

CODEX ALIMENTARIUS

INTERNATIONAL FOOD STANDARDS



Food and Agriculture
Organization of
the United Nations



World Health
Organization

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STANDARD FOR SMOKED FISH, SMOKE-FLAVOURED FISH AND SMOKE-DRIED FISH

CXS 311-2013

Adopted in 2013. Amended in 2016, 2018 and 2024.

2024 Amendments

Following decisions taken at the Forty-seventh Session of the Codex Alimentarius Commission in November 2024, amendments were made in Section 7.4 Labelling of non-retail containers by replacing the text with a reference to the *General standard for the labelling of non-retail containers of foods* (CXS 346-2021); and Section 8 Sampling, examination and analysis was amended by replacing methods of analysis and numeric performance criteria with a reference to the *Recommended methods of analysis and sampling* (CXS 234-1999).

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 characterized 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 percent 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 Section 3 and Section 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* [CXC 68-2009]).¹

3.4 Decomposition

The product of susceptible species shall not contain more than 10 mg of histamine per 100 g 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, colours and preservatives used in accordance with Tables 1 and 2 of the *General standard for food additives* (CXS 192-1995)² in food category 09.2.5 (Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms) and its parent food categories and only certain acidity regulators, antioxidants and packaging gases as indicated in Table 3 of the *General standard for food additives* are acceptable for use in foods conforming to this standard.

4.2 Smoke-flavoured fish

Acidity regulators, colours and preservatives used in accordance with Tables 1 and 2 of the *General standard for food additives* in food category 09.2.5 (Smoked, dried, fermented, and/or salted fish and fish products, including molluscs, crustaceans, and echinoderms) and its parent food categories and only certain acidity regulators, antioxidants and packaging gases as indicated in Table 3 of the *General standard for food additives* are acceptable for use in foods conforming to this standard.

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* (CXS 193-1995).³

5.2 Polycyclic aromatic hydrocarbons (PAH)

Smoking of fish should be done in a manner that minimizes 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*.

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* (CXC 1-1969)⁴ 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* (CXC 52-2003).⁵

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* (CXG 21-1997).⁶

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 8.2.2 and/or Section 8.2.3.

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 foods* (CXG 61-2007).⁷

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 minimize the risk of *Clostridium botulinum*.

6.6 Histamine

The product shall not contain histamine that exceeds 20 mg/100 g 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 pre-packaged foods* (CXS 1-1985),⁸ 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 Section 2.1; "smoke-flavoured X" if treated by the processes described in Section 2.2; "smoke-dried X" if treated by the processes described in Section 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

The labelling of non-retail containers should be in accordance with the *General standard for the labelling of non-retail containers of foods* (CXS 346-2021).⁹

8. SAMPLING, EXAMINATION AND ANALYSIS

8.1 Sampling

8.1.1 *Sensory and physical examination*

Attribute sampling plan *General guidelines on sampling* (CXG 50-2004),¹⁰ Section 4.2, Table 10, using AQL of 6.5 percent.

8.1.2 *Determination of net weight*

Sampling plans by variables with unknown standard deviation (s-method) *General guidelines on sampling*, Section 4.3, Table 14.

8.2 Examination

8.2.1 *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 the *Recommended methods of analysis and sampling* (CXS 234-1999)¹¹ and the *Guidelines for the sensory evaluation of fish and shellfish in laboratories* (CXG 31-1999).¹²

8.2.2 *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 atlantic herring and salted sprat* (CXS 244-2004)¹³ or other validated methods for parasites acceptable to the competent authority having jurisdiction.

8.2.3 *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 percent translucency and candled with a light source giving 1 500 lux 30 cm above the sheet.

8.3 Analysis

For checking the compliance with this standard, the methods of analysis and sampling contained in CXS 234-1999 relevant to the provisions in this standard shall be used.

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 recognized 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 Section 8.2.3 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:

- the total number of defectives as classified according to Section 9 does not exceed the acceptance number (c) of an appropriate sampling plan (AQL of 6.5) in the *General guidelines on sampling* (CXG 50-2004);¹⁰
- 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 percent of the declared weight; and
- 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 *Recommended methods of analysis and sampling* [CXS 234-1999]).¹¹

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);¹⁴
- freezing at -35 °C at the thermal centre of the product for 15 hours (all parasites)^{15,16,17,18}; and
- freezing at -20 °C at the thermal centre of the product for 168 hours (7 days)^{15,16,17,18}(all parasites).

ANNEX 2

EXAMPLES OF COMBINATIONS OF PRODUCT ATTRIBUTES THAT MINIMIZE 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 percent aqueous phase salt would be required in order to provide complete protection at temperatures between 3 °C and 10 °C, or 10 percent 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 percent 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 minimize 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.¹⁹ 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.

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 microenvironments 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 the 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% and 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.

NOTES

¹ FAO and WHO. 2009. *Code of practice for the reduction of contamination of food with polycyclic aromatic hydrocarbons (PAH) from smoking and direct drying processes*. Codex Alimentarius Code of Practice, No. CXC 68-2009. Codex Alimentarius Commission. Rome.

² FAO and WHO. 1999. *General standard for food additives*. Codex Alimentarius Standard, No. CXS 192-1995. Codex Alimentarius Commission. Rome.

³ FAO and WHO. 1995. *General standard for contaminants and toxins in food and feed*. Codex Alimentarius Standard, No. CXS 193-1995. Codex Alimentarius Commission. Rome.

⁴ FAO and WHO. 1969. *General principles of food hygiene*. Codex Alimentarius Code of Practice, No. CXC 1-1969. Codex Alimentarius Commission. Rome.

⁵ FAO and WHO. 2003. *Code of practice for fish and fishery products*. Codex Alimentarius Code of Practice, No. CXC 52-2003. Codex Alimentarius Commission. Rome.

⁶ FAO and WHO. 1997. *Principles and guidelines for the establishment and application of microbiological criteria for foods*. Codex Alimentarius Guideline, No. CXG 21-1997. Codex Alimentarius Commission. Rome.

⁷ FAO and WHO. 2007. *Guidelines on the application of general principles of food hygiene to the control of Listeria monocytogenes in foods*. Codex Alimentarius Guideline, No. CXG 61-2007. Codex Alimentarius Commission. Rome.

⁸ FAO and WHO. 1985. *General standard for the labelling of pre-packaged foods*. Codex Alimentarius Standard, No. CXS 1-1985. Codex Alimentarius Commission. Rome.

⁹ FAO and WHO. 2021. *General standard for the labelling of non-retail containers of foods*. Codex Alimentarius Standard, No. CXS 346-2021. Codex Alimentarius Commission. Rome.

¹⁰ FAO and WHO. 2004. *General guidelines on sampling*. Codex Alimentarius Guideline, No. CXG 50-2004. Codex Alimentarius Commission. Rome.

¹¹ FAO and WHO. 1999. *Recommended methods of analysis and sampling*. Codex Alimentarius Standard, No. CXS 234-1999. Codex Alimentarius Commission. Rome.

¹² FAO and WHO. 1999. *Guidelines for the sensory evaluation of fish and shellfish in laboratories*. Codex Alimentarius Guideline, No. CXG 31-1999. Codex Alimentarius Commission. Rome.

¹³ FAO and WHO. 2004. *Standard for salted atlantic herring and salted sprat*. Codex Alimentarius Standard, No. CXS 244-2004. Codex Alimentarius Commission. Rome.

¹⁴ FAO. 2004. Fisheries Technical Paper 444. Assessment and management of seafood safety and quality. Rome. FAO.

¹⁵ Bier, J. 1976. Experimental Anisakiasis: Cultivation and Temperature Tolerance Determinations. *Journal of Milk and Food Technology*. 39:132–137.

¹⁶ Deardoff, T.L. et al. 1984. Behaviour and Viability of Third-Stage Larvae of *Terranova* sp. (Type HA) and *Anisakis simplex* (Type I) Under Coolant Conditions. *Journal of Food Protection*. 47:49–52.

¹⁷ Health and Welfare Canada. 1992. *Code of practice for the preparation of raw, marinated and partially cooked fin fish*. (In consultation with Canadian Restaurant and Food Service Association, Fisheries Council of Canada and Fisheries and Oceans Canada).

¹⁸ USFDA. 2001. Centre for Food Safety & Applied Nutrition (June 2001), Fish and Fisheries Products Hazards and Controls Guidance, Chapter 5. *Parasites*, 3rd Edition.

¹⁹ 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.