



**JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON FISH AND FISHERY PRODUCTS**

**Thirty-third Session
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**PROPOSED DRAFT CODE OF PRACTICE FOR PROCESSING OF FISH SAUCE
(At Step 3 of the Procedure)**

Comments submitted by European Union, Japan, Kenya, Philippines and United States of America

EUROPEAN UNION

1. Reception of raw material

1.1 Fish

Technical Guidance

The EUMS propose to insert the following bullet point:

- ***Fish intended for fish sauce fermentation should be kept until processing at 4°C or below. Refer to Section 8.1.2***

Usually small vessels harvest pelagic fish such anchovies without ice aboard. To avoid decomposition fish has to be chilled without undue delay. This is necessary especially when small catches must be collected for further processing of high quality fish sauce on a large scale.

Rapid chilling of fish immediately after death is the most important element for preventing the formation of histamine. Generally, fish should be placed in ice or in refrigerated seawater or brine at 4.4 °C or less within 6 h from death. (FDA 2001 see literature: Visciano et al. J Food Biochem 31 (2007) 577-588) To keep the level of histamine preferably low before fermentation, it is a must to cool the fish.

Red-flesh pelagic fish such anchovies usually contain considerable amounts of the free amino acid histidine. After harvesting bacteria convert increasingly histidine by decarboxylation to histamine depending on storage time and temperatures before the fermentation process starts. Rodtong et al. (Food Microbiology 22, 475-482 (2005) conclude in their work that ice storage can considerably minimize the formation of histamine in anchovy because histamine –forming bacteria do not grow well at low temperatures. Yongsawatdigul (Journal of Food Science, Vol. 69, 4, 312-319, 2004) reports that an increase of biogenic amines during fermentation of fish sauce made from fresh or moderately fresh anchovy is rather inconsiderable. Cadaverine and histamine have in these sauces the most important percentages of the total sum of biogenic amines. The most important conclusion of these examinations is that biogenic amines do not increase during long-term storage of fish sauce. If there are any biogenic amines in fish sauce, they arise from bad manufacturing practice before the fermentation process. See also literature about histamine content in fish sauce: Ostermeyer et al. Inf. Fischereiforschung, 56, 1-18, 2009, Schröder et al. Fleischwirtschaft International; 26. 2011, 81-87.

1.2 Salt requirements

Technical Guidance

The EUMS propose to insert the following bullet point to be in compliance with the Standard for Fish Sauce (Codex Stan 302-2011):

- ***Salt used should be of food grade quality and conform to the Codex Standard for Food Grade Salt (Codex Stan 150-1985)***

The reception and storage of raw materials should also cover the ingredients and additives, fermentation aids, packaging materials and labels as following:

X. Ingredients and additives, fermentation aids, packaging materials and labels (processing steps ...)

17. Ingredients and additives

The EUMS propose to insert the microbiological contamination.

Potential hazards: chemical, physical **and microbiological** contamination

JAPAN

General comments

Since Japan considers this Code of Practice is supposed to be a new section of the *Code of practice for fish and fishery products* (CAC/RCP 52-2003), Japan would like to propose to add the section “X.1 General”, “X.2 Identification of hazards and defects” and “X.3 Processing operations” to harmonize with other sections: Sections 7 to 16.

Specific comments

Proposals for amendments and comments of Japan are described in ***Italics and bold***.

para9

9. A member of EWG suggested adding a harvest vessel step as it is the point in the production chain where preventive controls for the hazards of histamine and botulinum toxin in fish sauce begin. The co-chairs are of the view that the processors could conduct the sensory evaluation to control quality of fresh fish before being used as raw material in fish sauce processing and evaluate histamine levels in final products to control ***histamine formation-its toxin***. Good practices for harvest vessels have been addressed in the subsection 3.1 “*Fishing and Harvesting Vessel Design and Construction*” under the section 3 “*Prerequisite programme*” of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003). In addition, the processing steps for other aquatic animals and their products delineated in CAC/RCP 52-2003 are generally begun at raw material reception. So, the harvest vessel step was not introduced.

Rationale: histamine is not a toxin.

Appendix II

8. Blending

Potential hazards: unlikely

Potential defects: Ingredient measurement errors, unauthorized food additives

Technical Guidance:

- Total Nitrogen (TN) of fermentation extract batches should be analyzed before blending. TN ***Total nitrogen (Rationale: editorial)*** and amino acid nitrogen content in the final product must be in compliance with *Standard for Fish Sauce* (CODEX STAN 302-2011).
- To achieve good quality fish sauce, ingredients should meet the required characteristics and appropriated concentrations.
- All utensils should be clean.

- Food additives and levels used need to be in compliance with the *Standard for Fish Sauce* (CODEX STAN 302-2011), and used in compliance with *General Standard for Food Additives* (CODEX STAN 192-1995), and other relevant regulations. Food additives used need to be identified with names and identification numbers which are complied with *Codex Class Names and the International Numbering System for Food Additives* (CAC/GL 36-1989).

- Before mixing, chemical properties, essential quality factors should be monitored, and the results should be recorded.

14. Transportation/distribution *Potential hazards: unlikely*

Also refer to Section 17.4

Potential defects: contaminated and damage containers and cartons

Technical Guidance:

-
- Cartons should be cleaned, dry, durable and suitable for the intended use and avoid the damage of the packaging materials.
- Cartons should be applied to avoid the damage of containers.
- ~~Cleanliness and suitability of the vehicles should be inspected before transportation.~~
- ~~Sanitation of the cargo should be verified before loading.~~
- ~~Care should be taken before loading to avoid damage and contamination of the products and to ensure the packaging integrity.~~

Rationale: these three bullets are covered in the section 17.4)

15. Application of fermentation aids

Potential hazards: microbiological contamination

Potential defects: unlikely

Technical Guidance:

- Fermentation aids should be stored at appropriate temperature in order to avoid deactivation of fermentation aids.

Rationale: The purpose of this guidance should be indicated.

- When Enzymes and bacterial cultures *are may be* used as fermentation aids *for non-traditional fish sauce products, they should be handled to minimize the microbiological contamination.*

Rationale: Since “non-traditional fish sauce products” is not defined, this sentence may cause confusion. We should focus on technical guidance to control microbiological contamination. From that point of views, we would like to propose a revised text.

KENYA

Specific comments

Scope

We feel that the scope is too wide so we have shortened it to be precise to give guidance on what to be covered in the body of the code. The scope will read as follows:

This Code will address the general processing steps and technical guidance to be employed by fish sauce manufacturers which could vary from country to country. Potential hazards and defects at each processing step starting from raw material reception and ending with final product distribution will also be identified. In addition, each processing step will include technical guidance for controlling the identified hazards and defects that help ensuring consumer safety and product quality.

2. Definitions

Fish sauce – fish sauce is a translucent and not turbid liquid product with salty taste and fish flavour obtained from the fermentation of a mixture of fish and salt at an appropriate ratio.

3. Example of a Flow Chart of Fish Sauce Processing

We propose to include the harvesting stage to the flow chart to minimize histamine formation resulting from proteolytic denaturalization and the reference can be made concerning harvesting to CAC/RCP 52-2003 Code of Practice for Fish and Fishery Products.

1.2 Salt requirements

Bullet one: The quality of salt used in salting of fish should be food grade ~~possess~~ with an appropriate composition ~~for the product~~.

Bullet two: Salt used should be inspected to ensure that it is clean, ~~not used before~~, free from foreign matter and foreign crystals, and shows no visible sign of contamination with dirt, oil, bilge or other extraneous materials.

Justification: we have struck the word ‘not used before’ since salt cannot be used twice in any products.

14/ Transportation/distribution

Technical guidance

bullet one: Cartons should be cleaned, dry, durable and suitable for the intended use and avoid the damage of the packaging materials.

Bullet two: Cartons liners should be applied to avoid the damage of containers.

We propose to add the word ‘liners’ after the word ‘carton’.

17. Ingredients and additives

Technical guidance:

Bullet one: Ingredients and additives should be stored in appropriately conditions to maintain their integrity ~~in terms of temperature and humidity~~.

18. Packaging materials

Bullet one: Packaging used should be stored in appropriately conditions ~~in terms of temperature and humidity~~.

PHILIPPINES

General Comments

The Philippines acknowledges the work done by the EWG led by Thailand and Vietnam in drafting the herein Code of Practice and provides the following suggestions for consideration:

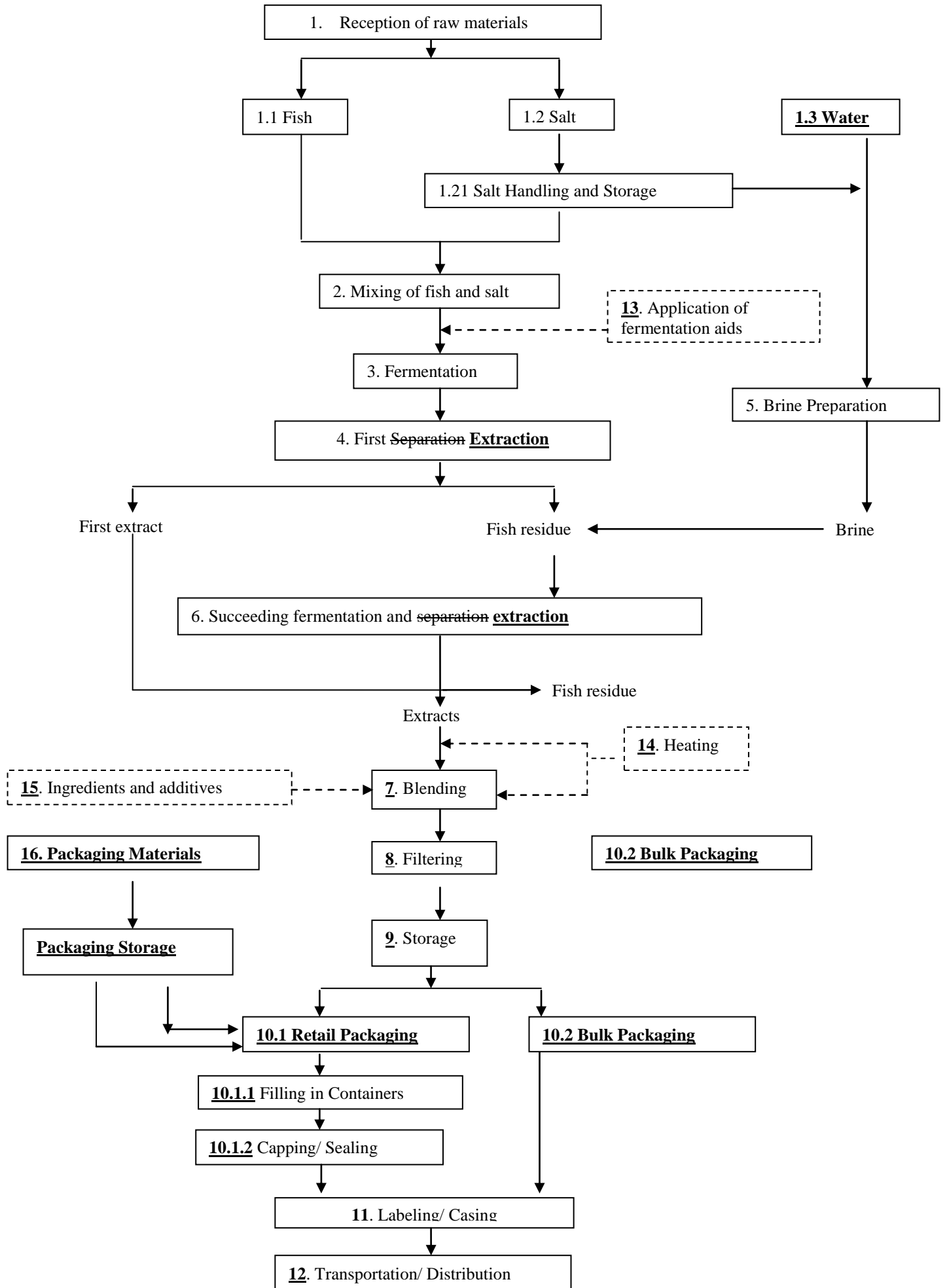
Specific Comments

The Philippines would like to add the following in the Flow Chart of Fish Sauce Processing:

1. **Water** is inserted as one box as this is a component in the preparation of brine.
2. **Packaging materials** should not be optional, as these are also essential components that would affect product quality and safety.
3. To use the term **Extraction** rather than Separation to be consistent with Sec. 2.2 of the Standard on Fish Sauce (CODEX STAN 302-2011).
4. To put together in one box **Succeeding Fermentation and Extraction** as these steps could be undertaken several times, depending on country practices.
5. New boxes were introduced to differentiate bulk packaging from retail packaging.

6. Bottling is changed to **Filling in Containers** to take into account the variety of suitable packaging materials that could be developed in the future, apart from glass bottles.
7. **Sealing** is also included under Capping as may be appropriate for other packaging materials.
8. **Casing** is incorporated with labeling to account for bulk packing.
9. Renumbering of the boxes was done as appropriate.

Example of a Flow Chart of Fish Sauce Processing



Suggest:**I. Reception of raw materials**

1.1 Fish

Potential hazards: histamine, microbiological contamination, biotoxins, chemical contamination (including pesticides **from aquaculture**), physical contamination

Justification

Pesticides are unlikely to be present in offshore marine waters, hence the addition of **from aquaculture** where the likelihood of contamination may occur.

Suggest:*Technical Guidance:*

- For fish or parts of fish, raw materials specifications should include the following characteristics:
 - microbiological criteria (to prevent the processing of raw material containing **high microbial load**/microbiological toxins) for fish with risk;
 - veterinary drug residues and **pesticides** (when raw fish material are from aquaculture);
- ~~Skills should be acquired by Fish handlers~~ **should be familiar in sorting fish species that pose** and appropriate personnel in sensory evaluation techniques to ensure that raw fish meet essential quality provisions of appropriate Codex Standards and in sorting of fish species that pose a risk of biotoxins such as ciguatoxin in large carnivorous tropical and subtropical reef fish.
- Fish greater than 12 cm in length ~~that required gutting on arrival at the processing facility~~ should be gutted efficiently without undue delay and with care to avoid contamination.
- Fish should be rejected if it is known to contain harmful, decomposed or extraneous substances that ~~are unable to~~ **cannot** be reduced or eliminated to an acceptable level by normal procedures of sorting or preparation.

Justification

Editorials for clarity and/or brevity.

Suggest:**1.2 Salt requirements**

Potential defects: ~~incorrect composition~~ **salt impurities**

Technical guidance:

- ~~The quality of salt used in salting of fish should possess an appropriate composition for the product.~~ **Salt used should be food grade as indicated in the Standard for Food Grade Salt (CODEX STAN 150-1985).**
- The composition of salt differs according to ~~the~~ origin. Mine salt and solar salt of marine origin contain several other salts such as calcium sulphate, magnesium sulphate and chloride as impurities.
- Solar salt is ~~recommended to~~ **may** be stored at least 2 months before using in order to obtain a good ~~taste~~ fish sauce **flavour**.
- ~~Salt used should be inspected to ensure that it is clean, not used before, free from foreign matter and foreign crystals, and shows no visible sign of contamination with dirt, oil, bilge or other extraneous materials.~~
- The size of the salt granules used should be carefully considered. Medium size salt crystal is **preferable** ~~should used. Use clean salt without contaminants. If s~~ Small size salt **crystal causes rapid lost of moisture in** is used, the outer skin of fish **which may lead to** will rapidly loose moisture and salt burn can occur which will prevent salt penetration into the fish. ~~Consequently, the inner flesh of fish can be spoiled. In case of~~ Too large salt crystal, it can **exhibits** slowly **penetration rate**, thus fish might be spoiled before preservation effect of salt occurs.

Justification

Editorials for clarity.

Suggest:**1.2.1 Salt handling and storage**

Potential defects: ~~unlikely~~ moisture absorption

Justification

Salt is hygroscopic, thus care must be exercised to maintain the necessary humidity in the storage area and contact of salt to water.

Technical guidance:

- Salt should be **properly packed, stored and** transported ~~and stored dry and hygienically covered~~ in salt bins, storerooms, containers or in plastic sacks.

Justification

Editorials for clarity.

Suggest:**2. Mixing of fish and salt**

Technical Guidance:

- Fish and salt should be mixed thoroughly, **manually or mechanically** ~~by trained personal or machines~~ to ensure the proper contact of salt to fish so as to prevent the growth of ~~pathogens~~ microorganisms and the decomposition during fermentation. ~~All the apparatus used to mix fish and salt should be rust free and resistant to salt.~~

Justification

Editorials for clarity. The second sentence is omitted as this should be covered by GMP.

Suggest:

- In order ~~to control the ratio of fish to salt for preventing~~ spoilage and growth of pathogenic bacteria, ~~proper ratios of fish to food grade salt should be met. Common weight to weight ratios are 3:1, 5:2, 3:2. In any case,~~ the concentration of salt should not be less than 20% by weight. ~~The~~ Common ratios of **fish to salt** by weight are 3:1, 5:2 and 3:2.

Justification

Editorials for clarity.

Suggest:**3. Fermentation****Justification**

Editorials for clarity.

Technical Guidance:

- ~~Care should be taken to ensure the cleanliness of the fermentation area and tanks. Fermenting tanks should be able to prevent product contamination.~~

Justification

The bullet is omitted as this should be covered by GMP.

Suggest:

- Fermentation **period** ~~be in between~~ **range from** ~~4- 6~~ -18 months to achieve good quality of fish sauce from natural fermentation in a tropical zone. When fermentation aids are used, the period can be varied, **but** ~~However, the fermentation process should not~~ **be** ~~take less than 6 months.~~

Justification

Editorials for clarity.

Suggest:**4. First ~~separation~~ extraction****Justification**

To use the term **Extraction** for consistency with the Standard on Fish Sauce (CODEX STAN 302-2011).

Suggest:

Technical Guidance:

- ~~All utensils should be clean.~~

Justification

The bullet is omitted as this should be covered by GMP.

Suggest:

- Liquid should be translucent solution. ~~First extract should contain~~**ing** acceptable level of total nitrogen content.

Justification

Editorials for clarity.

Suggest:**6. Succeeding Fermentation and Extraction****Justification**

These steps (6 and 7) are done successively and could be repeated depending on the practices of countries.

Suggest:**87. Blending**

Technical Guidance:

- ~~Total Nitrogen (TN) of fermentation extract batches should be analyzed before blending. Total nitrogen and amino acid nitrogen content in the final product must be in compliance with *Standard for Fish Sauce* (CODEX STAN 302-2011).~~

- **Batches of fish sauce extracts should be analyzed for safety & quality requirements in compliance with the *Standard for Fish Sauce* (CODEX STAN 302-2011) before blending.**

Justification

Editorials for clarity. The statement would cover both quality and safety parameters

Suggest:

- ~~All utensils should be clean.~~

Justification

The bullet is omitted as this should be covered by GMP.

Suggest:

- ~~Before mixing, chemical properties, essential quality factors should be monitored, and the results should be recorded.~~

Justification

The bullet is omitted as this is covered by the re-written sentence in bullet 1

Suggest:

98. Filtering

Technical Guidance:

- ~~Filtering system should be cleaned and kept in an appropriate environment to prevent contamination.~~

Justification

The bullet is omitted as this should be covered by GMP.

Suggest:

- **An appropriate** ~~f~~Filtering system should be **used and** checked regularly ~~to ensure its ability to operate properly.~~

Justification

Editorials for clarity.

Suggest:**109. Storage**

Technical Guidance:

- ~~The storage tanks with lid should be clean, resistant to rust and salt, located in an appropriated area.~~
- **The product should be stored properly and kept from any source of contamination.**

Justification

The bullet is omitted as this should be covered by GMP. A new bullet is proposed.

Suggest:**110. ~~Bottling~~ Filling in containers****Justification**

The change in title from Bottling to Filling in Containers would cover the variety of suitable packaging materials apart from glass bottles.

Suggest:

Technical Guidance:

- ~~Bottling~~ Filling machines should be kept clean to prevent contamination.
- ~~Defected~~ Defective containers should be ~~taken out~~ not be used to ~~avoid the damage of the filling and capping machine.~~

Justification

Editorials for clarity.

Suggest:**131. Labelling/~~packaging casing~~****Justification**

Casing takes into account packing of bulk containers, usually for export.

Suggest:**142. Transportation/distribution**

Technical Guidance:

- Cartons should be ~~applied~~ **used** to ~~avoid the damage of~~ **protect** containers from **damages**. Cartons should be cleaned, dry, ~~usable~~ **usable** and suitable for the intended use ~~and avoid the damage of the packaging materials.~~

Justification

Editorials for clarity.

Suggest:

- ~~• Cleanliness and suitability of the vehicles should be inspected before transportation.~~
- ~~• Sanitation of the cargo should be verified before loading.~~
- ~~• Care should be taken before loading to avoid damage and contamination of the products and to ensure the packaging integrity.~~

Justification

The bullets were omitted as this should be covered by GMP.

Suggest:**1513. Application of fermentation aids****Justification:**

Renumbering editorial for consistency.

Suggest:**1614. Heating**

Potential hazards: ~~unlikely~~ **microbial growth**

Potential defects: ~~over heating~~ **flavour change due to protein denaturation**

Justification

Inappropriate heating may be favourable to growth of microorganisms and may also cause protein denaturation that could affect product flavour.

Suggest:**1715. Ingredients and additives**

Technical guidance:

- ~~• Ingredients and additives should be stored in a dry and clean place under hygienic conditions.~~

Justification

The bullet is omitted as this should be covered by GMP.

Suggest:**1816. Packaging**

Potential hazards: decomposition

Potential defects: presence of foreign matters

- All packaging materials shall be of food grade and/or suitable to the product and shall meet the requirement as stated in Section 3.5 in the Standard for Fish Sauce (CODEX STAN 302- 2011).

USA**General Comments**

The U.S. does not support advancement of this text as currently drafted because it does not include adequate guidance for control of preformed *Clostridium botulinum* toxin and histamine. In our Specific Comments (below), the U.S. proposes the addition of a harvest vessel step to Section 1. Reception of Raw Materials, because this is the point in production where preventive controls for these important hazards should begin.

Rationale

Good hygienic practices at later stages of production are not a substitute for HACCP-type controls for hazards introduced in the raw material. If harvest vessel and transportation controls for *C. botulinum* toxin and histamine are not implemented, acute illness or death can occur.

Fish sauce is produced from small low value fish that traditionally receive minimal control for hazards introduced on the harvest vessel and/or during transport as compared to larger more valuable fish. This causes a greater likelihood for hazards introduced with the raw material to cause an unsafe condition in finished fish sauce. The Code of Practice should include guidance on controlling these hazards in this unique raw material.

Uneviscerated fish are used to make fish sauce. The spores of *C. botulinum* are more likely to occur in viscera. *C. botulinum* grows and produces toxin in the anaerobic environment of fermented uneviscerated fish (Sobel et al. 2004, Wainwright 1993). *C. botulinum* toxin is stable under both high salt and/or acid conditions (Huss & Petersen 1980). One author postulates that fermentation conditions may inactivate *C. botulinum* toxin, however there is no experimental evidence that this occurs, and fermentation conditions are extremely variable.

The raw material used to make fish sauce typically has histamine levels greater than 15 PPM, which indicates a lack of temperature control during harvest and/or transportation. High histamine in the raw material is strongly associated with high histamine in finished fish sauce (Brillantes et al. 2002). Histamine formation is slowed by salting and fermentation, however high histamine introduced with the raw material is not eliminated and remains in finished fish sauce.

References:

Brillantes S, Paknoi S, Totakien A. Histamine formation in fish sauce production. *J. Food Science.* 67:6, 2002.

Huss H, Petersen R. The stability of *Clostridium botulinum* type E toxin in salty and/or acid environment. *J. Food Technology.* 15:6, 1980

Sobel J et al. Foodborne botulism in the United States, 1990-2000. *Emerging Infectious Diseases.* 10:9 1606-1611, 2004

Wainwright RB. Hazards from northern native foods. In *Clostridium botulinum Ecology and Control in Foods.* Marcel Dekker, New York. Hauschild AHW and Dodds KL, eds. 1993

Specific Comments

Introduction, first paragraph, and 5th & 6th sentence – delete:

~~The most popular marine fish used as a raw material in fish sauce processing is anchovy which is generally in a small size, not greater than 12 cm in length. Anchovies yield fish sauce products of high quality with the characteristic aroma and reddish brown colour.~~

Reason:

These sentences appear to promote fish sauce made from anchovies; however any fish can be used to make high quality fish sauce.

Introduction, first paragraph, 3rd to last sentence – edit as follows:

~~Other ingredients~~ **Processing aids like such as** enzymes **and/or bacterial inoculates** can be added **used** to improve **assist** the fermentation process.

Reason:

Both enzymes and bacterial inoculates are used and are more accurately characterized as “processing aids” rather than “additives” or “ingredients.”

Introduction, first paragraph, 2nd to last sentence – edit as follows:

Salt is an essential ingredient in fish sauce production in order to control **pathogens and** the types of **fermentation** microorganisms **present**, and **to** prevent defective fermentation.

Reason:

Salt is essential for product safety in this product.

Introduction, second paragraph, 2nd sentence – edit as follows:

Potential hazards and defects at each processing step starting from raw material ~~reception~~ **harvest** and ending with final product distribution will also be identified.

Reason:

Harvest vessel and transportation controls are important to include in a code of practice for fish sauce (see general comments).

Introduction, second paragraph, last sentence – edit as follows:

In addition, each processing step will include technical guidance for controlling the identified hazards and defects that help ensuring consumer safety and product quality.

Reason:

Editorial.

Flowchart, box #6 – change box to dashed line, and edit as follows:

6. Succeeding ~~fermentation~~ **extractions**

Reason:

Succeeding extractions are optional; therefore the box should be dashed to indicate an “optional” step.

Consistent with the Fish Sauce Standard, subsequent application of water and salt to the fermentation residue (solid remnant after removal of liquefied portion) is considered an extraction rather than a true fermentation because the metabolic breakdown of the fish is essentially completed after 12 months.

Add new first step before “Reception of raw materials” as follows (also add to flow chart, and renumber):

1. Harvest Vessel Operations, and Transport to Processor

Potential hazards: scombrototoxin (histamine) formation, microbiological contamination (including *Clostridium botulinum* toxin formation), physical contamination

Potential defects: decomposition, foreign matter

Technical guidance:

- **The kinds of fish commonly used to make fish sauce (e.g., Families Engraulidae, Clupeidae) are susceptible to histamine formation. High histamine in the raw material is associated with high histamine in finished fish sauce. Time and temperature controls, and/or salting controls, should be implemented to control histamine during harvest and transport.**
- **All uneviscerated fish are susceptible to *Clostridium botulinum* growth and toxin formation. In order to control toxin formation, time and temperature controls, or salt controls, should be implemented during harvest and transport. In addition, fish over 11 cm in length should be eviscerated to allow oxygen penetration; to facilitate rapid cooling or salt penetration; and to remove the digestive track where *C. botulinum* spores are most likely to occur.**
- **Harvest vessels should have mechanical refrigeration systems, or an adequate supply of ice and containers, to rapidly cool fish to 4.4° C or below and to hold them at that temperature until unloading. For salting, salt should be mixed with fish in an appropriate ratio to attain the target water phase salt (i.e., 10%) or target water activity (i.e., 0.85) within the target time period (i.e., 24 hours from harvest).**
- **Cooling, and/or maintenance of salt, controls should be in place at the vessel offloading/holding site and on transportation vehicles.**
- **Fish temperature, or adequacy of ice or salt, should be monitored during harvest and transportation using the principles of HACCP discussed in Section 5 of this Code. Periodic measurements and checks should be documented in a record that demonstrates to the processor or competent authority that hazards were adequately controlled in the lot delivered.**
- **Foreign matter and inappropriate fish species should ideally be removed or separated on the harvest vessel.**

Reason:

Fish sauce has an enhanced risk of scombrototoxin poison because of the traditional methods used to handle the raw material. *C. botulinum* poisonings have been reported numerous times due to consumption of salted fermented fish products similar to fish sauce. If cooling and/or salting controls, and evisceration controls are inadequate, and the product is not boiled to destroy toxin, then acute illness or death can occur. Harvest vessels, holding and transportation have been shown to be the important critical control points for these hazards.

1. Reception of raw materials, 1.1 Fish, potential hazards and defects – edit as follows:

Potential hazards: histamine, microbiological contamination (**including Clostridium botulinum toxin**), biotoxins, chemical contamination (~~including pesticides~~), physical contamination

Potential defects: decomposition, ~~physical contamination~~ **foreign matter**

Reason:

It may not be recognized that botulinum toxin is a potential hazard in the raw material, and therefore it should be specifically listed.

Pesticides are a typical chemical contaminant and need not be specifically listed.

Foreign matter has been the customary term for a defect, while ‘physical contamination’ is usually considered a hazard.

1. Reception of raw materials, 1.1 Fish, Technical Guidance, first bullet - revise as follows:

- For **Fish**, or parts of fish, raw materials **receiving** specifications should include the following characteristics:
 - **As appropriate, harvest vessel and transportation records documenting that the fish were rapidly chilled and maintained at 4.4° C or below;**
 - **As appropriate, harvest vessel and transportation records documenting that the fish were adequately salted to achieve the target water activity within the target time;**
 - **Organoleptic and chemical indicators of decomposition** characteristics, such as appearance, odour, **appearance**, texture, ~~chemical indicators of decomposition and/or contamination, for example, histamine,~~ total volatile basic-nitrogen (TVBN), ~~histamine, heavy metals, pesticide residues, nitrates;~~
 - **Chemical contaminants such as heavy metals, pesticide and drug residues, [nitrates];**
 - **Microbial Biotoxin** criteria (to prevent the processing of raw material containing microbial toxins, **i.e., domoic acid, ciguatera toxin**) for fish with a risk;
 - **Veterinary drug residues** (when raw fish material ~~are~~ **is** from aquaculture).
 - **Foreign matters;**

Reason:

To add guidance on gathering preventive control monitoring records for the raw material.

To separate ‘chemical contaminants’ from ‘chemical indicators of decomposition’ because chemical contaminants are a hazard. We are unsure why ‘nitrates’ are listed (preservative?)

To use the term “biotoxin” rather than “microbial,” and to mention biotoxins that occur in fish, i.e., domoic acid (a hazard in small planktivorous fish) and ciguatera toxin. Note that shellfish are not included in the Fish Sauce Standard.

1. Reception of raw materials, 1.1 Fish, Technical Guidance, third bullet - revise as follows:

- **Uneviscerated** Fish greater than ~~42~~ **11** cm in length that ~~required~~ **should be gutted** on arrival at the processing facility, ~~should be gutted~~ **should be gutted** efficiently, without undue delay and with care to avoid contamination. **For any size raw material, if harvest vessel and transport controls for Clostridium botulinum toxin formation are not adequately applied and documented, then the raw material or final product should be boiled to destroy potential C. botulinum toxin.**

Reason:

It is important to provide appropriate guidance for control of *C. botulinum*. Evisceration is not the primary control.

1. Reception of raw materials, 1.1 Fish, Technical Guidance, last bullet - revise as follows:

- Information about the harvesting area, **and harvest vessel and transportation temperature and/or salting records** should be **collected and** recorded. **Records should be retained for trace-back purposes.**

Reason:

Records indicating that the histamine and *C. botulinum* hazards were controlled on the harvest vessel and during transportation should be collected and retained for trace-back purposes.

1. Reception of raw materials, 1.1 Fish, Technical Guidance - add two new bullets as follows:

- **Histamine verification sampling should be performed using a sample size large enough and an acceptance level low enough (e.g., < 15 mg histamine/ kg) to provide some assurance (other than documentary records) that harvest vessel cooling and/or salting controls were adequate.**
- **Product received should be kept chilled (≤ 4.4 ° C) until the target water activity is attained during the salting step.**

Reason:

Histamine is mentioned in the 1st bullet as an indicator of decomposition; however guidance is needed on monitoring histamine as a hazard. This step helps validate adequacy of histamine controls implemented during harvest and transportation.

The second bullet introduces guidance on maintaining cooling at reception.

1. Reception of raw materials, 1.2 Salt requirements – add bullet as follows:

- **Salt used should be of food grade quality and conform to the Standard for Food Grade Salt (CODEX STAN 150-1985).**

Reason:

The salt requirement from the Fish Sauce Standard should be incorporated, as appropriate to this section title.

2. Mixing fish with salt – add potential hazard as follows:

Potential hazards: histamine, microbiological contamination (*Clostridium botulinum* and *Staphylococcus aureus* toxins), **metal inclusion**

Reason:

Metal inclusion can occur if mechanically mixed.

2. Mixing fish with salt, technical guidance, 1st bullet - revise as follows into two bullets:

- Fish and salt should be mixed thoroughly by trained personal or machines to ensure the proper contact of salt to fish so as to **achieve the water activity required to** prevent the growth of pathogens and prevent **histamine production** ~~decomposition~~ during fermentation. ~~All the apparatus used to mix fish and salt should be rust-free and resistant to salt.~~ **Before the target water activity is achieved pathogen growth and histamine formation is controlled by adequate cooling.**
- All the apparatus used to mix fish and salt should be **easily cleanable**, rust-free and resistant to salt. **Mechanical mixers should not introduce unapproved substances, or metal fragments.**

Reason:

It is important to include guidance on target water activity and cooling, and to separate different hazard types. Fermentation is a decomposition process; therefore salt does not “prevent decomposition”.

2. Mixing fish with salt, technical guidance, 2nd bullet – revise as follows:

- In order to control the ratio of fish to salt for preventing spoilage and growth of pathogenic bacteria, proper ratios of fish to food grade salt should be met. Common weight to weight ratios are 3:1, 5:2, 3:2. ~~In any case, the concentration of salt should not be less than 20% by weight.~~

Reason:

The listing of 20% salt by weight (ratio fish to salt of 4:1) does not correspond to any of the mixing ratios listed. It is unclear where, when and how 20% salt by weight is monitored, and why a ratio is not listed.

2. Mixing fish with salt, technical guidance – add two new bullets as follows:

- **Fish should attain 10 percent water phase salt, or water activity below 0.85, within 24 hours of mixing, as measured in the centers of the largest fish.**
- **Refer to Section 11 of this Code for further guidance on salting fish**

Reason:

These are appropriate targets for percentage water phase salt or water activity, and time.

It will be helpful to users of the Code to provide a reference to the section of the COP about salting.

3. Fermenting – revise potential hazards, and technical guidance as follows:

3. Fermenting

Potential hazards: **scombrototoxin (histamine), botulism toxin, microbiological contamination, chemical contaminants (including heavy metals)**

Technical Guidance:

- Care should be taken to ensure the cleanliness of the fermentation area and tanks. Fermenting tanks should be able to prevent product contamination. **The tanks and their covers should be clean, and resistant to rust and corrosion due to salt that may cause heavy metal contamination. Tanks should be constructed to be easily cleaned and sanitized between uses.**
- **Percent Water Phase Salt, and/or Water Activity, should be monitored during fermentation to control pathogen growth and toxin formation (e.g., *Clostridium botulinum* and *Staphylococcus aureus*), and histamine formation.**
- Fermentation **at ambient, or controlled, temperature** should be between 10-18 months to achieve good quality of fish sauce from natural fermentation ~~in a tropical zone~~. When fermentation aids are used, the period can be varied. ~~However, the fermentation process should not take less than 6 months.~~

Reason:

Galvanized steel lids may corrode in a high salt environment introducing heavy metals into the product. Cement tanks may not be properly constructed for easy cleaning and sanitizing

If WPS or water activity is not controlled *C. botulinum* and *S. aureus* toxin formation can occur, and histamine can be produced.

Fermentations do not need to be conducted at ambient temperatures as implied by the phrase “in a tropical zone.” Controlled temperatures are preferred for uniform quality and product safety.

Fermentations using processing aids such as enzymes and/or bacterial cultures may take less than 6 months.

5. Brine preparation – revise bullet as follows:

Brine, preferably saturated, added to fish residues should be prepared from potable water and food grade salt for succeeding ~~fermentation~~ **extractions**.

Reason:

See comment above for the Flow Chart.

6. Succeeding fermentation – revise title, potential hazards and technical guidance as follows:

Succeeding ~~fermentation~~ **extractions (optional step)**

Potential hazards: unlikely **scombrototoxin (histamine), botulism toxin, microbiological contamination, chemical contaminants**

Technical Guidance:

- Succeeding **brine** extractions of the fish residues could be carried on as desirable extracts are obtained **according to a standard operating procedure.**
- **Percent Water Phase Salt, and/or Water Activity, should be monitored during extractions in order to control pathogen growth and toxin formation (e.g., *Clostridium botulinum* and *Staphylococcus aureus*), and scombrototoxin formation.**

Reason:

The term ‘extraction’ should replace ‘fermentation.’ This step is optional. See the comment for the Flow Chart (above).

An established procedure should be used for multiple extractions

Microbiological contamination and scombrototoxin production are risks that also need to be controlled during extractions.

8. Blending – revise section as follows:

8. Blending Mixing of Ingredients and Additives

Potential hazards: unlikely **Microbiological contamination, Scombrototoxin (histamine), *Clostridium botulinum* toxin, unsafe unauthorized additives, unlabeled allergens**

Potential defects: Ingredient measurement errors, unauthorized food additives

Technical Guidance:

- Total Nitrogen (TN) of fermentation and extract batches should be analyzed before blending. Total nitrogen and amino acid nitrogen content in the final product must be in compliance with *Standard for Fish Sauce* (CODEX STAN 302-211).
- **Water phase salt or water activity should be determined during blending to assure that adequate salinity is maintained after addition of other ingredients.**
- **Histamine levels in different batches should be analyzed before mixing. The histamine level in each batch should be in compliance with CODEX STAN 302-211 Standard for Fish Sauce. If high histamine levels are found in a batch, the cause should be determined, by trace back of production and harvest vessel records, and the problem corrected.**
- **If preventive controls for *Clostridium botulinum* toxin formation are inadequately implemented or documented during any step from the harvest vessel through blending, or if required by the receiving country, then the final product (or raw material) should be boiled to destroy any *Clostridium botulinum* toxin.**
- To achieve good quality fish sauce, ingredients should meet the required characteristics and appropriated concentrations.
- All utensils should be clean.
- Food additives and levels used need to be in compliance with the *Standard for Fish Sauce* (CODEX STAN 302-2011), and used in compliance with *General Standard for Food Additives* (CODEX STAN 192-1995), and other relevant regulations. Food additives used need to be identified with names and identification numbers which are complied with Codex *Class Names and the International Numbering System for Food Additives* (CAC/GL 36-1989).
- [Before mixing, chemical properties, essential quality factors should be monitored, and the results should be recorded.]
- **Any allergenic ingredients should be declared (see 13 Labeling/Packaging).**

Reason:

These proposed changes provide a more descriptive title and guidance on controlling pathogens and mixing batches with different histamine content. High histamine fish sauce should not be diluted to achieve 400 PPM histamine in the final product.

Some countries may require boiling to destroy botulinum toxin in fermented fish products because traditional methods of production introduce a significant risk

The second to last mixing bullet may be adequately covered in the bullets above, but can be retained.

10. Storage – revise section as follows:

10. Storage

Potential hazards: ~~unlikely~~ **microbiological contamination, scombrotoxin, physical contamination, heavy metals**

Potential defects: ~~unlikely~~ **foreign matter**

Technical Guidance:

- The storage tanks with covers should be clean, resistant to rust and salt, **and free of heavy metal contaminants (lead, mercury, etc.); and** located in an appropriate area.
- **The salinity of the product must be maintained to control microbiological contamination and scombrotoxin formation.**
- **The batches, or lots, in storage should be identified for trace back purposes.**

Reason:

Information on hazards/defects, and technical guidance on storage is important to include in the Code.

13. Labeling/packaging – add technical guidance bullet as follows:

- **It is recommended that a 'best before date' be included on the label because oxidation reactions can occur despite an unopened container. Instruction on how to store fish sauce after opening should be included on the label in order to maintain product quality. For example, the label should advise that the color can turn darker brown to black, sensory characteristics can change, and sediments and salt crystals may form at the bottom of container. It is recommended to conduct research on shelf-life under various storage conditions.**
- **If the food includes an ingredient known to cause hypersensitivity as defined in the General Standard for the Labelling of Prepackaged Food (Section 4.2.1.4), the labels should be checked to assure that the ingredient is properly declared.**

16. Heating –

Some information should be provided about the reason for heating. If it is sometimes a pasteurization step, or is performed in order to inactivate *C. botulinum* toxin, then this section needs elaboration.

17. Ingredients and additives – revise potential defects as follows:

Potential defects: ~~unlikely~~ **depends on ingredient**

Reason:

Ingredients may present potential hazards and defects, as alluded to in the reference in the 4th bullet to defects.

18. Packaging materials - revise potential defects as follows:

Potential defects: ~~unlikely~~ **foreign matter, damaged/broken, poor seal**

Reason:

Packaging can introduce defects, as reflected in the 3rd bullet.