CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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Agenda Item 6 **CX/FH 16/48/7add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty-eighth Session

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Comments on the

PROPOSED DRAFT GUIDANCE ON HISTAMINE CONTROL AND SAMPLING PLANS FOR HISTAMINE

HISTAMINE WORKPLAN

Comments Submitted by:

El Salvador, European Union, Ghana, Kenya, Iran (Islamic Republic of), Morocco, Thailand, United States, African Union

EL SALVADOR

- Recommendation on Question 1: What approach is preferred for drafting the histamine control guidance?

Consolidate histamine control guidance into a single annex in the Code and reference the annex in the appropriate sections of the Code for clarity and to prevent repetition.

- Recommendation on Question 2: Should the incorporated table exclude the data about 1) annual production, 2) market name and 3) histidine levels?

We agree with the recommendation to exclude the “market name” column, as these names vary widely depending on the region or country. The “annual production” column should also be excluded to integrate it into a Codex document; however, it is pertinent as an indicator, given that it connects production, consumption, and contamination risk.

The “histidine level” column should be kept. We suggest attaching thereto a recommendation or warning to establish risk-based controls and emphasize the importance of Good Manufacturing Practices.

When Table 2.3 is included in Codex documents, we suggest placing a legend that notes that only certain information has been taken from the FAO/WHO document, such that the user is referred to the expert document and the work that the FAO/WHO has already carried out is highlighted.

It is important for the CCFH to establish the purpose of including Table 2.3 in the FAO/WHO expert document.

- Recommendation on Question 4: Should the existing susceptible species lists in the commodity standards be replaced with a reference to the new table of susceptible species that will be incorporated into the Code?

Review existing lists, supplement with and link them to a reference of the updated list of susceptible species in the revision of the Code.

- Recommendation on Question 5: Should work start on Histamine Control Guidance first, followed later by Histamine Sampling Plan Guidance?

We support the eWG’s proposal to first begin work on the proposed draft guidance on histamine control and then on preparing guidance for the sampling plans for histamine.

- Recommendation on Question 6: Should CCFH consider alternative sampling plans for different purposes, and subsequently clearly define the different purpose(s) that require development of sampling plans/guidance?

We recommend that the CCFH discuss the purpose of sampling plans.

If sampling plans were to be necessary for different purposes, these purposes would need to be clearly defined in the guidelines in the document prepared by Codex. They should also be scientifically sound and their application feasible.

EUROPEAN UNION

RECOMMENDATION 1: Approach to revision of Code of Practice for Fish and Fishery Products.

The European Union and its Member States (EUMS) agree with the recommendation. The EUMS suggest and support drafting a single document (new annex or section).

The EUMS suggest that when in the different sections of the Code of Practice for Fish and Fishery Products (COP) a reference to this hazard is made, it should be indicated that a dedicated specific guidance is available.

RECOMMENDATION 2: Data in FAO/WHO Table of fish associated with scombrotoxin fish poisoning or high free histidine levels.

The EUMS agree with the recommendation and suggest removing from the table data on histidine levels, subject to great variations, annual production and market names.

As regards the fact that CCFH should discuss the purpose of inclusion of the table, and, depending on the purpose, the inclusion of Salmonidae should be decided, the EUMS agree with this proposal. It is questionable to keep the salmon species in the list for the purpose of the COP since the SFP-like symptoms that justified their inclusion to the list have been reported in one old publication (Bartholomew et al., 1987). This has never been published afterwards, which could suggest that, even if the mode of action has been tentatively elucidated (not confirmed), it is not a major issue. Together with the fact that SFP-like outbreaks linked to Salmonidae consumption have never been published for more than 20 years, this supports the deletion of Salmonidae from the table.

RECOMMENDATION 3: Replace current Family lists in the commodity standards with reference to the FAO/WHO susceptible species list.

The EUMS agree to replace the existing susceptible species lists in the commodity standards with a reference to the new table of susceptible species that will be incorporated into the Code. The EUMS have no objections to locate the list (or applicable species in the list) as an annex in the applicable commodity standards, in addition to the Code.

RECOMMENDATION 4: Start histamine control guidance work first, followed later by work on sampling plans.

The EUMS agree with the recommendation.

RECOMMENDATION 5: Alternative sampling plans for different purposes.

The EUMS support the recommendation; in particular the EUMS recommend that before sampling plans are developed their purpose has to be clearly defined. Preference should be given to develop (a) sampling plan(s) which shall be included in the concerned commodity standards and whose purpose is to check compliance of an inspected lot with the provisions of the standard. Alternative sampling plans aiming at monitoring the proper functioning of established hygiene control programmes should be preferably placed in the Code of Practice for Fish and Fishery Products to avoid ambiguity in interpreting the commodity standard. Those alternative sampling plans must take into account what has been agreed at the last CCFFP as regards the decomposition limit and the safety limit.

The EUMS agree that if an alternative sampling plan purpose is agreed to, then Japan and the US should research and draft sampling guidance for this purpose, in addition to drafting guidance for the risk-based plan used to determine individual lot compliance with the commodity standard.

The EUMS support that only the purpose, and not a specific plan, is discussed before the EWG document is produced. CCFH work in this subject area should be scientifically sound and feasible to implement.

GHANA

Recommendation 1: Approach to revision of Code of Practice for Fish and Fishery Products.

Comments: Ghana supports drafting a single guidance section on histamine control, given that histamine control guidance is similar among food operations. This consolidated section can be referenced in specific sections of the Code of Practice for Fish and Fishery Products.

Recommendation 2: Data in FAO/WHO Table of fish associated with scombrotoxin fish poisoning or high free histidine levels.

Comments

- Ghana agrees with the recommendation that "mean annual production" data should be excluded from the FAO/WHO Table of fish associated with SFP which will be integrated in the guidance document, since it has no direct relevance for the control of histamine in fish.
- Ghana supports the exclusion of "market name" from the FAO/WHO Table of fish associated with SFP since countries may have different market names for the same fish. Ghana recommends the use of scientific name (family, genus and species) as these are internationally standardized nomenclature.
- Ghana notes that data on histidine levels in fish is useful information that could help improve knowledge and contribute to risk management of histamine in fish. However, given the potential for misinterpretation of histamine data, reference could be made to the source where histidine levels of fish could be obtained. The introduction section of the annex could include a statement that:

  "Species with low histidine level can also be associated with SFP if temperature controls are not maintained".

- The retention of Salmonidae will depend on the purpose of the Table to be included i.e. whether to list fish associated with SFP or to list fish that develop high histamine. Ghana looks forward to further discussion on this subject.

Recommendation 3: Replace current Family lists in the commodity standards with reference to the FAO/WHO susceptible species list.

Comments: Inclusion of susceptible species list in the commodity standards is essential for the application of the product standards. As a minimum, the family names of the susceptible fish species should be maintained in the relevant commodity standards.

Recommendation 4: Start histamine control guidance work first, followed later by work on sampling plans.

Comments: Work should start on Histamine Control Guidance first, followed later by Histamine Sampling Plan Guidance. This approach is logical and allows adequate time to reflect on the possible content of the future sampling plan guidance to be developed.

Recommendation 5: Alternative sampling plans for different purposes

CCFH should focus on Codex's principal aim for establishing Sampling plans i.e. *"Codex Methods of Sampling are designed to ensure that fair and valid sampling procedures are used when food is being tested for compliance with a particular Codex commodity standard"*. In the case of this work, the main focus for developing/revising sampling plans should be to develop risk-based criteria that will enable the determination of compliance with health-based histamine limit in the specific commodity standard. Such sampling plans should also be practical and feasible to implement.

IRAN (Islamic Republic of)

Question 1: **Based on the discussion above, what approach is preferred for drafting the histamine control guidance?**

As histamine has a great role in marine products poisoning, its consideration as a separate guideline is recommended.

Question 2: Should the incorporated table exclude the data about 1) annual production, 2) market name and 3) histidine levels?

The "mean annual production" and "histidine level" are needed for risk assessment and exposure assessment in the society. Both items are necessary for risk management strategies and will help in PLANNING. For example, histidine level shows that which species should be used more carefully.

Question 3: Should Salmonidae be included or excluded when incorporating Table 2.3 into the Code, or possibly included with a footnote?

Based on risk assessment guidance, some commodities might have less potential in showing further side effects but as they are used in the high frequencies, their role should be considered concisely. In is not recommended to remove Salmonidae species from table. But, it can be mentioned in bottom of the table with the lower content of histidine and histamine levels. On the other hand, the descending order in histamine level is suggested. Also, it is recommended that a footnote be added regarding the necessity of histamine analysis even in species containing low levels of histidine.

Question 4: Should the existing susceptible species lists in the commodity standards be replaced with a reference to the new table of susceptible species that will be incorporated into the Code?

As we recommend the preparation of a separate file for histamine control, addition of full table is preferred where needed.

Question 5: Should work start on Histamine Control Guidance first, followed later by Histamine Sampling Plan Guidance?

Yes, we support the EWG Comments.

Question 6: Should CCFH consider alternative sampling plans for different purposes, and subsequently clearly define the different purpose(s) that require development of sampling plans/guidance?

We also support inclusion of sampling plans for different purposes. The "Sampling" draft should be prepared after finalization of "Histamine control" draft by which critical control points are cleared (the draft is HACCP-based, as mentioned).

KENYA

General Comment:

Question 1: **Based on the discussion above, what approach is preferred for drafting the histamine control guidance?**

***Comment*: The format will depend on the scope and will become more obvious during revision of the Code. This will of course follow the CODEX format.**

The current guidance to control scombrotoxin is inadequate in scope and depth. This work is a revision of an existing COP and HACCP plan should be taken into consideration to identified the critical control points (CCP) regardless of the format which eWG will agreed upon.

Question 2: Should the incorporated table exclude the data discussed in 1), 2), or 3) above?

***Comment*:** There is no need to have "**mean annual production**" data since histamine is not being controlled during the production and therefore should be removed from the table. We have also noted that **market name** is not necessary due to variation of names from different countries. The fish scientific names can be used instead of market names for they are harmonized worldwide.

Question 3:

Should Salmonidae be included or excluded when incorporating Table 2.3 into the Code, or possibly included with a footnote?

Comment: Kenya believe that Salmonidae should be included when incorporating Table 2.3 into the Code.

Question 4:

Should the existing susceptible species lists in the commodity standards be replaced with a reference to the new table of susceptible species that will be incorporated into the Code?

Comment: It is important to replace the existing species lists with a reference to the new table which will updated during revision of the Code.

Question 5:

Should work start on Histamine Control Guidance first, followed later by Histamine Sampling Plan Guidance?

***Comment*:** Kenya supports the recommendation to first focus on the proposed histamine control guidance for a revised Code of Practice for Fish and Fishery Products that should be drafted and distributed before the next meeting on CCFH . The Sampling plan can be done during in session at the CCFH meeting or a day before the meeting on a Sunday.

Question 6: Should CCFH consider alternative sampling plans for different purposes, and subsequently clearly define the different purpose(s) that require development of sampling plans/guidance?

Comment: Any alternative sampling plans and associated guidance are not necessary at the moment and if required should be scientifically sound and feasible to implement.

PROPOSED SAMPLING PLAN FOR HISTAMINE IN FISH

Fish Inspection Program Sampling Procedures

1. Purpose

The purpose of this document is to provide guidance to inspectors in the sampling tasks associated with equipment selection, lot identification, sample unit determination, sample selection, sample labelling and sample storage and transportation.

2. Scope

This document outlines the procedures governing the sampling of fish and fish products and water and ice subject to inspection.

3. Tools and Material Required for Sampling

- **Kenya fish handling standard KS 05 -1399 Pt 1-2**
- **Fisheries Act Cap 378**
- **Fisheries (Safety of fish, fishery products and fish feeds) Regulations 2007**
- **Food Drug and Chemical Substances Act Cap 254**

3.1 Definitions

Aseptic Technique

Consists of taking a clean specimen without cross contaminating the sample or the surrounding areas. It is important to use aseptic technique in packaging the sample for transport.

Attribute Sampling Plan

the decision to accept or reject a lot is dependent on the number of sample units which have or do not have a particular attribute, property or characteristic.

Container

any type of receptacle, package, wrapper, or confining band used in packing or marketing fish.

Consumer

the final user of a product. (i.e., a person or an institution, such as a hospital, hotel, organization or restaurant which purchases a product for its own use.)

Destructive Inspection

an inspection in which the container or product is destroyed, modified or rendered unusable.

Inspector

- a person designated as an Inspector pursuant to **Fisheries Act Cap 378**

Lot

- with respect to fish, other than fresh fish, means a shipment or part of a shipment of fish that is of the same species, is processed in the same manner by the same producer, is packaged in the same size of container and bears the same label in accordance to **Fisheries (Safety of fish, fishery products and fish feeds) Regulations 2007**

. A lot of fresh fish refers to a shipment or part of a shipment of fish which has been processed in the same manner by the same producer in a 24-hour period. For fresh fish, the lot may contain more than one species of fish.

Lot size

The number of units of product in a lot.

Non-destructive Inspection

An inspection in which the container is not destroyed.

Pre-packaged product

Any product packaged in a container in such a manner that it is ordinarily sold to, or used or purchased by a consumer without being re-packaged.

Random Sample

One in which all elements in the lot have an equal and independent chance of being included in the sample.

Representative Sample

One in which the sample units selected for the sample exhibit all the attributes of the lot proportionately.

Sample

A collection of one or more sample units selected from a lot for inspection. The sample comprises all of the sample units drawn for examination or testing purposes from a particular lot.

Sampling Plan

Specifies the number of sample units required to make an accurate inspection decision (acceptance or rejection) on a lot. The number of sample units required may depend upon the net weight of the units, the number of units in the lot, and the type of hazard associated with the inspection analysis being performed.

Sample Size (n)

The number of sample units comprising the total sample drawn from a lot or production.

Sample Unit

One of a number of individual containers, or a portion of a fish or primary container examined or evaluated as a single unit.

Ammonia

The odour/flavour stimulus usually associated with ammonia production from such processes as protein breakdown and illustrated by ammonia-based cleaning compounds.

Bilge

The odour/flavour stimulus associated anaerobic bacterial growth and which is illustrated by the intense rank odour of bilge water.

Blocks

Cohering fish flesh consisting of fillets, pieces of fillets or minced fish flesh which have been frozen in uniform rectangular shapes for further processing.

Boned

Fish fillets in which a major effort has been made to remove bones including pin bones.

Boneless

Fish fillets in which the processor has removed all bones including pin bones or fish products where the processing technology results in the end product having no bones (1 bone≥ 1 mm in diameter).

Broken

With respect to fresh and frozen shrimp, a portion of shrimp containing less than five segments for counts less than 150/kg and less than 4 segments for counts greater than 150/kg Also known as pieces.

Candling

The process used in the detection of parasites by placing fillets on a clear translucent lighted surface.

Cartilage

With respect to crustaceans, this term is used to refer to hard or pliable chitinousendoskeletal structures such as tendons or connective tissues.

Chalky Texture

Dry and powdery, leaving the sensation of a chalky solution in the mouth.

Defrosted Fish

A process by which fish is changed from the frozen state to a thawed state under controlled time and temperature conditions such that the internal product temperature does not exceed 4°C after the thawing has been completed.

Dehydration

A white or yellow abnormality on the surface of frozen fish which masks the colour of the flesh and penetrates below the surface. This defect caused by the sublimation process can only be removed with a knife or other sharp instrument.

Distinct

Capable of being readily perceived (by sight, smell, touch or taste) through a sharp clear unmistaken impression, not blurred, obscured or indefinite.

Faecal

The odour/flavour stimulus such as that associated with sewage.

Feedy

The odour/flavour stimulus resulting from the food consumed by the fish.

Fillets

Slices of fish flesh of irregular size and shape have been removed from the carcass of the fish by cuts made parallel to the backbone, and from which all internal organs, head, fins, bones, except intramuscular or lateral bones and all discolored flesh have been removed; or, slices of fish flesh described above that have been cut into sections.

Fresh

Natural raw fillets or minced fish which has not been changed to any other state by freezing, cooking, curing, etc.

Frozen

Fish that has been changed from the natural (fresh) state to that in which the thermal centre of the product has been frozen to a temperature of -21°C or colder, and the fish is maintained at a temperature of -26°C or colder.

Fruity

The odour/flavour stimulus such as that associated with citrus fruits.

Head

With respect to shrimp, the cephalothorax, or any portion thereof large enough to contain an eye.

Honeycombing

A condition characterized by decomposition of the flesh resulting in pitting of the meat, occurring sometimes on the surface of the cut of the meat, but more often in between the layers of fish flesh and corroborated by the presence of histamine.

Hydrogen Sulphide

The odour/flavour stimulus associated with rotten eggs. A reference is hydrogen sulphide gas.

Iodoform

The odour/flavour stimulus associated with some iodine compounds, and having a chemical-like or medicinal quality. A reference is triiodomethane.

IQF

An acronym for individually quick frozen fillets.

Jelly

Fish flesh which has an abnormally high moisture content of 86% or more by weight resulting in the flesh having a gelatinous texture and a glossy translucent appearance.

Layer Pack

A fillet pack where the fillets are individually separated by cellowrap.

Liver Stain

A discolouration ranging from yellow to dark brown caused by intestinal contents contacting the flesh of shrimp.

Mealy Texture

Soft, dry and friable (easily crumbled), like meal.

Minced Fish

Particles of fish flesh that have been separated from clean, sound fish material free from internal organs, heads and discolored flesh.

Musty

The odour/flavour stimulus associated with the presence of mold or mildew decay of wood. A reference is geosmin.

Oxidized Oil

The odour/flavour stimulus associated with the oxidation of fats or oils.

Persistent

Existing without significant change; not fleeting.

Pungent

A sharp or stinging sensation of an odour such as that of aldehyde.

Putrid

The odour/flavour stimulus associated with the advanced decay of protein.

Rancid

The odour/flavour stimulus associated with oxidized oil or an oil such as linseed oil.

Readily Detectable

Visible under normal inspection conditions and procedures; not requiring artificial aids such as magnification.

Saltfish-like

The odour/flavour stimulus such as that associated with saltfish.

Sickly-sweet

An odour/flavour stimulus having an unpleasant or cloying sweetish characteristic, such as that of chloroform.

Sour

The odour/flavour stimulus associated with acidic compounds such as vinegar and characterized by a pungent sensation.

Sour Milk-like

The odour/flavour stimulus associated with the bacterial breakdown of milk.

Vegetable

The odour/flavour stimulus associated with certain vegetables such as turnips or cabbage.

Vein

With respect to shrimp, the visible intestinal tract which runs dorsally along the abdomen.

Yeasty

The odour/flavour stimulus associated with the primary fermentation process as illustrated by the production of wine or the rising of bread.

3.2 Sampling Plans and Inspection Levels

Sampling plans are necessary to query one or more characteristics of a lot because not every unit in a large lot can be inspected. Sampling plans are designed to ensure defensible, statistically valid decision making regarding the acceptance or rejection of a lot.

For **sensory, chemical indicator, package integrity and net content** analyses, Kenya has adopted the Food and Agriculture Organization of the United Nations (FAO) / World Health Organization (WHO) Codex Alimentarius Sampling Plans for Prepackaged Foods (CAC/RM 42-1969).

Selection of the appropriate Inspection Level is dependent on the current stage of inspection. Inspection Level I is chosen when the quality of the lot is not in question as in initial inspections. Inspection Level II is used when the quality of goods is in question and a referee method is required for the examination or re-examination of the lot (re-inspection). **An increased number of sample units affords greater protection against the inherent risk associated with sampling.**

3.3 Equipment

Use equipment, materials and apparatus which are appropriate for maintaining the condition of the sample.

When obtaining samples, ensure there is no potential for cross-contamination from equipment, materials and apparatus (e.g., aseptic technique).

List of suggested equipment, materials and apparatus include but not limited to:

- inspector notebook
- hand coverings (plastic gloves, rubber gloves)
- safety boots and/or rubber boots (for plant inspections), hard hat, coveralls, hairnet
- adhesive tape and clear adhesive tape
- utility knife
- hand towels
- plastic bags (various sizes), sampling bottles, tags and labels
- flashlight
- thermometer
- sanitizer and saw
- clean, hard-sided cooler and ice packs
- chlorine kit

4. Procedures

4.1 General

Sampling must be conducted in a manner which will maintain the integrity and continuity of the sample associated with the lot (from the time the sample is drawn to the completion of the inspection).

The sampling conditions should be such that inspectors have access to the entire lot without interference. An inspector must note and report any interference encountered because it may compromise the sample.

A sample identification system should be in place which will permit an inspector to assign a unique identification number for the sample associated with a lot, affix all pertinent information to the sample, and document sampling information for record keeping purposes.

4.2 Defining the Lot

Define the lot in accordance with the definition given in Section 3 mentioned above.

When dealing with fish or fish products which possess the same label, but are packaged in different styles (e.g., different sauces) consider the different styles to be of one lot.

4.3 Defining a Sample Unit

Define the sample unit according to the following instructions:

1. When a lot consists of pre-packaged product, each package and the package thereof constitutes a sample unit.
2. For fresh and frozen minced fish block and minced fish fillet or fresh and frozen finfish, the sample unit shall consist of a container of fish and the contents thereof.
3. Use one of the following 3 approaches when sampling from **bulk packages**:
    i. the sample shall consist of the bulk package and the contents thereof;
    ii. for fresh or individually frozen whole or dressed finfish or fresh or individually frozen finfish fillets, the individual fish or fillet may be considered as a representative sub-sample; and
    iii. for scenarios other than described in **section ii**), a 1 kg sub-sample of product obtained from the bulk pack may be considered a representative sample.
4. In lots consisting of salt or pickled fish packed in boxes or barrels, the container constitutes the sample unit. Inspect the entire contents of the container.
5. When a lot of fresh fish consists of more than one species, all of the sample units used to form a sample shall consist of one species type.
6. When inspecting large fish, each fish constitutes a sample unit. When an inspector has confidence a representative sub-sample may be obtained from a large, whole fish, the sub-sample becomes the sample unit. The sub-sample must be obtained in a manner which does not compromise the integrity of the sample.
   To obtain a representative sub-sample from large, whole fish for chemical and microbiological analysis, take 3 one-inch slices from each of the following areas:
    1. behind the pectoral fins;
    2. halfway between the first slice and the vent; and
    3. behind the vent. These 3 slices form the sample unit, representing the large fish.

When sampling for sensory analysis, the 3 slice method described above is recommended. If in the inspector's view, fewer or more slices are required to make an accurate decision on the quality of the lot, the inspector may exercise his/her discretion to decide what constitutes a representative sample unit for that fish. If the inspector decides only one slice is required as a representative sub-sample from the fish, the one slice should not be taken from behind the vent because this slice does not usually exhibit signs of early decomposition.

4.4 Determining the Number of Sample Units Required

Determine the number of sample units required. The sample units needed for other analyses (i.e. chemistry) may be drawn from the units selected for sensory evaluation, where appropriate.

When a sample unit is drawn for more than one analysis, ensure the sample unit is of sufficient mass to perform all of the required analyses.

When microbiological analysis is required, submit the samples to the microbiological section for analysis first to ensure the integrity of the sample is not jeopardized.

For export certificates, there may be instances where the number of sample units required may be specified. Follow the directions associated with the export certificate.

4.4.1 Sensory, Net Content and Package Integrity

The sampling plan for these analyses is the Codex Alimentarius Sampling Plan for Pre-packaged Foods (CAC/RM 42-1969) found in **Annex A**. Decide which inspection level is appropriate (Level I for initial inspections and Level II for re-inspections).

Using the parameters of net weight per sample unit and the lot size (**see Annex A determine the number of sample units required for inspection**).

Note: the Sampling Plan in Annex A applies to destructive and non-destructive sampling for net content.

4.4.2 Container Integrity

4.4.2.1 Initial Inspection

- Draw 200 sample units from a minimum of 40 cases with no more than 5 sample units being selected from each case.
- For lots with less than 200 sample units, inspect all units. Record the total number of containers on the report form.

4.4.2.2 Re-inspection

- Select a minimum of 250 cases. Draw 1250 cans from the cases but do not select more than 5 cans from one case.
- When there are fewer than 1250 units, examine each unit and record the number on the report form.

Note: Stop sampling immediately, detain the lot and advise the owner when the following conditions are found:

- wet, stained or damaged cases are detected.
- leaker, swollen can or flipper is found.

4.4.3 Sampling for Microbiological Analysis

4.4.3.1 General Procedures

All samples shall accurately reflect microbiological conditions at the time that sampling is performed. To maintain sample integrity, follow the procedures listed below.

- If possible, sample final product already packaged.
- Procure the samples using an aseptic technique so as to not contaminate both the sample and the product being sampled.
- Draw **5** sample units (minimum of 250 g per unit) per lot unless otherwise specified.

4.4.3.2 Sampling Raw Shellfish

- Examine samples of shell stock, shucked unfrozen shellfish, and live shellfish within 24 hours after collection. When analysis is unavoidably delayed beyond 24 hours, report the actual time elapsed between collection and analysis.
- Use heavy plastic bags (6 mil gauge) for shell stock collection to ensure that shells to do not puncture the plastic and compromise the sample integrity.
- Take 5 units of 12-18 shellfish per unit. This number should ensure the selection of 10 sound animals suitable for shucking. Ensure the shellfish yield approximately 200 g of meat and shell liquor.
- Using an aseptic technique, transfer the shellfish to the sample jar with sterile forceps or alternatively, samples of the final product may be taken in the packing cans or containers.
- Consumer packages are acceptable for examination.

4.4.3.3 Sampling Running Water

- Collect 1 sample unit of water in a clean container of suitable size. Use a container with 100 to 200 ml capacity for routine water analysis.

- To obtain a representative sample from a tap, open the tap fully and allow the water to run for 2 or 3 minutes or a sufficient time to permit clearing of the service line.
- Leave sufficient head space in the water sampling container so the sample can be adequately mixed by shaking.

4.4.3.4 Procuring Ice Samples

- Take 1 sample unit of ice from the ice storage area in a sterile plastic jar or bag. Maintain the frozen state of the ice.

4.4.4 Sampling for Chemical Analysis

4.4.4.1 General Sampling

- See **Annex B** for descriptions of chemical analyses.
- Chemical analyses require 5 sample units for initial inspection (with the exception of Chemical Indicators, which require a **minimum of 6 sample units** depending on the size of the lot, in accordance with **Annex A** .For re-inspections, a sample size of 10 units is required. For re-inspections of chemical indices analysis, use Inspection Level II of the sampling plan given in **Annex A**.
- Sample units chosen for chemical analysis should not undergo any adulteration (such as rinsing with water) which may change the chemistry results.

4.4.4.2 Chemical Indicators (includes histamine, indole and total volatile base nitrogen (TVBN))

- The sampling plan for chemical indicators is the same as that for sensory evaluation **Annex A**
- After performing the sensory evaluation, forward what remains of the sample to the chemistry laboratory immediately.

4.4.4.3 Additive and Proximate Analysis

- Draw **5** sample units each consisting of a **minimum of 100 g**. For sample units which are less than 100 g, submit all of the available sample for analysis.

4.4.4.4 Product Safety Parameters and Drug Residues

- Draw **5** sample units each consisting of a **minimum of 200 g**.
- When sampling for drug residue analysis, sample 5 entire fish or full fillets.
- Ensure that samples submitted for drug residue analysis are not exposed to areas or equipment where medicated feed has been stored or used.

4.4.4.5 Chemical Contaminants

- For lots which contain fish or fish products of similar size, draw **5** sample units each consisting of a **minimum of 100 g**.
- **Mercury:** For lots which contain fish or fish products of varying sizes, draw 5 units which represent the size distribution in the lot.

4.4.4.6 Other Chemical Testing

- For **species identification** draw one **(1)** individual fish, fillet or package, a minimum of 100 g.
- For other types of chemistry sampling, draw 5 units of 100 g.

4.4.5 Sampling for Shellfish Toxin Analysis

4.4.5.1 Import and QMP samples

- Take 5 units of 12-18 shellfish per unit. This number should ensure the selection of 10 shellfish suitable for shucking. Ensure the shellfish yield approximately 200 g of meat and shell liquor.
- When sampling geoducks (*Panope generosa*), take 3geoducks. Analysis is conducted on the viscera of the 3 geoducks.
- When sampling crabs, take 3 crabs. Analysis is conducted on the viscera of the 3 crabs.

4.4.5.2 Molluscan Shellfish Monitoring Program

- Take 1 unit of 12-18 shellfish. This number should ensure selection of 10 sound shellfish suitable for shucking. Ensure the shellfish yield approximately 200 g of meat and shell liquor.

4.5 Locating and Identifying the Lot

Ensure all containers of product are available and accessible for sampling. Where applicable, obtain the following information prior to inspection to ensure the correct lot is being sampled:

- reason for inspection (e.g., initial inspection)
- location of the lot
- name and address of agent/owner
- lot size (number of cases, containers per case)
- lot codes and their interpretation
- brand name
- product type and style of pack
- container type and unit weight
- processing establishment
- country of origin or destination
- requirements for importing country when an export certificate is being issued.

4.6 Selecting Sample Units

Select a systematic random sample from the lot. Please refer **to Annex C** for further instruction. When an inspector thinks it is not possible to draw a true random sample, the inspector may draw a representative sample from the lot.

4.7 Labelling Samples

1. Record details of sampling in a notebook (i.e., lot location, no. of samples drawn, unique identification no., time of sampling, codes drawn).
2. Ensure all samples are accompanied by a completed sample information form. Include the following information where appropriate:
    - type of analysis required
    - country of origin
    - collection date and time
    - packer and packer code
    - shipment identification number
    - held tag number (if product is detained)
    - lot size and unit weight
    - samplers's name
    - lake code (body of water and landmarks), statistical area and sub-area
    - length and weight of fish (contaminant sampling)
    - number of units sampled
    - plant name and registration number
    - harvest site (shellfish samples)
    - harvest date (shellfish samples)

- processing date
- species and product type
- farm and pen information (farmed fish)
- inspection status and type (Alert, random, etc.)
- name of importer
- analyses required for export certificate
- cost recoverable (yes/no)-optional

3. Include any other relevant information when requesting **chemistry** analyses which would assist in performing the analysis or assessing the results, such as:

1. for packaged fish, a copy of the label;

2. observations of abnormal odours, taste, colours, or texture; and

3. for **species identification**, the common name as labeled on the package of the product and the suspected substituted species.

Label as soon as they are obtained, all samples using waterproof tags and markers for identification purposes. Do not allow the marker/tag to come in direct contact with the sample. In the case of large whole fish, tag each fish.

Include the sample sheet in a separate plastic bag with the sample. Mark pre-packaged products as soon as the unit is drawn.

4.8 Sample Storage and Transportation

4.8.1 Special considerations regarding sample storage and shipping

1. **Microbiology**
    1. Until the sample is analyzed, maintain the sample under conditions which will preserve the original bacterial flora as completely as possible. Maintain the sample at a maximum of 5°C. In some instances, samples must be frozen. Do not freeze samples unless the laboratory has been consulted. Freezing is undesirable because bacterial numbers may decrease in the sample.
    2. Fresh samples must be refrigerated (5°C) until analyzed. When storing samples, remember that analysis of unfrozen product should take place within 24 hours of sampling. Note the time of sampling and the time of analysis. Reports must state whether or not the samples have been frozen.
    3. Refrigerate (do not freeze) samples of shucked or live **shellfish** immediately after collection by packing in crushed ice and keeping them in ice until examined. The shellfish must not come into direct contact with ice. Care must be taken with these samples to minimize cold shock by insulating these samples from direct contact with refrigerant while still ensuring samples are chilled. For example, frozen ice packs can be placed below and above the samples with insulating layers of newsprint or other food- quality insulating material placed between the refrigerant and the sample.
    4. **Water samples:** The bacterial examination of impure water and sea water samples must begin within 6 hours of collection. The storage of water samples should not exceed 24 hours. Should this time limit be exceeded, record the actual time between sampling and analysis.
2. **Proximate analysis and chemical indicators:** Curtailing bacterial growth and limiting autolytic spoilage is facilitated through temperature control. Keep the product at a temperature below -20°C where possible. Do not leave thawed samples on bench for any long period of time. The growth of bacteria in the sample may influence the analysis of the product. For **proximate analysis**, prevent the dehydration of the sample.

4.8.2 Sample Storage

Ensure that the integrity of the sample is maintained by proper storage. Maintain the state of the sample.

1. Keep **frozen** samples in a freezer (at -18°C) or in a carton/cooler with ice packs and ship the sample as quickly as possible to ensure that the sample remains in the frozen state.

2. Store unfrozen samples at refrigeration temperatures (below 5°C). When the time of storage is lengthy, it may be necessary to freeze the samples.
3. Keep cans at ambient room temperature.

4.8.3 Sample Shipping or Delivery

Samplers may have to ship samples to another location for testing or the samples may be delivered to other inspection personnel at the same location. When providing samples to other inspection staff at the same location, ensure the other staff are notified (with a hard copy of the sample sheet) and information regarding the location of the sample (freezer, cooler, etc.) when the sample is delivered.

When **shipping** a sample:

1. Make arrangements with receiving person at the laboratory prior to shipping the sample;
2. Address the shipment to the person and include the person's phone number;
3. Ensure perishable samples are properly marked for handling by the carrier;
4. Advise the laboratory of the estimated arrival time of the sample and the carrier information. If the inspector is not able to contact the laboratory or if the microbiology sample delivery cannot be completed within 24 hours, he/she should consider the merits of sampling at another time; and
5. Take special precautions when transporting samples of canned product that are obviously swollen or under pressure. Place swollen cans in plastic bags and transport inside a box or cooler.

4.9 Receipt by Laboratory

Log in the samples upon arrival at the laboratory, noting the time received and the condition at the time of receipt (i.e., physical damage, temperature). If the condition compromises the sample integrity, the sample may be rejected.

Check the sample information form to ensure all pertinent information has been included. If the form contains insufficient information, contact the inspector for the missing information (additions to be dated and initiated).

5. Sampling for External Organizations

Fish Inspection personnel may receive requests to perform sampling for external groups or organizations (e.g., county governments). In these instances, the external organizations may have sampling policy and procedures that differ from those specified in this document. Please follow the procedures specified by the organization requesting the sample when it is for their purposes.

6. Annexes

Annex A -Sampling Plans

Annex B-Categorization of Chemical Analyses

Annex C-Systematic Random Sampling

Annex D- Attribute Sampling Plans

Annex A - Sampling Plans

MOROCCO

Question 1: *Based on the discussion above, what approach is preferred for drafting the histamine control guidance?*

Comments: Morocco is for maintaining the following informations shown in the table2.3. : scientific name; mean annual production and free histidine levels for fish associated with scombrotoxine fish poisoning or high free histidine levels.

Justification: The presence of high level of free histidine in fish flesh is among the necessary conditions for histamine production. From a food safety point of view, the level of free histidine in fish is a relevant information for risk assessment of histamine among s species. Knowing the histidine free level may lead to a better control of histamine. Since the main goal of the present work is food safety, so it'sevident to maintain the histidine free level in the table 2.3.

It is also necessary to respect the terms of reference laid departing for the preparation of paper on histamine, which would henceforth be the basic document for the control of histamine risky.

Annual production is relevant information because of the socio-economic impact of sector-related activities of marine fisheries on the populations of countries.

Question 2: *Should the incorporated table exclude the data discussed in 1), 2) or 3) above?*

Comments: Market names could be excluded from table 2.3. However, for food safety considerations, the level of free histidine is a related information, which should be maintain in table 2.3.

Question 3: *Should Salmonidae be included or excluded when incorporating Table 2.3 into the Code, or possibly included with a footnote?*

Comments: Morocco is not for exclusion for *Salmonidae* from table 2.3

Justification:There is evidence in scientific literature that salmon has already been responsible for incidents of scombroidic fish poisoning (SFP). Thus, excluding Salmonidae from table 2.3induces a loss of an important information that the consumer have the right to know. For food safety concerns, and given that Salmonidae were already incriminated in SFP-like incidents provides sufficient arguments to maintain them in table 2.3.

the fact that Salmonidae has already been incriminated in SFP-like incidents provides sufficient grounds to maintain them in table 2.3.

> ***Regarding the criminalization of salmonidae in histamine poisoning, we are in a situation of uncertainty. In such situation, do we not enforce the precautionary principle? That is to say, keep salmonidae in Table 2.3 to the availability of scientific evidence that demonstrates unequivocally that salmonidae are in no way responsible for histamine poisoning. This is the approach that seems logical and correct and not the other way is to remove the salmonidae in Table 2.3 and wait until the evidence proves that they are responsible for SFP for inclusion again in the table.***

THAILAND

1. Approach to revision of Code of Practice for Fish and Fishery Products

After taking into consideration the format of Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003) which is HACCP-based document, we think that it might be more suitable to elaborate histamine guidance in each applicable section of the Code.

2. Data in FAO/WHO Table of fish associated with scombrotoxin fish poisoning or high free histidine levels

We are of the opinion that the objective of the Table should be focused on the histidine level. Thus, Salmonidae may be excluded from the Table.

Also, the Table might later be related to the species need to be sampled for the commodity standards.

The Table may include common name, scientific name and histidine level for references.

3. Replace current Family lists in the commodity standards with reference to the FAO/WHO susceptible species list

The existing susceptible species lists should be replaced with the reference to the new Table. It can be located as an annex in the applicable commodity standards, in addition to the Code.

4. Start histamine control guidance work first, followed later by work on sampling plans

Histamine Control Guidance should start first to allow time to prepare draft sampling plan guidance.

5. Alternative sampling plans for different purposes

When there is a need, we think that the different purposes of sampling plans should be developed in accordance with the agreement from the 39th Session of CCFFP which is as follows:

- when sufficient safety control measures are effectively implemented in the entire food chain, increasing the sample size would not necessarily increase accuracy nor safety of products.

- sampling plans should be risk-based, practical, feasible and not adding a burden to producers while still ensuring food safety.

UNITED STATES

COMMENTS ON THE SPECIFIC RECOMMENDATIONS

Recommendation 1:

Japan and the United States should draft revised histamine guidance taking into consideration the existing format of the Code and minimization of cross-references. Elaboration of a new annex or section for histamine control guidance should be considered; however, the Code needs to be carefully studied, and the final format may need to be reconsidered when the draft document is available for comment.

Comment: The United States supports Recommendation 1.

Recommendation 2:

Integrate the [susceptible species] Table without data on annual production, histidine level, and market names (Family and scientific names only).

CCFH should discuss the purpose of inclusion of the Table and, depending on the purpose, the inclusion of Salmonidae should be decided.

Comment: The United States supports Recommendation 2.

Regarding the 2nd sentence of Recommendation 2:

The integrated Table should list fish known to form scombrotoxin, as indicated by histamine, the marker used for control purposes.

Scombrotoxin-like illnesses have been reported in connection with the consumption of salmon products, and it is suspected that biogenic amines, with or without the presence of histamine, may be responsible for the illnesses; however, more research is needed to determine the nature of scombrotoxin-like poisoning attributed to salmon. Therefore, at this point, the U.S. supports excluding salmon from the list of susceptible species.

Recommendation 3:

Replace the existing susceptible Family lists in commodity standards with a reference to the updated susceptible species list (reformatted table).

Locate the list in the Code (as appropriate during revision).

Consider locating the list (or applicable species on the list) as an annex in the applicable commodity standards, in addition to the Code.

Comment: The United States supports Recommendation 3.

Regarding the 3rd sentence of Recommendation 3:

The U.S. supports including the applicable species list as an annex in the commodity standards. This will be easier for users to reference, and, in some cases, the list of susceptible species for a particular commodity standard will be much shorter than the complete list.

Recommendation 4:

Japan and the U.S. should draft the revision of the Code of Practice for Fish and Fishery Products for EWG comment following CCFH48 (November 2016). Subsequently, Japan and the U.S. should prepare the histamine sampling plan guidance document for EWG comment following CCFH49 (November 2017).

Comment: The United States supports Recommendation 4.

Recommendation 5:

CCFH should discuss and determine if alternative sampling plans are needed (in commodity standards or the Code), and if so, clearly define the purpose. If an alternative sampling plan purpose is agreed to, then Japan and the U.S. should research and draft sampling guidance for this purpose, in addition to drafting guidance for the risk-based plan used to determine individual lot compliance with the commodity standard. It is recommended that only the purpose, and not a specific plan, is discussed before the EWG document is produced. CCFH work in this subject area should be scientifically sound and feasible to implement.

Comment: The United States supports Recommendation 5.

The United States is primarily concerned with the required sampling plan (or adequate guidance) used to determine if a lot/shipment of unknown history (lot in isolation) is in compliance with the standard.

If alternative sampling plans are proposed, such as to monitor production control systems, their purpose and requirements should be clearly defined and differentiated from the plan used to determine individual lot/shipment compliance with the standard.

AFRICAN UNION

Question 1: Based on the discussion above, what approach is preferred for drafting histamine control guidance?

AU Position: Considering that histamine control is similar among operations, AU recommends that generic histamine control guidance is developed as a single annex in the Code of Practice for Fish and Fishery Products**.** The annex can be referenced in relevant sections of the Code of Practice to minimize repetitions.

Question 2: Should the incorporated table exclude the data discussed in 1), 2) or 3)?

AU Position:

1) AU supports the general recommendation that **"mean annual production"** data are irrelevant for the purpose of considering application of histamine control during production and should be removed from the incorporated table. Annual production data are derived from different production seasons (times). In the control of histamine in fish, it is not the production time that matters, but rather the temperature under which the fish is handled. Production volume is not a safety issue hence should not be incorporated in the table. AU however recommends that a statement on annual production could be included in the introduction section of the document to indicate the level of consumption of fish and the potential public health risk if the fish has high level of histamine.

2) AU does not support inclusion of **"market name"** due to variation of names among countries. Scientific name (family, genus and species) should rather be used since they are globally harmonized names.

3) AU is of the opinion that despite concerns that some users may interpret histidine (histamine precursor) level data to mean that certain species are low risk and do not need temperature controls, hence should not be included in the Guidance for Histamine Control. However, knowledge of such data should also contribute significantly to risk management of histamine in fish. AU therefore proposes that histidine level data should be included in the annex with a footnote as follows:

"Species with low histidine level can also be associated with Scombrotoxin Fish Poisoning (SFP) if temperature controls are not maintained".

Question 3: Should *Salmonidae* be included or excluded when incorporating table 2.3 into the Code, or possibly included as footnote?

AU Position: AU recommends that *Salmonidae* be excluded when incorporating table 2.3 into the Code because while Salmon have caused illnesses with SFP-like symptoms, the histamine levels in the suspect Salmon were low and it has been postulated that unknown toxin(s) may be responsible for the illnesses.

Question 4: Should the existing susceptible species list in the commodity standards be replaced with a reference to the new table of susceptible species that will be incorporated into the Code?

AU Position: AU recommends the inclusion of susceptible species list in the commodity standards. This is vital for the application of the standards. As a minimum the family names of the susceptible fish species should be maintained in the relevant commodity standards. AU therefore supports the recommendation that CCFH should consider locating the list (or applicable species in the list) as an annex in the applicable commodity standards, in addition to the Code.

<u>Question 5</u>: Should work start on Histamine Control Guidance first, followed later by Histamine Sampling Plan Guidance?

AU Position: AU recommends that work should start on Histamine Control Guidance first, followed later by Histamine Sampling Plan Guidance. The Sampling Plan depends on Control Guidance. This approach is logical and allows adequate time to reflect on the possible content of the future Sampling Plan Guidance to be developed.

<u>Question 6</u>: Should CCFH consider alternative Sampling Plan for different purposes, and subsequently clearly define the different purpose(s) that require development of Sampling Plan/Guidance?

AU Position: AU supports the elaboration of alternative Sampling Plan for different purposes as noted in the document (CX/CAC 16/39/7, section 3b). However, the EWG should take into consideration that the principal aim of Codex in establishing sampling plan i.e. "***Codex Methods of Sampling are designed to ensure that fair and valid sampling procedure are used when food in being testing for compliance with a particular Codex commodity standard"***.

The main focus for developing/ revising Sampling Plan should be on risk-based criteria. This approach will enable the determination of compliance with health–based histamine limit in the specific commodity standard. Such Sampling Plan should also be practical and flexible to implement.