. CONTROLLING THE HAZARDS (CONTINUED)

Sampling for *L. monocytogenes* should be undertaken during or after production but not after cleaning and disinfection. If undertaken after cleaning and disinfection, there is a chance that any *L. monocytogenes* present could be difficult to detect due to being in a temporary physiologically stressed state.

Although not a legal requirement, it can be useful to also monitor for other *Listeria* species. A report for a given sample stating '*Listeria monocytogenes*: Not detected / area swabbed' and '*Listeria* species including *L. monocytogenes*: Detected / area swabbed' means that a *Listeria* species other than *L. monocytogenes* was detected. The detection of other *Listeria* species is an indicator of conditions supporting the potential presence of *L. monocytogenes*.

See The Control and Management of *Listeria monocytogenes* Contamination of Food for information on follow-up action if *L. monocytogenes* or other *Listeria* species are detected on a food contact surface or on a non-food contact surfaces and investigating the source of contamination.

2.10 Ensure That Cold-Smoked Salmon Meets Microbiological Criteria

Food must comply with relevant microbiological criteria set in legislation[3] (Commission Regulation (EC) No 2073/2005). Microbiological testing should be undertaken as appropriate by FBOs, on a risk-based frequency, to verify the effectiveness of their Food Safety Management System. Microbiological testing may also be appropriate when validating the Food Safety Management System. Although not a legal requirement, it is strongly recommended that FBOs use an accredited laboratory for analysis. (See FSAI publication Best Practice for Testing Foods when Assessing Compliance with the Microbiological Criteria Specified in Commission Regulation (EC) No 2073/2005 which includes a useful questionnaire).

[3] Regulation 2073/2005 microbiological criteria as set out in this section are those required under the European Union Law. It should be noted that some third countries such as the USA have a zero tolerance for *L. monocytogenes* in Ready to Eat foods. FBO should check specific requirements before exporting to third countries.

L. monocytogenes Food Safety Criteria for ready-to-eat foods able to support the growth of *L. monocytogenes* usually apply to ready-to-eat cold-smoked salmon. There are two possible scenarios, with different testing requirements, depending on an FBO's knowledge of *L. monocytogenes* growth in their own product.

Scenario 1

If an FBO cannot demonstrate that *L. monocytogenes* levels in the product will not exceed 100 cfu/g throughout shelf-life, a "not detected in 25g" criterion applies before the food leaves the FBO's control. When verifying compliance, this FBO tests product samples using the *L. monocytogenes* detection method. The sampling plan specifies the testing of 5 sample units from the same batch[4] using the latest version of the *L. monocytogenes* detection method ISO 11290-1 or a validated alternative method. The batch is deemed unsatisfactory if *L. monocytogenes* is detected in one or more of the 5 sample units.

Scenario 2

Where an FBO has knowledge (e.g. based on specialised shelf-life studies) of the growth of *L. monocytogenes* in the product, this FBO may set intermediate *L. monocytogenes* limits, which must be low enough to guarantee that the product will not exceed 100 cfu/g at the end of its shelf-life. When verifying compliance, this FBO tests product samples using the enumeration method (counts). The sampling plan specifies the testing of 5 sample units[5] from the same batch using the latest version of the *L. monocytogenes* enumeration method ISO 11290-2 or a validated alternative method. The batch is deemed unsatisfactory if *L. monocytogenes* is found to exceed the intermediate limit set by the FBO in one or more of the 5 sample units.

[4]Regulation 2073/2005 does allow FBOs to reduce the number of sample units if they have historical documentation that can demonstrate that they have effective HACCP-based procedures. FSAI and SFPA strongly advise against this approach as it reduces the stringency of the sampling plan, making it less likely that pathogens will be detected if they are present. (See Guidance Note No. 27 on the Enforcement of Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs).

[5]As per footnote 4 above.

2. CONTROLLING THE HAZARDS (CONTINUED)

It is recommended that specialised shelf-life studies into the growth of *L. monocytogenes* are done in accordance with European guidance:

- Guidance Document on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. This document provides guidance on *L. monocytogenes* shelf-life studies for FBOs.
- EURL *Lm* Technical Guidance Document on challenge tests and durability studies for assessing shelf-life of ready-to-eat foods related to *Listeria monocytogenes*. This document provides guidance on *L. monocytogenes* shelf-life studies for labs.

Such studies (challenge tests or durability studies) are highly technical and require specialised laboratories[6].

If the applicable *L. monocytogenes* Food Safety Criterion limit is breached (i.e. unsatisfactory result obtained), the product cannot be placed on the market. If already on the market when the result becomes available, the product must be withdrawn or recalled. Actions should be taken to find the cause and prevent re-occurrence. The relevant competent authority (usually the Sea-Fisheries Protection Authority, (SFPA)) must also be notified without delay. Further information on product withdrawal and recall is provided in FSAI Guidance Note No. 10 Product Recall and Traceability.

For further information on legislative microbiological criteria, see FSAI Guidance Note No. 27 on the Enforcement of Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs.

[6] The EURL *Lm* has published guidance: EURL *Lm* Guidance Document to evaluate the competence of laboratories implementing challenge tests and durability studies related to *Listeria monocytogenes* in ready-to-eat foods. This document is intended for use by national Competent Authorities (CAs), National Reference Laboratories (NRLs) and other organisations that are involved in assessing laboratories.

An FBO may decide to carry out additional microbiological testing for micro-organisms outside those set in Commission Regulation (EC) No 2073/2005, for example *Listeria* species including *L. monocytogenes*, *Salmonella, E. coli, Clostridium perfringens*[7] or *Staphylococcus aureus*. FSAI Guidance Note No. 3: Guidelines for the interpretation of results of microbiological testing of ready-to-eat foods placed on the market sets guidance criteria for these micro-organisms and can be referred to for interpreting such results.

2.11 Assign an Appropriate Shelf-Life

The FBO must assign an appropriate shelf-life to the cold-smoked salmon, undertaking shelf-life studies where necessary. For perishable products, such as cold-smoked salmon, end of shelf-life date is usually indicated by the wording "Use by…..". Consumers should also be provided with instructions for appropriate use, e.g. "consume within x days of opening", home freezing instructions if applicable.

See FSAI Guidance Note No. 18 Validation of Product Shelf-Life.

See *2.10 Ensure That Cold-Smoked Salmon Meets Microbiological Criteria* above for information on specialised shelf-life studies into the growth of *L. monocytogenes*.

2.12 Maintain Records

For verification purposes, the Food Safety Management System should be documented and records maintained for a period of 3 years. This is a legal requirement under Irish S.I. 22 of 2020.

[7] Although non-proteolytic *Clostridium botulinum* is a hazard associated with vacuum packed foods such as cold smoked salmon, testing for non-proteolytic *C. botulinum* or its spores is not recommended under normal circumstances. Spores of *C. botulinum* are ubiquitous in the environment and may be present on the food. It is best to prevent *C. botulinum* growth and toxin production in food by putting sufficient controls in place (see *2.4 Control the Salting Step* above). The food poisoning micro-organism *Clostridium perfringens* is physiologically different to non-proteolytic *C. botulinum* and not considered a reliable indicator for *C. botulinum*. See UK Food Standards Agency Guidance The safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*.

3. LABELLING REQUIREMENTS

Cold-smoked salmon must be labelled in accordance with legislative requirements that are set in a number of different regulations, with overlapping requirements in some cases. They have been summarized in the following sections.

3.1 General Labelling for Pre-packed Smoked Salmon

Under the Food Information to Consumers (FIC) legislation (Regulation (EU) No 1169/2011), when labelling prepacked cold-smoked salmon for the final consumer and/or catering trade, the following mandatory information must be on the label:

- Name of the product,
- Full list of ingredients with allergens highlighted (see *3.2 Labelling of Allergens* below),
- Quantity of certain ingredients (QUID),
- Net quantity,
- Date of minimum durability (use by for fresh product, best before for frozen product),
- Any special storage conditions e.g. "*Store at 0 to 5°C*",
- Instructions for use where necessary e.g. "consume within x days of opening", home freezing instructions if applicable,
- Name and address of the FBO,
- Country of origin or place of provenance if its absence would be misleading to the consumer,
- Nutritional information.

If the final smoked salmon product is frozen before sale and sold defrosted, the name of the food shall be accompanied by the designation "defrosted" *(see 3.4 Exemptions to the "Defrosted" Labelling Requirement* below*)*.

For further information on FIC, see the FSAI publication Food Information on Prepacked Foods.

3.2 Labelling of Allergens

FBOs are legally required to declare the presence of specified allergens on the label of prepacked products. Fish is one of the allergens which must be declared. When listing the ingredients, FBOs must emphasise the allergenic substance/product through a typeset that clearly distinguishes it from the rest of the list of ingredients, for example by using different font, style or background colour:

"Salmon **(Fish)** 97%, Salt 3 %, oak smoke"

or

"**Salmon** 97%, Salt 3 %, oak smoke"

In addition, the label of prepacked fish may also signpost allergens on a voluntary basis, for example: "Allergen advice - see ingredients highlighted in bold".

3.3 Specific Fishery Product Labelling Requirements

Under the Common Organisation of Markets (CMO) Regulation (Regulation (EU) No 1379/2013), specific labelling requirements for fishery products apply to smoked salmon that only has ingredients from the smoking process and salt added. The items required to be on the label under the CMO are as follows:

- Common & scientific name of the species of fish,
- The production method ("caught" or "farmed"),
- Origin (country if farmed, catch area if wild caught),
- Category of fishing gear (if wild caught),
- Date of minimum durability,
- Whether the smoked salmon has been defrosted (see *3.4 Exemptions to the "Defrosted" Labelling Requirement* below).

The CMO Specific labelling requirements do not apply to cold smoked salmon where ingredients in addition to those from the smoking process and salt are added, e.g. cold smoked salmon containing sugar, pepper or dill.

3.4 Exemptions to the "Defrosted" Labelling Requirement

There are certain exemptions to the "defrosted" labelling requirement under both the FIC and CMO regulations. For example, if the raw salmon was frozen and defrosted before smoking, the smoked salmon label would not have to indicate "defrosted".

In the case where wild salmon is frozen before or after smoking for parasite control, the smoked wild salmon would not have to indicate "defrosted". This exemption does not apply to defrosted smoked salmon produced from farmed Atlantic salmon that is considered to present a negligible parasite risk.
See FSAI Fish Parasites webpage.

3. LABELLING REQUIREMENTS (CONTINUED)

3.5 Frozen Fishery Products Not Yet Labelled For the Final Consumer (i.e. Business to Business Sale)

There are specific requirements for frozen fishery products not yet labelled for the final consumer under Commission Regulation (EU) No 16/2012 which amended Regulation (EC) No 853/2004. Food businesses holding frozen fishery products have to make the following information available to their customers and, upon request, to the Competent Authority:

- The date of production
- The date of freezing, if different from the date of production.

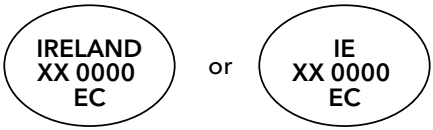
Date of production is the "date of harvesting" for all primary fishery products.

After the stage of primary production, the date of production is the "date of processing, cutting, mincing or preparation, as appropriate". Smoked salmon as a processed product falls into this category. For frozen food made from a batch of raw materials with different dates of production and of freezing, the oldest dates must be made available.

The form in which the information is made available is up to the choice of the supplier of the frozen food as long as the required information will be clearly available to and retrievable by the business operator to whom the food is supplied.

3.6 Identification Mark and Lot/Batch Code Labelling Requirements

Pre-packed products must include the food business's identification mark comprised of the approval number assigned by the supervising competent authority (usually the SFPA) in one or other of the following oval shaped formats:



The product must also have a unique lot/batch code to identify the product in the event that the product has to be recalled from the market.

3.7 Requirements if Making a Nutrition Claim or Health Claim

A **Nutrition Claim** is any claim which states, suggests or implies that a food has particular beneficial nutritional properties. Examples are "source of omega 3", "source of protein", "high protein", "contains phosphorus" and "source of potassium".

A **Health Claim** is any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health. Examples are "protein contributes to the maintenance of normal bones", "phosphorus contributes to the maintenance of normal teeth".

In order for a product to bear a nutrition or health claim, it must comply with the specific conditions of use for the particular claim and the principles set out in Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. See the FSAI publication Information on Nutrition and Health Claims.

See also the EU Register on nutrition and health claims made on food.

3.8 Labelling of Organic Smoked Salmon

In order to use the word 'organic' on the label of a product, either in the overall description of the product, or with reference to any ingredient, an FBO must be registered as an organic operator by the Department of Agriculture, Food and Marine (DAFM) and certified by one of the approved certification and inspection bodies contracted by DAFM.

In order to use the word 'organic' in the overall description of the product, i.e. "organic smoked salmon", all parts of the process including smoking must be certified as organic.

Queries on the organic requirements should be addressed to:

DAFM Organic Unit
Johnstown Castle
Co. Wexford.

E-mail: organic@agriculture.gov.ie.

See Appendix 1 for a labelling checklist.

APPENDIX 1
LABELLING CHECKLIST FOR COLD SMOKED SALMON

The symbol ✔ indicates that an item must be on the label.

Labelling Requirement	Individually prepacked fish for supply to retail establishments	Prepacked fish sold to wholesalers/other approved FBOs or supplied to mass caterers for further preparation
FIC Regulation (Regulation (EC) No 1169/2011)		
a. Name under which product is sold If previously frozen and defrosted, **"defrosted"** must accompany the name, with some exemptions. See *3.4 Exemptions to the "Defrosted" Labelling Requirement* above.	✔	For business to business sale, FIC information shall appear on the prepackaging or on a label attached thereto, or on the commercial documents. Notwithstanding this, the following FIC information must also appear on the external packaging: • product name, • date of minimum durability, • any special storage instructions, • name and address of Food Business Operator.
b. Full list of ingredients with allergens highlighted	✔	
c. Quantity of certain ingredients (QUID)	✔	
d. The net quantity	✔	
e. The date of minimum durability	✔	
f. Any special storage instructions or conditions of use, e.g. "*Store at 0 to 5°C*"	✔	
g. Instructions for use where necessary	✔	

Labelling Requirement	Individually prepacked fish for supply to retail establishments	Prepacked fish sold to wholesalers/other approved FBOs or supplied to mass caterers for further preparation
FIC Regulation (Regulation (EC) No 1169/2011)		
h. The name or business name and address of the Food Business Operator	✔	
i. Place of origin of the foodstuff if its absence might mislead the consumer to a material degree	✔	
j. Nutritional information	✔	
CMO Regulations – *applicable to smoked salmon where ingredients are only those from the smoking process and salt (Regulation (EC) No 1379/2013)*		
Common commercial name of species of fish	✔	All 5 items required (can be on label or accompanying commercial documentation)
Scientific Name	✔	
Production method (caught or farmed/cultivated)	✔	
Indication of catch area if caught at sea; country of origin if farmed/cultivated)	✔	
Fishing gear	✔	

APPENDIX 1 (CONTINUED)
LABELLING CHECKLIST FOR COLD SMOKED SALMON

The symbol ✔ indicates that an item must be on the label.

Labelling Requirement	**Individually prepacked fish for supply to retail establishments**	**Prepacked fish sold to wholesalers/other approved FBOs or supplied to mass caterers for further preparation**
Lot identification (Directive 2011/91 EU)		
Lot/Batch Code	✔	✔
Hygiene Package Regulations (Regulation (EC) No 853/2004 as amended)		
Oval identification mark with approval number.	✔	✔
For frozen product, date of production and date of freezing if different from the date of production.	Not applicable for product labelled for the final consumer.	Only applicable if product is not yet labelled for the final consumer. Information can be on the label or the accompanying commercial documentation.

APPENDIX 2
REFERENCES AND FURTHER INFORMATION

- BIM Wild Salmon Quality Guide. Bord Iascaigh Mhara.
- Codex Alimentarius (2009) Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes CXC 68-2009.
- Codex Alimentarius (2018) Standard for Smoked Fish, Smoke-Flavoured Fish and Smoke-Dried Fish CXS 311- 2013, amended 2016, 2018.
- European Commission (2013) Guidance Document on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.
- European Commission EU Register on nutrition and health claims made on food. Accessed October 2021.
- ESSA (2018) European Guide to Good Practice For Smoked and/or Salted and/or Marinated Fish. European Salmon Smokers Association.
- EURL *Lm*/ANSES (2012) Guidelines on Sampling the Food Processing Area and Equipment for the Detection of *Listeria monocytogenes*. French Agency for Food, Environmental and Occupational Health Safety and European Union Reference Laboratory for *Listeria monocytogenes*.
- EURL *Lm*/ANSES (2018) EURL *Lm* Guidance Document to evaluate the competence of laboratories implementing challenge tests and durability studies related to *Listeria monocytogenes* in ready-to-eat foods. French Agency for Food, Environmental and Occupational Health Safety and European Union Reference Laboratory for *Listeria monocytogenes*.
- EURL *Lm*/ANSES (2021) EURL *Lm* Technical Guidance Document on challenge tests and durability studies for assessing shelf-life of ready-to-eat foods related to *Listeria monocytogenes*. French Agency for Food, Environmental and Occupational Health Safety and European Union Reference Laboratory for *Listeria monocytogenes*.
- FSA (2020) The safety and shelf-life of vacuum and modified atmosphere packed chilled foods with respect to non-proteolytic *Clostridium botulinum*. UK Food Standards Agency and Food Standards Scotland.
- FSAI (2005) The Control and Management of *Listeria monocytogenes* Contamination of Food. Food Safety Authority of Ireland.

APPENDIX 2 (CONTINUED) REFERENCES AND FURTHER INFORMATION

- FSAI (2011) FSAI Microbial Factsheet Series *Listeria monocytogenes.* Food Safety Authority of Ireland.
- FSAI (2011) FSAI Microbial Factsheet Series *Staphylococcus aureus.* Food Safety Authority of Ireland.
- FSAI (2013) Guidance Note No. 10 Product Recall and Traceability. Food Safety Authority of Ireland.
- FSAI (2014) Food Information on Prepacked Foods. Food Safety Authority of Ireland.
- FSAI (2014) Guidance Note No. 27 on the Enforcement of Commission Regulation (EC) No 2073/2005 on Microbiological Criteria for Foodstuffs. Food Safety Authority of Ireland.
- FSAI (2017) Selling or Advertising Food Online. Food Safety Authority of Ireland.
- FSAI (2019) FSAI Guidance Note No. 18 Validation of Product Shelf-Life. Food Safety Authority of Ireland.
- FSAI (2020) Guidance Note No. 3 – Guidelines for the Interpretation of Results of Microbiological Testing of Ready-to-Eat Foods Placed on the Market. Food Safety Authority of Ireland.
- FSAI (2021) Information on Nutrition and Health Claims. Food Safety Authority of Ireland.
- FSAI (2021) Best Practice for Testing Foods when Assessing Compliance with the Microbiological Criteria Specified in Commission Regulation (EC) No 2073/2005. Food Safety Authority of Ireland.
- FSAI Fish Parasites webpage. Accessed October 2021. Food Safety Authority of Ireland.
- FSAI Foodborne Botulism webpage. Accessed October 2021. Food Safety Authority of Ireland.
- International Organization for Standardization (2018) ISO 18593:2018 Microbiology of the food chain – Horizontal methods for surface sampling.
- Thomas, D.J.I., Strachan, N., Goodburn, K., Rotariu, O., and Hutchison, M.L. (2012) A review of the published literature and current production and processing practices in smoked fish processing plants with emphasis on contamination by *Listeria monocytogenes.* Commissioned by Food Standards Agency, UK.

APPENDIX 3
LEGISLATION REFERENCES

Legislation references in this Information Notice are listed below ordered by year. All references to legislation should be viewed as a reference to the original legislation and to any corrections and amendments published since.

Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.

Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.

Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs.

Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods.

Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs.

Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004.

Directive 2011/91 of the European Parliament and of the Council of 13 December 2011 on indications or marks identifying the lot to which a foodstuff belongs.

Commission Regulation (EU) No 16/2012 of 11 January 2012 amending Annex II to Regulation (EC) No 853/2004 of the European Parliament and of the Council as regards the requirements concerning frozen food of animal origin intended for human consumption.

Regulation (EU) No 1379/2013 of the European Parliament and of the Council of 11 December 2013 on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000.

Irish Statute Book (2020) Statutory Instrument (S.I.) 22 of 2020 European Union (Food and Feed Hygiene) Regulations 2020.

This is not an exhaustive list of legislation applicable to cold-smoked salmon production.

To access food safety legislation, see the Food Safety Authority of Ireland website https://www.fsai.ie/legislation.html or the European Union's Eur-Lex website https://eur-lex.europa.eu/.

DISCLAIMER

This document is produced for information purposes only. It does not purport to be a comprehensive legal interpretation. Relevant European and National Legislation must be consulted.

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