

1. SCOPE

This standard applies to smoked, smoke-flavoured and smoke-dried fish prepared from fresh, chilled or frozen raw material. It deals with whole fish, fillets and sliced and similar products thereof. The standard applies to fish, either for direct consumption, for further processing, or for addition into speciality or minced products where fish constitutes only part of the edible contents.

It does not apply to fish treated with carbon monoxide (filtered, “clear” or ‘tasteless’ smoke), fish packaged in hermetically sealed containers processed to commercial sterility. Speciality or minced products as such are not included (e.g. fish-salads).

2. DESCRIPTION

Product and process definitions for smoked fish, smoke-flavoured fish and smoke-dried fish are considered separately under this section.

2.1 SMOKED FISH

2.1.1 Product definition

Smoked fish is prepared from fish that has undergone a hot or cold smoking process. The smoke must be applied through one of the smoking processes defined in Section 2.1.2 and the end product must have smoked sensory characteristics. Spices and other optional ingredients may be used.

2.1.2 Process definitions

- **“Smoking”** is a process of treating fish by exposing it to smoke from smouldering wood or plant materials. This process is usually characterised by an integrated combination of salting, drying, heating and smoking steps in a smoking chamber.
- **“Smoking by regenerated smoke”** is a process of treating fish by exposing it to smoke which is regenerated by atomizing smoke condensate in a smoking chamber under the time and temperature conditions similar to those for hot or cold smoking.
- **“Smoke Condensates”** are products obtained by controlled thermal degradation of wood in a limited supply of oxygen (pyrolysis), subsequent condensation of the resultant smoke vapours, and fractionation of the resulting liquid products.
- **“Hot smoking”** is a process in which fish is smoked at an appropriate combination of temperature and time sufficient to cause the complete coagulation of the proteins in the fish flesh. Hot smoking is generally sufficient to kill parasites, to destroy non-sporulated bacterial pathogens and to injure spores of human health concern.
- **“Cold smoking”** is a process of treating fish with smoke using a time/temperature combination that will not cause significant coagulation of the proteins in the fish flesh but that will cause some reduction of the water activity.
- **“Salting”** is a process of treating fish with salt of food grade quality to lower water activity in fish flesh and to enhance flavour by any appropriate salting technology (e.g. dry salting, brining, injection salting).
- **“Drying”** is a process in which the moisture content in the fish is decreased to appropriate required characteristics under controlled hygienic conditions.
- **“Packaging”** is a process in which smoked fish is put in a container, either aerobically or under reduced oxygen conditions, including under vacuum or in a modified atmosphere.
- **“Storage”** is a process in which smoked fish is kept refrigerated or frozen to assure product quality and safety in conformity with Sections 3 and 6.

2.2 SMOKE FLAVOURED FISH

2.2.1 Product definition

Smoke-flavoured fish is prepared from fish that has been treated with smoke flavours, without undergoing a smoking process as described in Section 2.1. The end product must have a smoked taste. Spices and other optional ingredients may be used.

2.2.2 Process definition

- **“Smoke flavours”** are either smoke condensates or artificial flavour blends prepared by mixing chemically-defined substances in known amounts or any combination of both (smoke-preparations).
- **“Smoke flavouring”** is a process in which fish or fish preparations are treated with smoke flavour. The smoke flavour can be applied by any technology (e.g. dipping, spraying, injecting, soaking).
- **“Smoke Condensates”** are products obtained by controlled thermal degradation of wood in a limited supply of oxygen (pyrolysis), subsequent condensation of the resultant smoke vapours, and fractionation of the resulting liquid products.
- **“Packaging”** is a process in which smoke-flavoured fish is put in a container, either aerobically or under reduced oxygen conditions, including under vacuum or in a modified atmosphere.
- **“Storage”** is a process in which smoke-flavoured fish is kept refrigerated or frozen to assure product quality and safety in conformity with Sections 3 and 6.

- “**Drying**” is a process in which the moisture content in the fish is decreased to appropriate required characteristics under controlled hygienic conditions.
- “**Salting**” is a process of treating fish with salt of food grade quality to lower water activity in fish flesh and to enhance flavour by any appropriate salting technology (e.g. dry salting, brining, injection salting).

2.3 SMOKE-DRIED FISH

2.3.1 Product definition

Smoke-dried fish is prepared from fish that has undergone a combined smoking and drying process and may include a salting process. The smoke must be applied through a smoke-drying process traditional for the respective country or an industrial smoke-drying process and the end product must have smoke-dried sensory characteristics. Spices and other optional ingredients may be used.

2.3.2 Process definition

- “**Smoke drying**” is a process in which fish is treated by combined smoking and drying steps to such an extent that the final product can be stored and transported without refrigeration and to achieve a water activity of 0.75 or less (10% moisture content or less), as necessary to control bacterial pathogens and fungal spoilage.
- “**Drying**” is a process in which the moisture content in the fish is decreased to appropriate required characteristics under controlled hygienic conditions.
- “**Salting**” is a process of treating fish with salt of food grade quality to lower water activity in fish flesh and to enhance flavour by any appropriate salting technology (e.g. dry salting, brining, injection salting).
- “**Packaging**” is a process in which smoke-dried fish is put in a container to avoid contamination and prevent rehydration.
- “**Storage**” is a process in which smoke-dried fish is typically kept at ambient temperature in a way to assure its safety and quality in conformity with Sections 3 and 6.

2.4 PRESENTATION

Any presentation of the product shall be permitted provided that it meets all requirements of this Standard, and it is adequately described on the label to avoid confusing or misleading the consumer.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 THE RAW MATERIAL

Smoked fish, smoke-flavoured fish and smoke-dried fish shall be prepared from sound and wholesome fish, which may be fresh, chilled or frozen, and of a quality to be sold for human consumption after appropriate preparation.

3.2 INGREDIENTS

All ingredients used shall be of food grade quality and conform to all applicable Codex standards.

3.3 WOOD OR OTHER PLANT MATERIAL FOR GENERATION OF SMOKE

Wood or other plant material used for the generation of smoke or smoke-condensates must not contain toxic substances either naturally or through contamination, or after having been treated with chemicals, paint or impregnating materials. In addition, wood or other plant material must be handled in a way to avoid contamination (refer to the *Code of Practice for the Reduction of Contamination of Food with Polycyclic Aromatic Hydrocarbons (PAH) from Smoking and Direct Drying Processes (CAC/RCP 68-2009)*).

3.4 DECOMPOSITION

The product of susceptible species shall not contain more than 10 mg of histamine per 100g fish flesh based on the average of the sample unit tested and all products in this Standard shall be free from persistent and objectionable odours and flavours characteristic of decomposition

3.5 FINAL PRODUCT

Products shall meet the requirements of this Standard when lots examined in accordance with Section 10, comply with the provisions set out in Section 9. Products shall be examined by the methods given in section 8.

4. FOOD ADDITIVES

4.1 SMOKED FISH

Acidity Regulators

INS Number	Additive Name	Maximum Level in Product
260	Acetic acid, glacial	GMP
330	Citric acid	GMP
325	Sodium lactate	GMP
334	Tartaric acid, L[+]	200 mg/kg
270	Lactic acid, L-, D-, DL-	GMP

326	Potassium lactate	GMP
327	Calcium lactate	GMP
Antioxidants		
INS Number	Additive Name	Maximum Level in Product
301	Sodium ascorbate	GMP
316	Sodium erythorbate (sodium isoascorbate)	GMP
325	Sodium lactate	GMP
Colours		
INS Number	Additive Name	Maximum Level in Product
129	Allura Red AC	300 mg/kg
160b(i)	Annato extracts, bixin-based	10 mg/kg, as bixin
110	Sunset yellow FCF	100 mg/kg
102	Tartrazine	100 mg/kg
Packaging Gas		
INS Number	Additive Name	Maximum Level in Product
290	Carbon dioxide	GMP
941	Nitrogen	GMP
Preservatives (for reduced oxygen packaged products only)		
INS Number	Additive Name	Maximum Level in Product
200-203	Sorbates	2000 mg/kg as sorbic acid
210-213	Benzoates	200 mg/kg as benzoic acid
4.2 SMOKE-FLAVOURED FISH		
Acidity Regulators		
INS Number	Additive Name	Maximum Level in Product
260	Acetic acid, glacial	GMP
330	Citric acid	GMP
325	Sodium lactate	GMP
334	Tartaric acid, L[+]	200 mg/kg
270	Lactic acid, L-, D-, DL-	GMP
326	Potassium lactate	GMP
327	Calcium lactate	GMP
Antioxidants		
INS Number	Additive Name	Maximum Level in Product
301	Sodium ascorbate	GMP
316	Sodium erythorbate (sodium isoascorbate)	GMP
325	Sodium lactate	GMP
Colours		
INS Number	Additive Name	Maximum Level in Product
129	Allura Red AC	300 mg/kg
160b(i)	Annato extracts, bixin-based	10 mg/kg, as bixin
110	Sunset yellow FCF	100 mg/kg
102	Tartrazine	100 mg/kg
Packaging Gases		
INS Number	Additive Name	Maximum Level in Product
290	Carbon dioxide	GMP
941	Nitrogen	GMP

Preservatives (for reduced oxygen packaged products only)

INS Number	Additive Name	Maximum Level in Product
200-203	Sorbates	2000 mg/kg as sorbic acid
210-213	Benzoates	200 mg/kg as benzoic acid

4.3 SMOKE-DRIED FISH

No additives are permitted in smoke-dried fish.

5. CONTAMINANTS**5.1 GENERAL PROVISIONS**

The products covered by this Standard shall comply with the maximum levels of the *General Standard for Contaminants and Toxins in Foods and Feed* (CODEX STAN 193-1995).

5.2. POLYCYCLIC AROMATIC HYDROCARBONS (PAH)

Smoking of fish should be done in a manner that minimises the formation of polycyclic aromatic hydrocarbons (PAH). This can be achieved by following the *Code of Practice for the Reduction of Contamination of Food with Polycyclic Hydrocarbons (PAH) from Smoking and Direct Drying Processes* (CAC/RCP 68-2009).

6. HYGIENE AND HANDLING**6.1 GENERAL PROVISIONS**

The products covered by the provisions of this Standard shall be prepared and handled in accordance with the appropriate sections of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and other relevant Codex texts such as codes of practice and codes of hygienic practice, such as the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

6.2 MICROBIOLOGICAL CRITERIA

The products shall comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CAC/GL 21-1997).

6.3 PARASITES

Products covered by this Standard shall not contain living parasites and particular attention needs to be paid to cold smoked or smoke-flavoured products, which should be frozen before or after smoking if a parasite hazard is present (see Annex 1). Viability of nematodes, cestodes and trematodes shall be examined according to Section 8.10 and/or 8.11.

6.4 LISTERIA MONOCYTOGENES

The ready to eat products shall comply with microbiological criteria for *Listeria monocytogenes* in ready-to-eat foods which was elaborated in the Annex II of the Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Ready to Eat Foods (CAC/GL 61-2007).

6.5 CLOSTRIDIUM BOTULINUM

Toxins of *Clostridium botulinum* are not allowed in smoked fish, smoke-flavoured fish and smoke-dried fish products. The formation of *Clostridium botulinum* toxin can be controlled through an application of a combination of science-based options such as packaging type, storage temperature, and water activity, e.g. by use of salt in the water phase. Examples are shown in the Table in Annex 2, which addresses these control options.

Countries where the products are to be consumed may allow these products in an uneviscerated state or may require evisceration, either before or after processing, in such a way as to minimise the risk of *Clostridium botulinum*.

6.6 HISTAMINE

The product shall not contain histamine that exceeds 20 mg/100g fish flesh in any sample unit tested. This applies only to susceptible species (e.g. *Scombridae*, *Clupeidae*, *Engraulidae*, *Coryphaenidae*, *Pomatomidae*, *Scomberesocidae*).

6.7 OTHER SUBSTANCES

The products shall not contain any other substance in amounts, which may present a hazard to health in accordance with standards established by the Codex Alimentarius Commission, and the final product shall be free from any foreign material that poses a threat to human health.

7. LABELLING

In addition to the provisions of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) the following specific provisions apply.

7.1 NAME OF THE FOOD

The name of the food must be "smoked X" if treated by the processes described in paragraph 2.1, "smoke flavoured X" if treated by the processes described in paragraph 2.2, "smoke-dried X" if treated by the processes described in paragraph 2.3, X being the common or usual name of the species of fish used in accordance with the law or customs of the country in which the food is sold, so as not to mislead the consumer.

7.2 ADDITIONAL LABELLING

Countries where the product is sold can determine whether the use of regenerated smoke must be indicated on the label.

7.3 STORAGE AND HANDLING INSTRUCTIONS

The label shall declare storage and handling instructions appropriate for the product.

7.4 LABELLING OF NON-RETAIL CONTAINERS

Information specified above shall be given either on the container or in accompanying documents, except that the name of the product, lot identification, and the name and address of the manufacturer or packer, as well as storage instructions, shall appear on the container.

However, the name and address of the manufacturer or packer may be replaced by an identification mark (e.g. plant approval number) provided that such a mark is clearly identifiable with the accompanying documents.

8. SAMPLING, EXAMINATION AND ANALYSIS

8.1 SAMPLING

Under development

8.2 SENSORY AND PHYSICAL EXAMINATION

Samples taken for sensory and physical examination shall be assessed by persons trained in such examination and in accordance with procedures elaborated in Sections 8.4 through 8.6 and the *Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories* (CAC/GL 31-1999)."

8.3 DETERMINATION OF HISTAMINE

Methods meeting the following method performance criteria may be used:

ML (mg/100g)	Minimum applicable range (mg/100 g)	LOD (mg/100 g)	LOQ (mg/100g)	RSDR (%)	Recovery	Applicable methods that meet the criteria
10 (average)	8 – 12	1	2	16.0	90 – 107	AOAC 977.13 NMKL 99, 2013 NMKL 196, 2013
20 (each unit)	16 – 24	2	4	14.4	90 – 107	AOAC 977.13 NMKL 99, 2013 NMKL 196, 2013

8.4 DETERMINATION OF NET WEIGHT

The net weight is determined as the weight of the product, exclusive of packaging material, interleaving material, etc.

8.5 TEMPERATURES FOR THAWING

Frozen samples of final products shall be thawed at refrigeration temperatures to maintain quality and safety.

8.6 DETERMINATION OF *LISTERIA MONOCYTOGENES*

The microbiological criteria for products in which growth of *L. monocytogenes* will not occur are based on the use of the ISO 11290-2 method. Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g. based on ISO 16140). The microbiological criteria for products in which growth of *L. monocytogenes* can occur are based on the use of ISO 11290-1 method. Other methods that provide equivalent sensitivity, reproducibility, and reliability can be employed if they have been appropriately validated (e.g. based on ISO 16140).

8.7 DETERMINATION OF *CLOSTRIDIUM BOTULINUM*

AOAC 977.26 for the detection of *C. botulinum* and its toxins in foods or other scientifically equivalent validated method. This method is not routinely performed on the product, but may be used when there is a suspicion of the presence of toxins.

8.8 DETERMINATION OF WATER PHASE SALT

The percentage salt (NaCl) in the aqueous phase can be determined by the following calculation:

$$\% \text{ salt aqueous phase} = \frac{\% \text{ salt} \times 100}{\% \text{ water} + \% \text{ salt}}$$

% Moisture: AOAC, 952.08, Sec. 35.1.13, *Solids (Total) in Seafood*

% Salt: AOAC, 937.09, Sec. 35.1.18, *Salt (Sodium Chloride) in Seafood*

8.9 DETERMINATION OF WATER ACTIVITY

Water activity is determined by NMKL 168, 2001 | ISO 21807:2004

8.10 DETERMINATION OF THE VIABILITY OF PARASITES

Methods used for extracting and testing the viability of parasites could include the method set out in Annex I for nematodes in the *Standard for Salted Herring and Sprats* (CODEX STAN 244-2004) or other validated methods for parasites acceptable to the competent authority having jurisdiction.

8.11 DETERMINATION OF VISIBLE PARASITES

The entire sample unit is examined for the presence of parasites non-destructively by placing appropriate portions of the thawed (if necessary) sample unit on a 5 mm thick acryl sheet with 45% translucency and candled with a light source giving 1500 lux 30 cm above the sheet.

9. DEFINITION OF DEFECTIVES

A sample unit shall be considered as defective when it exhibits any of the properties defined below.

9.1 FOREIGN MATTER

The presence in the sample unit of any matter, which has not been derived from the fish, does not pose a threat to human health, and is readily recognised without magnification or is present at a level determined by any method including magnification that indicates non-compliance with good manufacturing practice.

9.2 PARASITES

The presence of two or more visible parasites per kg of the sample unit detected by the method described in 8.11 with a capsular diameter greater than 3 mm or a parasite not encapsulated and greater than 10 mm in length.

9.3 ODOUR, FLAVOUR AND TEXTURE

A sample unit affected by persistent and distinct objectionable odours, flavours, or textures indicative of decomposition, or rancidity, burning sensation or other sensorial impressions not characteristic of the product.

10. LOT ACCEPTANCE

A lot will be considered as meeting the requirements of this standard when:

- (i) The total number of defectives as classified according to Section 9 does not exceed the acceptance number (c) of an appropriate sampling plan (AQL-6.5) in the *General Guidelines on Sampling* (CAC/GL 50-2004);
- (ii) The average net weight of all sample units is not less than the declared weight, provided there is no unreasonable shortage in any container and no individual container is less than 95% of the declared weight; and
- (iii) The essential composition and quality factors, food additives, contaminants, hygiene and handling and labelling requirements of Sections 3, 4, 5, 6 and 7 are met. For histamine no sample unit shall exceed 20 mg/100 g of fish flesh as per the sampling plan chosen. (Refer to Section 8.3).

ANNEX 1

Procedures sufficient to kill parasites

A method that is acceptable to the competent authority having jurisdiction shall be used to kill parasites.

Where freezing is required to kill parasites (i.e., cold smoked fish and smoke-flavoured fish) the fish must be frozen either before or after processing to a temperature time combination sufficient to kill the living parasites.

Examples of freezing processes that may be sufficient to kill some or all parasites are:

- Freezing at -20°C at the thermal centre of the product for 24 hours (for *Anisakis* species and *Pseudoterranova decipiens* only)¹;
- Freezing at -35°C at the thermal centre of the product for 15 hours (all parasites)²⁻⁵;
- Freezing at -20°C at the thermal centre of the product for 168 hours (7 days)²⁻⁵ (all parasites).

References:

1 FAO Fisheries Technical Paper 444 (Assessment and management of seafood safety and quality, 2004)

2 Bier, J. 1976. Experimental Anisakiasis: Cultivation and Temperature Tolerance Determinations. J. Milk Food Technol. 39:132-137.

3 Deardoff, T.L. et al. 1984. Behavior and Viability of Third-Stage Larvae of *Terranova* sp. (Type HA) and *Anisakis simplex* (Type I) Under Coolant Conditions. J. of Food Prot. 47:49-52.

4 Health and Welfare Canada (1992) (in consultation with Canadian Restaurant and Food Service

Association, Fisheries Council of Canada, and Fisheries and Oceans Canada). Code of practice for the preparation of raw, marinated, and partially cooked fin fish.

5 USFDA - Centre for Food Safety & Applied Nutrition (June 2001), Fish and Fisheries Products Hazards and Controls Guidance, Chapter 5 Parasites, 3rd Edition.

ANNEX 2**Examples of combinations of product attributes that minimise the likelihood of *Clostridium botulinum* toxin formation**

Countries where the products are to be consumed can be expected to make their science-based risk management choices with the assistance of this framework, e.g. select some options and exclude others, based on conditions within the country (e.g. nature and enforcement of refrigeration and shelf life controls; transportation times and conditions; variability in amount of salt in the aqueous phase that could occur despite best efforts to achieve a required percentage, etc.). This table applies to smoked fish and smoke-flavoured fish where the smoke flavour is provided by smoke condensates. If the smoke flavour is imparted by artificial flavour blends, then 5% aqueous phase salt would be required in order to provide complete protection at temperatures between 3°C and 10°C, or 10% aqueous phase salt would be required at any temperature over 10°C. This table does not apply to smoke-dried fish because the required water activity of 0.75 or below (moisture content level of 10% or less) inhibits the growth of all foodborne pathogens so that refrigeration is not required.

As an alternative to aqueous phase salt, certain time/temperature parameters can minimise the likelihood that *C. botulinum* will grow in the product. *C. botulinum* cannot grow and produce toxin at or below 3°C or below a water activity of 0.94. Other time/temperature combinations exist that similarly control the formation of toxin.¹ Where enforcement of shelf life as well as consumer acceptance of shelf life are norms, the country may select a system that relies on the combination of existing storage temperature conditions (i.e. during transport, retail storage, and consumer storage) and shelf life limitations.

¹ Skinner, G.E. and Larkin, J.W. (1998) Conservative prediction of time to *Clostridium botulinum* toxin formation for use with time-temperature indicators to ensure the safety of foods. (*Journal of Food Protection* 61, 1154-1160)

Temperature-abuse has a direct impact on the safety and shelf-life of the products. Time/temperature integrators may be a useful tool to determine if the products have been temperature-abused.

Product Temperature During Storage	Packaging	Aqueous Phase Salt (NaCl)	Comments
Below 3°C	Any packaging	Not applicable.	<i>C. botulinum</i> toxin cannot form below 3° C. Temperature monitoring is needed to ensure that the temperature does not exceed 3°C.
≥3°C to 5°C	Aerobically Packaged	No minimum water activity is needed. Nonetheless, where there is a possibility of severe time/temperature abuse, the country where the product is being consumed might choose an aqueous phase salt barrier of at least 3% to 3.5% (w/w) as an additional barrier.	When these products are packaged aerobically, 5°C is the maximum recommended storage temperature for the control of pathogens generally and for quality. The aerobic packaging does not necessarily prevent growth and toxin formation of <i>C. botulinum</i> . In air-packaged products, aerobic spoilage organisms provide sensory signs of spoilage before the formation of toxin by <i>C. botulinum</i> . In addition in air packaging it is possible for anaerobic micro-environments to exist and toxin may form if the product is subject to severe time/temperature abuse. For that reason, the country where the product is consumed should still require aqueous phase salt as a barrier to growth of non-proteolytic strains of <i>C. botulinum</i> if there are concerns about the ability of transporters, retailers or consumers to maintain time/temperature control.
Frozen (< or = -18°C)	Any packaging	Not applicable.	<i>C. botulinum</i> toxin cannot form when product is frozen. In the absence of adequate aqueous phase salt, toxin production can occur after thawing so, labelling information about the need for the consumer to keep the product frozen, to thaw it under refrigeration, and to use it immediately after thawing, is important.
(≥3°C to 5°C)	Reduced Oxygen (including vacuum packaging modified atmosphere packaging) +	Aqueous phase salt at minimum level of between 3% & 3.5% (w/w) may be selected by the country where the product is to be consumed.	Aqueous phase salt at a minimum level of between 3 and 3.5% (w/w) (aqueous phase salt) in combination with refrigeration will significantly delay (or prevent) toxin formation. For that reason, the country where the product is consumed should still require the higher aqueous phase salt as a barrier to growth of non-proteolytic strains of <i>C. botulinum</i> if there are concerns about temperature abuse of the product.