厚生労働行政推進調査事業費補助金（食の安全確保推進研究事業）
「国際食品規格策定プロセスを踏まえた食品衛生規制の国際化戦略に関する研究」
分担研究報告書

食品衛生部会、残留動物用医薬品部会及び輸出入食品検査認証部会に関する国際規格策定の検討過程に関する研究

研究分担者　　豊福　肇　　山口大学共同獣医学部

研究要旨：Codex 委員会の微生物ハザードのリスク管理に関連する作業を行う食品衛生部会、食品中の残留動物用医薬品の残留基準値設定等を行う残留動物用医薬品部会及び食品検査、食品コントロースシステム等について規格等を作成する輸出入食品検査認証部会での議論の動向等を調査して要点を整理するとともに、今後の我が国の食品安全行政の課題を指摘することを目的とした。調査対象として、今後の食品安全行政に特に重要になると考えられる課題を選択した。

A. 研究目的

Codex 規格は WTO/SPS 協定においては、食品安全の国際規格と位置づけられ、Codex 規格が存在する場合にはそれらに基づくか、少なくとも検討すべきとされているため、我が国の食品衛生規制を国際規格である Codex 規格より厳しくする場合には科学的根拠（リスク評価結果）を示すことが求められる。しかしながら、我が国の食品安全関連規制には Codex 規格と整合性がとれていないものが複数あり、解決しなければならない課題となっている。上記のように、Codex 規格は我が国の食品安全規制に大きな影響があるため、本研究では、我が国の食品安全行政の国際対応の改善に役立てるため、**残留動物用医薬品部会（CCRVDF）、食品衛生部会（CCFH）、及び食品輸出入検査・認証制度部会（CCFICS）**での議論の動向をまとめ、FAO/WHO からの科学的アドバイスの解析、我が国のコメント提出及び部会における対処方針を科学的に支援するとともに、課題についてまとめることを目的とした。

B. 研究方法

上記３部会の会議文書、会議での発言、電子的作業部会（EWG）でのコメント、部会報告書、会場内文書(Conference Room Documents), CCRVDF については JECFA,CCFH については JEMRA、ヒスタミンについては FAO/WHO からの報告書（科学的アドバイス）を参考にした。

平成 29 年度中に開催され、本研究の対象とした部会、物理的作業部会(PWG)及び EWG は第 23 回 CCRVDF (2016 年 10 月 17 日～21 日)以降に設置された EWG 及び第 24 回 CCRVDF への準備、第 48 回 CCFH(2016 年 11 月)以降に設置された EWG 及び第 49 回 CCFH (2017 年 11 月)及び第 23 回 CCFICS（2017 年 5 月）及びそれ以降に設置された EWG 並びに 2017 年 12 月に開催された PWG であり、それらの議題を中心に報告する。

C. 研究結果及び考察

C-1　第 23 回 CCRVDF)以降に設置された EWG

1）魚種グルーピングに関する討議文書作成 EWG

第 81 回 JECFA から CCRVDF に対し、魚種のグルーピング及び代表魚種を特定するよう要請があったことを受けて、第 23 回 CCRVDF においては、魚種グルーピングに関する討議文書を作

成する EWG（議長国：ノルウェー、共同議長国：日本）が設置された。

Draft Discussion Paper（一次、二次）の作成、議長との協議、日本からのコメント作成において、過去の CCFH での EWG 議長の経験等を踏まえ、アドバイスを提供した。特に第 1 次の各国からの承認情報を収集後、曝露評価をした魚からの ADI に占める割合は低く、外挿した他の魚からの曝露で ADI を占める割合も低いことから、1 魚種のデータで全魚種に外挿できるのではないかという意見が EWG の大勢をしめそうになった。これがあれば原則（環境水の塩分、環境温度、脂肪量、底生か否か、飼料）は重要ではないとの考えと思われた。これに対し、VICH 及び我が国の“目内の魚について外挿で MRL を設定するようにグループ化すべきという立場を残せるよう、Discussion Paper 作成にアドバイスを提供した。

2）可食臓器に関する討議文書（可食臓物の定義及び国際貿易上重要な可食臓器）作成のための EWG

第 81 回 JECFA から CCRVDF に対して可食臓器の定義を作成するよう要請があったことを受けて、第 23 回 CCRVDF において、可食臓器に関する討議文書を作成する EWG（議長国：ケニア）を設置することに合意した。

2017 年 2 月に EWG 議長からのコメント募集があり、同年 6 月 8 日にわが国から以下のコメントを提出した。

Japan would like to thank Kenya for chairing the electronic working group on edible offal tissue. Japan's responses to the questionnaire are as follows:

1. What is the general definition of offal tissues (provide source/reference) and definition of edible offal tissues in your country (provide source/reference)?

Edible offal means edible tissues and organs other than muscles, fat, liver and kidney from slaughtered animals. This definition is for setting maximum residue limits of veterinary drugs and pesticides.

Japan notes that CCPR is currently working on the revision of the *Classification for Food and Feed*, which includes a section on animal products. It would be important to harmonize with the CCPR work in order to keep consistency within Codex.

2. Provide a list of edible offal tissues consumed based on species in your country.

Examples of edible offal tissues consumed in Japan, include but are not limited to;
Cattle: Tongue, heart, rumen, reticulum, omasum, abomasum, small intestine, large intestine, rectum, sinew, uterus, tail
Swine: Tongue, heart, stomach, small intestine, large intestine, uterus, feet, cartilage bone
Chicken: Heart, gizzard, cartilage bone

3. Provide data from 2014 to 2016 on the quantity in tons of edible offal tissues traded locally and internationally from your country in the format provided here below;

There is no latest data on the quantity of edible offal tissues traded locally and internationally. For reference, data on the quantity of domestic production and import from 1999 to 2001 in Japan is shown in the below table.

Species	Edible offal tissue	Quantity of domestic Production (Metric Tons)			Quantity imported (Metric Tons)*		
	Year	1999	2000	2001	1999	2000	2001
Cattle	Tongue	2,116	2,099	1,811	41,843	44,821	41,067
	Heart	1,104	1,097	944	NA	NA	NA
	Organs except for liver	-	-	-	36,242	36,826	28,122
	Rumen	3,721	3,707	3,180	13,018	12,708	11,563
	Reticulum	1,007	999	862			
	Omasum	3,327	3,339	2,839			
	Abomasum	1,788	1,781	1,529			
	Small intestine	6,891	6,851	5,891	17,678	17,953	15,702
	Large intestine	3,639	3,615	3,112			
	Sinew	1243	1,229	1,064	24,498	24,856	17,068
	Uterus	298	296	254	NA	NA	NA
	Tail	1,993	1,975	1,706	NA	NA	NA
Swine	Tongue	7,222	7,186	7,022	NA	NA	NA
	Heart	5,496	5,468	5,344	NA	NA	NA
	Organs except for liver	-	-	-	11233	11985	10783
	Stomach	8,594	8,551	8,356	NA	NA	NA
	Small intestine	20,093	19,992	19,536	NA	NA	NA
	Large intestine	6,698	6,664	6,512	NA	NA	NA
	Uterus	3,065	3,050	2,980	NA	NA	NA
	Feet	30,436	30,283	29,593	NA	NA	NA

NA: Not available

*Frozen foods only. Chilled foods are not included.

3) MRL 設定を必要とする動物用医薬品の優先順位リストの EWG

第 23 回 CCRVDF において、作成したデータベースを引き続き維持すること、国際調査の結果を検討して、優先順位の高い動物用医薬品を特定するとともに、JECFA によるリスク評価のために必要なデータを特定するための EWG（議長国コスタリカ、米国）を設置することに合意した。

2017 年 3 月 25 日、EWG 議長から第 2 ラウンドのコメント募集が行われた。5 月 24 日に別添 C.2.1 で添付した回答を行った。

2017 年 7 月 1 日 EWG 議長からエクセルファイルが送付され、2nd round までに提出された各国からのコメントに基づき作成した優先度を付けるためのクライテリアに則って、各物質について優先度が高いか低いか等の第 3 ラウンドの input を同年 8 月 24 日までに回答することが求められた。

第 3 ラウンドでわが国から提出したコメントは以下のとおり。

Japan would like to thank Costa Rica and the United States of America for chairing the electronic working group on Prioritization of Countries' Needs for Veterinary Drug MRLs, and appreciates the opportunities to provide our comments on this issue.

Japan would like to propose some changes to the Appendix 4 to reflect that:

- Dipropionate imidocarb was already evaluated by JECFA in 2003, and imidocarb was identified as its active ingredient. Codex agreed MRLs of imidocarb in meat, edible offal and milk of cattle in 2005; and (http://www.fao.org/fileadmin/user_upload/vetdrug/docs/41-11-imidocarb_dipropionate.pdf)
- Ethion was already evaluated by JMPR in 1990 and MRL in spices has been set by CCPR. (http://www.fao.org/fao-who-codexalimentarius/standards/pestres/pesticide-detail/en/?p_id=34)

Japan also proposes some minor corrections to the Appendix 4. Some of veterinary drugs names listed in the appendix are changed to the more commonly-used names worldwide to avoid misunderstanding within members. Our proposals are shown in underlined and red color font in the attached file. If these proposals are accepted, the appendix 1 also needs to be modified accordingly.

Lastly, Japan notes that some of the listed substances have been recognized as important antimicrobials for human and veterinary medicines by international and national bodies. Antimicrobial resistance might be outside scope of the work, but the importance of antimicrobials can be a reference when considering MRL priorities in this EWG. Japan is of the view that antimicrobials should be managed strictly according to their GVPs and those residues in foods should be minimized as much as possible to ensure consumers' health. As such, we are adding a new column of "Notes on antimicrobial resistance priorities" and including the information on the priorities listed in *WHO Critically Important Antimicrobials for Human Medicine* and *OIE List of Antimicrobials of Veterinary Importance* in the Annex 4 as a reference for the EWG members.

また、同時に別添 C.2.2 も EWG に提出した。

C.2 第 24 回 CCRVDF 対処方針準備

2018 年 4 月 21-25 日シカゴで開催された第 24 回 CCRVDF の対処方針及びコメント作成のための科学的アドバイスを提供した。議題は次のとおり。

1 議題の採択

2　コーデックス総会及びその他の部会からの付託事項
3　FAO/WHO 及び第 85 回 FAO/WHO 合同食品添加物専門家会議（JECFA）からの関心事項
4　「動物用医薬品の登録に係る技術的要件の調和」（VICH）を含む OIE からの活動報告
5　ゲンチアナバイオレットのリスク管理に関する勧告（RMR）案（ステップ６）
6.1　ジルパテロール塩酸塩(牛の脂肪、腎臓、肝臓、筋肉）の最大残留基準値（MRL）原案（ステップ４）
6.2　アモキシシリン（魚類の切り身、筋肉)、アンピシリン（魚類の切り身、筋肉)、フルメトリン（はちみつ)、ルフェヌロン（サケ及びマスの切り身）及びモネパンテル（牛の脂肪、腎臓、肝臓、筋肉）の MRL 原案（ステップ３）
7　魚種のグループの MRL に関する討議文書
8　可食臓器に関する討議文書（可食臓器の定義及び国際貿易上重要な可食臓器）
9　CXG 71-2009 で規定されている動物用医薬品の定量及び同定のための一斉残留分析の使用に係る規準の改定に関する討議文書
10　JECFA の優先順位リストに掲載される新規物質の減少の理由の評価に関する討議文書
11　各国の MRL 設定の必要性に関するデータベース
12　JECFA による評価又は再評価を必要とする動物用医薬品の優先順位リスト案
13　その他の事項及び今後の作業
14　次回会合の日程及び開催地
15　報告書の採択

このうち、所要議題に対する対処方針案については以下のとおり。

議題 3. FAO/WHO 及び第 85 回 JECFA からの関心事項

JECFA からの情報

第 85 回 JECFA（2017 年、ジュネーブ）が検討を行った事項について、JECFA 事務局から報告される予定である。リスク評価及び MRL の検討を行った動物用医薬品 9 物質のうち、エチオン、ハルキノール及びシサプロニルの評価結果は以下のとおり。ジルパテロール塩酸塩は議題 6.1 で、アモキシシリン、アンピシリン、フルメトリン、ルフェヌロン及びモネパンテルについては議題 6.2 で検討される予定であり、情報収集対応のみ。

○エチオン（殺ダニ剤、殺虫剤）

第 85 回 JECFA は、適切な marker residue（規制対象物質）を決定できず、総残留比を設定することができなかった。第 85 回 JECFA は、ADI の設定根拠となった毒性学的エンドポイントは発生毒性試験における影響であって、アセチルコリンエステラーゼ阻害には関連しておらず、エチオンモノオキソンの既知の作用とリンクしていなかったことから、検討すべき残留物には、エチオンに係る全ての残留物（すなわち親化合物と全ての代謝物）が含まれると考えた。また、代謝物は牛では同定されなかった。利用可能なデータにはギャップがあり、不足しているデータが MRL の設定には不可欠であるため、第 85 回 JECFA は、現時点でエチオンの MRL を勧告できなかった。今後エチオンのリスク評価を行うためには、牛の薬物動態、代謝及び残留試験のデータ、組織中の marker residue を測定するためのバリデーションされた分析法の開発が必要である。

○ハルキノール（抗生物質）

第 85 回 JECFA は、ハルキノールの in vivo の変異原性及び発がん性の可能性を評価するために必要な情報が不足していることから、毒性学的 ADI を設定することができないと結論付け、健康影響に基づく指標値(HBGV)の欠如、組織（とくに肝臓及び腎臓）における残留物の同定が不完全であること及び組織における総残留比を設定するために必要なデータの不足を理由に、MRL を勧告しなかった。今後ハルキノールのリスク評価を行うためには、in vivo の変異原性及び発がん性に関するデータ、代謝

物同定のための放射性標識試験のデータなどが必要である。

○シサプロニル（外部寄生虫駆除剤）
第 81 回 JECFA は、イヌの 3 か月反復経口投与毒性試験で観察された影響の潜在的な懸念を理由に、ADI を設定することができなかった。第 85 回 JECFA では、新たなデータは提出されなかったが、スポンサー企業は、データギャップに対応するための代替方法をさらに明確化するよう要求した。今後シサプロニルのリスク評価を行うためには、ラット、イヌ及びヒトにおける比較薬物動態試験のデータ、イヌの反復経口投与試験におけるシサプロニルの影響に関するデータなどが必要である。

第 85 回 JECFA からの一般的検討事項
○動物用医薬品及び農薬の両方に用いる物質の長期暴露評価
○動物組織における動物用医薬品の残留物の相対的バイオアベイラビリティー及び/又は薬理活性の評価
○動物用医薬品の急性参照用量（ARfD）
○食品中の抗菌性物質のリスク評価を行うためのデータや方法論的アプローチ
などについて、JECFA 事務局から報告される予定である。

議題 4.「動物用医薬品の登録に係る技術的要件の調和」（VICH）を含む OIE からの活動報告

国際獣疫事務局（OIE）から、OIE がとくに重要視している薬剤耐性菌（AMR）の問題に対する取り組みについての報告を中心に、VICH を含む最近の活動の報告がなされる予定である。

議題 5. ゲンチアナバイオレットのリスク管理に関する勧告（RMR）案

（経緯）

第 78 回 JECFA は、ゲンチアナバイオレット（抗菌薬、抗真菌薬、駆虫剤）の ADI の設定及び MRL の勧告が適切でないと結論づけた。前回会合ではこの結論を踏まえ、ゲンチアナバイオレットのリスク管理に関する勧告（RMR）の内容について検討を行ったが、合意は得られなかった。このため、CCRVDF は次の RMR 案について、各国に対してコメント（ステップ 6）を要請し、それらのコメントに基づき今次会合で検討することとなった。

RMR 案

入手可能な科学的情報に基づく JECFA の結論を考慮すると、消費者にとって許容可能なリスクを表す、食品中のゲンチアナバイオレット又はその代謝物の残留の安全レベルはない。このため、関係当局は、食品中にゲンチアナバイオレットが残留することを防止すべきである。このことは、食用動物にゲンチアナバイオレットを使用しないことで達成可能である。

（対処方針）

議論の焦点は最終文を残すか削除するかである。米国等は最終文はあまりにも限定的であり、自分の国に最適な“食品中にゲンチアナバイオレットが残留することを防止するリスク管理措置“を選択する権利を制限しかねないと最終文の削除を提案することが予想される。遺伝毒性及び発がん性が疑われ、JECFA が ADI を設定不能と判断した物質を食用動物に使用すべきではないこと、また、これまで同様の物質（例、マラカイトグリーン）に対して CCRVDF が設定した RMR との整合性の観点から、最終文を維持する立場で対応する。

議題 6.1 ジルパテロール塩酸塩（牛の脂肪、腎臓、肝臓、筋肉）の MRL 原案（ステップ４）

（経緯）

ジルパテロール塩酸塩（β2-アドレナリン作動薬）について、第 81 回 JECFA がリスク評価を行い、MRL 案を勧告したが、前回会合において、データスポンサーから追加データの提出の意志が表明されたことから、ステップ 4 で留め置き、JECFA が追加データに基づき再評価を行

うこととなった。第85回JECFAがバイオアベイラビリティーに関して提出されたデータについて評価を行ったものの、前回勧告されたMRL案に変更はなく、当該MRL案について今回部会会合で議論を行う予定である。

（対処方針）

国際的に合意されたMRL設定方法に則り、科学的根拠に基づいたMRL案が勧告されていること及びJECFAによるリスク評価の結果、健康への悪影響が生じる可能性は極めて低いと考えられることから、MRL原案を支持するとの立場で対応する。

議題6.2アモキシシリン（魚類の切り身、筋肉）、アンピシリン（魚類の切り身、筋肉）、フルメトリン（はちみつ）、ルフェヌロン（サケ及びマスの切り身）及びモネパンテル（牛の脂肪、腎臓、肝臓、筋肉）のMRL原案（ステップ３）

（経緯）

第85回JECFAがリスク評価を行い、MRL案を勧告した動物用医薬品5物質（アモキシシリン、アンピシリン、フルメトリン、ルフェヌロン及びモネパンテル）のMRL原案について、今回会合で議論を行う予定である。

（対処方針）

国際的に合意されたMRL設定方法に則り、科学的根拠に基づいたMRL案が勧告されていること及びJECFAによるリスク評価の結果、健康への悪影響が生じる可能性は極めて低いと考えられることから、フルメトリン、モネパンテル及びルフェヌロンのMRL原案は支持するとの立場で対処する。アモキシシリン及びアンピシリンは、推定食事経由の慢性暴露の評価は問題はないものの、3種の魚のデータでfinfish（魚類全体）に基準を設定する提案をしているが、承認の無い魚にMRLは不要と考えられるので、目毎にMRLを設定するべきであると主張する。また、切り身と筋肉で同じMRLが提案されているが、FAO/WHOにその背景・根拠を質問し、なぜ、同じ数値で二つの部位（違いはスキンがあるかないか）を提案されているか確認の上、明確な説明がない場合には検査の実施上のことを考え、筋肉の基準一本化を提案する。

議題7. 魚種グループのMRLに関する討議文書

（経緯）

第81回JECFAからCCRVDFに対して魚種のグルーピング及び代表魚種を特定するよう要請があったことを受けて、前回会合において、電子作業部会（議長国：ノルウェー、共同議長国：日本）を設置し、魚種のグルーピングに関する討議文書を作成することに合意した。詳細は上述したとおり。

今回会合では、電子作業部会の検討結果に基づき議論が行われる予定である。

（対処方針）

統一したグルーピングは作成せず、申請者がfinfishやある程度のグループにMRLを設定したい場合には、それを裏付ける代謝や残留性等の試験データをCCRVDFとJECFAに提供することが重要であるとの立場で対処する。

議題8. 可食臓器に関する討議文書（可食臓物の定義及び国際貿易上重要な可食臓器）

（経緯）

第81回JECFAからCCRVDFに対して可食臓器の定義を作成するよう要請があったことを受けて、前回会合において、電子作業部会（議長国：ケニア）を設置し、可食臓器に関する討議文書を作成することに合意した。

今回会合では、電子作業部会が検討・作成した可食臓器の定義の案について議論する予定である。

（対処方針）

電子作業部会が作成した可食臓器の定義案は、動物形態学的には想定される可食臓器を全て含んだものになっているが、MRL設定を考慮

したものではないため、適切な定義となるよう適宜対応する。

議題 10. JECFA の優先順位リストに掲載される新規物質の減少の理由の評価に関する討議文書

（経緯）

前回部会会合において、HealthforAnimals は、JECFA に評価依頼する物質の数が減少していることについて言及し、JECFA の評価のための優先順位リストに掲載される新規物質の減少理由を体系的に評価するための討議文書を作成することを提案した。

今回会合では、HealthforAnimals が作成した討議文書に基づき議論を行う予定である。

（対処方針）

JECFA の限られたリソースを考慮しつつ、科学的データに基づく評価が引き続き行われることが重要であるとの立場で適宜対応する。

議題 11. 各国の MRL 設定の必要性に関するデータベース

（経緯）

CCRVDF は発展途上国から MRL 設定の要望のある動物用医薬品についてのデータベースを作成・維持する活動を行っている。前回部会会合において、作成したデータベースを引き続き維持すること、国際調査の結果を検討して、優先順位の高い動物用医薬品を特定するとともに、JECFA によるリスク評価のために必要なデータを特定するための電子作業部会を設置することに合意した。

今回会合では、電子作業部会の検討結果に基づき、MRL 設定の優先順位次付けのための規準及び優先度の高い物質のデータギャップを特定するための作業について検討を行う予定であり、適宜対応する。

議題 12. JECFA による評価又は再評価を必要とする動物用医薬品の優先順位リスト案

（経緯）

前回部会会合では、会期内の作業部会で各国より提案のあった動物用医薬品について検討を行い、優先順位リスト案を作成して部会に勧告した。部会は優先順位リスト案作成に係る PWG を設置し、各国からの提案について、今回会合部会の直前に開催される PWG の会合で検討することとなった。

（対処方針）

優先順位リストに掲載するための規準に照らして必要な情報が提案国から提出され、期日までに JECFA にデータを提出できることが確認できた物質については支持して差し支えないとの立場で対応する。

C-3　第 48 回 CCFH 後、第 49 回 CCFH までの間に設置された EWG

1）食品衛生の一般原則（CAC/RCP 1-1969）及び HACCP に関する付属文書の改正原案に関する作業部会

C.3.1.1　CCFH の HACCP 付属文書の Co-chairs による Drafting Workshop(WS)

2017 年 4 月 10 日（月）-12 日（水）カナダ、オタワ）で Drafting WS が開催された。

この Workshop に先立ち、各国から HACCP の例の提出が求められ、わが国からは豆腐、プレスハム、魚肉ソーセージの HACCP プランの一般的モデルを提出した。また、一般衛生管理、CCP、いわゆる OPRP の対比表案も作成した。

ワークショップの概要は以下のとおり。

参加国：ドイツ、フィンランド（Sebastian）、EU（Kris）、オーストラリア、インド（２人）、カナダ（Helene 他５人）、フランス（Prof. Oliver Cerf 他１名）、メキシコ（Ms Pamela Suárez Brito）、ニュージーランド（Ms. Judi Lee）、 米国（Ms. Jenny Scott 他 FSIS１人）、IDF（Claus）， IAF（ISO22000WG17 代表 Albert）、国際食鳥連盟（ドイツ人）、UK

（Jennifer Hopkins と Keven Hargin）、日本（豊福、横田）

議長は本来の WG 議長が病気のため、開催の前の週に、急に Kevin Hargin,(UK の Food Standard Agency, Head of Foodborne Disease Control)が依頼され、今回の Drafting workshop の議長を務めた。

初日：
Prof. Cerf の短いプレゼンの後、Introduction から General Principle を見直した。

Prof. Cerf は１）GHP, ２）enhanced GHP, ３）CCP（real time monitoring が可能）、４）Key Control Point(real time monitoring ができない CCP)の４つの概念を提案したが、本 WS 中に参加者から４つの分類という案は却下され、１から３のカテゴリー分けで行くことになった。CCP monitoring は real time であるべきという考えは一部参加者では支持されていて、４の一部は enhanced GHP と主張する者もいたが、そのあたりは未だにグレーゾーンであった。enhanced GHP はただの GHP から upgrade したものと、CCP から downgrade したものがあるという認識であった。

Introduction の元の５para はより短くすることにした。６para は GHP セクションへ，８para は HACCP セクションへそれぞれ移動させることにした。

消費者の役割（元のパラ１６）を残すか否かについて、かなり議論したが、結局残すことにした。

General Principle

豪から提案された food safety culture に関する文を挿入することに合意したはずだが翌日配布された版には含まれていなかった。（結局、FBO の role のところに記述することで合意した。）

Hazard Analysis がすべての基本だという考えを一般原則に入れることに合意した。

２日目_：

初日に一読した Introduction を再読した。(読後のものは別添 C.3.1.1)

午後は前日に配布された GHP の英国改定案もとに審議した。(審議後のものは別添 C.3.1.2。（ただし、すべてを記録したわけではない)

最後の coffee break 後（約１時間)、ハザード分析で、significant safety hazard が特定されず、GHP だけでコントロールできることが分かった場合、それを HACCP plan と呼べるのかについて議論した。結局、ハザード分析の結果、GHP のみ、GHP+HACCP いずれの場合であっても Hazard Control Plan と呼ぶことでコンセンサスに達した。

3 日目：

午前中、GHP, enhanced GHP, CCP の比較表（日本案をベースに英国が修正したバージョンを議論のベースに使用）について議論した。（議論後のものは添付 C.3.1.3）

午後から、現在の HACCP 付属文書において追加すべきことについて自由に各国がコメントした。改訂に当たっての大前提は simple, easy to understandable for everybody で合意した。

Enhanced GHP を決定するツールについて議論したもののコンセンサスには至らなかった。ただ、ハザード分析で significant hazard として特定されることが starting point であることは合意した。

今後　Guidance が必要な箇所は

* HACCP チームの能力
* Hazard 分析
* CL 設定の科学的根拠
* Validation, verification の違いの明確化

* Correcting action(対工程、対製品、再発防止の 3 本柱の明確化)
* Training section の強化
* CCP モニタリングで、real time の意味と定義

なお、各国から提出された Example については、議論する時間がなかった。

今回、参加者全員が納得した enhanced GHP の例は「加熱後のハムのスライサーの洗浄殺菌」と「牛乳のプレート殺菌後の冷却工程」であった。米国はリステリア問題を持ち出し、enhanced GHP の導入に積極的であった。（FSMA の sanitation control があるので当然と言えば当然である。）

比較表の中で、CCP の CL として observable は維持できたが、observable の例として、肉の加熱時、肉汁が透明になる肉の温度をあらかじめ validation した後の肉汁の透明性をモニタリングするという例はあまり支持が得られなかった。一方、牛乳の殺菌工程で、holding tube の保持時間（例：2 秒）は monitoring しないが、その代わり、ホモのポンプが適正に機能していることの観察は WG 内で抵抗なく受け入れられていた。

今後の予定：

2017 年 5 月はじめに Introduction（今回 2 読し、その際出たコメントをもとに Co Chair で調整したもの＝添付したものではない），GHP 部分(今回 1 読し、その際提出されたコメントをもとに Co Chair で調整したもの＝添付したものではない)、HACCP 部分（パラ毎に 3 日目午後の各国コメントを基に議長、副議長が新規テキスト追加&改訂する予定、ただし、場合によっては、更に改変・拡充すべき点を各国にコメントを募るのみになる可能性もあり。）が共同議長から提案され、コメント期間は約 1 か月となる見通し。

2) オタワ WS 以後の EWG

2017 年 5 月 7 日 EWG の共同議長から 1)カナダの WS の報告書、2)イントロダクション案、3)一般衛生管理案、4)HACCP 案、5)比較表案が提示された。

これに対し、6 月 9 日別添 C.3.2.1 のコメントを EWG に対し提出した。

さらに、作業文書に対し、別添 3.2.2 のコメントを作成し、10 月 3 日 Codex 事務局に提出した。

3) ヒスタミンの実施規範

日本（筆者）と米国が共同議長を務めた。

2017 年 7 月 25 日、EWG に別添 3.3.1 第 2 ラウンドでの議論の概要をまとめ、それらを取り入れた別添 3.3.2　第 3 ラウンド案を作成し、EWG に配布した。

そこまでの EWG の報告は次の通り。

28 加盟国（Argentina, Australia, Brazil, Canada, Chile, China, Costa Rica, Ecuador, France, Germany, India, Japan, Malaysia, Morocco, Mexico, New Zealand, Norway, Peru, Philippines, Poland, Portugal, Singapore, Spain, Switzerland, Thailand, United Kingdom, United States, and Uruguay), one member organization (European Union）及び 3 国際機関（FAO, WHO 及び ICMSF), さらに 1 NGO (NHF) が EWG に参加した。

The proposed draft document was initially drafted by the co-chairs, circulated twice for participant comments, and revised twice based on comments received.

The eWG did not consider Item d. in the terms of reference (“Consider if any products covered by the Code of Practice for Fish and Fishery Products need specialized or revised control guidance.”) This item may be better considered when aligning the existing Code with the draft section.

eWG の中での重要な討議事項は以下のとおり：

・One participant commented that all content relating to the application of HACCP principles on fishing vessels should be removed from the document. In their viewpoint, fishing vessels in developing countries only box and ice fish and these are primary production activities that should be excluded. And, that the FAO/WHO Expert Meeting concluded that histamine formation and SFP can be easily controlled, and the risk from SFP is best mitigated by applying basic GHPs and, where feasible, a HACCP system. In response to these comments, several changes were made to clarify that the draft guidance applies to vessels that use basic GMPs, and to vessels that use basic GMPs and HACCP systems. The Draft recommends that when establishments receive fish from vessels that apply basic GMPs without a HACCP system (i.e., without a documented structure and monitoring records), then the receiving establishment should monitor histamine levels in the fish.

・Several participants asked about the relationship between draft section X.2.4 (Histamine testing), and the work to be done later on sampling guidance. It was discussed that the later work was a revision of eleven Codex commodity standards that contain histamine safety limits, and that these standards were determined by CCFFP to have inconsistent, and possibly inadequate, sampling guidance for determining compliance of lots in trade with the histamine safety limit listed in the standard. The Code of Practice for Fish and Fishery Products serves a different purpose and contains guidance for producers on how to produce safe products with acceptable quality that will meet the end-product requirements of the Codex commodity standards.

・One participant asked where the new histamine section would fit in the code. It was discussed that the proposed draft was designed to be a separate section within the Code, and that it is analogous to existing sections because it covers a subset of fish and fishery products, and contains control guidance at production steps. It was noted that the Introduction to the Code (How to use this Code) explains the aim and layout of the Code, and that the Proposed Draft can be added within sections 10-19 (Processing of specific fish and shellfish products).

・One participant recommended revising an existing section of the adopted Code in order to reference the proposed draft section. It was discussed that significant editing to several sections of the existing Code will be required in order to reference the proposed draft section and to assure alignment of the existing guidance with the new guidance, and that work on aligning the existing Code should not begin until it is agreed to advance the proposed new section forward.

・ Several participants asked if the eWG was considering inclusion of Salmonidae in the table of at-risk species as listed in the terms of reference. It was noted that the FAO/WHO review was not completed, and inclusion of salmon, and the title of the table, would need to be

considered after completion of the FAO/WHO review.

Recommendations

The working group recommends that the Committee:

a. Consider advancing the proposed draft (Appendix I) as a new section in the Code.
b. Consider when to begin an eWG for aligning the existing Code with the draft new section, taking into consideration that this work may lead to significant revisions of the adopted Code, and that it will rely on overall CCFH agreement on the content of the draft new section.
c. Regarding the table of at-risk species for the Code derived from Table 2.3 in the FAO/WHO Expert Meeting Report:
1. Consider the inclusion of Salmonidae in the table based on the FAO/WHO review.
2. Consider the appropriate title for the table, which may depend on if Salmonidae are included.
3. Confirm where the table will be located (e.g., as a new annex in the Code.)

ヒスタミンの作業文書に対する日本のコメント作成中、農水省から「Distribution（流通）の内容を追加すべきとのコメントを提出したいとの協議」質問があった。農水省の言うように、対象が「Harvesting, Processing, Storage and Distribution」となっているにもかかわらず、Distribution の記載がないのもいかがなものかと思うのですが、Distribution を入れるのであれば、Transportation も入れるべきではないかと考えております。一方で、既に CAC/RCP 52-2003 に Transportation と Retail の section がありますので、この section にあえて記載の必要がないのではないかとも考えられますが、このガイダンスの構成として、どのように対応するのがよいかご教示いただけないでしょうかとの質問があった。

これに対し、「1）Histamine の section に「Harvesting, Processing, Storage and Distribution、Transportation と Retail を入れるのは entire food chain をカバーするという視点では良いと思います。ただし、ヒスタミンセクションの Transportation と Retail にヒスタミンのコントロールとして書くべきガイダンスがすでに CAC/RCP 52-2003 の Transportation と Retail の section に記載されている内容で十分なら、単に引用するだけで良いと思います。」と回答した。

結果的に、日本はコメントを提出しなかった。

しかし、10 月 19 日、米国のコメントを確認した農水省からコメントが寄せられ、それに回答した。（別添 3.3.3）

また、作業文書に対する各国コメントをレビューし、米国とともに、部会におけるレビューを円滑に進めるため、共同議長案を作成した（別添 3.3.4）

C-4 第 49 回 CCFH

第 49 回 CCFH 対処方針作成時、アドバイスを提供した。主要議題の対処方針は次の通り。

議題 4．食品衛生の一般原則（CAC/RCP 1-1969）及び HACCP に関する付属文書の改正原案(ステップ４)

前々回(第 47 回)会合で新規作業として採択することが合意され、議論されてきたもの。前回(第 48 回)会合においては、文書を三部構成（導入部、Good Hygiene Practice(GHP)及び Hazard Analysis and Critical Control Point（HACCP)）とすることや用語の整理、管理基準（CL）が存在しない場合や HACCP が適用できない場合の管理手法の記述の必要性について議論された。その結果、英国を議長国、フランス、ガーナ、インド、メキシコ及び米国を共同議長国とする電子作業部会を立ち上げ、

導入部の改正作業を引き続き行い、1 章 GHP 及び 2 章 HACCP の改正作業も同時並行で行うこと、経営陣の関与や責任、食品安全に関する企業風土・文化(culture)等の側面も盛り込むべきか検討すること、等の方針を確認した。また、今次会合（49CCFH）時に PWG を開催し、ステップ 3 で提出された各国コメントを検討した上で、本会合で議論するための修正原案を作成することで合意された。

電子作業部会から提案されている主な論点は以下の通り。

①全ての事業者が危害要因分析を行うべきかどうか。GHP のみで管理が十分な事業者の場合危害要因分析は不要か。

②GHP、CCP に加え、その他の管理措置（enhanced GHP （所謂 Operational PRP）について新たに定義するかどうか。

③第 1 章 GHP 中の「一次生産」における管理のセクションの記載について、文書全体が全ての事業者に向けたものであることから、原案では削除が提案されているが、元の文書の記載を残すか。

④第 1 章 GHP の「オペレーションの管理」のセクションに製品説明、手順説明、モニタリング手順、GHP の妥当性確認及び GHP の検証に関するパラグラフを新たに追加するかどうか。また、元の文書に記述されていた HACCP 関連や CCP となりえる温度と時間の管理等の記述を削除した場合、何をこのセクションに残すべきか。

⑤本文書が 2019 年にステップ 5 、2021 年にステップ 8 として採択されるためにとるべき、物理的または電子的な作業部会の設置を含む次のステップの決定。

これらの議論を含む今回の原案に対し、我が国は小規模を含めた全ての食品事業者にとって理解しやすく、活用しやすい内容となるよう可能な限り文書は簡素にし、元の文書構成を保つべきであるとの立場である。そのため、①GHP のみで管理が十分に行えることが明らかな食品事業者は必ずしも危害要因分析は必須でない、②新たな用語は可能な限り増やさない、③元の文書の通り、一次生産の記載を維持する、④第 1 章 GHP に HACCP に関する新たな記載を設けず、第 2 章 HACCP への追加修正に留め、第 1 章で HACCP 関連の記述が必要な場合には第 2 章の記述を参照すればよい、との立場で適宜対応する。

議題 5. 魚類及び水産製品に関する実施規範(CAC/RCP 52-2003)のヒスタミン管理ガイダンス文書原案（ステップ４）

本議題は、ヒスタミンの公衆衛生上のリスク低減の観点から、これまで魚類・水産製品部会(CCFFP)にて議論されてきたが、第 39 回総会(CAC)にて、CCFFP の無期限休会に伴い CCFH の新規作業として承認され、前回(第 48 回)会合では、本ガイダンス文書を魚類及び水産製品に関する実施規範(CAC/RCP 52-2003)の新たなセクションとして設けることが合意されたもの。

日本及び米国を議長国とする電子作業部会から提案されている主な論点は以下の通り。

①既存の実施規範の改訂につながる可能性を考慮しつつ、新たなセクションと既存の実施規範との並びをとるための電子作業部会をいつ始めるか。

②リスクの高い魚種を示す FAO/WHO 専門家会議報告の表 2.3 に関し、FAO/WHO のレビューに基づきサケ科を含めるかどうか、表題を何とするか、表をどこに配置するか。

以上の議論を含む今回の原案に対し、既存の実施規範との齟齬がないようにするとともに、科学的に適切かつ実効性のあるガイダンスが作成されるよう適宜対応する。

議題 6. その他の事項及び今後の作業

(a)新規作業/今後の作業計画

以下の 2 つの新規作業が提案されている。

①食品事業者のための食品アレルゲン管理の実施規範の新規作成

オーストラリア及び米国から、食品製造中の交差汚染防止や表示の役割を含めたアレルゲン管理について、食品事業者と政府のためのガイダンスを作成することが提案されている。アレルゲン汚染の管理措置は、議題４の食品衛生の一般原則（CAC/RCP 1-1969）及びHACCPに関する付属文書の改正において記載の追加が検討されており、アレルゲンの表示については包装食品の表示の一般基準(CODEX STAN 1-1985)にて定められているため、新規作業のスコープ、主な要素の明確化を図るとともに、既存の文書との関係について適宜聴取する。

②生物学的食中毒事件管理のガイダンス文書の新規作成

ＥＵから、食中毒事件の管理について、関係当局のためのガイダンスを作成することが提案されている。ガイダンスの内容は、平時の準備の促進及び事件管理の向上を想定し、適用範囲はまず生物学的危害とし、後にその他化学的危害まで範囲を広げるか検討すると提案されている。新規作業のスコープ、主な要素の明確化を図るとともに、国の食品管理システムの原則とガイドライン（CAC/GL 82-2013）、食品安全性の緊急事態における情報交換に関する原則とガイドライン（CAC/GL 19-1995）等既存の文書との関連を含め趣旨を適宜聴取する。

第49回CCFHの主な結論

第49回CCFH（2017年11月13日（月）～11月17日（金）、シカゴ（米国）にて開催された）の議論の概要と我が国の今後の課題についてまとめた

議題３　FAO、WHO及び他の国際政府間機関から提起された事項

(a) FAO/WHO合同微生物学的リスク評価専門家会議（JEMRA）からの経過報告及び関連事項

WHO及びFAOからCCFHの作業に関連したJEMRAの主な活動等が報告された。概要は以下のとおり。

志賀毒素産生性大腸菌(Shiga toxin-producing Escherichia coli:STEC)

・　FAO代表から、2017年9月に行われた第2回STEC FAO/WHO専門家会合の主な結果として、①STECは世界で健康・経済負荷となっており貿易への影響もあること、②最も重要とされる原因食品は、牛肉、野菜・果実、乳製品(主に未殺菌の製品)及び小型反芻獣の肉であること、③食品中STECに関連する重症となるリスクを予想するための、病原因子（遺伝子）の使用、④STECが食品安全リスクと明らかになった場合、モニタリングはリスクに基づいて、ハイリスク食品をターゲットとし、フードチェーン中効果的に介入が可能な箇所で実施すること、が報告された。

水質について

・　WHO代表から、FAO及びWHO専門家会合の主な結果として、「清浄水(clean water)」の普遍的な定義は出来ず、「用途に適する」目的を達成するためのリスクに基づくアプローチをとることが勧められること、またリスクに基づくアプローチはWHOの飲用水の水質のガイドラインとも一貫している旨、報告された。

・　部会としてFAO及びWHOによるアプローチを概ね支持した。今後の研究の後、報告がなされれればコーデックス文書の中で水質の問題をどのように対処するかの決定出来るようになることを確認した。

魚類及び水産製品中のヒスタミンについて

・　FAO代表から、サケ科のヒスタミン生成リスクに関する文献レビューの主な結果として、適切な時間・温度管理の下かつ製品の保存期間では、食中毒を起こすレベルのヒスタミンが生成される可能性は低いことが報告された。

議題 4.食品衛生の一般原則(CAC/RCP 1-1969)及び HACCP に関する付属文書の改正原案（ステップ４）

会合内 PWG での議論を踏まえ、作業部会議長である英国が作成した報告書（CRD2）に基づいて議論された。作業部会においては、原案の文書そのものについては議論せず、今後の作業方針となる以下の大前提について合意され、部会においてもそのまま支持された。

- 「一次生産」は独立したセクションとして残し、必要に応じて、文章全体で一次生産にも関係する記載部分を補強すること。
- 食品事業者は自らが扱う食品に関係するハザード及びそれらハザードを管理するための管理措置を理解・認識していなければならないこと。
- なお、食品事業者がハザードとその管理措置を把握するためには、何らかのハザード分析が必要になるが、これには政府機関や業界団体等が策定したガイダンスを参考にするなど様々な方法が考えられ、必ずしも HACCP の第一の原則として規定されているハザード分析と同義ではないことから、「ハザード分析」という用語は使用せずに、食品事業者の責務を説明すること。
- 業種等によっては、ハザードを管理する上で GHP のみで十分な場合もあること。
- 全ての食品事業者は GHP を導入する必要があること。GHP は単独で運用される場合もあれば、さらにハザードに特化した管理措置を取る上での前提条件プログラムとして運用される場合もあること。
- 管理措置には、3 種類(GHP、いわゆる OPRP、CCP）あることを記載すること。なお、いわゆる OPRP については、そのような管理措置があること自体については意見の一致を見たが、それをどう呼ぶか、用語を定義するか、GHP のセクションに記載するか/HACCP のセクションに記載するか等については、様々な意見が出され、合意できなかった。

また、今後、英国を議長国とし、フランス、ガーナ、インド、メキシコ及び米国を共同議長国とする電子作業部会を立ち上げ、以下の作業を行うことで合意した。

- 本会合での議論及び提出された各国コメントを踏まえ、引き続き、３つのパート（導入部、GHP、HACCP）の改正作業を行うこと。
- 具体例も用いながら、３つの管理措置（GHP、CCP、いわゆる OPRP）の関係を明確にすること。
- 食品事業者が自らの食品に関係するハザードを及びその管理措置をどのようにして理解するのか、その方法について明らかにすること。

さらに、次回会合時に PWG を開催し、ステップ３で提出された各国コメントを検討した上で、本会合で議論するための修正原案を作成し、次回 CCFH においてテップ 5/8 で次々回総会に諮ることを目指すこととされた。

議題 5. 魚類及び水産製品に関する実施規範（CAC/RCP52-2003）のヒスタミン管理ガイダンス文書原案（ステップ 4）

EWG の議長国である日本から、ガイダンス原案はヒスタミン管理において重要な点である漁船での管理を中心とすること、漁船における HACCP の実施は困難である旨のコメントがステップ３で提出された旨を説明した後、提出されたコメントを踏まえ、議長国が作成した報告書(CRD6)に基づいて議論された。

リスクの高い魚種を示す FAO/WHO 専門家会合報告書の Table2.3 に基づいて作成するリストにサケ科を含めるかどうかに関し、FAO/WHO が実施した文献レビューの結果が報告された。その結果、①40 年間で確認された健康被害例はごくわずかであること、②他の魚種に比べてサケ科のヒスチジンレベルは低いこと、③コーデックス基準よりは低いもののヒスタミンは生成されること、④大量に生産、貿易されているがヒスタミンを原因とする輸入拒否・却下は

ないことから、サケ科はヒスタミン食中毒の重大なリスクではないことが示された。

サケ科をリストに含めるべきかどうかについては各国から様々な意見が出された。FAO/WHOが実施した文献レビューの結果から、リスクに基づいた管理を行うべきであり、サケ科は含めずにリスクの高い魚種のみをリストに含めるべきという意見が出された一方で、少量のヒスタミンであっても、特に感受性の高いグループにとってはリスクとなり得ることから、サケ科も含め、FAO/WHO 専門家会合報告書の Table2.3 に掲載された魚種は全て含めるべき、とする意見もあった。

部会として、本原案は「魚類及び水産製品に関する実施規範(CAC/RCP 52-2003)」の一部となるものであり、既存のセクションにはリスクの高い魚種として６種が挙げられていることから、本ガイダンスでもサケ科を含めず同じ６種を記載することに合意した。なお、モロッコとモーリタニアは、（彼らの見解として）①この決定は、公衆衛生上の理由よりも経済的な正当性によって導き出されたこと、②FAO/WHO 専門家会合報告書において、サケによるヒスタミン食中毒が複数例確認されていること、③科学的不確実性が存在する場合、予防原則が適用されるべきであること、④ヒスタミンレベルが低いことをもって、ヒスタミン食中毒を引き起こす魚種のリストから除外することは正当化できないこと、からサケ科を含めないことについて留保を示した。

その他、漁船における HACCP 原則の実施についての記載の削除、しかし、漁船でのヒスタミンコントロール記録が存在することはより信頼性の高い消費者の保護を提供すること、漁船での温度管理の記録がない場合には、陸上受入施設で受入ロット毎にヒスタミン検査を行う必要があること及びその場合には受入を許容するヒスタミインリミットの設定の必要性とその際に考慮すべき点（や、捕獲されたばかりの魚のヒスタミンレベル等）についての記載等を修正し、本原案はステップ 5/8 で次回総会に諮ることが合意された。

今後は、引き続き日本と米国を共同議長国とする EWG（言語は英語）を立ち上げ、以下について検討することとされた。なお、チリが文書のスペイン語への翻訳を支援することを申し出た。

- 本ガイダンスを魚類及び水産製品に関する実施規範（CAC/RCP 52-2003）のどこに挿入するか及び挿入により同実施規範の他のセクションの修正が必要となるか
- ヒスタミンに関連する魚類と魚類加工品の規格基準中におけるサンプリング，検査及び分析セクションの改訂に関する作業

議題 6. その他の事項及び今後の作業

新規作業に関する会合内 PWG での議論を踏まえ、作業部会議長である米国が作成した報告書(CRD3)に基づいて以下の内容が議論された。

作業計画の優先順位決定のためのクライテリア

CCFH の作業計画表において、新規作業の内容を評価するためのクライテリアが点数化されておらず、優先順位の決定に寄与していないことから、米国が修正案を提案することになっていたもの。新規作業の開始を支持する新たな情報や技術（Currency of Information）が存在する（Yes）場合のみ、次の評価項目に進むこととし、公衆衛生に与える影響の度合い（高 20 点、中 14 点、低 8 点）、貿易への影響（世界的な貿易影響・高消費 10 点、地域的な貿易影響・高消費 5 点、世界的な貿易影響・低消費 4 点、地域的な貿易影響・低消費 2 点、貿易影響無し 0 点）について点数化することで合意された。また、策定されてから 5 年以上が経過した文書や、既存の文書との重複や不一致が見られる文書についても、同様に改訂の必要性を当該クライテリアで評価することとされたほか、提案された新規作業案について事前に各国の

コメントを求めること（注：現在、新規作業提案は、作業文書として回付されるのみで、各国コメントは求められていない。）等が合意された。

新規作業

a）食品事業者向け食品アレルゲン管理に関する実施規範

作業の目的及び対象が、①食品事業者及び政府機関に対して、交差汚染の防止など、食品製造におけるアレルゲン管理のためのガイダンスを提供すること、②アレルゲン管理には、『包装食品の表示の一般規格(CODEX STAN 1-1985)』で扱われるアレルギー表示も含まれること、を確認した上で、新規作業とすることで合意された。なお、提案国である米国から、実施規範の対象としては、食品アレルギーに焦点を当てることとし、食品不耐症については対象外と考えている旨、説明があった。

今後、提案国である米国及びオーストラリアが、コーデックス事務局からの指摘を踏まえ、i）食品表示との関係性、ii）専門家から科学的助言の必要性、iii)手続マニュアルにおいて求められている、５つの規準に照らした評価結果、が明確になるようプロジェクト・ドキュメントを修正し、コーデックス事務局を通じて第41回総会に提出することとされた。また、並行して、オーストラリア、英国、米国を共同議長とする電子作業部会を立ち上げ、実施規範原案を作成し、次回会合での議論に向けてステップ３でコメントを求めることとされた。

b）微生物による食品に起因する緊急事態/食中毒の管理のためのガイダンス

会合内PWGにおいては、本作業を開始する前に、CCFICSの文書（「食品安全上の緊急事態における情報交換に関するガイドライン(CAC/GL 19-1995)」、食品検査及び認証システムのツールとしてのトレーサビリティ/製品トレーシングの原則（CAC/GL 60-2006）等）や、WHOの「食品媒介疾患のアウトブレイク：調査と対策のためのガイドライン」、同じくWHOのINFOSAN(国際食品安全当局ネットワーク)、FAOのEMPRES（動植物の越境性病害虫に関する緊急予防システム）等、既存の文書や枠組みで何が不足しているか、ギャップ分析を行う討議文書の作成がまず必要で、それは必ずしもnegativeなものではないとの意見が我が国、米国等から示された。一方が、EU加盟国等からは、本作業の重要性・緊急性からに鑑み，作業開始を遅らせるべきではないとの主張が示され、議論の結果、①本新規作業の目的は、食品に関する緊急事態を管理するための、政府当局向けガイダンスを提供すること、②ガイダンスは、事前準備（preparedness）から、検知（detection)、対応(response)、復旧（recovery）までをカバーすること、③コーデックスやFAO/WHOの既存の文書を適宜、補完・連結することを意図していること、④各国の国内プログラムとINFOSANとの連携についても内容に含まれること等をプロジェクト・ドキュメントに明記した上で、新規作業とすることで合意された。

今後、提案者であるEUが、コーデックス事務局から指摘のあった、CCFHやCCFICS等が策定した既存のコーデックス文書との関係について、プロジェクト・ドキュメントに追記修正した上で、コーデックス事務局を通じて第41回総会に提出することとされた。また、並行して、デンマーク、チリ、EUを共同議長とする電子作業部会を立ち上げ、ガイダンス原案を作成し、次回会合での議論に向けてステップ３でコメントを求めることとされた。

その他

STECに関する討議文書について

米国、ウルグアイ及びチリが第50回会合に向けて討議文書を作成することとされ、その際、FAO/WHO専門家会議において、ヒトのSTEC食中毒に関与しているとされた食品カテゴリーは全て含めることとされた。

今後の作業計画

各国からの新規作業の提案を求める文書をコーデックス事務局から回付すること及び次回（第 50 回）会合時に CCFH における作業の優先順位に関する PWG（議長国：米国及びパナマ）を開催することで合意された。

議題 7. 次回会合の日程及び開催地

次回会合は 2018 年 11 月 12～16 日にパナマで開催される予定。

C-5　第 23 回コーデックス食品輸出入検査・認証制度部会（CCFICS）報告

2017 年５月１日（月）から５月５日（金）にかけて、メキシコシティ（墨）において開催された標記会合の概要は以下のとおり。

議題４　国の食品管理システムの規制面での実施状況のモニタリングに関するガイダンス原案（ステップ６）

米国より、本ガイダンス案は、第 19 回部会（2012）から議論が開始され、各国がどのように自国の NFCS の能力を評価し管理しているかについての質問票の取りまとめ、本作業及びプロジェクト文書案の適用範囲の見直し、原則及びガイドライン案の概略の定義づけを含む一連の協議の段階を経て作成されたものであり、第 39 回総会にてステップ５として採択された本案は、最終採択の準備が整ったとの説明がなされた。

議長から、本案は広範囲に及ぶ協議を経て作成されており、これ以上内容について検討しても実質的な変更をもたらす可能性は低いこと、修辞的な変更はすでに協議プロセスで考慮されていることから、現在のテキストを修正なしで採択すべきであるとの提案がなされた。

［主な議論］

本部会は、本案があらゆるレベル（部会並びに物理的及び EWG）で議論されていること、ステップ６にて提出されたコメントは既に過去の会合にて議論され、解決が図られているものであること、この原則とガイダンスは管轄当局関係機関が NFCS の有効性を評価することを助け継続的な改善を促進すること、状況により将来改訂される可能性があることが確認され、現在の文書から変更はせず、次回の総会にて採択することを概ね支持した。

ブラジルは、付属書 B にある、評価指標の例示を本案から削除し、information document として Codex website に掲載すべきとコメントした。

［結論］

本ガイダンス案をステップ８で次回第 40 回総会に採択を求めるよう諮ることで合意された。

議題５　食品の清廉性／信憑性に関する討議文書

討議文書の準備国であるイランより、討議文書について概要及びパラ 28 に記載されている部会への勧告が説明された。

議長から、本討議文書は、食品の清廉性／信憑性に関する疑問に対処するために総合的なアプローチを要求するための文書であり、既存の本部会に関する文書について食品の清廉性／信憑性への取り組みに係るギャップがあるか分析する必要性について勧告されていることが述べられた。しかしながら、ギャップ分析の目的や評価基準を明確にすることが、次のステップを決定するために必要であることが指摘された。

［主な議論］

“食品の信憑性（food authenticity）”、“食品の清廉性（food integrity）”、“食品偽装（food fraud）”及び“経済的な動機による不純物添加（economically motivated adulteration（EMA））”の用語に関し、基本的な概念の定義について、これらの用語の解釈に相違が生じる可能性があることから、新規作業とその適用範囲の詳述に至る前に、定義を明確

にするための更なる努力が必要であるとされた。

この分野の複雑性と分野横断的な特性を踏まえ、他部会を含むコーデックス全体に対し、横断的かつ総合的なアプローチがとられる必要があること、個別食品部会は、個別食品の品質要求事項を定めることを通じて、食品の清廉性／信憑性を決定することに貢献しうるが、本部会が一般的かつハイレベルのガイダンスを提供するよりよい場であることが確認された。また、一つの部会が一つの文書を通してこの複雑な問題に対処することは困難であること、とるべき措置は、偽装の検出に限らず、偽装への対策も目指すべきであることが確認された。

CCFO から示された懸念（議題２参照）について、本件は魚油だけでなくあらゆる油類及び他の個別食品に関連するものであるため、本部会がすべての個別食品規格に適用できる回答を示すことが重要であることが確認された。

本部会は、本件の難しさを認識した上で、既存のコーデックス文書について、ギャップ分析だけでなく、既にどのように、またはどの程度食品の清廉性／信憑性がカバーされているか明確な絵を得るため、コーデックスの文書をレビューすることとし、まずは本部会に関する文書から実施することとした。

我が国からコーデックス事務局に対し、本部会には他部会に関する文書をレビューする権限があるか質問したところ、コーデックス事務局から、コーデックス手続きマニュアルは、本部会がそのようなレビューを行うことを妨げる規定はないが、本部会が他部会の文書にあらゆる修正を勧告する場合は、当該関係部会によって検討され、実施されなければならないと回答した。

[結論]

部会は、イランを議長、カナダと欧州連合を共同議長とする EWG を設置することに合意した。その付託事項は次のとおり。

・食品の清廉性／信憑性、食品偽装及び EMA の定義を明確にし、本部会に関する文書の一次評価のための作業範囲を詳述すること

・定義に基づき、本部会に関する既存の文書について、ギャップと潜在的にある問題の軽減への影響（プラスかマイナスか）を特定するための一次評価を行うこと

・評価結果及び更なる作業又は新規作業の必要性を示した討議文書を作成すること

議題６　システムの同等性に関する討議文書

EWG の議長国であるニュージーランドより、討議文書で提案された新規作業は、同等性について明確に言及している３つのコーデックス文書（CAC/GL 26-1997、GL 34-1999 及び GL 53-2003）を補完するだろうとの説明がなされた。

既存のコーデックス文書（CAC/GL 26-1997 及び GL 34-1999 ）については、システムの同等性について検討する国がどのように手続きを進めていくかについて実用的なガイダンスを示していない。GL 53-2003 は衛生措置の同等性に焦点を絞ってしるため、全体的なシステム同等性のプロセスについて限定的な適用しかない。そのため、本討議文書では、既存の文書と矛盾しない形で、システム同等性の評価を始め、実施しようとする国を支援するためのガイダンスが必要であることが強調された。

また、EWG の共同議長である米国及びチリから、提案された新規作業は、各国に対し NFCS の一部又は全体の同等性を決定するためのプロセスについて、明確なガイダンスを提供することを意図していることが説明された。

本部会は、EWG の議長であるニュージーランドが改訂した討議文書（CRD17）を元に議論することとなった。

[主な議論]

システム同等性の使用に関する追加のガイダンスを作成することについて幅広い支持があり、その中で、①情報交換を含めた、システム

同等性に合意するためのより詳しいガイダンスが必要であること、②本ガイダンスは、国が複雑な問題に対処するのを助け、不必要な貿易制限を減らし、管轄当局関係機関の（人的・財政的）資源を節約するのに資すること、③本ガイダンスは、システム同等性を進展させ実行するための明確な勧告を提供し、CAC/GL 34-1999の利用を促進するものとし、かつ食品の輸出入のシステム同等性に焦点を当てるべきであること、④本ガイダンスは、既存のコーデックス文書と矛盾せず、重複を避けること、⑤本ガイダンスは、食品の輸出国と輸入国がシステム同等性の議論を始めるための基礎となるものとし、各国のシステムの発達状況を考慮すること、⑥本作業は、食品安全の保証はリスク分析アプローチにより達成されるべきであるとのコーデックス手続きマニュアルの記載を考慮しつつ、貿易障害とならない形で実施されるべきであること、及び⑦新規作業は、輸出国の食品管理システムに関し輸入国が有する経験、知識及び信頼の評価を促進する因子並びにシステム同等性の評価基準を記述すべきであることが確認された。

この新規作業の結果を独立した文書とすべきか、既存のコーデックス文書の付属書とすべきかについては、様々な意見が出されたが、部会は、新規作業の結果の位置づけを議論するのは時期尚早であり、新規作業の作成過程で決まるものとした。

CAC/GL 53-2003について、技術的な要求が機能する事例を特定することができなかったため、システム同等性は扱われず、SPS措置の同等性に焦点を当てることになった。議長から、CAC/GL 82-2013が作成され、NFCSの重要な特性及びその目的がどのように満たされるかが示されたので、今後、各国は、個別の措置について同等性を確立していくという複雑なプロセスを行うよりも、食品安全と食品貿易の公正な実施の両方をカバーするシステムの同等性を確立する可能性があることが指摘された。

ブラジルは、本件がCAC/GL 53-2003と重複している可能性があることを踏まえ、独立文書としてのガイドラインを作成する新規作業を開始することに留保を示した。議長から、新規作業が単独文書になるか、既存の文書の付属文書になるかは新規作業のフォーマットと内容により、作業の過程で決定することになるだろうとの説明がなされた。

新規作業の開始を助けるため、部会は、改訂されたプロジェクト文書(CRD17)を詳細に検討し次のとおりに対していくつかの修正を行った。

・新規作業が単独文書または既存文書の付属文書になる、もしくは既存文書の修正になる可能性について、目的及び適用範囲に追記する。
・FAO/WHO食品管理システム評価ツールを参照することを他の国際機関が行った作業に追記する。
・CAC/GL 53-2003を考慮することを明確化する文書を提案と既存文書との関係に関する情報に追記する。

[結論]

部会は、本新規作業を開始し、改訂されたプロジェクト文書を次回第40回総会に送付し承認を求めること、総会により新規作業が承認されることを条件として、ニュージーランドを議長、チリと米国を共同議長とするEWG（PWGを開催する可能性あり）を設置し、コメント募集及び次回会合における検討のため回付文書を準備すること、並びに新規作業の結果が独立文書となるか既存文書の付属書となるかを、文書作成の過程で検討することに合意した。

議題７　貿易における関係機関による電子証明書の使用及びペーパーレス証明への移行に関する討議文書

EWGの議長国であるオランダより、討議文書及び改訂されたプロジェクト文書（CRD23）について説明がなされた。また、本部会の開催に先駆けて開催された、ペーパーレス証明のガイ

ダンスの策定に関するワークショップを紹介した。

[主な議論]

電子証明／ペーパーレス証明は、食品の国際貿易を保証するためにその使用が増加しており、その傾向は今後も続くことに広く同意が得られた。したがって、ペーパーレスの電子証明に関する調和したガイダンスの作成は時宜にかなっており、電子証明の使用を促進することが予想されること、電子証明は、より透明性があり簡潔なアプローチをとることができるため、輸出国の負担を減少する可能性を秘めていることが確認された。

ペーパーレス証明の新しいガイダンスを作成することを支持する観点から、①ガイダンスは、電子システムが利用できない場合の緊急時対応策の必要性、情報交換システムの信頼性、電子セキュリティ対策と電子署名の検証、電子情報を交換するためのプラットフォームの適合性といった要素を考慮すべきであること、②輸出国と輸入国では(技術的な能力や利用可能なリソースを含む) NFCS におけるニーズと要求事項が異なっているため、紙による証明と電子証明の両方の使用を許容する柔軟性があるべきで、ペーパーレス証明への移行は段階的アプローチ (step-by-step approach) をとるべきであること、③現在の自国の手続や規制を更新する必要性、多様な分野における技術支援についての発展途上国のニーズを考慮すること、④ペーパーレス証明の実施は、資金及び発展途上国への技術援助の可能性、並びに経験と情報の共有に前向きなペーパーレス証明の経験国からの支援次第であること、⑤ガイダンス作成に当たっては、IPPC/OIE/WCO/WTO 等の既存の取り組みやシングルウィンドウの考え方についても考慮に入れるべきであることが確認された。

部会は、CRD23 を基に、プロジェクト文書の改訂について次のとおり決定した。

・CAC/GL38-2001 を改訂する本作業はペーパーレス証明を用いることに焦点を当てることを踏まえ、プロジェクト文書のタイトルを改訂する。

・カバーすべき主な要点は、①ペーパーレス証明へ移行するために段階を踏んだアプローチを考慮する必要があること、②電子証明システムを容易にする、情報交換メカニズム、データマッピング、法律上の規制変更のための要件を理解し解釈するために必要な基本概念を定義すること、③必要に応じて、IPPC/OIE/WCO/WTO 等の国際機関による電子証明の試みを考慮すること。

[結論]

部会は、ペーパーレス電子証明を取り入れて CAC/GL 38-2001 を改訂する新規作業を開始し、改訂されたプロジェクト文書を次回第 40 回総会に送付し承認を求めること、総会により新規作業が承認されることを条件として、オランダを議長とし、オーストラリアを副議長とする EWG を設置し、コメント募集及び次回会合における検討のため回付文書を準備することに合意した。

議題８　食品安全における第三者証明（認証）への規制のアプローチに関する討議文書

カナダより、討議文書について説明がなされ、作業の範囲は、ビジネス間の食品安全のための自発的な第三者認証スキームに適用することが強調された。そのようなスキームは、スキームの規準に対する独立した第三者による監査や検査を含み、また、新規作業の範囲から、NFCS において公的管理の一部として行う公式な証明書の発行を除くことが説明された。このため、混乱を避けるため、“third-party certification scheme”を“third-party assurance scheme”に変更することが提案された。

さらに、討議文書は、①第三者認証を使用に関する公的部門機関と民間部門私的機関の協

力における課題と機会、②第三者認証プログラムにおける産業投資の恩恵を受けるために各国が採った様々なアプローチ、③食品安全における第三者認証プログラムへの規制当局によるアプローチにおいて考慮されるべき原則を強調したことが説明された。

[主な議論]

部会は、議題の重要性を幅広く認識し、新規作業の開始を支持した。また、①各国の管轄当局関係機関は、自国の NFCS 内のリソースをより効果的に使用することを目的として、食品事業者のリスクプロファイリングをよりよく知らせるための第三者認証スキームを検討し用いることが増加していること、②第三者認証スキームは、NFCS を強化することはあっても NFCS に置き換わることはないこと、スキームの基準はコーデックスのような国際標準を考慮に入れるべきであること、③第三者認証スキームを利用することは、管轄当局関係機関と食品産業の食品安全を改善する可能性があり、その一方で、各ステークホルダーが決められた役割と責務内で活動することを許容するものであること、④管轄当局関係機関が NFCS において第三者認証をどのように、どのような条件下で使用するかについてのガイダンスを作成することは時宜にかなっており、貿易障壁を防止できる可能性があること、既にそのようなスキームを使用している国の経験から利益を得ることができること、⑤次の原則を規定することが重要であること;第三者認証スキームの完全性（integrity)、能力（competency）及び自発的な特性（voluntary nature）について保証する;国の管轄当局関係機関によるスキームの利用を義務付けるのではなく検討することを可能とする;スキームの規制的要素を管轄当局関係機関が使用する。⑥第三者認証スキームの使用に関するガイダンスは、食品安全に限定せずコーデックスの二つの付託事項(食品安全と公正な食品貿易）を対象とし、作成においては CAC/GL 26-1997 を参照し、当部会の文書との一貫性を確保すべきであることが確認された。

ブラジルは、第三者認証がまだ普及していないことから、このようなガイダンスの策定が食品輸出国、輸入国に経済的影響を与える可能性があるとの懸念を示した。また、新規作業として着手することは時期尚早であり、追加的な議論によって規制のアプローチの更なる分析や食品産業に関わる様々な分野への影響の評価が可能となるだろうとコメントした。

新規作業を支持する観点から、部会は、プロジェクト文書について検討し、①混乱を避けるため“third-party certification scheme”ではなく“third-party assurance scheme”を使用すること、②コーデックスの二つの付託事項を反映して「公正な食品貿易」を含むよう、プロジェクト文書を修正すること、③新規作業の目的が、輸出入のためだけでなく NFCS 内の規制上の取り決めや公的なコントロールを強化するためであることが明確になるよう修正すること、④対象範囲からの除外に関して、NFCS の要件外の認証スキーム構成要素及び売買契約上の取り決めによる民間規格の二つを追加するよう修正すること、⑤項目と関係の無い文章を削除すること、⑥カバーすべき主な内容において、基準設定の取り決めと国/国際規格の活用を２つに分割し、“robustness”を“credibility and integrity”に置換すること、⑦作業の優先付け基準の評価において、第三者スキームが食品安全を強化するだろうことが明確となるよう文言を修正すること、⑧当該分野における他の国際機関による既存の作業において、国際機関のリスト以外の機関の作業も考慮できるよう、修正すること、⑨外部機関からの技術的なインプットの必要性において、コーデックスのオブザーバーではない“Global Food Safety Initiative”を削除することを決定した。

[結論]

部会は、食品安全と公正な食品貿易における第三者認証スキームへの政府アプローチに関するガイドラインを作成する新規作業を開始し、改訂されたプロジェクト文書を次回第40回総会に送付し承認を求めること、総会により新規作業が承認されることを条件として、イギリスを議長とし、カナダとメキシコを共同議長とするPWGの可能性もあるEWGを設置し、コメント募集及び次回会合における検討のため回付文書を準備することに合意した。

議題９　食品輸出入検査･認証制度部会の今後の課題と方向性に関する討議文書

オーストラリアが更新した本部会の今後の課題と方向性に関する討議文書に基づき、について議論が実施された。

本討議文書は、第22回部会（2016）での議論を基に、２つの要素（附属書A及びB）で構成されており、附属書Aは本部会に関連する新たな国際的な問題を示し、付属書Bは本部会が優先すべき作業分野の予備評価と特定の枠組みを示している。前者は網羅的なリストでも新規作業を約束することを意図したものでもないこと、後者はメンバーによる評価の方法を提案したものであることが説明された。

議長は、メンバーが、各自の戦略的展望から多少なりとも知見を得ることこと、特定の関心分野に対処するために国際基準がどのくらい存在しているかを評価し、それにより新たな問題を完全に緩和するために必要な将来の手順を考察することという２つの目標を達成できる附属書Aについて、ユニークな価値があると述べた。また、部会に対して、附属書Aに記載されている項目が、戦略的課題を正確に記しているかについて検討すること、文書の改良のためのフィードバックを行うよう促した。

［主な議論］

部会は、再編成された文書を承認し、附属書Aに関連しては、①受入拒否された食品に対するアピールメカニズムを追加すること、②“Increasing electronic transactions and ICT capabilities”にはインターネット商取引を含むようその対象範囲を拡大すべきであること、③食品生産等の新たな技術に関係する3つの項目は1つに統合できること、④（正当な規制が科せられる）新しい食品を通じて世界の人口増加のニーズを満たす可能性がある観点から“novel food”/“new food”を“New food-production, -processing, -transport and -distribution technologies”に組み込むべきであること、⑤“Private standards”は、過去に議論されており、本部会にてさらに検討する要請がなされていないことから、含めるべきではないこと、⑥国際的な食品貿易に関連した食品廃棄（food waste）について、新たな地球規模の問題として含めるべきであることを要求した。

特定の重要な新規の問題にどのように対処するかに関して、議長は、このリストが本部会の作業に関する重要な領域を概説しており、メンバー及びオブザーバーはこの件に関して提案することができると述べた。また、附属書Aは作業すべき案件のリストではなく、メンバーが自己評価や問題の分析を行って、本部会へ討議文書を提出することを目的としていることを強調した。

一方、附属書Bについて、特に貿易への影響の可能性を決定するための指標について、“fair trade practices”の “global trade impact”を評価していくには、更なる作業が必要であるとの懸念も示された。

［結論］

部会は、附属書Aについて、オーストラリアとカナダが、第24回部会における検討のため、本部会で出された問題等を考慮に入れて更新すること、附属書Bについて、オーストラリアが次回の部会にて、優先すべき分野の予備評価と同定の枠組みを修正することに合意した。

議題10　その他の事項及び今後の作業

発展途上国が表明したPWGに定期的に出席するための財源に限りがあることへの懸念に関して、議長は、このような困難を認識した上でも、ある種の作業はEWGを通じて効果的に実施することができるが、NFCSなどの複雑な問題については、PWGが文書の作成に役立つと述べた。また、発展途上国の要求を捉え価値のある成果を生み出す点において効果的であるPWGの利点について強調した。

議長は、PWGの可能性も残した、「システム同等性」及び「第三者認証スキームへの規制アプローチ」に関するEWGに言及し、2018年10月の第24回部会の前に、2017年11～12月にチリにて、2018年４～５月にアイルランドもしくは英国にてPWGを開催することを提案した。さらに、ウェブ会議システム等を利用して、物理的に参加できない国へリアルタイムによる参加を進めることを提案した。

［主な議論］

部会は、提案を幅広く支持し、①複雑な作業にはPWGが必要なため、過去に異なる地域にてPWGやワークショップを開催してきた経験を再確認した、②PWGにウェブ会議システム等の利用を加えることで参加が促進されるだろうこと、③PWGは効果的ではあるが、必要な時にだけの最小限にとどめるべきであること、④メンバーが可能な限り参加しやすくするため、第24回部会の直前に、PWGの成果を検討するワークショップやPWGの開催を検討すべきであること、⑤ウェブベースでの会議を実施する際に時間帯の違いを考慮する必要があることが確認された。

ブラジルは、コーデックスの作業に幅広い参加が可能となるので、発展途上国はEWGをより望んでおり、PWGは、その設置に係るガイドラインに示されているものと他のアプローチを考慮した上で部会の合意に基づく場合に限るべきで、PWGがやむを得ない場合は、幅広い参加を保証することが重要であると述べた。

議長は、PWGとウェブベースの形式を組み合わせることで、世界各国が参加できる物理・電子的ハイブリッド作業部会となることを明確にした。

［結論］

部会は、①「システム同等性」及び「第三者認証スキームへの規制アプローチ」に関するガイダンスを作成ためのPWGを、南米（チリ）とヨーロッパ（アイルランドか英米国）にて開催すること、②いずれの作業部会も各議題２日ずつ計４日実施すること、③どちらの作業部会も、幅広い参加を可能にするためウェブ会議システム等を通じて中継されることに合意した。

議題11　次回の開催日時及び開催地

第24回食品輸出入検査・認証制度部会は2018年10月にオーストラリアで開催される予定。詳細については、コーデックス事務局と議長国の豪州が調整することとされた。

C-6 第23回CCFICS以降に設置された電子的証明書に関するEWG（GUIDELINES FOR DESIGN, PRODUCTION, ISSUANCE AND USE OF GENERIC OFFICIAL CERTIFICATES）（議長国オランダ）

第１ラウンド提出コメント

１）タイトルに対し、：

At this moment, we think it is not necessary to change the title, because these guidelines cover both paper and electronic certificate, including, not limit to paperless use of certificates.

We think, however, that we should to clarify the definition on “paperless electronic certificate” and “electronic certificate”.

２）SECTION 2 – SCOPE AND OBJECTIVES

5. These guidelines provide assistance in identifying the information and attestations in paper and/or electronic documents that can be provided by competent authorities.
（下線部追加を提案）理由：：To make sure these guidelines cover both paper and/or electronic documents
6. These guidelines are equally applicable to official certificates regardless of their mode of transmission, e.g., paper or electronic. And paperless use of electronic certificates does not excluding the use of the paper certificate.
（下線部追加を提案）
理由は紙の証明書の使用を排除しようとするものではないことを明確にするため）
Section 3　定義
paperless electronic certificate と electronic certificate を区別するため、paperless electronic certificate の定義を設けることを提案した。
Section 4　原則
E. Official certificates, regardless of their mode of transmission and their contents, should present information in a form that simplifies and expedites the clearance process while meeting the importing country requirements.

理由：It is necessary to clarify the necessity of alignment with single window approach according to WTO Trade Facilitation agreement.

F. The competent authority of the exporting country is ultimately responsible for any certificate it issues or authorizes to be issued.

理由 We think it is not necessary rewording this paragraph because definition of "Certificates" in GL38 "are those paper or electronic documents, which describe and attest to attributes of consignments of food destined for international trade".

SECTION 9 – ISSUANCE OF OFFICIAL CERTIFICATES (RESPONSIBILITY OF CERTIFYING OFFICERS, SECURITY AND PREVENTION OF FRAUD)
このタイトルを改正する必要ないとコメントをだした。

Principle F
The competent authority of the exporting country is ultimately responsible for any certificate it issues or authorizes to be issued.
このパラの rewording は不要とコメントを出した。
Para 35, 36, and 38 で paper の後に "and/or electronic "の追加を提案した。または "paper" を削除し、paper and electronic certificates を両方含むように"Certificate" のみにする提案をした。

これらに対する作業部会の議長からの回答は以下のとおり。
タイトル
"At this moment, we think it is not necessary to change the title, because these guidelines cover both paper and electronic certificate, including paperless use of certificates.
We think, however, that we should to clarify the definition on "paperless electronic certificate" and "electronic certificate".
パラ５、６の修正提案は受け入られる。
原則 E の改正提案は受け入れられなかった。
理由は、It is necessary to clarify the necessity of alignment with single window approach according to WTO Trade

Facilitation agreement.
原則 F　の修文案も受け入れられなかった。理由は We think it is not necessary rewording this paragraph because definition of "Certificates" in GL38 "are those paper or electronic documents, which describe and attest to attributes of consignments of food destined for international trade".
セクション 9 のタイトル及び原則 F の修文案は受け入れなれなかった。
パラ 35，36，38 の挿入(and/or electronic)は受け入れられた。

第 2 ラウンド（2017 年 3 月）では次のようなコメントを提出した。
We think it is necessary to develop a definition of "paperless electronic certificate" and other definitions in order to have common recognition.
In addition, we think that it is necessary to define the issuance and receipt of certificates for paperless electronic certification because there is possible gap in perception of issuance/receipt between issuing and recipient countries, depending on communication status (e.g. when communication error on a network occurs).

パラ３０に下線部の挿入を提案した。
30. The importing country, <u>where financial circumstances allow,</u> should have in a paperless environment:
- national legislation or regulation to accept electronically official certificates;
- confidence in the reliability and security of the electronic certification system and messages of the importing country as well as the transport layer infrastructure;
- capability to acknowledge the receipt of the electronic exchanged official certificate.
挿入の理由：Because system construction requires a budget.

第 2 ラウンドで追加された Para41 に対し
41. Competent authorities should promote to businesses electronic information exchange that supports electronic certification and enables paperless use of official certificates.

"promote to businesses" の意味がわからないので、このパラの追加の真意を確認した。

C-7　食品安全及び食品貿易の公正な取引における第三者認証制度への規制アプローチに関するガイダンス及びシステム同等性の使用に関するガイダンス起草のための物理的作業部会（PWG）

議題１：食品安全及び食品貿易の公正な取引における第三者認証制度への規制アプローチに関するガイダンス
議題２：システム同等性の使用に関するガイダンスの起草のため、議題１は 2017 年 12 月 11,12 日、議題２は 12 月 13,14 日にチリで PWG が開催された。議長国は、議題１はイギリス、カナダ、議題２はニュージーランドが務めた。

出席者：食品監視安全課輸入食品安全対策室藤本係員、山口大学　豊福、農林水産省大臣官房政策課　辻山調査官）
参加国は 15 カ国・地域（豪州,カナダ、ブラジル、チリ、EU,インドネシア、UK,コロンビア,インド,南ア，パラグアイ,ニュージーランド、メキシコ、米国，FAO,CODEX 事務局
※なお、本 PWG は WEB を通じて同時に参加することができ、アルゼンチン、ノルウェー、ジャマイカ及びタイの 4 か国が参加した。

議題１　食品安全及び食品貿易の公正な取引における第三者認証制度への規制アプローチ

に関するガイダンス

【概要】

本ガイダンス案は第三者認証制度(以下、「3PAS」という。)を National Food Control Systems （NFCS）の一部としてどのように用いるかについて、原則とガイドラインを作成しようとするものである。

本 PWG では、初日午前に、第三者認証機関（IFS)、第三者認証を取得している民間企業（WALMART）から、第三者認証の利点についてプレゼンがあった。初日午後より、ガイドライン案について各国からコメントを出し合い、パラ毎にテキストを修正し、また次の eWG に向けた論点の洗い出しを行った。

３PAS の主な内容は次のとおり。

イントロダクションでは

・規制機関（以下、CA という。）は、食品事業者の規制上の監督を強化するため、スキームの credibility 及び integrity の評価に基づき、３PAS が創生した情報及びデータを使用することを選択することもありえる。

・このガイダンスは規制機関が３PAS を評価するのに用いる枠組みと規格を提供する。

・ CAC/GL 82-2013, Principles and Guidelines for National Food Control Systems と一緒に読むべきである.

目的では

2. 本ガイダンスは、規制機関が３PAS のメリットを評価し、NFCS を補完し、強化するために使用する時に使用する枠組みを提供する。

そうすることで、

- 任意の 3PAS の特徴の共通理解を促進（promote）することを求め
- CAがスキームを評価するときに使用できる客観的な規格を提供
- 規制要件への順守を会社が達成するのを助けるうえでの３PAS の役割

NFCS の一部として CA によってそのようなスキームが使用される際の一貫性のあるアプローチをプロモートする目的である。

3. このガイダンスは CA の政策判断を支援し、CA が規制の監督または情報の共有を行うとき、任意の 3PAS の要素を考慮するため、一貫性のあるアプローチをプロモートすることを意図している。

このガイダンスは CA に、規制において３PAS を考慮することを求めるのではないし、規制している食品事業者に３PAS の使用を強制するものではない

このガイダンスは公的な監視、公的な認証システム（法執行権限を有する）をカバーするものではない。購入者と販売者間の契約上約定に適用されるものではない

【PWGにおける論点と我が国の対処方針に対する対応】

・我が国の対処方針と対応

① ガイダンスの目的、想定、活用方法を明確にする。そのため、経験国の活用状況の説明や例示を求める。

→目的は規制機関が 3PAS のメリットを評価し、NFCS を補完し、強化するために使用する時に使用する枠組みを提供することである。PWG での議論において、議長の UK から口頭での例示があったが、次の EWG のため参考資料として必要であることを強調し、例示に対応してもらうよう求めた。

第三者認証制度が、輸出入時の必須条件とならないことを確保する

→現時点では確保できている。

② 定義については、議論がある程度進んだのちに検討する

→次の EWG に持ち越しとなった。

③ 第三者認証のあるべき原則を決める必要はなく、管轄当局が採用する認証制度のあるべき原則のみに止まるよう対処する

→後者であることを前提の議論であるため、論点とする必要はない事項であった。

④　　パラ 28 にあるが、第三者認証の制度及び遵守状況について、権限のある政府機関が評価せずに NFCS に組み込むことは不可能。国における第三者認証制度の評価方法や権限についてより明確にし、実用性を確保する
→実用性の確保はできている。
⑤　　輸入時の監視体制に相手国の第三者認証制度を活用できる規定か確認する。活用できる場合、輸入国の管轄当局が、認証を受けた施設を監督できることを確保
→第三者認証制度は民間認証であり、これは世界的に利用されているところである。輸入国管轄当局が第三者認証制度を輸入時監視体制に活用することを妨げる規定はない。活用方法については活用する当局次第である。本文書では規制機関が 3PAS のスキームオーナーと情報交換することを想定しているが、輸入者に 3PAS 情報を求めることは本文書の枠の外になり、それを妨げるものではない。
なお、輸入国管轄当局が施設監督することを妨げる規定はない。

議題２　システム同等性の使用に関するガイダンス
【概要】
食品安全と国際貿易における公正な取扱をさらに促進するための手段として、輸出国と輸入国の食品コントロールシステム（以下、「NFCS」という。）の同等性（輸出国の NFCS が輸入国のそれとは異なっている場合でも、同レベルの Objective を達成する精度を有することが証明された場合には、同等の措置として認める概念。）の評価方法等について、ガイドラインを作成しようとするものである。
本 PWG では、ガイドライン素案を元に、EWG の各国コメントを議論し、パラ毎にテキストを修正・追加していく方式をとった。

【pWG における論点と我が国の対処方針に対する対応】
・我が国の対処方針と対応
①　　ガイダンスの目的、想定、活用方法を明確にする。そのため、経験国の活用状況の説明や例示を求める。
→本文書の目的は輸出入国の規制機関が消費者の健康を守り、食品貿易における公正な取扱いを促進する手段として、システム同等性認証を使用する際の実務的なガイダンスを提供するためのものである。議長国のニュージーランドに対し、すでに米国・EU 等とのシステム同等性の議論の例示を求めたが、ショートペーパーにまとめられる内容ではないことから難色を示された。現在の状況から変更となる点を明確にする
・既存の文書から変更したい部分を明確にし、必要性や実行可能性を確保
→変更点は、既存文書とのギャップを埋める部分（衛生措置のみから、NFCS 全体に焦点を拡大したことに伴う同等性判断のための新たな要件の設定や、過去文書からの整理すべき事項等）である。必要性や実行可能性は現時点では確保できている。
・システム同等性の評価に係る作業が必要最低限となるよう対処
→現時点では必要最低限となるよう対処できていると思われる。
・現在の手続きで担保されている透明性等が損なわれることのないよう対処
→透明性が損なわれることのないよう対処できている。
②　　定義については、議論がある程度進んだのちに検討する
→次の EWG に持ち越しとなった。
③　　前提要件（prerequisite considerations）について、目的等を明確にするとともに、強制力を伴うような文言を避ける
→前提要件については、本 PWG では議論が深まらなかった。なお、強制力を伴うような文言は避けられている。
④　　システム同等性の評価によって達成すべき要件（ALOP 等）を明確にする
→本文書では key objective または

DECISION CRITERIA という言葉で表されている。食品貿易における公正な取引に関する NFCS において、比較する物差しは、定性的なものになり、その国々、対象となる NFCS によって異なるため、明確に記載することはできないのではないかと考える。

D. 結論

CCRVDF の魚のグルーピングについて、データが少ないなか finfish 全体に MRL を設定するのではなく、VICH のガイドラインを参考に、加盟国で使用が承認されている魚のグループを対象にした MRL 設定を目指していきたい。CCRVDF においては、JECFA の評価を受けた後の CCRVDF がリスク管理者としてできること、できないこと、すべきこと、すべきではないことの整理が重要になってくると考えられた。

CCFH の食品衛生の一般原則及び HACCP 適用のためのガイダンスは我が国の食品衛生法等の一部改正（HACCP 及び HACCP の考え方を取り入れた衛生管理）に密接な関係があるので、食品安全の一層の向上を図りつつ、我が国の中小事業者にも実施できるものにするように、一層の注視が必要であると考えられた。

ヒスタミンのガイダンス文書は一度の部会でステップ 5/8 で仕上げることができた。サンプリング計画については、共同議長国として、また、魚食国の１つとして、科学的根拠に基づく規格を、2018 年の第 50 回 CCFH においてステップ５，８で総会へ進めるように目指したい。

CCFICS では、今後、3PAS が食品事業者間で普及した場合、現在の規制機関の規制にその情報を活用することで、NFCS の一層の向上が図れるような枠組みを作っていければ、我が国の公衆衛生の向上につながると考えられた。システム同等性については、既存文書との重複を避けつつ、また輸入国の負担が一方的にならないよう注意しつつ、食品安全の向上と国際貿易の公正な取引の妨げにならないような文書作成に貢献すべきと考える。

E. 研究発表

1. 論文発表

(1)豊福　肇. コーデックス委員会などにおけるヒスタミン制御、月刊 HACCP, 23(5), 50-55, 2017

(2) 豊福肇. 食品のリスク分析・評価に基づく科学的な衛生監視指導体制の現状と課題、公衆衛生. 81(8), 618-625. 2017

(3)　豊福　肇. HACCP 導入の制度化に当たって～検証のための検査の役割と意義～月刊 HACCP, 24(1), 20-25, 2017

2.学会発表

なし

3．厚生労働省の担当職員を対象とした研修会

食品微生物学の基礎、コーデックスの食品衛生の一般原則と HACCP, 食品に関連した微生物規格の原則、微生物リスク評価及びリスク管理のガイドラインに関する５つの講義、計 6 時間を担当。

F. 知的財産権の出願・登録状況

特になし

別添 C.2.1

Japan's comments on discussion paper on edible offal tissue

Japan would like to thank Kenya for chairing the electronic working group on edible offal tissue. Japan's responses to the questionnaire are as follows:

1. What is the general definition of offal tissues (provide source/reference) and definition of edible offal tissues in your country (provide source/reference)?

Edible offal means edible tissues and organs other than muscles, fat, liver and kidney from slaughtered animals. This definition is for setting maximum residue limits of veterinary drugs and pesticides.

Japan notes that CCPR is currently working on the revision of the *Classification for Food and Feed*, which includes a section on animal products. It would be important to harmonize with the CCPR work in order to keep consistency within Codex.

2. Provide a list of edible offal tissues consumed based on species in your country.

Examples of edible offal tissues consumed in Japan, include but are not limited to;
Cattle: Tongue, heart, rumen, reticulum, omasum, abomasum, small intestine, large intestine, rectum, sinew, uterus, tail
Swine: Tongue, heart, stomach, small intestine, large intestine, uterus, feet, cartilage bone
Chicken: Heart, gizzard, cartilage bone

3. Provide data from 2014 to 2016 on the quantity in tons of edible offal tissues traded locally and internationally from your country in the format provided here below;

There is no latest data on the quantity of edible offal tissues traded locally and internationally. For reference, data on the quantity of domestic production and import from 1999 to 2001 in Japan is shown in the below table.

Species	Edible offal tissue	Quantity of domestic Production (Metric Tons)			Quantity imported (Metric Tons)*		
		1999	2000	2001	1999	2000	2001
Cattle	Tongue	2,116	2,099	1,811	41,843	44,821	41,067
	Heart	1,104	1,097	944	NA	NA	NA
	Organs except for liver	-	-	-	36,242	36,826	28,122
	Rumen	3,721	3,707	3,180	13,018	12,708	11,563
	Reticulum	1,007	999	862			
	Omasum	3,327	3,339	2,839			
	Abomasum	1,788	1,781	1,529			
	Small intestine	6,891	6,851	5,891	17,678	17,953	15,702
	Large intestine	3,639	3,615	3,112			
	Sinew	1243	1,229	1,064	24,498	24,856	17,068
	Uterus	298	296	254	NA	NA	NA
	Tail	1,993	1,975	1,706	NA	NA	NA
Swine	Tongue	7,222	7,186	7,022	NA	NA	NA
	Heart	5,496	5,468	5,344	NA	NA	NA
	Organs except for liver	-	-	-	11233	11985	10783
	Stomach	8,594	8,551	8,356	NA	NA	NA
	Small intestine	20,093	19,992	19,536	NA	NA	NA
	Large intestine	6,698	6,664	6,512	NA	NA	NA
	Uterus	3,065	3,050	2,980	NA	NA	NA
	Feet	30,436	30,283	29,593	NA	NA	NA

NA: Not available

*Frozen foods only. Chilled foods are not included.

Appendix 3: Prioritization of High Priority Veterinary Drugs in need of Codex MRLs
This is the criterial list porpuse for the participant countries in this first round of comments.

Indications: In the column number 5 "Agreement" please mark with a "X" if the country is agrre or do not about the criterial.

Country	Selection of Criterial	Criterial description	Justification	Agrerment	
				Yes	No
Argentina	Conserve or maintain in the starting list	.Include or Maintain active ingredient of importance for a country /region for which there are not MRLs Codex as a international reference, or regional or national agencies such as EMA or FDA, whose MRLs and tolerances are internationally accepted by developing countries as quoted The RTCA.	The lack of international reference of MRLs is the main problem facing developing countries in conducting a risk analysis for the establishment of national MRLs and withdrawal periods for veterinary drugs.		
Chile	Conserve or maintain in the starting list	Vetrinary Drugs without MRL from CODEX. (Codex scape). Interest in evaluating widely used products without an MRL CODEX	MRL JECFA evaluation, for countries that do not carry out this evaluation		
Chile	Conserve or maintain in the starting list	Maintain Vetrinary drugs without an MRLs by Codex (Codex Scape)	N.I		
Chile	Conserve or maintain in the starting list	Mantain Vetrinary drugs Widely used in animal production systems. Interest in evaluating widely used products without an MRL CODEX	Veterinary drugs with greater use, greater need for definition		
Chile	Conserve or maintain in the starting list	Maintain veterinary drugs which are the only product available for a particular purpose, specific products for a specific disease.	They are of Critical use and therefore it is relevant to have a JECFA evaluation		
Chile	Conserve or maintain in the starting list	Only for antibiotics and their relationship with Antimicrobial resistance and Human use	It is advisable to apply Criterial used by OIE to define criticality of a drug according to document "LIST OF IMPORTANT ANTIMICROBIAL AGENTS FOR VETERINARY MEDICINE"		
Chile	Conserve or maintain in the starting list	Veterinary drugs for species that do not have alternatives, since there are no MRLs. There are species for which there are very few drugs with defined MRLs, as is the case with bees.	It necessary to evaluate this production and the residues of Medicamentos in Matriz Honey. Currently CODEX does not have MRLs for this matrix and international honey trade has increased over time		
Costa Rica	Elimination from the starting list	Exclude veterinary drugs wich that already have MRLs from the JMPR.	The veterinary drug has Codex MRLs from JMPR, which can be used as a reference.	x	
Costa Rica	Elimination from the starting list	Exclude veterinary drugs that have FDA and EMEA MRLs	Our country has Central American regulation to establish the order of adoption of MRLs, which in addition to Codex Alimntarius also includes agencies such as FDA and EMEA.	x	
Costa Rica	Conserve or maintain in the starting list	Maintain veterinary drugs that already have an initial evaluation for some species.	This would be an starting point for JECFA and scientific sponsors for research on other non-traditional species.	x	
Japan	Conserve or maintain in the starting list (Putting in a high priority)	A substance which has already been toxicologically evaluated by JECFA or JMPR.	It seems to be easy to evaluate these compounds, and the availability of data could be promising. The previous JECFA or JMPR toxicological evaluation could be served as a starting point.	X	
Japan	Conserve or maintain in the starting list (Putting in a high priority)	A substance which is being used as veterinary drug for certain food producing animals in several countries, and Codex MRLs in such animal tissues do not exist.	It is meaningful to set MRLs for these compounds to improve food safety and fair practice in food trade.	X	
Japan	Conserve or maintain in the starting list (Putting in a high priority)	A substance whose health concerns and/or food trade implications are identified.	It is meaningful to set MRLs for these compounds to improve food safety and fair practice in food trade .	X	
Panamá	Conserve or maintain in the starting list	Veterinary drugs that have initial evaluation by JECFA in one or more species	The initial assessment would serve as a starting point for JECFA to expand to other species in which it is used.	x	
Panamá	Conserve or maintain in the starting list	Veterinary drugs which has Codex MRLs on specific tissues of one or more matrices	The initial evaluation will serve as a starting point for JECFA to expand the research and establish the MRL for other tissues of interest in species in which it is used.	x	
Panamá	Elimination from the starting list	Veterinary medicinal products that have Codex MRLs in different tissues and species in which they are used	There is no need to update the Codex MRL or further research by JECFA.		
Perú	Conserve or maintain in the starting list	Maintain Vetrinary drugs without an MRLs by Codex	MRL JECFA evaluation, for countries that do not carry out this evaluation		
Venezuela	Conserve or maintain in the starting list	Active principle of importance as a country for which there are no internationally agreed CODEX MRLs	The lack of information on MRLs is one of the major problems in our regions when evaluating a risk analysis.		

N.I: Not indicate

別添 C.2.2

Japan's comments on the draft report on discussion paper on edible offal tissue

Japan appreciates the efforts of Kenya for leading the EWG on edible offal. We would like to provide our comments on this issue.

Japan can support the overall conclusion and the proposed definition of edible offal. Japan thinks that the proposed definition of edible offal is mainly based on morphology, and in this aspect, it would fully cover the all possible organ and tissue to be consumed. However, the CCRVDF also needs to consider it for the purpose of MRL setting as a risk manager. In particular, the following questions need to be addressed:

- What is a representative tissue or organ for establishing MRL in edible offal?
- What data are required for elaborating MRL in edible offal?
- Can the current food consumption data be utilized for JECFA to estimate dietary exposure from edible offal? Additional consumption data is needed?

The eighty-first JECFA conclusion on zilpaterol implied that residue data on edible offal other than liver and kidney and animal metabolism data might be required to recommend MRL in edible offal and to estimate dietary exposure from edible offal. The eighty-first report of the JECFA states, "*The Committee concluded that there were insufficient zilpaterol residue data to adequately consider exposure to residues in lungs and other edible offal of cattle apart from liver and kidney. No non-radiolabelled residue depletion data were provided for any cattle tissues other than liver, kidney and muscle. For lung tissue, there were no actual residue data available in cattle, just estimates based on ratios of plasma versus respiratory tissue radioactivity from preliminary radiolabel studies in rats. For edible offal, the only bovine data available were from a preliminary radiolabel study, with only two data points for tripe at each of the 12- and 48-hour withdrawal periods.*"

~~Therefore~~The issue might be outside the terms of reference of this EWG, so Japan would like to propose that the EWG recommend the CCRVDF to discuss the above-mentioned points to facilitate the discussion on edible offal.

Appendix 4: Application of Criteria to Starting List of High Priority Veterinary Drugs in need of Codex MRLs

Use this sheet to apply the criteria to the starting list.

別添C.2.2

	Starting List of High Priority Veterinary Drugs in Need of Codex MRLs												Must meet both high priority criteria to remain in the list		Must meet at least one of the moderate priority criteria to remain in the list			Low priority criteria for consideration in narrowing the list to ten.		
	Origen/Country	Veterinary Drug Name (active ingredient)	Existing Codex MRLs (CCIVDP)	Food producing species in which this veterinary drug is used	Tissues	Purpose for which this veterinary drug is used in this species	Disease of concern	Evaluation JECFA	COMMENTS	JMPR Evaluation	Codex MRL (CCPR)	Notes on antimicrobial resistance priorities	There are no Codex MRLs for the veterinary drug in the requested species and tissues. (If there are existing MRLs, please indicate which species or tissues for which you need MRLs)	There is a specific human health concern or trade implications associated with this veterinary drug.	This veterinary drug is widely used in animal production systems.	This is the only veterinary drug for a particular purpose or disease. (If yes, please indicate purpose/disease.)	This veterinary drug is for a species with few Codex MRLs. (If yes, please specify species of interest.)	This veterinary drug does not have EMA MRLs or FDA tolerances.	This veterinary drug has a JECFA or JMPR toxicological evaluation.	This veterinary drug has Codex MRLs in other species or tissues.
1	Starting List	Albendazole, albendazole sulfoxide (Ricobendazole), albendazole sulfone	Yes. Adoption in 1993 Not specified	Swine, Horse, Goats and Poultry, Sudamerican camels	Muscle, Liver, Fat, Milk and Kidney.	Antiparasitic agent	Control and prevention of endoparasites	Latest evaluation in 1989											Yes, JECFA	Yes
2	Starting List	Abamectin	Yes. Adoption in 2003 for Cattle	Pig, Horse, Goats and Sheep.	Muscle, Liver, Fat, Milk and Kidney.	Antiparasitic agent	Control and prevention of parasites infections	Latest evaluation in 1989	*Codex Alimentarius is only in Fat, Liver and Kidney of Cattle*	Latest evaluation in 2015. ADI of 0–0.001 mg/kg bw was set. The ADI also applies to the 8,9–Z isomer and the 24-hydroxymethyl metabolite of abamectin.	Plant commodities only								Yes, JECFA and JMPR	Yes
3	Starting List	Amoxicillin, Amoxicillin trihydrate.	Yes. Adoption in 2012 for Cattle, Pig and Sheep	Fish, Goats and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Control of bacterial infections.	Latest evaluation in 2011				WHO Critically Important antimicrobials for human medicine OIE: VCIA			Yes. Used in Japan, U.S., EU, etc.				Yes, JECFA	Yes
4	Starting List	Ampicillin, Ampicillin sodium, Ampicillin trihydrate.	No	Cattle, Pig, Horse, Goats, Sheep, Fish and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of pneumonia and Control of bacterial infections.	No				WHO Critically Important antimicrobials for human medicine OIE: VCIA	Yes, No Codex MRLs in any species		Yes. Used in Japan, U.S., EU, etc.				No	No
5	Starting List	Amitraz	No		Honey (Bees), Muscle, Liver, Fat, Milk and Kidney.	Ectoparasitic	Parasitosis, acariosis	No		Latest evaluation in 1998. ADI of 0.01 mg/kg bw was set.	Plant commodities Cattle* Pigs* Sheep* *The MRL accommodates external animal treatment.		Yes, No Codex MRL in honey			The number of vet drugs for honeybees is limited.			Yes, JMPR	No
6	Starting List	Amprolium	No	Cattle, Pig, Goats, Sheep and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Control of coccidiosis	Prevention and control of coccidiosis.	No					Yes, No Codex MRLs in any species		Yes. Used in Japan, U.S., EU, etc.				No	No
7	Starting List	Bacitracin, Bacitracin Zinc, Bacitracin metilen disilicato	No	Cattle, Pig, Rabbit, Goat, Sheep, Turkey and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of enteric and respiratory diseases	No				WHO Important antimicrobials for human medicine OIE: VHA	Yes, No Codex MRLs in any species		Yes. Used in Japan, U.S., EU, etc.				No	No
8	Added by Appendix 2	Benzylamine	No	Cattle, horse and pig	N.I	Non-steriodal anti-inflammatory	N.I		Veterinary Drug using and register in the country										No	No
9	Added by Appendix 2	Bromhexine	No	Poultry, Cattle and pig	N.I	Mucolytic agent	N.I		Veterinary Drug using and register in the country				Yes, No Codex MRLs in any species						No	No
10	Starting List	Cefalexin	No	Cattle, Pig, Horse, Goat, Sheep and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Antimicrobial, Treatment of enteric and respiratory diseases	No				WHO Highly Important antimicrobials for human medicine OIE: VCIA	Yes, No Codex MRLs in any species						No	No
11	Starting List	Cefquinome	No	Cattle, Pig, Horse and Goat	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Control anf treatment of bacterial infections.	No				WHO Critically Important antimicrobials for human medicine OIE: VCIA	Yes, No Codex MRLs in any species						No	No
12	Starting List	Ceftiofur	Yes. Adoption in 1999 for Cattle and Pig	Horse, Sheep, Goat and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of enteric and respiratory diseases	Latest evaluation in 1997				WHO Critically Important antimicrobials for human medicine OIE: VCIA			Yes. Used in Japan, U.S., EU, etc.				Yes, JECFA	Yes
13	Added by Appendix 2	Ceftriaxone	No	Cattle	N.I	Antimicrobial agent	Control of bacterial infections.		*Veterinary drug register and use in the country*			WHO Critically Important antimicrobials for human medicine OIE: VCIA	Yes, No Codex MRLs in any species						No	No
14	Starting List	Cypermethrin and alfa-cypermethrin	Yes. Adoption in 2006 for Cattle and Sheep	Bees, Pig, Horse, Goat	Honey (Bees), Muscle, Liver, Fat, Milk and Kidney.	Ectoparasitic	Parasitosis, acariosis	Latest evaluation 2004		Latest evaluation in 2005. 0–0.02 mg/kg bw (2006) Group ADI for cypermethrin, including alpha-cypermethrin and zeta-cypermethrin, was set.	Plant commodities mammals other than marine Poultry Milk								Yes, JECFA and JMPR	Yes
15	Starting List	Cloxacillin	No	Cattle, Pig, Horse, Goat, Sheep and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of enteric and respiratory diseases	No				WHO Highly Important antimicrobials for human medicine OIE: VCIA	Yes, No Codex MRLs in any species						No	
16	Starting List	Colistin	Yes. Adoption in 2008 for Goats, Rabbits, Sheep, Turkey, Poultry and Cattle	Pig and Horse	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Growth promoter, Treatment of enteric infection	Latest evaluation in 2006				WHO Critically Important antimicrobials for human medicine OIE: VHA			Yes. Used in Japan, U.S., EU, etc.				Yes, JECFA	Yes
17	Added by Appendix 2	Coumaphos	No	Cattle	Muscle, Liver, Fat, Milk and Kidney.	Antiparasitic agent	Control and prevention of endo/ectoparasites infections	No	MRL by Australia				Yes, No Codex MRLs in any species						No	
18	Starting List	Diminazene	Yes. Adoption in 1997 for Cattle	Cattle, Sheep, and Goats	Muscle, Liver, Fat, Kidney, Milk	Trypanocide	Trypanosomosis	Latest evaluation in 1994											Yes, JECFA	Yes
19	Added by Appendix 2	~~Diproprionate imidocarb~~ Imidocarb	Yes. Adoption in 2005 for Cattle	Cattle and horse	N.I	External antiparasitical agent	N.I		Veterinary Drug using and register in the country				~~Yes. No Codex MRLs in any species~~						Yes, JECFA	Yes
20	Added by Appendix 2	Enramycin	No	Poultry and pig	Muscle, peel+fat, liver, Kidney	Treatment for bacteral infections for gram – or gram +. Activity against *Clostridium Perfringens* .	Necrotic enteritis	No				OIE: VHA	Yes, No Codex MRLs in any species						No	
21	Starting List	Enrofloxacin	No	Cattle, Cuyes, Rabbit, Pig, Horse, Goat, Sheep, Duck, Goose and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of enteric and respiratory diseases	No				WHO Critically Important antimicrobials for human medicine OIE: VCIA	Yes, No Codex MRLs in any species		Yes. Used in Japan, U.S., EU, etc.				No	
22	Added by Appendix 2	Enrofloxacin	No	Shrimp	Tissue	Antimicrobial agent	Infections by bacterial gener as *Vibrio*		Veterinary drug register and use in the country			WHO Critically Important antimicrobials for human medicine OIE: VCIA	Yes, No Codex MRLs in any species						No	
23	Added by Appendix 2	Ethion	No	Cattle	N.I	External antiparasitical agent	N.I		Veterinary Drug using and register in the country	Latest evaluation in 1990. 0–0.002 mg/kg bw was set.	Spices		Yes, No Codex MRLs in any species						Yes, JMPR	
24	Starting List	Fipronil	No	Bees, Cattle, Pig, Cuyes, Goat and Sheep	Honey (Bees), Muscle, Liver, Fat, Milk and Kidney.	Ectoparasitic	Control of ectoparasites	No		Latest evaluation in 2000. 0–0.0002 mg/kg bw Group ADI for fipronil and fipronil-desulfinyl was set.	Plant commodities Cattle Poultry Milk		Yes, No Codex MRLs in any species						Yes, JMPR	
25	Starting List/Added by Appendix 2	Florfenicol	No	Cattle, Cuyes, Rabbit, Pig, Horse, Goat, Sheep, Duck, Goose, Poultry, Shrimp	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Tratamiento de enfermedades entéricas and respiratorias; Infections by bacterial gener as *Vibrio* in shrimp	No	Veterinary drug register and use in the country			WHO Highly Important antimicrobials for human medicine OIE: VCIA	Yes, No Codex MRLs in any species		Yes. Used in Japan, U.S., EU, etc.				No	
26	Added by Appendix 2	Flavofosfolipol	no	Poultry and Cattle	Muscle	Antimicrobial agent	Regulator of intestinal microflora.	No	Priority 3				Yes, No Codex MRLs in any species						No	
27	Starting List	Flumethrin	No	Bees and Cattle	Muscle, Liver, Fat, Milk and Kidney.	Ectoparasitic	Control of ectoparasites	No		Latest evaluation in 1996. ADI of 0.004 mg/kg bw was set. And nowdays is included in tphe priority list (REP17/RVDF, Apendix XI)	Cattle Cattle milk *The MRL accommodates external animal treatment.		Yes, No Codex MRLs in any species						Yes, JMPR	
28	Added by Appendix 2	Fosfomycin	no	Poultry and pig	Muscle	Antimicrobial agent	Treatment of enteric and respiratory diseases by E. coli, Mycoplasma, Salmonella and Pasteurella	No	Priority 2			WHO Critically Important antimicrobials for human medicine OIE: VHA	Yes, No Codex MRLs in any species						No	
29	Added by Appendix 2	Fumagillin	no	Bees	Honey	Antimicrobial agent	nosemosis	No	Because there are not MRL it has autorization to use just in a time with not flow of honey. Priority 1				Yes, No Codex MRLs in any species						No	
30	Starting List	Gentamicin	Yes. Adoption in 2001 for Cattle and Pig	Rabbit, Horse, Goat, Sheep and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of enteric and respiratory diseases	Latest evaluation in 1998				WHO Critically Important antimicrobials for human medicine OIE: VCIA			Yes. Used in Japan, U.S., EU, etc.				Yes, JECFA	Yes
31	Starting List	Ivermectin	Yes. Adoption in 1993 for Cattle, Sheep and Pig	Horse, Goat, Camel and Poultry.	Muscle, Liver, Fat, Milk and Kidney.	Antiparasitic agent	Control and prevention of endo/ectoparasites infections	Latest evaluation in 2015	The actual adoption of JECFA recomendation is						Yes. Used in Japan, U.S., EU, etc.				Yes, JECFA	Yes
32	Added by Appendix 2	Ivermectin	Yes. Adoption in 1993 for cattle, sheep and pig.,	Sheep and pig	Muscle, Liver, Fat, Milk and Kidney.	Antiparasitic agent	Control and prevention of endo/ectoparasites infections	Last evaluation 2015 in Cattle. Previos evaluation for Sheep in 2002.	Re-evaluation for Sheep and pig, considering a new DAI recomending by JECFA 2015										Yes, JECFA	Yes

33	Starting List	Isometamidium Chloride	Yes. Adoption in 1995 for Cattle	Cattle	Muscle, Liver, Fat, Milk and Kidney.	Trypanocide	Trypanosomosis	Latest evaluation in 1992											Yes, JECFA	Yes
34	Added by Appendix 2	Methylparaben	No	Cattle	N.I	External antiparasitical agent	N.I		Veterinary Drug using and register in the country				Yes, No Codex MRLs in any species						No	
35	Starting List	Oxytetracycline	Yes.Adoption in 2003 for Cattle, Pig, Sheep. Oxitetracycline just for Fish and giant shrimp	Bees, Camel, Horse and Goat	Honey (Bees), Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of enteric and respiratory diseases	Latest evaluation in 1998	JECFA recomended this MRL about active ingredient combined or individual			WHO Highly Important antimicrobials for human medicine OIE: VCIA				The number of vet drugs for honeybees is limited.			Yes, JECFA	Yes
36	Added by Appendix 2	Pyrrolidone	No	Cattle	N.I	Antimicrobial agent	N.I		Veterinary Drug using and register in the country				Yes, No Codex MRLs in any species						No	
37	Added by Appendix 2	Propylparaben	No	Cattle	N.I	External antiparasitical agent	N.I		Veterinary Drug using and register in the country				Yes, No Codex MRLs in any species						No	
38	Added by Appendix 2	Progonyr	No	Cattle and pig	Muscle, Liver, Fat, Milk and Kidney.	Antiparasitic agent	Control and prevention of endo/ectoparasites infections	No	MRL by Japan				Yes, No Codex MRLs in any species						No	
39	Starting List	Tiamulin	No	Cattle, Pig, Horse, Goat, Sheep, Turkey and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of enteric and respiratory diseases	No				WHO Important antimicrobials for human medicine OIE: VHIA	Yes, No Codex MRLs in any species		Yes. Used in Japan, U.S., EU, etc.				No	
40	Starting List	Toltrazuril	No	Cattle, Camel, Pig, Rabbit, Goose, Goat, Poultry and Sheep	Muscle, Liver, Fat, Milk and Kidney.	Control of coccidiosis	Prevention and control of coccidiosis,	No	http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Report/2009/11/WC500015632.pdf				Yes, No Codex MRLs in any species						No	
41	Starting List	Trimethoprim	No	Cattle, Ouyes, Rabbit, Camel, Pig, Horse, Goat and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of enteric and respiratory diseases	No	http://www.ema.europa.eu/docs/en_GB/document_library/Maximum_Residue_Limits_-_Report/2009/11/WC500015681.pdf			WHO Highly Important antimicrobials for human medicine OIE: VCIA	Yes, No Codex MRLs in any species						No	
42	Starting List	Tulathromycin	No	Cattle, Pig, Goat, Sheep, and Poultry	Muscle, Liver, Fat, Milk and Kidney.	Antimicrobial agent	Treatment of enteric and respiratory diseases	No				WHO Critically Important antimicrobials for human medicine OIE VCIA	Yes, No Codex MRLs in any species		Yes. Used in Japan, U.S., EU, etc.				No	
43	Added by Appendix 2	Tylvalosin	No	Pig, poultry, turckey and faisans	Muscle and eggs	Antimicrobial agent	Treatment of enteric and respiratory diseases	No				WHO Critically Important antimicrobials for human medicine	Yes, No Codex MRLs in any species						No	

N.I: Not indicate
VCIA: Veterinary Critically Important Antimicrobials
VHIA: Veterinary Highly Important

別添 C3.1.1

GENERAL PRINCIPLES OF FOOD HYGIENE: GOOD HYGIENIC PRACTICES (GHPs) AND THE HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM (HACCP)

INTRODUCTION

1. People have the right to expect the food they eat to be safe and suitable for consumption. Foodborne illness and foodborne injury are unpleasant and in some circumstances can be severe or fatal. But there are also other consequences. Outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation. Food spoilage is wasteful, costly and can adversely affect trade and consumer confidence.

2. International food trade and foreign travel are increasing, bringing important social and economic benefits. But this also makes the spread of illness around the world easier. Eating habits too, have undergone major changes in many countries over the last two decades and new food production, preparation, storage, and distribution techniques have developed to reflect this. Effective food hygiene practices, therefore, are vital to avoid the adverse human health and economic consequences of foodborne illness, foodborne injury, and food spoilage. Everyone, including primary producers, manufacturers and processors, food handlers and consumers, has a responsibility to assure that food is safe and suitable for consumption.

3. This document outlines a framework of general principles that enables competent authorities to oversee food safety and suitability and which should be understood and followed by food business operators (FBOs) at all stages of the food chain. These principles will enable food businesses to develop their own food hygiene systems, taking into account the nature of the operation, relevant hazards, and appropriate control measures, as well as requirements set by competent authorities.

4. Pre-requisite programmes (PRPs) which include Good Hygiene Practices (GHPs), Good Manufacturing Practices (GMP), Good Agricultural Practices (GAP), among others, lay the foundation for producing safe and suitable food. Following a hazard analysis it may be determined that GHPs may be sufficient for some FBOs to control all food safety hazards. Since not all of these hazards pose the same risk, there may be a need to pay particular attention to certain GHPs as hazard control measures in specific circumstances. FBOs without the resources to carry out a hazard analysis may be assisted by HACCP-based systems provided externally.

5. Where a step is identified that controls a significant hazard critical to the safety of food, this step should be designated as a Critical Control Point (CCP) as defined within the *Hazard Analysis and Critical Control Point (HACCP)* System.

6. The first section describes *Good Hygienic Practices for Food Safety and Suitability (GHPs)*. GHPs are the basis of all food hygiene systems to support the production of safe and suitable food. GHPs can be stand-alone food hygiene measures or programs prerequisite to *Hazard Analysis and Critical Control Point* (HACCP) which is described in the second section. HACCP may not be applicable to all type of food businesses, in particular at the stages of primary production. However, the principles of HACCP can be applied to certain activities related to primary production [e.g. administration of veterinary drugs].

OBJECTIVES

7. The *General Principles of Food Hygiene: Good Hygienic Practices (GHPs) and the Hazard Analysis and Critical Control Point (HACCP)* System aims to:

- provide principles and guidance on the application of good hygienic practices applicable throughout the food chain to provide food that is safe and suitable for consumption;
- provide principles on the application of ~~recommend a risk-based approach based on~~ HACCP ~~principles and provide guidance on its application~~;
- clarify the relationship between PRPs, GHPs and HACCP, taking account of the size and nature of the food business operation; and
- provide principles on which sector and product-specific codes of practice are established.

SCOPE

8. This document provides a framework for producing safe and suitable food for human consumption by outlining necessary food safety and hygiene conditions and applying, where appropriate, specific food safety control measures at certain steps throughout the food chain. The document is intended for use by food business operators (including primary producers, manufacturers/processors, food service operators and retailers) and competent authorities, as appropriate.

コメント [豊福肇1]: もう少し説明が必要。外部が HA を行った場合は HACC based system と呼ぶ。

コメント [豊福肇2]: Significant food safety hazard が特定されたら、CCP か enhanced GHP で Control する

書式変更: フォント : 10.5 pt

書式変更: 取り消し線

USE

General

9. This document is generally applicable to competent authorities and food businesses, and provides flexibility to meet the needs of different types of food businesses in the context of international food trade.

10. There will be situations where some of the specific requirements contained in this document are not applicable. The fundamental question in every case is "what is necessary and appropriate on the grounds of the safety and suitability of food for consumption?"

11. The text indicates where such questions are likely to arise by using the phrases "where necessary" and "where appropriate". In practice, this means that, although the requirement is generally appropriate and reasonable, there will be some situations where it is neither necessary nor appropriate on the grounds of food safety and suitability. In deciding whether a requirement is necessary or appropriate, an evaluation of the potential harmful effects to consumers should be made, taking into account any relevant scientific information available. This approach allows the requirements in this document to be flexibly and sensibly applied with a proper regard for the overall objectives of producing food which is safe and suitable for consumption. In so doing it takes into account the wide diversity of food chain practices and varying degrees of risk involved in producing and handling food.

Roles of Competent Authorities, Food Business Operators, and Consumers

12. Competent authorities should decide how best they should apply these general principles through legislation, regulation or guidance to:

- protect consumers from illness or injury caused by contaminated food;
- provide assurance that food is safe and suitable for human consumption;
- maintain confidence in domestically and internationally traded food; and
- provide education which effectively communicates the principles of food hygiene to food business operators and consumers.

13. Food business operators should apply the hygienic practices and food safety principles set out in this document to:

- develop and implement ~~processes~~ food hygiene system ~~rocesses~~ that provide food that is safe and suitable for its intended use;
- ensure food handlers are competent ~~trained~~ as appropriate to their job activities;
- ensure that consumers have clear and easily understood information to enable them to identify the presence of food allergens, protect their food from contamination, and prevent the growth/survival of foodborne pathogens by storing, handling and preparing it correctly; and
- contribute to maintaining confidence in domestically and internationally traded food.
- Develop food safety culture

14. Consumers are expected to follow relevant guidance and instructions for food preparation and apply appropriate food hygiene measures to ensure that their food is safe and suitable for consumption.

GENERAL PRINCIPLES

(i) Food safety hazards shall ~~must~~ be controlled using a preventative approach to ensure food safety and suitability. The approach should consider GHPs alone, and/or GHP and HACCP in an integrated way where relevant.

(ii) GHPs should ensure that food is produced in a sanitary environment in order to reduce the presence of contaminants.

(iii) The application of GHPs should be subject to monitoring, corrective actions, verification and where appropriate, documentation.

(iv) GHPs should provide the foundation for a HACCP system ~~to be effective~~.

(v) The design and implementation of HACCP should ~~can~~ enhance the control of food safety.

(vi) Hazard analysis should identify all hazards associated with the ingredients, the production process and its environment (e.g. equipment and facility, food handlers) and specify the significant hazards that should be controlled to ensure food safety. Hazard analysis should be appropriate to the size and nature of the business.

書式変更: 下線
書式変更: 下線, 取り消し線 (なし)
書式変更: 取り消し線
書式変更: 下線
書式変更: 取り消し線
書式変更: 下線
書式変更: 取り消し線
書式変更: 下線
書式変更: 下線
書式変更: 下線
書式変更: 取り消し線
書式変更: 下線
書式変更: 取り消し線
書式変更: 下線

(vii) Validation of hazard control measures that are critical to achieve an acceptable level of food safety should be science-based (reference to Codex GL 69-2008).

(viii) The application of hazard control measures should be subject to monitoring, verification, corrective actions and ~~where appropriate,~~ documentation.

(ix) Food Safety Control Systems should be reviewed periodically and when there is a change in the food business, *e.g.* new process, new ingredient, new product, new equipment, to determine if modifications are needed.

(x) Communication on food safety and suitability should occur as appropriate across the food chain.

書式変更: 下線

書式変更: 取り消し線

コメント [豊福肇3]: IDF suggested Milk Code を参照に、control measures に関する communication を food chain 全体で行うように書き換え

Definitions

[To be developed based on terms used in Sections 2 and 3]

Pre-requisite programs

Hazard control measure

GENERAL PRINCIPLES OF FOOD HYGIENE: GOOD HYGIENIC PRACTICES (GHPs) AND THE HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM (HACCP)

GOOD HYGIENE PRACTICES

Introduction

1. The establishment, implementation and maintenance of Good Hygienic Practices (GHPs) assist in controlling the introduction of food safety hazards to food products through the work environment and apply from primary production through to handling of the final product. They provide the basic conditions and activities that are necessary to support the production of safe and suitable food at all stages of the food chain. The type of GHPs needed depends on the food sector in which the food business operates and encompasses other equivalent terms including Good Agricultural Practice (GAP) and Good Manufacturing Practice (GMP).

2. Application of GHPs may be sufficient to control all hazards in the operation depending on the size and nature of the food business and the associated risks. Significant food safety hazards identified in the operation should be controlled by hazard control measures, either through application of GHPs designed to control a specific food safety hazard, or where appropriate, through application of HACCP, or a combination of both.

3. Where particular GHPs are designed to reduce significant food safety hazards, but are not at a critical control point step, these are referred to in the Food Safety Control System as ['enhanced GHPs / operational GHPs'], for example, cleaning of a meat slicer to remove or reduce the presence of *Listeria monocytogenes*. Where appropriate, the monitoring of ['enhanced GHPs / operational GHPs'] should be documented and subject to corrective action and verification in line with HACCP principles.

4. GHPs provide the foundation from which HACCP is developed. HACCP is described further in Section #. Annex # also provides further guidance on a simplified implementation of a Food Safety Control System which applies flexibility in the HACCP approach, taking into account the size and nature of the food business.

5. An appropriate location, layout, design, construction and maintenance of premises and facilities are essential for implementation of GHPs and HACCP to be effective.

コメント **[HJ1]:** Suggestion to include a paragraph on flexible approach to HACCP in the Annex

コメント **[HJ2]:** New text to link to concepts introduced in the Intro section

SECTION I: ESTABLISHMENT DESIGN AND STRUCTURE ~~AND FACILITIES~~

OBJECTIVES:
Depending on the nature of the operations, and the risks associated with them, premises, equipment and facilities should be located, designed and constructed to ensure that:

- contamination is minimised;
- design and layout permit appropriate maintenance, cleaning and disinfection~~s~~ and minimise air-borne contamination;
- surfaces and materials, in particular those in contact with food, are non-toxic in intended use and, where necessary, suitably durable, and easy to maintain and clean;
- where appropriate, suitable facilities are available for temperature, humidity and other controls; and
- there is effective protection against pest access and harbourage.

RATIONALE:
Attention to good hygienic design and construction, appropriate location, and the provision of adequate facilities, is necessary to enable hazards to be effectively controlled.

Location of establishment

~~**Establishments**~~

6. Potential sources of contamination need to be considered when deciding where to locate food establishments, as well as the effectiveness of any reasonable measures that might be taken to protect food. Establishments should not be located anywhere where, after considering such protective measures, it is clear that there will remain a threat to food safety or suitability. In particular, establishments should normally be located away from:

• environmentally polluted areas and industrial activities which pose a serious threat of contaminating food;
• areas subject to flooding unless sufficient safeguards are provided;
• areas prone to infestations of pests;
• areas where wastes, either solid or liquid, cannot be removed effectively.

~~**Equipment**~~

~~Equipment should be located so that it:~~
~~• permits adequate maintenance and cleaning;~~
~~• functions in accordance with its intended use; and~~
~~• facilitates good hygiene practices, including monitoring.~~

コメント **[HJ3]:** Incorporated in paragraph below.

~~**PREMISES AND ROOMS**~~

Design and layout of food establishment

7. Where appropriate, the internal design and layout of food establishments and equipment should permit good food hygiene practices, permit adequate maintenance and cleaning, and ~~including~~ protect~~ion~~ against cross-contamination between and during food operations ~~by foodstuffs~~.

8. Where possible, layout should separate between contaminated and 'clean' areas and work areas should be designed to allow one-directional production flow. Where physical separation is not possible, raw and ready to eat food preparation should be separated in time with suitable cleaning and disinfection between uses.

コメント **[豊福肇4]:** 壁、時間差以外にも距離、エアーフロー、ついたてタイプ等 separate する方法はあるはず（byUS）

Internal structures and fittings

9. Structures within food establishments should be soundly built of durable materials, ~~and be~~ easy to maintain, easy to clean and where appropriate, ~~able to be~~ disinfect~~ed~~. In particular the following specific conditions should be satisfied where necessary to protect the safety and suitability of food:

- the surfaces of walls, partitions and floors should be made of impervious materials with no toxic effect in intended use;
- walls and partitions should have a smooth surface up to a height appropriate to the operation;
- floors should be constructed to allow adequate drainage and cleaning;
- ceilings and overhead fixtures should be constructed and finished to minimize the build-up of dirt and condensation~~,~~ and the shedding of particles;
- windows should be easy to clean, be constructed to minimize the build-up of dirt and where necessary, be fitted with removable and cleanable insect-proof screens~~. Where necessary, windows should be fixed~~;
- doors should have smooth, non-absorbent surfaces, ~~and~~ be easy to clean and, where necessary, disinfect;
- work~~ing~~ surfaces that come into direct contact with food should be in sound condition, durable, ~~and~~ easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent, non-toxic materials~~, and inert to the food, to detergents and disinfectants under normal operating conditions.~~

コメント **[豊福肇5]:** 削除文は復帰

Temporary/mobile food ~~premises~~ establishments and vending machines

10. Premises and structures covered here include market stalls, ~~mobile sales and~~ street vending vehicles, temporary premises ~~in which food is handled~~ such as tents and marquees.

11. Such premises and structures should be sited, designed and constructed to avoid, as far as reasonably practicable, contaminating food and harbouring pests. In applying these specific conditions and requirements, any food hygiene hazards associated with such facilities should be adequately controlled to ensure the safety and suitability of food.

FACILITIES

Water supply

12. An adequate supply of potable water with appropriate facilities for its storage, distribution and temperature control, should be available whenever necessary to ensure the safety and suitability of food.

13. Potable water should be as specified in the latest edition of WHO Guidelines for Drinking Water Quality, or water of a higher standard. Non-potable water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food), shall have a separate system. Non-potable water systems shall be identified and shall not connect with, or allow reflux into, potable water systems.

Drainage

14. Adequate drainage and, where necessary, waste disposal systems for fats and oils ~~and facilities~~ should be provided. They should be designed and constructed so that the risk of contaminating food or the potable water supply is avoided.

Waste Disposal

15. Containers for waste, by-products and inedible or ~~dangerous~~ hazardous substances, should be specifically identifiable, suitably constructed, where possible made of impervious material and, closable. ~~and, where appropriate, made of impervious material.~~ ~~Arrangements should be in place to dispose of animal by-products appropriately.~~

16. Containers used to hold hazardous~~dangerous~~ substances should ~~be identified and, where appropriate,~~ be lockable to prevent malicious or accidental contamination of food.

Cleaning

~~15.~~17. Adequate facilities, suitably designated, should be provided for cleaning food, utensils and equipment. Such facilities should have an adequate supply of hot and cold potable water where appropriate. Separate cleaning materials should be used for highly contaminated areas.

Personnel hygiene facilities and toilets

18. Personnel hygiene facilities should be available to ensure that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food. Where appropriate, facilities should include:

- adequate means of hygienically washing and drying hands, including soap, wash basins and a supply of hot and cold (or suitably temperature controlled) water;
- lavatories of appropriate hygienic design ~~which do not open directly into food handling areas~~; and
- adequate changing facilities for personnel.

19. Such facilities should be suitably located and designated. Where necessary ~~possible~~, hand washing and food washing should be done in separate sinks.

~~**4.4.5 Temperature control**~~

~~Depending on the nature of the food operations undertaken, adequate facilities should be available for heating, cooling, cooking, refrigerating and freezing food, for storing refrigerated or frozen foods, monitoring food~~

コメント **[豊福肇6]:** Facilities の water supply と Control of Operation の水は合体させることに合意。また、FAO/WHO による専門家会合を踏まえ修正

コメント **[豊福肇7]:** Too specific なので削除

コメント **[豊福肇8]:** なぜ、動物副生物だけなのか？

コメント **[豊福肇9]:** 削除した部分は復帰（by US）

コメント **[豊福肇10]:** 一次生産を考えると無理、要は汚染の原因とならなければいいのではないか。

~~temperatures, and when necessary, controlling ambient temperatures to ensure the safety and suitability of food.~~

Air quality and ventilation

20. Adequate means of natural or mechanical ventilation should be provided, in particular to:

- minimize air-borne contamination of food, for example, from aerosols and condensation droplets;
- control ambient temperatures;
- control odours which might affect the suitability of food; and
- control humidity, where necessary, to ensure the safety and suitability of food.

21. Ventilation systems should be designed and constructed so that air does not flow from contaminated areas to clean areas and, where necessary, they can be adequately maintained and cleaned.

Lighting

22. Adequate natural or artificial lighting should be provided to enable the undertaking to operate in a hygienic manner. Where necessary, lighting should not be such that the resulting colour is misleading. The intensity should be adequate to the nature of the operation. Lighting fixtures should, where appropriate, be easy to clean and protected to ensure that food is not contaminated by breakages.

Storage

23. Where necessary, adequate facilities for the safe and hygienic storage of food products, food ingredients, food packaging materials and non-food chemicals (including cleaning materials, lubricants, fuels), should be provided.

24. Where appropriate, food storage facilities should be designed and constructed to:
• permit adequate maintenance and cleaning;
• avoid pest access and harbourage;
• enable food to be effectively protected from contamination ~~and cross contamination~~ during storage; and
• where necessary, provide an environment which minimizes the deterioration of food (such as by temperature and humidity control).

25. The type of storage facilities required will depend on the nature of the food. Where necessary, separate, secure, storage facilities for cleaning materials and hazardous substances should be provided.

EQUIPMENT

General

26. Equipment and containers (~~other than once-only use~~except for single-use ~~containers and packaging~~) coming into contact with food, should be designed and constructed and located to ensure that~~, where necessary,~~ they can be adequately cleaned~~,~~ and where necessary, disinfected and maintained to avoid the contamination of food. Equipment and containers should be made of materials with no toxic effect in intended use. Where necessary, equipment should be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection~~, monitoring~~ and~~, for example,~~ to facilitate inspection for pests.

Food control and monitoring equipment

27. In addition to the general requirements in paragraph ~~#~~4.3.1, equipment used to cook, heat treat, cool, store or freeze food should be designed to achieve the required food temperatures as rapidly as necessary in the interests of food safety and suitability, and maintain them effectively.

28. Such equipment should also be designed to allow temperatures to be monitored and controlled. Where necessary, such equipment should have effective means of controlling and monitoring humidity, air-flow and

any other characteristic likely to have a detrimental effect on the safety or suitability of food. These requirements are intended to ensure that:

- harmful or undesirable micro-organisms or their toxins are eliminated or reduced to safe levels or their survival and growth are effectively controlled;
- where appropriate, critical limits established in HACCP ~~based~~ plans can be monitored~~; and~~.
- ~~temperatures and other conditions necessary to food safety and suitability can be rapidly achieved and maintained.~~

SECTION II: CONTROL OF OPERATION

OBJECTIVES:
To produce food that is safe and suitable for human consumption by:
- formulating design requirements with respect to raw materials, composition, processing, distribution, and consumer use to be met in the manufacture and handling of specific food items;
- designing, implementing, monitoring and reviewing effective control systems.

RATIONALE:
To reduce the risk of unsafe food by taking preventive measures to assure the safety and suitability of food at an appropriate stage in the operation by controlling food hazards.

CONTROL OF FOOD HAZARDS

29. Food business operators should control food hazards through the use of integrated systems based on GHPs and, where applicable, ~~such as~~ HACCP. They should:

- identify any food safety hazards in the operation;

• **identify** any steps in their operations which are critical to the safety of food;
• **implement** effective control procedures at those steps;
• **monitor** control procedures to ensure their continuing effectiveness; and
• **review** control procedures periodically, and whenever the operations change.

~~These systems should be applied throughout the food chain to control food hygiene throughout the shelf-life of the product through proper product and process design.~~

~~Control procedures may be simple, such as checking stock rotation calibrating equipment, or correctly loading refrigerated display units. In some cases a system based on expert advice, and involving documentation, may be appropriate. A model of such a food safety system is described in *Hazard Analysis and Critical Control (HACCP) System and Guidelines for its Application* (Annex).~~

30. Application of GHPs may be sufficient to control all hazards in the operation depending on the size and nature of the food business and the associated risks. Significant food safety hazards identified in the operation should be controlled by hazard control measures, either through application of GHPs designed to control a specific food safety hazard, or where appropriate, through application of HACCP, or a combination of both.

コメント [豊福肇11]: Intro とダブり

コメント [豊福肇12]: HACCP との関係で再度要みなおし

KEY ASPECTS OF ~~HYGIENE~~ FOOD SAFETY CONTROL SYSTEMS

Time and temperature control

31. Inadequate food temperature control is one of the most common causes of foodborne illness or food spoilage. Such controls include time and temperature of cooking, cooling, processing and storage. Systems should be in place to ensure that temperature is controlled effectively where it is critical to the safety and suitability of food.

32. Temperature control systems should take into account:
• the nature of the food, e.g. its water activity, pH, and likely initial level and types of micro-organisms;

• the intended shelf-life of the product;
• the method of packaging and processing; and
• how the product is intended to be used, e.g. further cooking/processing or ready-to-eat.

33. Such systems should also specify tolerable limits for time and temperature variations. Temperature recording devices should be checked at regular intervals and tested for accuracy.

Specific process steps

~~34. Other steps which contribute to food hygiene may include, for example:~~
~~• Blast chilling~~
~~• Thermal processing e.g. pasteurisation~~
~~• High pressure processing~~
~~• Irradiation~~
~~• Drying~~
~~• Curing~~
~~• Chemical preservation~~
~~• Vacuum or modified atmospheric packaging~~

Microbiological and other specifications

35. Management systems described in paragraph ## offer an effective way of ensuring the safety and suitability of food. Where microbiological, chemical or physical specifications are used in any food safety control system, such specifications should be based on sound scientific principles and state, where appropriate, monitoring procedures, analytical methods and critical ~~action~~ limits.

コメント **[豊福肇13]:** HACCP の検証としての検査なら、HACCP セクションへ

Microbiological cross-contamination

36. Pathogens can be transferred from ~~one~~ raw foods to ready-to-eat foods~~another~~, either by direct contact or indirectly ~~by~~ via food handlers, contact surfaces, cleaning equipment or through splashing or ~~the~~ airborne particles. Raw, unprocessed food should be physically ~~effectively~~ separated from ready-to-eat foods, or where there is not possible, through time separation of activities with effective cleaning and disinfection of surfaces and equipment in between uses. ~~either physically or by time, from ready-to-eat foods, with effective intermediate cleaning and where appropriate disinfection.~~

37. In some food operations, a~~A~~ccess to processing areas may need to be restricted or controlled. Where risks are particularly high, access to processing areas should be only via a changing facility with strict biosecurity controls. Personnel may need to be required to put on clean protective clothing including footwear and wash their hands before entering.

コメント **[豊福肇14]:** どういう意味か明確にすべき（byUS）

38. Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and ~~where necessary~~ disinfected after raw food preparation, particularly when meat and poultry~~,~~ has been handled or processed.

Physical and chemical contamination

39. Systems should be in place to prevent contamination of foods by foreign bodies such as glass, ~~or~~ metal shards from machinery and~~,~~ dust~~, harmful fumes and unwanted chemicals~~. In manufacturing and processing, suitable detection or screening devices should be used where necessary. Procedures should be in place for food handlers to follow in the case of breakage. Equally systems should be in place to prevent contamination of foods by harmful chemicals.

Allergenic Contamination

40. Allergens are potential hazards and should be considered as part of the food safety control system. Presence of allergens should be identified in food ingredients and products and strict controls put in place to prevent their cross-contamination of other foods. The use of separate production lines and separate storage facilities may be necessary, and cross contamination controls must be adhered to.

コメント **[HJ15]:** New suggested text

INCOMING RAW MATERIALS ~~REQUIREMENTS~~

41. No incoming ~~raw~~ material or ingredient should be accepted by an establishment if it is known to contain parasites, undesirable micro-organisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and/or processing. Where appropriate, specifications for raw materials should be identified and applied.

42. Raw materials or ingredients should, where appropriate, be inspected and sorted before processing. Where necessary, laboratory tests should be made to establish fitness for use. Only sound, suitable raw materials or ingredients should be used.

43. Stocks of raw materials and ingredients should be subject to effective stock rotation.

PACKAGING

44. Packaging design and materials should provide adequate protection for products to minimize contamination, prevent damage, and accommodate proper labelling. Packaging materials or gases where used must be non-toxic and not pose a threat to the safety and suitability of food under the specified conditions of storage and use. Where appropriate, reusable packaging should be suitably durable, easy to clean and, where necessary, disinfect.

WATER

In contact with food

45. Only potable water should be used in food handling and processing, with the following exceptions:

• for steam production, fire control and other similar purposes not connected with food; and
• in certain food processes, e.g. chilling, and in food handling areas, provided this does not constitute a hazard to the safety and suitability of food (e.g. the use of clean sea water).

46. Water recirculated for reuse should be treated and maintained in such a condition that minimize ~~no~~ risk to the safety and suitability of food results from its use. The treatment process should be effectively monitored.

47. Recirculated water which has received no further treatment and water recovered from processing of food by evaporation or drying may be used, provided its use does not constitute a risk to the safety and suitability of food.

As an ingredient

48. Potable water should be used wherever necessary to avoid food contamination.

Ice and steam

49. Ice should be made from water that complies with section ###. Ice and steam should be produced, handled and stored to protect them from contamination.

50. Steam used in direct contact with food or food contact surfaces should not constitute a threat to the safety and suitability of food.

~~**MANAGEMENT AND SUPERVISION**~~

~~The type of control and supervision needed will depend on the size of the business, the nature of its activities and the types of food involved. Managers and supervisors should have enough knowledge of food hygiene principles and practices to be able to judge potential risks, take appropriate preventive and corrective action, and ensure that effective monitoring and supervision takes place.~~

DOCUMENTATION AND RECORDS

51. Where necessary, appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf-life of the product. Documentation can enhance the credibility and

コメント **[豊福肇16]:** 工場内だけではない。一次生産もカバーするので、もと幅広い水を検討する必要あり

コメント **[豊福肇17]:** ~~Zero~~ risk はありえない（by US）

コメント **[HJ18]:** Moved to Section on Training and Management

effectiveness of the food safety control system and demonstrate that all reasonable care and due diligence has been taken to protect the health of consumers.

RECALL PROCEDURES

52. Managers should ensure effective procedures are in place to deal with any food safety hazard and to enable the complete, rapid ~~recall~~ withdrawal of any implicated lot of the finished food from the market. Where a product has been withdrawn because of an immediate health hazard, other products which are produced under similar conditions ~~and~~ which may also present a ~~similar~~ hazard to public health, should be evaluated for safety and may need to be withdrawn. The need for public warnings and a product recall from consumers should be considered.

53. Recalled products should be held under supervision until they are destroyed, used for purposes other than human consumption, determined to be safe for human consumption, or reprocessed in a manner to ensure their safety.

SECTION III: ESTABLISHMENT SANITATION ~~CLEANING AND~~ MAINTENANCE and PEST CONTROL ~~AND SANITATION~~

OBJECTIVES:
To establish effective systems to:

- ensure adequate and effective ~~appropriate~~ maintenance and cleaning procedures;
- control pests; and
- manage waste; ~~and~~

~~– monitor effectiveness of maintenance and sanitation procedures.~~

RATIONALE:
To facilitate the continuing effective control of food hazards, pests, and other agents likely to contaminate food.

General cleaning and maintenance

54. Establishments and equipment should be kept in an appropriate state of repair and condition to:

• facilitate all ~~sanitation~~ cleaning procedures;

• function as intended, particularly at critical steps (see paragraph ~~#5.1~~);

• prevent contamination of food, such as~~e.g.~~ from metal shards, flaking plaster, debris and chemicals.

55. Cleaning should remove food residues and dirt which may be a source of contamination. The necessary cleaning methods and materials will depend on the nature of the food business. Disinfection may be necessary after cleaning.

56. Attention should be paid to hygiene during cleaning and maintenance operations so as not to compromise food safety. Open food should be stored or covered and cleaning products suitable for food contact surfaces should be used in food preparation areas.

57. Cleaning chemicals should be handled and used carefully and in accordance with manufacturers' instructions (e.g. using the correct dilutions) and stored, where necessary, separated from food, in clearly identified containers to avoid the risk of contaminating food.

Cleaning procedures and methods

58. Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow, vacuum cleaning or other methods that avoid the use of water, and chemical methods using detergents, alkalis or acids.

59. Cleaning procedures will involve, where appropriate:

• removing gross visible debris from surfaces;

• applying a detergent solution to loosen soil and bacterial film (cleaning) ~~and hold them in solution or suspension~~;

• rinsing with water (hot water where possible) ~~which complies with section 4#,~~ to remove loosened soil and residues of detergent;

• dry cleaning or other appropriate methods for removing and collecting residues and debris maybe useful in soe operation when water enhance the risk of microbiological contamination; and

コメント [豊福肇19]: Proposal by US

• where necessary, clearing should be followed by disinfection with subsequent rinsing unless the manufacturers' instructions indicate on scientific basis that rinsing is not required.

Cleaning Programmes

60. Cleaning and disinfection programmes should ensure that all parts of the establishment are appropriately clean, and should include the cleaning of cleaning equipment.

61. Cleaning and disinfection programmes should be continually and effectively monitored for their suitability and effectiveness and where necessary, documented.

62. Where written cleaning programmes are used, they should specify:

• areas, items of equipment and utensils to be cleaned;

• responsibility for particular tasks;

• method and frequency of cleaning; and

• monitoring arrangements.

63. Where appropriate, programmes should be drawn up in consultation with relevant specialist expert advisors.

PEST CONTROL SYSTEMS

General

64. Pests pose a major threat to the safety and suitability of food. Pest infestations can occur where there are breeding sites and a supply of food. Good hygiene practices should be employed to avoid creating an environment conducive to pests. Good sanitation, inspection of incoming materials and good monitoring can minimize the likelihood of infestation and thereby limit the need for pesticides.

Preventing access

65. Buildings should be kept in good repair and condition to prevent pest access and to eliminate potential breeding sites. Holes, drains and other places where pests are likely to gain access should be kept sealed. Wire mesh screens, for example on open windows, doors and ventilators, will reduce the problem of pest entry. Animals should, wherever possible, be excluded from the grounds of factories and food processing plants.

Harbourage and infestation

66. The availability of food and water encourages pest harbourage and infestation. Potential food sources should be stored in pest-proof containers and/or stacked above the ground and away from walls. Areas both inside and outside food premises should be kept clean and free of spillages. Where appropriate, refuse should

be stored in covered, pest-proof containers. Any potential harbourage, such as old, ~~disused~~ unused equipment should be removed.

Monitoring and detection

67. Establishments and surrounding areas should be regularly examined for evidence of infestation.

Eradication

68. Pest infestations should be dealt with immediately by a competent person or company and without adversely affecting food safety or suitability. Treatment with chemical, physical or biological agents should be carried out without posing a threat to the safety or suitability of food. The cause should be identified and corrective action taken to prevent a recurrent problem.

Waste Management
~~**6.4 WASTE MANAGEMENT**~~

69. Suitable provision must be made for the removal and storage of waste. Waste must not be allowed to accumulate and overflow in food handling, food storage, and other working areas and the adjoining environment except so far as is unavoidable for the proper functioning of the business.

70. Waste stores must be kept appropriately clean and free of pests.

MONITORING EFFECTIVENESS

71. Sanitation ~~Sanitation Cleaning programmessystems~~ should be monitored for effectiveness and~~,~~ periodically verified, by means such as audits or pre-operational inspections, ~~or,~~ W~~w~~here appropriate, microbiological sampling and testing of the environment and food contact surfaces can verify the effectiveness of cleaning programmes. Cleaning and maintenance procedures should be~~and~~ regularly reviewed and adapted to reflect any change~~sd~~ in circumstances.

72. Cleaning procedures which are [Operational GHPs / Enhanced GHPs] and are hazard-specific should be monitored and subject to corrective action, verification and documentation in line with HACCP principles as appropriate.

SECTION IV: PERSONAL HYGIENE

OBJECTIVES:
To ensure that those who come directly or indirectly into contact with food ~~are not likely to contaminate food by~~:

- maintaining an appropriate degree of personal cleanliness;
- behaving and operating in an appropriate manner.

RATIONALE:
People who do not maintain an appropriate degree of personal cleanliness, who have certain illnesses or conditions or who behave inappropriately, can contaminate food and transmit illness to consumers.

Health Status

73. People known, or suspected to be suffering from or to be a carrier of a disease or illness likely to be transmitted through food, should not be allowed to enter any food handling area if there is a likelihood of their contaminating food. Any person so affected should immediately report illness or symptoms of illness to the management.

74. Medical examination of a food handler should be carried out if clinically or epidemiologically indicated.

Illness and Injuries

75. Conditions which should be reported to management so that any need for medical examination and/or possible exclusion from food handling can be considered, include:

• jaundice;

• diarrhoea;

• vomiting;

• fever;

• sore throat with fever;

• visibly infected skin lesions (boils, cuts, etc.);

• discharges from the ear, eye or nose.

Personal Cleanliness

76. Food handlers should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head covering, and footwear. Cuts and wounds, where personnel are permitted to continue working, should be covered by suitable waterproof dressings.

77. Personnel should wash their hands regularly and ~~always wash their hands~~ when personal cleanliness may affect food safety, ~~for example:~~in particular:

• at the start of food handling activities;

• immediately after using the toilet; and

• after handling ~~raw food, or~~ any contaminated material~~, such as waste. where this could result in contamination of other food items; they should avoid handling ready-to-eat food, where appropriate.~~

Personal Behaviour

78. People engaged in food handling activities should refrain from behaviour which could result in contamination of food, for example:

• smoking;

• spitting;

• chewing or eating;

• sneezing or coughing over unprotected food.

79. Personal effects such as jewellery, watches, pins or other items should not be worn or brought into food handling areas if they pose a threat to the safety and suitability of food.

Personal Hygieneについても、何らかの記録が必要

Visitors

80. Visitors to food manufacturing, processing or handling areas should, where appropriate, wear protective clothing and adhere to the other personal hygiene provisions in this section.

コメント [豊福肇20]: GHP は対象が幅広いので、これでは狭すぎる

SECTION V: TRANSPORTATION

OBJECTIVES:
Measures should be taken where necessary to:

- protect food from potential sources of contamination;
- protect food from damage likely to render the food unsuitable for consumption; and
- provide an environment which effectively controls the growth of pathogenic or spoilage micro-organisms and the production of toxins in food.

RATIONALE:
Food may become contaminated, or may not reach its destination in a suitable condition for consumption, unless effective control measures are taken during transport, even where adequate hygiene control measures have been taken earlier in the food chain.

General

81. Food must be adequately protected during transport. The type of conveyances or containers required depends on the nature of the food and the conditions under which it has to be transported.

Requirements

82. Where necessary, conveyances and bulk containers should be designed and constructed so that they:

• do not contaminate foods or packaging;

• can be effectively cleaned and, where necessary, disinfected;

• permit effective separation of different foods or foods from non-food items where necessary during transport;
• provide effective protection from contamination, including dust and fumes;

• can effectively maintain the temperature, humidity, atmosphere and other conditions necessary to protect food from harmful or undesirable microbial growth and deterioration likely to render it unsuitable for consumption; and

• allow any necessary temperature, humidity and other conditions to be checked.

Use and Maintenance

83. Conveyances and containers for transporting food should be kept in an appropriate state of cleanliness, repair and condition. Where the same conveyance or container is used for transporting different foods, or non-foods, effective cleaning and, where necessary, disinfection should take place between loads.

84. Where appropriate, particularly in bulk transport, containers and conveyances should be designated and marked for food use only and be used only for that purpose.

85. Food should be stored hygienically off the floor ~~and where possible, palletised to facilitate official verification checks.~~

コメント [豊福肇21]: ８４，８５は相反していないか？

SECTION VI: PRODUCT INFORMATION AND CONSUMER AWARENESS

OBJECTIVES:
Products should bear appropriate information to ensure that:

- adequate and accessible information is available to the next person in the food chain to enable them to handle, store, process, prepare and display the product safely and correctly;
- the lot or batch can be easily identified and recalled if necessary.

Consumers should have enough knowledge of food hygiene to enable them to:

- understand the importance of product information;
- make informed choices appropriate to the individual; and
- prevent contamination and growth or survival of foodborne pathogens by storing, preparing and using it correctly.

Information for industry or trade users should be clearly distinguishable from consumer information, particularly on food labels.

RATIONALE:
Insufficient product information, and/or inadequate knowledge of general food hygiene, can lead to products being mishandled at later stages in the food chain. Such mishandling can result in illness, or products becoming unsuitable for consumption, even where adequate hygiene control measures have been taken earlier in the food chain.

Lot identification

86. Lot identification is essential in product recall and also helps effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985, Rev. 1(1991)) applies.

Product Information

87. All food products should be accompanied by or bear adequate information to enable the next person in the food chain to handle, display, store, ~~and~~ prepare and use the product safely and correctly.

Product Labelling

88. Pre-packaged foods should be labelled with clear instructions to enable the next person in the food chain to handle, display, store and use the product safely. Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985, Rev. (1991)) applies.

Consumer Education

89. Health education programmes should cover general food hygiene. Such programmes should enable consumers to understand the importance of any product information and to follow any instructions accompanying products, and make informed choices. In particular consumers should be informed of the relationship between time/temperature control and foodborne illness.

SECTION VII: TRAINING AND MANAGEMENT

コメント [豊福肇22]: Overarching part へ

OBJECTIVE:
Those engaged in food operations who come directly or indirectly into contact with food should be trained, and/or instructed in food hygiene to a level appropriate to the operations they are to perform.

RATIONALE:
Training is fundamentally important to any food hygiene system.
Inadequate hygiene training, and/or instruction and supervision of *all* people involved in food related activities pose a potential threat to the safety of food and its suitability for consumption.

Awareness and Responsibilities

90. Food hygiene training is fundamentally important. All personnel should be aware of their role and responsibility in protecting food from contamination or deterioration. Food handlers should have the necessary knowledge and skills to enable them to handle food hygienically. Those who handle strong cleaning chemicals or other potentially hazardous chemicals should be instructed in safe handling techniques.

Instruction and Supervision

91. The type of supervision needed will depend on the size of the business, the nature of its activities and the types of food involved. Managers and supervisors should have the necessary knowledge of food hygiene principles and practices to be able to judge potential risks and take the necessary action to remedy deficiencies.

92. Periodic assessments of the effectiveness of training and instruction programmes should be made, as well as routine supervision and checks to ensure that procedures are being carried out effectively. ~~Managers and supervisors of food processes should have the necessary knowledge of food hygiene principles and practices to be able to judge potential risks and take the necessary action to remedy deficiencies.~~

Training Programmes

93. Factors to take into account in assessing the level of training required include:

- the nature of the food, in particular its ability to sustain growth of pathogenic or spoilage micro-organisms;
- the manner in which the food is handled and packed, including the probability of contamination;
- the extent and nature of processing or further preparation before final consumption;
- the conditions under which the food will be stored; and
- the expected length of time before consumption.

Refresher Training

94. Training programmes should be routinely reviewed and updated where necessary. Systems should be in place to ensure that food handlers remain aware of all procedures necessary to maintain the safety and suitability of food.

Management Commitment

コメント **[HJ23]:** Addressing the request to consider this aspect

95. Fundamental to the successful functioning of any food safety control system is the commitment from Management to incorporate food safety into the business objectives of the organisation and to communicate the importance of producing safe food, both for the consumer and the business.

Management~~rs~~ should continually improve the effectiveness of the food safety systems in place by:

- ensuring that roles and responsibilities are clearly communicated in the food businesses ~~organisation~~;
- ensuring the availability of resources;
- maintaining the integrity of the food safety management system when changes are planned and implemented;
- ~~conducting Management reviews to~~ verifing that controls are working and documentation is up to date;
- to ensure the appropriate training and supervision is in place for food handlers;
- ensuring compliance with relevant statutory and regulatory requirements; and
- fostering a strong food safety culture within the food businesses ~~organisation~~.

[Drafted by Japan]

Comparison of GHP, Enhanced GHP and CCP

	GHP	Enhanced GHP /~~KCP?~~	Application of CM at a CCP
When applied/identified?	Before hazard analysis., +adaptation after HA	After hazard analysis.	
Scope	• General condition and activities ~~controls~~ to create the environment (both external and internal) for safe food • Not specific to any hazard. but results in • Prevention of contaminants.	Control measures for ~~Specific to~~ significant hazard(s) [in food] and/or processing [environment]. ~~(capture that this could be upgraded from GHP or down grade from CCP)~~	control measures applied at a step that that are critical for significant hazard(s) in food
Validation of the effectiveness of the CM	Generally not needed (insert footnote re case by case basis, Generally not carried out by FBOs themselves) e.g. cleaning products validated for effective used by manufacturer.	Yes, validation should be carried out (~~based on existing validation methods, developed using guidance on validation methods or based on evidence provided by FBO~~) (refer to CAC GL69－2008)	
Criteria	~~Generally~~ ~~Some case, Not applicable?~~ ~~Observable?~~ Some aspects of GHP may have criteria which are measurable or observable considering a wide range of GHP. ~~Yes, where relevant [and feasible] by IDF~~	Criterion measurable or observable which separates acceptable procedure from unacceptable.	Yes Critical limit which separates acceptable products from unacceptable • measureable (e.g.. temperature, pH, Aw), or • observable (e.g.. ~~visual appearance, texture~~). •

[Drafted by Japan]

Monitoring	Yes, where relevant [and feasible]	Yes, but usually non-continuous. Frequency dependent on the operation.	Yes, in real time ● continuous, or ● at frequency sufficient to guarantee CCP in control
Corrective actions when loss of control is indicated	~~Yes, where relevant, but not for products. Usually correct inadequate practice.~~ • For process/procedure: Yes, [where relevant] • For products: usually not relevant, ~~based on the situation evaluation.~~	• For process/procedure: Yes. • For products: Yes, when necessary, based on the situation evaluation.	For process/procedure: Yes, Corrective actions as appropriate to prevent reoccurrence For products: yes, pre-determined actions
Verification	Yes, where relevant, usually scheduled	Yes. Scheduled verification of implementation of control measure and the control system (ref to GL69)	
Record Keeping (monitoring)	Yes, where relevant	Yes	
Documentation	Yes, where relevant	Yes	

COMMENTS FROM THE GOVERNMENT OF JAPAN

GENERAL COMMENT

Throughout the document, the term **"food safety control system"** should be used to indicate "GHP, enhanced GHP and HACCP" instead of **"food hygiene system"** since "food safety control system" is defined in the "Guidelines for the Validation of Food Safety Control Measures (CAC/GL 69-2008)" (Food Safety Control System: the combination of control measures that, when taken as whole, ensures that food is safe for its intended use.) At this moment, there is no definition of "food hygiene system" within Codex, and since we have a defined term "food safety control system" which is very similar to "food hygienic system", we should avoid creating a similar wording.

SPECIFIC COMMENTS

INTRODUCTION

Paragraph 3

3. ~~This document outlines a framework of general principles that enables competent authorities to oversee food safety and suitability and which should be understood and followed by food business operators (FBOs) at all stages of the food chain.~~ These principles will enable food businesses **operators (FBOs)** to develop their own food hygiene systems, taking into account the nature of the operation, relevant hazards, and appropriate control measures, as well as requirements set by competent authorities. **This document outlines a framework of general principles that enables competent authorities to verify food safety and suitability and which should be understood and followed by FBOs at all stages of the food chain.**

Rationale: The primary responsibility of food safety is on the shoulder of FBOs. Therefore, the first target readers of this document are FBOs, and the sentence related to FBOs should come first, followed by the sentence related to competent authorities.

Paragraph 4

4. Prerequisite programmes (PRPs) which include Good Hygiene Practices (GHPs), Good Manufacturing Practices (GMPs), Good Agricultural Practices (GAPs), among others, lay the foundation for producing safe and suitable food. Following a hazard analysis **(see Section xxx in Part 2 (HACCP)),** it may be determined that GHPs may be sufficient for some FBOs to control all food safety hazards. Since not all hazards pose the same risk, there may be a need to pay particular attention to certain GHPs as hazard control measures in specific circumstances. Hazards identified as significant, therefore, should be controlled by hazard control measures either through application of such 'enhanced' GHPs or within a Hazard Analysis and Critical Control Point (HACCP) system. FBOs without the resources to carry out a hazard analysis may ~~be assisted by HACCP-based systems provided externally~~ **use external resources,** e.g. generic HACCP~~-based systems~~ **plans** provided by the competent authority or food industry[1].

Rationale:

1st proposal: Reference should be inserted here to clearly demonstrate the linkage between the Introduction and Part 2 (HACCP).

2nd proposal: "HACCP-based system" can be replaced by a more generic term "Generic HACCP plans" which is clear and easy to understand.

Paragraph 5

5. The first section of this document describes good hygienic practices which are the basis of all food hygiene systems to support the production of safe and suitable food. GHPs can be stand-alone food hygiene measures or programs prerequisite to *Hazard Analysis and Critical Control Point* (HACCP) which is described in the second ~~section~~ **Part**. ~~HACCP may not be applicable to all types of food businesses,~~ **Though certain types of FBOs may face difficulties to implement HACCP, HACCP can basically be applied throughout the food chain from primary production to final consumption and its implementation should be guided by scientific evidence of risks to human health.** ~~in particular at the stages of primary production, the principles of HACCP can be applied to certain activities related to primary production, e.g. administration of veterinary drugs.~~

Rationale: We believe that HACCP can be applied throughout the food chain from primary production to final consumption. This is the first principle (see the 3rd paragraph in "PREAMBLE", Part 2). With regards to the proposal of deletion in the end of paragraph, we think this is too specific and could be added in the introduction of the HACCP part.

Paragraph 13

13. Consumers ~~are expected to~~ **should play their roles by** follow**ing** relevant guidance and instructions for food preparation and apply**ing** appropriate food hygiene measures to ensure that their food is safe and suitable for consumption.

Rationale: The role of consumer should be more clearly indicated in this paragraph.

GENERAL PRINCIPLES

(i) Food safety hazards (biological, chemical, physical) should be controlled using a preventative approach to ensure food safety and suitability.

(ii) GHPs should ensure that food is produced in a sanitary environment in order to reduce the presence of contaminants.

(iii) GHPs should provide the foundation for a HACCP system to be effective.

~~(iv) [The design and implementation of HACCP should enhance food safety.]~~

Rationale: The principle (v) and new proposal (v) bis cover the old principle (iv) more clearly.

(v) Hazard analysis should identify all hazards associated with the ingredients, the production process and its environment (e.g. equipment and facility) and specify the significant hazards that should be controlled to ensure food safety. Hazard analysis should be appropriate to the size and nature of the business.

(v)bis. Significant hazards should be controlled by hazard control measures.

Rationale: This principle is logical, and a bridge between principle (v) and (vi). During hazard analysis, if significant hazards are identified, then they should be controlled by hazard control measures.

(vi) Hazard control measures that are critical to achieve an acceptable level of food safety should be scientifically validated[2]**.**

(vii) The application of hazard control measures should be subject to monitoring, corrective actions, verification, and documentation, as appropriate.

(viii) Food Hygiene Systems should be reviewed periodically and when there is a change in the food business, *e.g.* new process, new ingredient, new product, new equipment, to determine if modifications are needed.

(ix) Communication on food safety and suitability should be maintained between all relevant parties as appropriate to ensure the integrity of the entire food chain.

Part 1 – GOOD HYGIENE PRACTICES

Introduction

~~Where this section refers to food establishments, this includes primary production settings as appropriate.~~

Rationale: We propose to delete this sentence and to restore the entire "SECTION III-PRIMARY PRODCUTION" since Section III-Primary Production includes recommendations specific to primary production stage and is heavily referred to by various Codex texts related to food hygiene, including Code of Hygienic Practices for Fresh Fruits and Vegetables (CAC/RCP 53-2003). This proposal is in line with the decision made during the in-session WG at the CCFH 48 (see A3, CRD 14 of 48th CCFH).

Design and layout of food establishments

The internal design and layout of food establishments and equipment should permit good food hygiene practices, permit adequate maintenance and cleaning, and protect against cross-contamination between and during food operations.

~~Where possible, layout should provide physical separation (e.g. walls) between contaminated and clean areas.~~ **The clean areas and dirty areas should be separated to minimize cross-contamination** ~~Work areas should be designed to allow one-directional production flow. Where physical separation is not possible,~~ **through** measures such as **physical separation (e.g. walls),** location (e.g. distance), partitions, traffic flow **(e.g. one-directional production flow)**, airflow, and separation in time, with suitable cleaning and disinfection between uses~~, should be used to prevent contamination~~.

Rationale: The concept and purpose of clean/dirty arrears should be described first. The ways/means of the separation could be various depending on the nature and size of food business, so should not be so specific. Physical separation or one-directional

production flow are examples of the measures to minimize the cross-contamination and can be listed with other measures.

Internal structures and fittings, the last bullet point

- work surfaces that come into direct contact with food should be in sound condition, durable, easy to clean, maintain and disinfect. They should be made of smooth, non-absorbent, non-toxic materials**, and inert to the food, to detergents and disinfectants under normal operating conditions**.

Rationale: We believe the last part should be kept since this concept is not captured in the current draft.

Cleaning and washing facilities

Adequate facilities, suitably designated, should be provided for **washing food**, cleaning utensils and equipment coming into contact with food. Such facilities should have an adequate supply of hot and cold potable water where appropriate.

Separate cleaning equipment, suitably designated, should be used for highly contaminated areas, e.g. toilets.

Rationale: The facility to wash food should also be provided.

KEY ASPECTS OF HYGIENE CONTROL ~~SYSTEMS~~

~~Hazard identification should take into account the allergenic nature of some foods.~~ Presence of allergens e.g. nuts, milk and cereal grains should be identified in food ingredients and products and controls should be put in place to prevent their presence in foods where they are not labelled. Controls to prevent cross-contact of foods containing allergens with other foods should be implemented e.g. separate storage facilities. Where cross-contact cannot be guaranteed, consumers should be informed.

Rationale: We propose to delete the first sentence and add the sentence “Allergenic nature of foods should also be taken into consideration.” under the section “6. List All Potential Hazards ….” in Part 2 (HACCP guidelines).

INCOMING MATERIALS

Incoming materials including food ingredients should be purchased according to specifications and their compliance with these specifications should be verified. No ~~raw~~ **incoming** material should be accepted by an establishment if it is known to contain chemical, physical or microbiological hazards which would not be reduced to an acceptable level by normal sorting and/or processing.

~~Raw~~ **Incoming** materials or ingredients should, where appropriate, be inspected and sorted before processing. Where necessary, laboratory tests should be made available to establish fitness for use.

Stocks of ~~raw~~ **incoming** materials and ingredients should be subject to effective stock rotation.

Rationale: Editorial.

Water in contact with food

The quality of water used in primary production may vary. For additional information on water for primary production, see **relevant Codex texts, e.g.** ~~section 3.2.1.1 in~~ the Code of Hygienic Practice for Fresh Fruits and Vegetables (CAC/RCP 53-2003) **and the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003)**.

Rationale: The information on water for primary production is provided in several Codex documents.

Monitoring Effectiveness

Sanitation programmes should be monitored for effectiveness and periodically verified by means such as audits or pre-operational inspections. Where appropriate, microbiological sampling and testing of the environment and food contact surfaces should be carried out to verify the effectiveness of cleaning programmes. ~~Cleaning~~ **Sanitation** and maintenance procedures should be regularly reviewed and adapted to reflect any changes in circumstances and documented as appropriate.

Rationale: Editorial.

Lot identification

Lot identification is essential in product recall**/withdrawal** and also helps effective stock rotation. Each container of food should be permanently marked to identify the producer and the lot. Codex General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985, Rev. 1(1991)) applies.

A traceability/product tracing system should be designed and implemented according to the *Principles for Traceability/Products tracing as a tool within a Food Inspection and Certification System* (CAC/GL 60-2006), especially to enable the **product recall/**withdrawal ~~of the products~~, where necessary.

Rationale: To be consistent with the term used in the footnote 6 in the "*Principles for Traceability/Products tracing as a tool within a Food Inspection and Certification System* (CAC/GL 60-2006)".

Management Commitment

~~Managers~~**Top management** should continually improve the effectiveness of the food ~~hygiene~~ **safety control** system in place by:

- ensuring that roles and responsibilities are clearly communicated in the food business;
- ensuring the availability of resources;

- maintaining the integrity of the food ~~hygiene~~ **safety control** system when changes are planned and implemented;
- verifying that controls are working and documentation is up to date;
- ensuring the appropriate training and supervision is in place for personnel;
- ensuring compliance with relevant statutory and regulatory requirements; and
- ~~enable~~ **enabling** a strong food safety culture by demonstrating commitment to providing safe and suitable food and encouraging appropriate food safety behaviours.

Rationale:

1st proposal: Just for clarity. The term "manager" is not defined, and may mean different level in the food business. In this section, it should be clear that these roles are under the top management.

2nd & 3rd proposals: See our "General comments"

4th proposal: For grammatical consistency.

Part 2 – HACCP SYSTEM AND GUIDELINES FOR ITS APPLICATION

DEFINITIONS

~~***[Hazard Control Plan]:*** A document prepared in accordance with the principles of HACCP which identifies appropriate control measures to ensure control of hazards which are significant for food safety in the operation.~~

[HACCP plan: ~~A hazard control plan which has identified critical control points~~.] **A document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration.**

Rationale: We think the original definition of HACCP plan in the current Codex HACCP annex is appropriate, and do not feel the necessities to change it.

Hazard: A biological, chemical or physical agent in, ~~or condition of,~~ food with the potential to cause an adverse health effect.

Rationale: We recall that there was a general consensus on this deletion in the previous eWG on HACCP and so reflected in the proposed draft document (see para 9 of the CX/FH 16/48/5).

1. ASSEMBLE HACCP TEAM

Where such expertise … HACCP in house. Alternatively, generic HACCP ~~based systems~~ **plan** developed externally may be used by FBOs where appropriate and should be tailored to the food operation.

Rationale: See above.

2. DESCRIBE PRODUCT

A full description of the product should be drawn up, including reletant safety information such as: composition, physical/chemical structure (including Aw, pH, etc.), microcidal/static treatments (heat-treatment, freezing, brining, smoking, etc.), packaging, durability and storage conditions and method of distribution. Within businesses with multiple products, for example, catering operations, it may be effective to group products with similar characteristics or processing steps, for the purpose of development of the HACCP plan. ~~Any critical limits already established for food safety hazards should be considered and accounted for in the HACCP plan, e.g. regulatory limits applied to fresh poultry.~~

Rationale: The last sentence should be moved to "8. ESTABLISH CRITICAL LIMITS FOR EACH CCP".

4. CONSTRUCT FLOW DIAGRAM

Comment: We propose to keep the current "12 Steps" structure (i.e., Step 4 and Step 5 should not be merged).

6. LIST ALL POTENTIAL HAZARDS ASSOCIATED WITH EACH STEP, CONDUCT A HAZARD ANALYSIS, AND CONSIDER ANY MEASURES TO CONTROL IDENTIFIED HAZARDS

Based on the information collected in the step 2 to 5 above, the HACCP team (see "assemble HACCP team" above) should list all of the hazards that may be reasonably expected to occur at each step according to the scope from primary production, processing, manufacture, and distribution until the point of consumption.

Rationale: The interrelation between preliminary information collected during the steps 2 to 5, and hazard analysis should be stated here.

In conducting the hazard analysis, wherever possible the following should be included:

· the likely occurrence of hazards and severity of their adverse health effects;

· the qualitative and/or quantitative evaluation of the presence of hazards ;

· survival or multiplication of micro-organisms of concern;

· production or persistence in foods of toxins, chemicals or physical agents; and,

· conditions leading to the above**;**

· **allergenic nature of some foods.**

Rationale: Pease refer to our comment on "KEY ASPECTS OF HYGIENE CONTROL SYSTEMS" above.

In some cases, it may be acceptable for a more basic hazard ~~examination~~ **analysis** to be carried out by FBOs which identifies groups of hazards (microbiological, physical, chemical**, allergen**) to control the sources of these hazards without the need for a full hazard analysis. Generic HACCP~~-based tools~~ **plans** provided externally, for example, by industry or regulators, are designed to assist with this step.

Rationale:

1st proposal: We should avoid creating a new term "hazard examination". In this sentence, "hazard analysis" is appropriate.

Allergen should be added as a group of hazard.

8 ESTABLISH CRITICAL LIMITS FOR EACH CCP

Critical limits should be scientifically validated to obtain evidence that hazard control measures, if properly implemented, are capable of controlling hazards to an acceptable level. **When the result of the validation study shows that critical limit(s) is (are) not effective, the food safety team should modify the control measure(s) and critical limit(s).** FBOs may not always need to commission studies themselves to validate control measures. They could be based on existing literature or carried out by a third party e.g. cleaning products validated for effective use by the manufacturer. **Any critical limits already established for food safety hazards should be considered and accounted for in the HACCP plan, e.g. regulatory limits applied to fresh poultry.**

Rationale:

1st proposal: We feel that the action to be taken when the results of the validation study shows that critical limit(s) is (are) not effective should be added here.

2nd proposal: Please see our comment on the "2. DESCRIBE PRODUCT" above.

9. ESTABLISH A MONITORING SYSTEM FOR EACH CCP

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures ~~must~~**should** be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in ~~real-~~time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.

Rationale:

1st proposal: In Codex guideline documents, we should use "should" instead of "must".

2nd proposal: In the context of this sentence, it should be "in time" (i.e., information should be available to make adjustments without delay), not "in real-time".

Comments of Japan

on the Proposed Draft Revision of the General Principles of Food Hygiene

at Step 3 (CX/FH 17/49/5)

The Government of Japan is pleased to submit the following comments on the Proposed Draft Revision of the General Principles of Food Hygiene for consideration at the forthcoming 49th Session of the Codex Committee on Food Hygiene.

General Comments

- We recall that one of the main objectives of this new work (the revision of GPFH and HACCP guidelines) was to assist SLDBs in the implementation of food hygiene principles, and we would like to emphasize that we should continue our work bearing that point in mind and keep the texts as simple and user-friendly as possible.
- In line with the above comment, we believe that we should keep the original structure as much as possible as agreed before.
- Though we generally understand the concept of so-called "enhanced-GHPs", we have some doubts about the usefulness to fully elaborate this concept as one of the three pillars (together with GHP and CCP) in the Codex texts as it might create more confusions especially among SLDBs. Briefly touching upon the concept in the HACCP chapter might be sufficient.
- We propose to restore the entire section on primary production since that section included recommendations specific to primary production stage and is heavily referred to by various Codex texts related to food hygiene, including Code of Hygienic Practices for Fresh Fruits and Vegetables (CAC/RCP 53-2003). This proposal is in line with the decision made during the in-session WG at the CCFH 48 (See A3, CRD 14 of 48th CCFH).

Specific Comments

INTRODUCTION

Comment: We find that INTRODUCTION part well describes the relationship between GHP and HACCP.

Para 4A:

Comment: We support the Option 4A.

Rationale: There are cases where we can determine GHPs are sufficient for some FBOs to control all food safety hazards without conducting hazard analysis by referring existing models or guidance etc. Also, we oppose introducing a new concept of "basic" hazard analysis (as in Option B) since it might create another argument about what is basic, and what isn't.

Para 4B, Annex1:

Comment: We propose to delete this decision tree.

Rationale: The flow of the tree is not logical as it is and rather confusing.

Para 6, Comparison Table:

Comment: We propose to keep this comparison table in square brackets during the work and to decide its fate (keep it or delete it) upon completion of the text.

Definitions, "Food hygiene system" and "Food safety control system":

Comment: We propose to consider whether the Committee should create a new term to cover GHP, enhanced GHP (if the CCFH agrees) and HACCP. The proposed term in the draft "food hygiene system" may cause confusions since HACCP covers more than food hygiene. One quick fix could be to use the existing term "food safety control system" as a term encompassing both hygiene practices and control measures.

Chapter 1 (GOOD HYGIENE PRACTICES)

Comment: It would be desirable to construct this chapter in a manner that this chapter alone would suffice in order for FBOs without the need for conducting a hazard analysis to apply essential food hygiene control.

PRIMARY PRODUCTION:

Comment: We propose to restore the entire section on primary production.

Rationale: Refer to the General Comments.

Para 28-33:

Comment: We propose to move the paragraphs 28-33 to the HACCP section to maintain the original format and structure as much as possible as agreed before.

Rationale: Refer to the General Comments.

PEST CONTROL SYSTEMS, Monitoring and detection:

Comment: We do not see the clear necessity to further elaborate the text on monitoring and detection of pests.

Rationale: Major pests, trends, key areas of infestation etc. should be different depending on the type of food or facility.

SECTION IV: PERSONAL HYGIENE
OBJECTIVES:

To ensure that those who come directly or indirectly into contact with food:
- ~~Maintain~~ **maintain** appropriate personal health;
- maintain~~ing~~ an appropriate degree of personal cleanliness; and
- behave and operate in an appropriate manner.

Rationale: Editorial.

SECTION VI: PRODUCT INFORMATION AND CONSUMER AWARENESS
OBJECTIVES, 5th line~:

Consumers should have enough knowledge of food hygiene to enable them to:
- understand the importance of product information;
- make informed choices appropriate to the individual; and
- prevent contamination and growth or survival of foodborne pathogens by storing, preparing and using it correctly

The WHO Five Keys to Safer Food assists in this process.
Information for industry or trade users…

Rationale: We believe that the WHO Five Keys are useful educational tools for consumers and already referred to in other Codex food hygiene-related documents.

Chapter 2 (HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEM AND GUIDELINES FOR ITS APPLICATION)

Para 5:

Comment: We support the introduction of this paragraph.

Rationale: It would be a realistic approach for SLDBs, who have difficulties in fully introducing HACCP system in accordance with 12 steps, to utilize external resources (such as existing models, guidance etc.), and then gradually adapt it to suit their own facilities' situation.

Para 33:

Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures should be able to detect loss of control at the CCP. Further, monitoring should ideally provide this information in ~~real-~~time to make adjustments to ensure control of the process to prevent violating the critical limits.

Rationale: From a logical perspective, this should be "in-time", not "in real-time". (i.e., Information should be available in time to make necessary adjustments before actual loss of control at CCPs occurs.)

别添 C3.3.1

CCFH Histamine EWG 2017
3rd draft of Proposed Draft Revision of the Code of Practice for Fish and Fishery Products
New section [X] for fish at risk for scombrotoxin formation

~~[Table of contents (temporary to facilitate review):~~

Proposed draft:

SECTION [X] – HARVESTING, PROCESSING, STORAGE AND DISTRIBUTION OF FISH AND FISHERY PRODUCTS AT RISK FOR SCOMBROTOXIN (HISTAMINE) FORMATION

Preamble

This section complements other sections of the Code by providing detailed control recommendations for the prevention of scombrotoxin fish poisoning (SFP). This section only applies to specific marine finfish species (listed in Annex [Z]) at risk of developing hazardous levels of histamine.

~~Hazard Analysis and Critical Control Point (HACCP) systems and their prerequisite programmes are used to control the SFP hazard. Refer to Section 5 and Section 3 of this Code for guidelines on developing and using HACCP and prerequisite programmes. On fishing vessels that have not~~

~~adopted HACCP, equivalently effective good manufacturing practices (GMPs) may be used.~~ This section contains specific guidelines for preventing SFP; however, within the scope of this Code, it is not possible to provide all the appropriate controls and alternatives that may apply to every operation because these will vary with each particular operation.

Scombrotoxin fish poisoning (SFP) is a worldwide food safety challenge that, in some parts of the world, accounts for the largest proportion of fish-borne illness cases. Individuals suffering from SFP may show one or more symptoms including flushing, swelling, rash, itching, headache, heart palpitations, abdominal cramps, diarrhea, and vomiting. In some cases, exacerbation of asthma and more serious cardiac manifestations may occur. Symptoms typically develop rapidly (from 5 minutes to 2 hours after ingestion of implicated fish), with a usual duration of 8–12 hours, although symptoms may persist for up to several days. SFP is ~~considered to be~~ rarely~~, if ever,~~ fatal.

Scombrotoxin fish poisoning is caused by the ingestion of certain species of marine fish (listed in Annex [Z]) that have been allowed to develop biogenic amines such as histamine. These species generally contain high levels of free histidine in their musculature and are more likely to form hazardous levels of histamine after death when subjected to time-temperature abuse.

Although detailed components of scombrotoxin have not been identified, it is generally accepted that biogenic amines produced by spoilage bacteria, especially histamine, play an important role in the pathogenesis of SFP. Other biogenic amines that are also produced during fish spoilage, such as cadaverine and putrescine, are thought to increase the toxicity of histamine. However, in most epidemiological studies, SFP is associated with high histamine levels in the ~~associated~~ implicated fish, and the controls used to inhibit histamine-producing bacteria and enzymes are also expected to be effective at preventing the formation of other biogenic amines. Therefore, histamine serves as a useful indicator compound for scombrotoxin, and histamine is monitored for scombrotoxin control purposes.

Histamine is produced in fish and fishery products by spoilage bacteria that are part of the natural microflora of the skin, gills, and gut of freshly caught fish. After the fish die, these bacteria migrate into the previously sterile fish musculature where they multiply if time and temperature are not controlled. When histamine-producing bacteria multiply in fish flesh, they produce ~~the enzyme~~ histidine decarboxylase enzymes (HDC), which convert~~s~~ naturally present histidine into the toxic metabolite histamine.

Rapid multiplication of histamine-producing bacteria can be prevented by chilling fish immediately after death and maintaining the fish in a chilled, or frozen, state from harvest to consumption. However, once sufficient bacterial multiplication has occurred to produce histidine decarboxylase, enzymatic activity can continue to ~~slowly~~ produce histamine slowly at refrigeration temperatures.

コメント **[A1]:** US comment.

コメント **[A2]:** Co-chair: Awkward sentence. It is either rarely fatal or never fatal.

コメント **[A3]:** US comment

コメント **[A4]:** Co-chair: To introduce abbreviation shown later, and to indicate that there is more than one HDC.

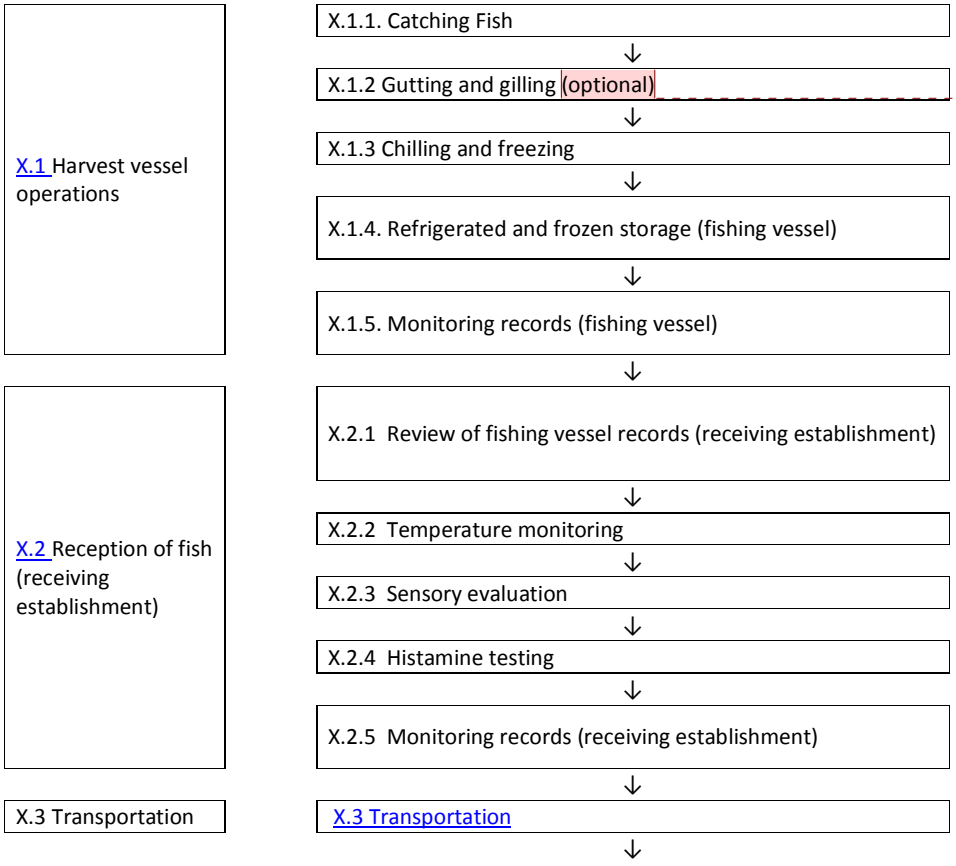
Histamine formation is effectively controlled by adherence to good manufacturing practices to maintain hygienic quality of fish, and by using HACCP principles to control detrimental fish time- ~~and~~ temperature exposure.

The following subsections contain technical guidance for the control of histamine formation at key steps in the food chain (harvesting, receiving, transportation, and processing~~, and retail~~ operations).

The relevant guidelines in subsection X.1 (Harvest vessel operations) also apply to the harvest of aquacultured fish.

Figure X.1. Example flow chart for the production of fish at risk of scombrotoxin formation.

This flow chart is for illustrative purposes only. For implementation of HACCP principles, a complete and comprehensive flow chart has to be drawn up for each product.



コメント **[A5]:** NZ comment

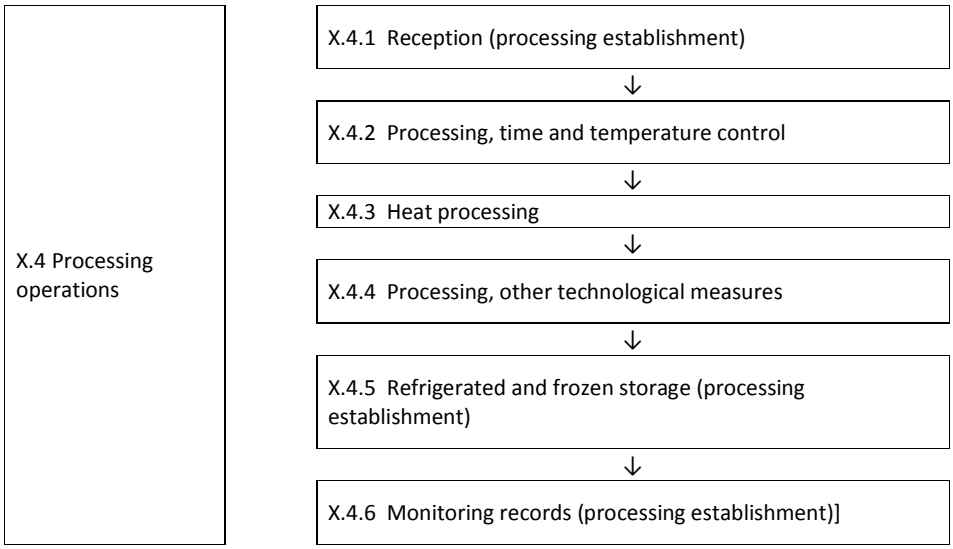
コメント **[A6]:** In response to comment from NZ, changing to "time-temperature" in most places throughout document to be consistent.

コメント **[A7]:** NZ comment

コメント **[A8]:** Aquaculture added in response to comment from Singapore.

コメント **[A9]:** Text parallels Figure 7.1 (Bivalve mollusc flow chart)

コメント **[A10]:** Brazil comment



X.1 Harvest vessel operations

Fishers use many different harvesting methods throughout the world, employing hooks, nets, and traps. ~~in w~~Waters and environmental ~~at different~~ temperatures vary depending on geographic location and season. In all cases, live retrieval or quick retrieval of dead fish, rapid chilling of the fish in a timely manner, and maintenance of the fish at ~~inhibitory~~ cold temperatures, are critical to prevent ~~inhibit~~ histamine formation ~~in freshly harvested fish~~.

Time for histamine formation can vary substantially at the same temperature because different histamine-producing bacteria with different histamine-producing activity may be present. Time ~~and~~ temperature critical limits should take into account ~~for~~ the potential ~~of~~for histamine production under the worst case conditions for the particular operation.

The fishing ~~boat~~vessel ~~,~~and equipment, and the methods used, should be designed or adapted to ~~control~~prevent histamine formation for the catch sizes, fish sizes, fish species, and air and water temperatures encountered. Vessel crews should be trained in ~~the~~ hygienic practices and temperature control methods and understand their importance, and responsible crew members should be trained in HACCP principles used to control histamine formation, where possible.

Use of HACCP principles to control fish time-temperature exposure on the harvest vessel is an effective means to prevent hazardous levels of histamine formation, and ~~preferable to~~provides better consumer protection than the alternative approach of testing ~~for~~ histamine levels in fish after delivery. ~~Where onboard record-keeping is impractical, such as for small artisanal day~~

コメント **[A11]:** NZ and US comments

コメント **[A12]:** US comment

コメント **[A13]:** NZ comment

コメント **[A14]:** NZ comment

コメント **[A15]:** Morocco comment

コメント **[A16]:** Change in response to comment from Morocco.

コメント **[A17]:** US comment (with slight modification)

~~boats, the operation that receives the fish from the day boat may be able to obtain the appropriate fishing trip information in order to monitor histamine control for the boat.~~

コメント **[A18]:** Co-chair: Line removed from X.1 because redundant with similar line in section X.1.5 Monitoring records (harvest vessel), where subject is a better fit.

X.1.1 Catching fish

- The time period that nets or hooks are left in the water, and the number and rate of fish caught, should be optimized to allow live landing of fish where practical.
- If captured fish are held in the sea for too long following death, decomposition commences, and histamine can begin to form. The warmer the seawater, the more rapid the decomposition and the greater the risk of histamine formation. Dead fish that exhibit marginalized quality attributes, consistent with ~~deleterious~~exposure to time-~~/~~temperature abuse, ~~exposures~~ should not be ~~brought~~retained on board the vessel, or, if retained, should be segregated and ~~labelled~~identified properly to allow testing and proper disposition when off-loaded. In addition, the harvesting methods should be modified in a way that no dead fish with marginal quality will be brought on board.
- Before landing fish, the deck area and equipment should be hygienically cleaned to avoid contamination of fish (see Section 3.4 Hygiene control program), and the chilling medium should be ready and at the target temperature.
- Fish should be removed from nets and hooks as quickly as possible to prevent death or to minimize the period from death until chilling of the fish.
- Critical limits should be established for the time period between death of the fish and the start of chilling that will effectively prevent histamine production. Time of death of the fish may be the time slaughtered onboard, or where the actual time of death is not observed or truly known, an estimated time based on an observable event, such as the time of deployment of a longline when some of the fish are landed dead ~~and the actual time of death is not observed or truly known~~.
- The time period between death of fish and chilling that will effectively prevent histamine formation can vary based on the ocean and air temperatures encountered, the sizes and species of fish caught, and other relevant factors particular to the harvesting operation. See the FAO/WHO Expert Report (Section 6.1.1 Chilling)[1] for further guidance on establishing time-~~/~~temperature critical limits for fish after death.
- The rate or volume of catch should not exceed the ability of the crew to quickly initiate chilling, and should not exceed the capability of the vessel's chilling system to maintain critical limits for cooling media temperature, or sufficiency of ice.
- Rough handling, overcrowding and over stacking of fish should be avoided where practical because crushing, bruising, and lacerations of the skin accelerate the spread of histamine-producing bacteria from the gut, gills, and skin into the fish musculature.

X.1.2 Gutting and gilling (optional)

コメント **[A19]:** NZ comment

コメント **[A20]:** US comment

コメント **[A21]:** Brazil comment

コメント **[A22]:** NZ comment

コメント **[A23]:** Brazil comment

[1] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.1.1 Chilling.) Link: http://www.fao.org/fileadmin/user_upload/agns/pdf/Histamine/Histamine_AdHocfinal.pdf

- Histamine-producing bacteria are universally present in the gut, gills, and skin of fish at the point of capture. Rapid removal of guts and gills, and rinsing of the gut cavity, significantly delays histamine formation in the muscle.
- For large fish, removing the gut aids chilling by allowing chilling media (e.g. ice, refrigerated seawater) access to the visceral cavity, resulting in more rapid chilling of this bacteria-laden region of the fish.
- Care should be taken and hygienic practices should be maintained during gutting and gilling in order to minimize the spread of bacteria from the guts, gills, skin, and other contamination sources, into the muscle tissue.

X.1.3 Chilling and freezing

Rapid chilling as soon as possible after death is the most crucial aspect of histamine control because bacterial growth and histamine formation accelerate exponentially with time under unrefrigerated conditions. Few prolific histamine-producing bacteria will grow and multiply at refrigeration temperatures, and the growth rates of those that do are much reduced.

- Sufficient ice to completely surround each fish, or preferably, ice/seawater slurries or refrigerated seawater (RSW) should be used to bring the internal temperature of fish to below 4°C as quickly as possible after death to slow bacterial growth and enzymatic activity.
- Freezing is more effective than refrigerated chilling and maintaining chilled temperaturesholding in preventing histamine formation. It is good practice to gut the fish before freezing. Freezing to -18 °C, or below, will stop the growth of histamine-producing bacteria and will prevent any preformed histidine decarboxylase enzymes from producing additional histamine.
- Note that freezing does not detoxify preformed histamine, nor does it effectively eliminate histamine-producing bacteria and enzymes, which can become active when temperatures increase again, such as during such things as processing or meal preparation.
- Crew members responsible for chilling should provide feedback to the catching operation to assure that the rate or volume of incoming fish does not exceed the ability to rapidly chill the fish within established time/-temperature critical limits and maintain the fish in a chilled state.
- Care should be taken to manage the chilling of dead fish to ensure that none are inadvertently left exposed on deck past the critical time limit for the conditions.
- Refrigeration and other chilling equipment should be in good repair, and operated in a manner that quickly chills fish without physical damage. For example, fish should be packed loosely in ice slurries, RSW, and brine tanks to allow good circulation and rapid cooling.
- Where ice is used, fishing vessels should have sufficient ice for the amount of fish that could be caught and for the potential length of the fishing trip. For further information see FAO Fisheries Technical Paper 436 (The use of ice on small fishing vessels)[2].

コメント **[A24]:** NZ comment

コメント **[A25]:** Edit in response to comment from Australia.

[2] *FAO Fisheries Technical Paper 436* ("The use of ice on small fishing vessels.") Link: http://www.fao.org/docrep/006/Y5013E/y5013e00.htm#Contents

- For larger eviscerated fish~~, evisceration is recommended and~~ the belly cavity should be packed with ice, or other cooling media, ~~to ensure~~for more rapid chilling of this ~~critical area~~bacteria-laden region of the fish ~~and to aid internal muscle cooling~~.
- Critical limits and monitoring methods and frequencies should be established for the onboard chilling/freezing process. For example, limits may be established for maximum loading volumes and rates, maximum starting temperature for RSW and/or brine tanks, and monitoring frequencies to ensure an adequate chilling environment is maintained for the duration of the chilling operation for each harvested set[3] of fish.

X.1.4 Refrigerated and frozen storage (fishing vessel and transfer vessel)

- ~~After chilling, f~~Fish should be stored at ~~the lowest~~a temperature as close as possible to 0°C (~~e.g., below~~at ~~4~~°C or below) until off-loading.
- Refrigerated storage at 4°C or below will inhibit growth and enzyme production for most histamine-producing bacteria, and will slow the growth of the less prolific histamine-producing bacteria that can grow at refrigerated temperatures.
- Ice, where used, should completely surround the stored fish and be regularly monitored throughout the trip and replenished as necessary.
- Refrigerated seawater and/or brine temperature should be monitored and carefully controlled in order to help maintain inhibitory temperatures.
- Continuous temperature recording devices should be used where practical in refrigerated and frozen storage compartments to enable inadequate conditions to be identified and appropriate actions taken to minimize consumer risk.

X.1.5 Monitoring records (fishing and transfer vessel)

- Records of histamine control monitoring activities should be maintained ~~where~~in a way that they can be readily retrieved for trace-back to possible causes if elevated levels of histamine are detected later.
- Records should be made available to the receiving establishment that offloads the fish from the vessel to provide evidence that histamine controls were implemented properly and effectively by the ~~harvest~~fishing and transfer vessel ~~operation~~.
- Vessel records should include documentation of actual observed activities and times pertinent to onboard controls for all histamine-forming fish harvested from each fishing set on each fishing trip.
- The records kept depend on the operation and may include:
  - Ocean water temperature and air temperature
  - Dates and times of earliest fish death, and times to get fish into appropriate chilling media
  - Initial RSW and/or brine tank temperatures
  - Brine, RSW, or storage compartment refrigeration temperature monitoring records or checks for adequacy of ice during the chilling operation and during holding of the fish for the duration of the fishing trip.

[3] A "set" means the fish from one set net, or the fish from one set long-line, etc..

コメント **[A26]:** Edit in response to a NZ comment.

To align with, and differentiate from, the similar bullet under X.1.2 Gutting and gilling.

コメント **[A27]:** Footnote added in response to comment from Australia.

コメント **[A28]:** Germany comment

コメント **[A29]:** Edited in response to comment from Australia;

And, to be consistent with other sections of the Code, i.e., section 4.1 (Time and Temperature Control):

"For species prone to scombrotoxin production, time and temperature control may be the most effective method for ensuring food safety. It is therefore essential that fresh fish, fillets, shellfish and their products that are to be chilled be held at a temperature as close as possible to 0 °C."

コメント **[A30]:** Germany comment

コメント **[A31]:** Australia comment

コメント **[A32]:** Germany comment

コメント **[A33]:** Australia comment

コメント **[A34]:** Japan comment

コメント **[A35]:** Co-chair: added "transfer vessel" to be consistent with comment from Germany.

Note: The subsection title, "Harvest vessel operations" is broader, and can be considered to cover both fishing and transfer vessels.

- A responsible crew member should review the monitoring records daily ~~and/or at delivery,~~ to confirm that critical limits were met, and that appropriate corrective actions were taken when necessary.
- Where onboard record keeping is impractical, such as ~~F~~for small artisanal day boats ~~that have difficulty maintaining records~~, the operation receiving the fish may be able to monitor and record ~~most, if not~~ all ~~, of~~ the parameters necessary to assure histamine control ~~parameters for the boat, such as~~(e.g., time of departure and return, air and water temperature, adequacy of ice and fish internal temperature~~at departure and return, air and water temperature~~, etc.~~, as applicable~~), and avoid the need to test histamine levels at ~~reciept~~receipt.
- If some of the fish stored on the vessel are at risk for histamine formation because critical limits were exceeded, then these fish should be ~~identified,~~ segregated and ~~labeled~~identified in order to allow targeted testing and proper disposition at ~~the receiving establishment~~unloading.

X.2 Reception of fish (receiving establishment)

Fish reception (at the establishment where the fish are offloaded from the fishing or transfer vessel) is an important control point for histamine because this is where vessel records, fish temperatures, signs of decomposition, and histamine levels are best monitored and decisions are made as to whether the fish are safe to accept for processing or to proceed in commerce.

Reception controls may need to be specific to both the harvest vessels as well as to any collection/transfer vessels that deliver the fish to the receiving establishment.

If deficiencies in fishing vessel controls are found at receiving, feedback should be provided to the vessel operator, and the cause(s) of the problem should be evaluated and corrected before future deliveries from the fishing vessel are considered. In addition, appropriate corrective actions regarding the delivered fish should be taken and recorded.

During offloading of fish from the harvest vessel (and at any point of transfer in the supply chain), care should be taken that the cold chain is maintained. For example, fish should be offloaded quickly, fish totes should not be left exposed to elevated temperatures, and fish should be re-iced or placed under refrigeration in a timely manner. Frozen fish should be handled in a manner to maintain the frozen state.

X.2.1 Review of fishing vessel controls and records (receiving establishment)

Review of fishing vessel histamine control systems and monitoring records, when available, is an effective method to ensure that appropriate ~~strategies~~procedures were followed to help control histamine formation in the fish while on the fishing vessel.

- Refer to Section X.1.5 Monitoring records (fishing vessel).
- Vessel records applicable to histamine control should be requested and reviewed by the receiving personnel to determine if they are complete and reflect appropriate harvest and onboard handling practices, and that all applicable fishing vessel critical limits ~~are~~were met.

コメント **[A36]:** US comment

コメント **[A37]:** Co-chair: Used language from similar sentence removed from X.1.

コメント **[A38]:** Clarifications made in response to NZ and EU comments.

The phrase "may be able to" was not replaced with "shall" or "should" because the receiving facility may not be able to collect all the information needed to assure HACCP-based control (e.g., boat out long enough for fish to potentially develop histamine at ambient temperatures, and boat provides no records on when fishing started or when fish were iced.) In which case the receiving facility should test histamine levels.

コメント **[A39]:** Brazil comment

コメント **[A40]:** France comment

コメント **[A41]:** US comment

コメント **[A42]:** NZ comment

- If vessel records are incomplete~~, or a required corrective action is missing or unclear, reception personnel should verify that fishing vessel personnel have identified the problem and taken appropriate corrective actions.~~ and the receiving establishment cannot reliably ensure that the specific delivery of fish was harvested, handled, and stored in a manner that prevents histamine formation, such as by intensified histamine sampling and testing, the delivery should be rejected. ~~If future actions are required, such as equipment repairs, then reception personnel should follow-up to ensure these corrections are made.~~
- Sometimes the impact of a critical limit deviation on the fishing vessel may be minimized if the records clearly show that only part of a delivery was affected (e.g., one brine well or one specific fishing set during the fishing trip) and if the affected fish can be effectively segregated from the rest of the delivery when the vessel is unloaded. Precautions should be taken to ensure none of the other fish in the delivery have been affected.
- Histamine testing can be used when vessel records are not available or unclear. However, this testing can be less reliable because histamine may be unevenly distributed within and between fish, and fish with high histamine are difficult to find using limited or small sample sizes. Sampling and testing that is statistically meaningful in terms of appropriate consumer protections can be resource intensive. Histamine testing at fishing vessel reception is therefore best used as verification of the effectiveness of a properly implemented and documented histamine control system on the fishing vessel. (Refer to Section X.2.4 Histamine testing.)

X.2.2 Temperature monitoring

- Fish internal temperatures should be measured at reception to help ensure that fish were properly stored onboard the fishing and transfer vessel.
- For fish stored in ice, the adequacy of ice surrounding the fish should also be observed and recorded at the time of offloading the fishing vessel, along with internal temperature measurements. More fish should be monitored when the quantity or distribution of ice appears inadequate. Temperatures near the surface of exposed un-iced portions should be measured, as well as deep core temperatures of the fish, to ensure all edible portions of the fish are taken into consideration in the assessment.
- Fish should be randomly selected from throughout the fishing vessel delivery lot. The number of fish temperatures monitored and recorded should be sufficient to provide reasonable assurance that temperatures appeared to be controlled by the vessel crew. Variations in species, morphologies, and sizes of fish should be considered and captured in the selection of fish monitored for temperature.
- If an internal temperature in a sample fish exceeds 4°C, then the entire fishing vessel delivery lot should be considered at ~~elevated level of histamine~~ risk ~~for elevated histamine~~. Higher temperatures usually correspond to higher histamine risk, however, h~~H~~igher deep core temperatures may need to be accounted for when larger fish have been delivered soon after harvest such that the core temperatures have not yet chilled to 4°C or below despite implementation of appropriate chilling procedures. ~~Science-~~

コメント **[A43]:** US comment

コメント **[A44]:** Co-chair: Removed last sentence because it does not fit with the change made with the comment.

And, not needed because usually the vessel owner/operator would follow-up on equipment repair, rather than the reception personnel.

コメント **[A45]:** NZ comment

コメント **[A46]:** US comment

コメント **[A47]:** Germany comment

コメント **[A48]:** To clarify, in response Morocco comment.

コメント **[A49]:** Australia comment

~~based~~ C~~c~~ooling curves based on studies applicable ~~for~~to the specific fishing sector are useful to ascertain proper temperature critical limits for fish at receiving in these circumstances. If a deviation from the temperature critical limits occurs, the cause should be determined and corrected, and ~~thorough~~intensified ~~risk-based~~ histamine testing performed, or the vessel lot rejected.

X.2.3 Sensory evaluation

Sensory evaluation of fish at reception is a useful screening method to identify fishing vessel delivery lots that have been mishandled or subjected to time ~~and~~ temperature abuse and, hence, are at risk of elevated histamine levels. Neither histamine formation nor decomposition occurs in the absence of time-temperature abuse. However, the correlation between histamine level and sensory evidence of decomposition is not absolute, and histamine formation often occurs without readily detectable sensory indicators of decomposition. Therefore, sensory evaluation should not be used as the only or final assurance that the histamine level is acceptable, and reliable vessel control records or ~~risk-based~~ histamine testing, along with temperature monitoring, should be part of a complete receiving control system.

- Fish for sensory ~~examination~~evaluation should be chosen randomly from throughout the fishing vessel delivery lot. Deliveries of multiple species with different compositions, morphologies, and sizes should be taken into account in the sampling strategy. It may be appropriate to select more fish from portions of the delivery identified by vessel records or temperature examination to be at greater risk for histamine formation.
- The number of fish examined should be sufficient to provide assurance that the fishing vessel crew appear to have been vigilant about time-temperature exposures of the fish. The number of samples should be increased when conditions or fishing methods are more likely to introduce variable time-temperature exposures of fish, e.g., longlining, unusually warm weather, unusually large catch size, limited remaining ice, etc.
- Evidence of abuse that may be conducive to histamine formation is indicated when the fish sensory attributes indicate marginal quality, not only when the sensory attributes show advanced decomposition. See FAO "Sensory Assessment of Fish Quality"[4] and Codex "Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories"[5] for guidance on sensory evaluation of fish.
- If sensory evidence of decomposition is detected at reception, it indicates that controls on the fishing vessel may be inadequate and that the entire vessel lot is at risk for elevated histamine. The cause of the decomposition should be determined and the necessary procedural corrections, or equipment repairs, verified. It is justifiable to reject the entire delivery based on inadequate time~~/~~-temperature control; however, if further evaluation is used to determine if some of the fish are suitable for human consumption, then intensified ~~risk-based~~ histamine sampling and testing should be performed on the

[4] FAO/Torry Advisory Note No. 91, "Sensory Assessment of Fish Quality." Link: http://www.fao.org/wairdocs/tan/x5989e/x5989e00.htm

[5] CAC/GL 31-1999, "Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories." Link: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B31-1999%252FCXG_031e.pdf

コメント **[A50]:** Co-chair: The difference between a regular cooling curve and a "science-based" cooling curve is unclear.

コメント **[A51]:** US comment

コメント **[A52]:** US comment

コメント **[A53]:** NZ comment

コメント **[A54]:** Singapore comment

コメント **[A55]:** US comment

delivery. The testing should also include the decomposed fish to determine if the decomposition was conducive to histamine formation.

X.2.4 Histamine testing

When a fishing vessel delivering fish has implemented a histamine control system based on HACCP principles, and review of vessel records is one of the controls used by the receiving establishment, then histamine testing is only used as a periodic verification procedure to ~~periodically access~~assess if the vessel control system is adequate and working properly. The number and frequency of the verification tests carried out depend on the number of vessel suppliers and the type of fishery from which the receiving establishment receives fish. If verification test results signal potential lapses in care of the fish, then the frequency of verification testing should be increased until testing and other evidence suggest that the vessel operators have implemented effective corrective measures (e.g., a series of consecutive problem-free deliveries).

When a fishing vessel delivering fish uses GMPs, but has not implemented a histamine control system based on HACCP principles using monitoring and establishing its records that provide assurance and evidence of control, then histamine testing becomes a critical control point at reception rather than a verification procedure, and testing should be applied to every vessel delivery lot. If histamine levels do not meet the ~~testing criteria~~required limit, the vessel should be notified and the cause determined and corrected. In addition, the affected fishing vessel delivery lot should be rejected.

The histamine testing guidance in this subsection is also applicable to periodic verification of histamine controls used during later production, storage and transportation steps, as well as for testing to determine product disposition when critical limits are exceeded.

X.2.4.1 Histamine testing, ~~acceptable~~achievable histamine level

- ~~Histamine acceptance levels at vessel reception should be lower than the acceptable levels in product further along the distribution chain because the presence of histamine-forming enzymes, as evidenced by histamine levels approaching 15 mg/kg, is likely to result in additional increases with time and exposure to non-refrigerated temperatures during further processing and handling.~~
- Freshly harvested scombrotoxin-forming fish typically have histamine levels below 2 mg/kg, and food business operators that apply HACCP principles can achieve a histamine level lower than 15 mg/kg[6].
- Marginally elevated histamine levels indicate poor implementation of hygienic processes and ~~HACCP~~histamine controls during harvest, chilling and/or on-vessel storage, and a significant risk that some fish in a lot will have unacceptable histamine levels.

[6] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.1 Management of histamine production in fish and fishery products.)

コメント **[A56]:** Co-chair: editorial

コメント **[A57]:** Clarification made in response to comments received from EU, Japan and Morocco.

コメント **[A58]:** NZ comment

コメント **[A59]:** Sentence added in response to New Zealand comment.

Normally, histamine testing is only used as a periodic verification procedure, except when receiving from vessels that do not keep control records based on HACCP principles, in which case histamine testing is used as a critical control point at vessel reception.

コメント **[A60]:** Changed "acceptable" to "achievable" in section title in response to comments from Morocco and Brazil.

The second bullet that lists achievable levels was moved to the top to be consistent with the new section title.

コメント **[A61]:** US comment

コメント **[A62]:** Co-chair: Applies if HACCP is implemented, or not.

コメント **[A63]:** US comment

- Histamine achievable ~~cceptance~~ levels at vessel reception should be lower than the achievable ~~acceptable~~ levels in product further along the distribution chain because the presence of histamine-forming enzymes, as evidenced by histamine levels approaching 15 mg/kg, is likely to result in additional increases with time and exposure to non-refrigerated temperatures during further processing and handling.

X.2.4.2 Histamine testing, sampling strategies

- Sampling plans for histamine should be selected based on statistical performance parameters to be effective. Statistical tables and ~~tools~~computer programs provide the information needed to design a sampling plan based on the histamine limits, the degree of protection, and the confidence in results desired. The FAO/WHO Histamine Sampling Tool[7] is a useful application designed for this purpose.
- Determining sampling plan performance usually requires an estimate of the standard deviation of the level being measured. The standard deviation of the histamine levels can be estimated from the global data provided in the FAO/WHO Expert Report (Table 5.1)[8], or it can be estimated when ~~adequate~~ appropriate data have been collected, including worst case scenarios, at the receiving location.
- Because histamine is distributed unevenly in lots (has a high standard deviation), hazardous fish are statistically difficult to find using small sample numbers. The FAO/WHO Expert Report (Section 6.2.2.2)[9] suggests using histamine accept/reject levels ("value for m") that are lower than the target acceptable limit in order to reduce the number of samples required to achieve a given level of confidence in the testing results.
- More sample units should be tested whenever vessel records, sensory analysis, or fish temperatures indicate possible lapses in time ~~and/~~ temperature control that could result in elevated histamine.

X.2.4.3 Histamine testing, analytical methods

- It is best to test the raw fish material upon arrival from the fishing vessels, where individual loin sections can be identified. As the fish get processed into various market forms, or product from different vessel lots gets comingled, assessments of the suitability and safety of the fish from the individual fishing vessels becomes more difficult and less effective.
- Several reliable test methods exist for determining histamine levels in fish. The FAO/WHO Expert Report (Section 2.5 Analytical methods for histamine)[10] lists some of the available methods.

[7] *FAO/WHO Histamine Sampling Tool*. Link: http://www.fstools.org/histamine/

[8] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Table 5.1 Parameters of the Normal distribution fitted to the logarithm of the concentration of histamine, and probability of exceeding the limit of 200 mg/kg for each survey referenced in Table 3.2.)

[9] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.2.2.2 Using the known standard deviation and the derived mean to design a sampling plan.)

[10] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 2.5 Analytical methods for histamine.)

コメント **[A64]:** Moved from top bullet with section title change. Includes change made with US comment (shown above). And, change from "acceptable" to "achievable".

コメント **[A65]:** Clarification edits, in response to comment from France.

Options are 3rd party tables and computer programs that require user expertise. The FAO/WHO Histamine Sampling Tool is easier to use and provides the same mathematical output.

コメント **[A66]:** US comment

コメント **[A67]:** US comment

- The receiving establishment should confirm that the testing method used is properly validated for the detection limits used ~~and is reliable for the species~~. The staff responsible for the sampling and testing should receive training in the procedures used.
- The part of the fish selected for testing will significantly affect the test results. Test portions should be cut from the head-end of the lower loin near the gills because that area has the highest probability of elevated histamine in abused raw fish. Sufficient representation (e.g., approximately 250 grams~~, or typical serving size~~) of fish muscle, should be collected to prepare for analysis. For smaller fish, in addition to the lower anterior loin portion, the upper anterior loin, and the mid-section of the lower loin, in that order, can also be collected, and for very small fish, multiple fish may need to be collected to acquire a representative sample unit of fish muscle (e.g., approximately 250 grams). The entire sample unit should be thoroughly blended so that the smaller aliquot used for the analytical method is representative of the entire sample unit.
- To screen deliveries more economically ~~when histamine levels are consistently low~~, sample units from different fish can be optionally combined (composite sample) to reduce the number of histamine analyses required, provided that the histamine level critical limit is lowered proportionately. For example, after independently grinding each of 3 individual sample units, a portion (e.g., 100 grams from each of the 250 gram ground units) can be further blended together and used for a single composite sample analysis. In this case, the critical limit must be divided by 3 in order to ensure detection of one unit exceeding the critical limit within the composite sample. If the lower critical limit is exceeded, further analysis of the retained individually ground portions from each of the 3 sample units making up the composite may be ~~required~~performed to determine if any sample unit ~~actually~~ exceeds the ~~normal~~non-composited critical limit. Note, the ability to composite multiple sample units is limited by the lowest histamine level that is accurately quantified by the analytical method in use.

X.2.5 Monitoring records (receiving establishment)

- Histamine control records should be maintained at the receiving establishment for trace-back to possible causes if elevated histamine is discovered further along the distribution chain.
- Receiving establishment monitoring records may include, but are not limited to:
  - Relevant information about vessel delivery lot (e.g., vessel name and type, captain's name, date/time of offloading, type and volume (weight) of ~~different~~ fish ~~received~~off-loaded)
  - Copies of the fishing vessel's monitoring records that were reviewed (refer to Section X.1.5, Monitoring records (fishing vessel)
  - Sensory ~~examination~~evaluation results
  - Internal temperatures at the time of offloading
  - Histamine test results, when applicable.
- A responsible person should examine, as a part of verification activity, the monitoring records before product release to confirm that critical limits were maintained, and that appropriate corrective actions were taken when necessary.

コメント **[A68]:** Morocco comment

コメント **[A69]:** US comment

コメント **[A70]:** US comment

コメント **[A71]:** US comment

コメント **[A72]:** "Optionally" added to further clarify, in response to comment from Brazil.

コメント **[A73]:** US comment

コメント **[A74]:** US comment

コメント **[A75]:** NZ comment

X.3 Transportation

- Refer to Section 20 (Transportation)
- Refer to Section X.1.4 (Refrigerated and frozen storage)
- Transport vehicles or vessels should be adequately equipped to keep fish cold by mechanical refrigeration or by completely surrounding the fish with ice or other cooling media.
- Vehicles or vessels should be pre-chilled before loading fish where applicable.
- Refrigerated compartment temperatures, or cooling media such as ice slurries, should be monitored during transportation between locations (e.g., receiving establishment, processing establishment, distributor, market, etc.) using continuous temperature recording devices (where practical), and the receiving establishment should review the temperature record from the device. Devices should be periodically calibrated for accuracy.
- At delivery, internal temperatures of a representative sample of fish, ~~or~~and adequacy of ice or other cooling media when applicable, should be monitored by receiving personnel as described in Section X.2.2 Temperature monitoring.
- If a temperature control critical limit is exceeded, the cause of the problem should be identified and corrected by the operator of the vehicle or vessel. The affected lot may be rejected by the receiving personnel, or the receiver may perform ~~risk-based~~intensified histamine analysis on representative fish collected throughout the lot, and the lot rejected if any fish are over the histamine critical limit (See subsection X.2.4).

X.4 Processing operations

This section applies to processing on land or at sea (e.g., factory vessel, mother ship)

X.4.1 Reception (processing establishment)

- If fish are delivered directly from the fishing vessel to the processing establishment, then refer to Section X.2 Reception (receiving establishment).
- If fish are delivered by transport vehicle or vessel, then refer to Section X.3 Transportation.
- If the processing establishment is a secondary processor receiving product from a primary processor (e.g., receiving establishment ~~,~~or factory vessel), then the secondary processor should ensure that the primary processor uses HACCP or a similar control system designed to prevent formation of hazardous levels of histamine.
- When~~At times,~~ it ~~may be~~is impractical ~~or unreliable~~ for the initial receiving establishment to conduct all the appropriate histamine controls listed in subs~~in S~~ection X.2 (i.e., vessel records review, temperature monitoring, sensory evaluation, and histamine testing~~Reception (receiving establishment). In these cases~~, then the processing establishment ~~may~~should conduct these activities, ~~but~~and should ensure that the controls and decisions are applied to intact fishing vessel lots that are not comingled with other lots. However, fish internal temperatures (and adequacy of ice, where applicable) should always be monitored ~~both~~ at vessel delivery (to evaluate

コメント **[A76]:** Co-chair: Edit to be consistent with Section X.2.2.

コメント **[A77]:** US comment

コメント **[A78]:** US comment

コメント **[A79]:** Added reference to testing section in response to comment from NZ.

コメント **[A80]:** Listed the specific activities to provide better clarity, in response to comment from Japan.

Other editorial changes made to reduce length and increase clarity.

コメント **[A81]:** Changed to "should", in response to EU and Singapore comments. The term "shall" is typically avoided in recommended codes of practice.

コメント **[A82]:** Adequacy of ice added in response to Singapore comment.

Note that records for the fishing trip may not be available if fishing operations do not use HACCP principles, in which case the receiving facility or initial processor should perform histamine testing as a critical control point.

vessel control), as well as ~~and~~ at the processing establishment ~~reception~~ (to evaluate transport ~~cooling~~control).

X.4.2 Processing, time and temperature control

When fish undergo processing (e.g., thawing, cutting, re-chilling, salting, drying, pickling, smoking, canning) it is important that they are not held at temperatures for sufficient time that histamine-producing bacteria can grow and produce histamine to hazardous levels.

- Scientific studies and microbial growth models[11] may be used to estimate the exposure times and temperatures that result in elevated histamine levels.
- Histamine formation is quite variable and strongly depends on the previous handling of the raw material and the different species of histamine-producing bacteria that are present; therefore, the worst case scenario should be considered when establishing critical limits.
- The acceptable maximum histamine level used to establish processing time-temperature critical limits should take into consideration any further handling, processing, storage, and preparation that may lead to further histamine formation before consumption.
- The measure used for time ~~and~~ temperature critical limits should be the cumulative product non-refrigerated time-temperature exposure over all processing steps.
- Processing room temperature should be maintained as cool as practical during processing operations, and product exposure times should be minimized. For example, fish should be iced, or returned to refrigerated storage, during production breaks or production flow slow-downs.
- Controlled product flow and batch monitoring is an effective strategy to ensure product is not subjected to unacceptable time ~~and~~ temperature exposures. For example, periodically measure the ambient temperature and the time for a marked batch to begin and complete the processing step.
- Air thawing of raw material should occur at refrigerated temperatures to prevent excessive warming of the surface of the fish. Immersion in circulating cold water or spraying with cold water may be used to shorten thawing time. For re-chilling and refreezing, see Subsection X.1.3.
- When time ~~and~~ temperature critical limits are exceeded, the cause should be determined and corrected. In addition, ~~risk-based~~intensified histamine testing should be performed (see section X.2.4.2) before releasing affected product for human consumption. Alternatively, product should be rejected.

X.4.3 Heat processing

- ~~Proper~~Adequate heat treatment (e.g., cooking, hot smoking) can kill histamine-producing bacteria and inactivate ~~the enzyme~~ histidine decarboxylase enzymes. *Morganella morganii* is probably the most heat resistant of the histamine-producing bacteria, and in Australian salmon/ kahawai at temperatures between 58 and 62°C, the

[11] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.1.9 Microbiological modelling.)

コメント **[A83]:** Co-chair: editorial

コメント **[A84]:** Co-chair: Added "non-refrigerated" for clarity.

コメント **[A85]:** US comment

コメント **[A86]:** US comment

コメント **[A87]:** Australia comment

コメント **[A88]:** Co-chair: It is not necessarily "proper" if not intending to control histamine at this step.

D-values for eliminating these bacteria and their associated HDC enzymes were between 15 and 1.5 minutes (FAO/WHO 2012). ~~The food business operator should ensure that an adequate heat treatment is carried out in order to avoid the development of histamine-producing bacteria.~~

- Once formed, however, histamine itself is heat stable and is not destroyed by heat. Therefore, histamine controls during harvesting, and during other steps prior to thermal processing, are critical to prevent inclusion of previously formed histamine in the finished product.
- If the product is exposed to bacterial contamination and ~~unrefrigerated~~ temperature abuse after initial heating, histamine formation may start again. Thus, for products such as hot smoked fish, care should be taken to avoid contamination after smoking. Additionally, refrigerated storage is essential unless the water activity is reduced sufficiently or some other means is used to prevent bacterial growth.
- For commercially sterile canned or pouched products, the container protects the product from bacterial recontamination, and no further histamine is produced when stored at ambient temperatures. However, once the product package is opened, histamine formation can occur again if the product is recontaminated in the absence of ~~commence without proper~~ preventative time-temperature controls.

X.4.4 Processing, other technological measures

Time and temperature control is the recommended method for preventing histamine formation in fresh, frozen, and refrigerated processed fish products.

Some products and processes (e.g., fermenting, smoking, salting, drying, pickling, acidifying, preserving, modified atmosphere packaging) introduce other technological factors that may inhibit the introduction and/or growth of histamine-producing bacteria. The interaction of these factors is complex and often unpredictable. For example, increased salt content, or increased acidity, may decrease or increase histamine production, depending on conditions.

Thorough scientific studies, and proper establishment and validation of control parameters for each specific process and product, are imperative to ensure the safe manufacture of foods that incorporate other technological measures as an element of histamine control. (See Guidelines for the Validation of Food Safety Control Measures, CAC/GL 69 - 200.)

The safe application of any of these treatments is dependent on the rapid chilling and maintenance of chilled temperatures of the raw fish material from the time of death of the fish until the proper inhibitory or destructive control attributes contributed by the treatments have been achieved. And, depending on the treatment, the finished product may need to remain chilled until consumed to ensure safety.

X.4.5 Refrigerated and frozen storage (processing establishment)

- Refer to Section X.1.4 Refrigerated and frozen storage (fishing vessel).
- For products whose preparation does not include a heating step or other means to eliminate histamine-producing bacteria and their enzymes, the presence of histamine-

コメント **[A89]:** Added wording on heat treatment from FAO/WHO Expert Report in response to comment from NZ.

コメント **[A90]:** Removed per comment from NZ. The second sentence does not add any useful information.

The heating process does not need to kill histamine producing bacteria and denature their enzymes if the product will be chilled, frozen or otherwise processed to prevent histamine formation.

コメント **[A91]:** Australia comment

コメント **[A92]:** Australia comment

producing bacteria means that refrigerated storage will continue to be a critical control point for the inhibition of histamine formation throughout the shelf-life of the products until consumed.

X.4.6 Monitoring records (processing establishment)

- Processing establishment monitoring records may include, but are not limited to:
  - Transport vehicle or transport vessel temperature log or adequacy of ice, and fish internal temperatures
  - Temperatures and exposure times of product during unrefrigerated processing steps
  - Critical control point monitoring records for other validated methods used to control histamine formation in processed fish
  - Refrigerated storage temperature logs.
- A responsible person should examine the monitoring records before product release to confirm that critical limits were maintained, and that appropriate corrective actions were taken when necessary.
- The processing facility should use histamine testing to periodically verify that histamine controls are working properly (Refer to section X.2.4).

コメント **[A93]:** Co-chair: editorial

コメント **[A94]:** Added bullet and reference to X.2.4 in response to NZ comment on use of histamine testing at processing establishments.

Dear EWG Members,

Thank you for providing comments on the 2nd Draft. We have incorporated most of the comments into the 3rd and final EWG draft. Most members were satisfied with the draft overall; therefore, we did not make significant changes based on only a few comments; however, we did make some additional revisions in response to significant comments to provide better clarity.

The changes made are shown in the attached 'track-change' 3rd Draft. Comments and questions with more substantial replies are discussed below.

General Comments

Section 6 (Aquaculture production), subsection 6.2.1

> Comment [Singapore]: Suggested text:
>
> Aquaculture products pose broadly the same hazards that are present in corresponding varieties caught in the wild (Section 5.3.3.1). Potential hazards that are specific to aquaculture products include residues of veterinary drugs in excess of recommended guidelines and other chemicals used in aquaculture production, and contamination of faecal origin where the facilities are close to human habitation or animal husbandry. **Section[X] describes the guidance for the control of histamine formation for wildly caught finfish at risk of developing hazardous levels of histamine and is also applicable to their corresponding aquacultured fish species.**

Co-chair response: It is anticipated that significant editing of the existing Code will be required to reference a new histamine section, and to assure alignment of existing guidance with new guidance. Work on editing the existing Code should begin after the new section is more firmly established.

Flow chart

> Comment [Australia]: The format of the flow chart requires additional consideration as some elements may not occur in the sequence listed, i.e. gutting and gilling may occur as part of the harvest vessel operation or could occur as part of the processing operation.

Co-chair reply: The flow chart is an example, acting mainly to orient the reader to the product flow used within the text. During work on other Code sections, it has been found that showing all possible alternative paths can lead to an overly complicated flow chart. This is why the flow charts in the Code are always labeled as "examples". In most cases, operations that use a different order of productions steps can easily match the guidance to the actual order used.

Implementing HACCP for fishing vessels

> Comment [Morocco]: All matters concerning the application of HACCP at fishing vessel should be deleted from the document.

Rationale: In most cases, in fishing vessels in developing countries, the only operations performed on-board are catching, putting in boxes and icing. Fishing under these conditions can be considered as a primary production. This document should exclude the application of HACCP in boats that make primary production as approved in most international regulations.

The Expert Report specifies that "The expert meeting concluded that histamine formation and SFP can be easily controlled. The risk from SFP is best mitigated by applying basic GHPs and, where feasible, a HACCP system "

Co-chair reply: In response to these comments, several changes were made to clarify that the draft guidance applies to vessels that use basic GMPs, and to vessels that use basic GMPs and HACCP systems. The Draft recommends that when establishments receive fish from vessels that apply basic GMPs without a HACCP system (i.e., without a documented structure and monitoring records), then the receiving establishment should monitor histamine levels in the fish.

Time & Temperature

Comment [Morocco]: In the entire document, do not mention the 'time-temperature' couple but keep only the 'temperature'

Rationale:
Morocco does not agree to add the "time" factor as a primary parameter responsible for the production of histamine and reminder that the two essential factors at the origin of the production of histamine are:

- failure to respect the temperature: breakage of the cold chain
- failure to comply with good hygiene practices causing bacterial contamination, whether of internal or external origin

Many conditions can affect the growth of biogenic amine producers. Temperature is the main determinant as mentioned in the FAO/WHO Expert Meeting report on page 6. And, if other parameters will be added as 'time', all other parameters that have an effect on the production of histamine such as pH, salt content, Aw, fish species, histidine content, eviscerated fish or not,... must be added. As mentioned in the expert report on page 6. 'Other important factors can be involved, including pH, salt, oxygen availability and competition with other spoilage microorganisms'.

Co-chair reply: Bacteria require time to grow and produce histamine. Time is not considered a critical factor during the period that properly handled fish are stored below 4°C because this temperature prevents growth of histamine producing bacteria, and the fish will decompose due to other spoilage organisms before histamine levels become too high. However, time is a critical factor when fish are exposed to elevated temperatures, such between death and chilling, or when exposed to ambient temperatures during processing. Section 6.1.1 Chilling of the FAO/WHO Expert Meeting Report (referenced in the Draft) covers time from death to chilling, including effect of evisceration. Other factors (e.g., pH, salt, oxygen) used for specific processing methods are discussed in Draft section X.4.4 (Processing, other technological measures).

Specific comments

X.1.4 Refrigerated and frozen storage (fishing vessel)

> Comment [France]: (Line 201) After chilling, fish should be stored **for the shortest period** at the lowest temperature possible (e.g., below 4°C) until off-loading.

Co-chair reply: The intent of this bullet is to clearly indicate that storing fish below 4°C is the main factor for histamine control during refrigerated storage. If fish are chilled within the appropriate time period after death, and stored below 4°C, histamine should not develop before the end of their useable shelf life. However, time of storage can become critical if fish are stored above 4°C, or fish were previously temperature abused and contain significant histidine decarboxylase.

Note that it is not generally recommended to monitor time during refrigerated storage in order to control histamine; however, time should be monitored for quality/shelf-life purposes. Therefore, inserting the proposed text may cause confusion between quality guidance (not covered in this section) and safety guidance, to store fish below 4°C to arrest growth of histamine producing bacteria.

X.2.3 Sensory evaluation (Line 334)

> Comment [Australia]: Is it possible to provide more specific advice at this point, e.g. the same as the citation to the FAO/WHO Histamine Sampling Tool at L. 385.

Co-chair reply: There is nothing equivalent to the FAO/WHO Histamine Sampling Tool that is neatly tailored for assessing decomposition within fish deliveries with the same goal, i.e., prevention of scombrotoxin exposure. We could ask FAO/WHO if they are interested in developing one. This is also applicable to temperature monitoring.

Statistical tables are available that use binomial-type distributions with various assumptions to consider the risk management options regarding the protections desired and the probabilities of detecting defects at given levels of prevalence, versus the sample size.

The EWG does not currently have time to consider more detailed sensory and temperature sampling guidance, but it could be considered later.

X.2.4 Histamine testing

> Comment [EU, Japan, Morocco]:
>
> Lines 351-354:
>
> > When a fishing vessel delivering fish has implemented a histamine control system based on HACCP principles **or GMPs**, and review of vessel records is one of the controls used by the receiving establishment, then histamine testing is only used as a verification procedure to periodically access if the vessel control system is adequate and working properly.
>
> Lines 362-364:

When a fishing vessel delivering fish has not implemented a histamine control system based on HACCP principles **or GMPs**, then histamine testing becomes a critical control point at reception rather than a verification procedure, and testing should be applied to every vessel delivery lot.

Rationale: In the preamble of the draft, it is mentioned that fishing vessels which have not adapted HACCP may use GMPs alternatively.

Co-chair reply: The proposed change was not made; however, the two paragraphs discussed in the comments were revised to better clarify the two strategies presented.

The language "equivalent GMPs" was removed from the Preamble based on the following rationale provided by the U.S.:

> "Regarding the revised wording proposed by the co-chairs: The term "equivalently effective GMPs" is problematical. For a great long while, prior to HACCP, many countries had GMP guidance and/or law established. When HACCP was introduced, it was recognized as a superior approach and was adopted by these countries and by CODEX. GMPs, per se, are not "equivalently effective" and it is a misnomer to frame them as such in this document."

Two histamine control strategies are described for receiving fish from vessels in the first and second paragraphs of X.2.4 (subject of the comments).

Strategy 1: Review of vessel records (vessel uses HACCP principles). Histamine testing is performed periodically as a part of verification procedures.

Similarly (described later in draft) shore based operators may be able to provide control based on HACCP principles for day-boats that are not out long enough for histamine to form at ambient temperatures.

Strategy 2: Vessel records are not provided (vessel uses traditional GMPs). Histamine testing is performed on each lot received.

It would appear to be inappropriate to include "or GMPs" in the first strategy, unless GMPs are further defined to include vessel monitoring records based on HACCP principles, which would be redundant and probably confusing.

It would also appear inappropriate to exclude "GMPs" from the second strategy, because GMPs are used in order to produce a quality product that passes histamine testing.

X.2.4.1 Histamine testing, acceptable histamine level

Comment [Brazil, Morocco]: delete the second bullet.

~~Freshly harvested scombrotoxin-forming fish typically have histamine levels below 2 mg/kg, and food business operators that apply HACCP principles can achieve a histamine level lower than 15 mg/kg[1].~~

Rationale: The information can cause misunderstanding interpretation, because levels above 2 mg/kg on vessels or higher than 15 mg/kg in food business operator that apply HACCP principles as a criteria are much lower than acceptable levels. It means that could be considered inappropriate to process and be rejected despite the fact the fish be below the acceptable levels.

Co-chair reply: The language came directly from the FAO/WHO Expert Meeting Report. It was written with the intent to inform and/or teach readers that histamine levels are controllable to levels much lower than "acceptable levels". If fact, fish that are truly harvested and handled properly (using GMPs and HACCP) should not contain elevated level of histamine at all. Fish with histamine levels < 2 ppm are routinely produced on a daily basis around the world.

The language is not prescriptive. No one is being asked to reject fish with histamine levels > 2 ppm or > 15 ppm. To further clarify this, the following change was made to the Section Title:

X.2.4.1 Histamine testing, ~~acceptable~~ **achievable** histamine level**s**.

X.4.3 Heat processing. (Lines 523-525)

Comment [NZ]: This section refers to a number of different parameters e.g. proper heat treatment (e.g., cooking, hot smoking) can kill histamine-producing bacteria and inactivate the enzyme histidine decarboxylase. Is it possible to add the parameters to this document? Similarly lines 533-535 refer to a reduction in water activity that is sufficient to prevent bacterial growth. Can applicable water activity parameter(s) be added here?

Co-chair reply:

Information on heat inactivation was previously included in the Draft based on a reference in the FAO/WHO Expert Meeting Report (Osborne and Bremer 2000), and this information was removed based on comments from EU and UK.

The Guidance removed was:

"For example, in one study, histamine production was stopped when fish flesh inoculated with heat tolerant histamine-producing bacteria was held at 62°C for about 2 minutes."

The Osborne and Bremer study (J. Food Prot., 2000. 63(2): 277–280) states:

"Times required at 58, 59, 60, 61, and 62°C to ensure a final product that will not produce histamine during subsequent temperature abuse were estimated to be 15.27, 8.81, 4.79, 2.68,

[1] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.1 Management of histamine production in fish and fishery products.)

and 1.46 min, respectively. The times were calculated for a worst-case scenario, where product is grossly contaminated."

The language from the FAO/WHO Expert Report:

> "Morganella morganii is probably the most heat resistant of the histamine-producing bacteria, and in Australian salmon/ kahawai at temperatures between 58 and 62°C, the D-values for eliminating these bacteria and their associated HDC enzymes were between 15 and 1.5 minutes[2]."

In the new draft document, we inserted the sentence above based on NZ comment, however, if you want to propose the specific reference, please submit it as a country comment.

We have no further information on parameters for water activity.

X.2.4.3 Histamine testing, analytical methods

> Comment [Brazil]: 5th bullet: Please provide some clarification on the scientific base used to support a pool of samples in the screening test.

Co-chair reply: Pooling of samples is optional. It is not based on a scientific theory, but is a simple mathematical calculation. The composite sample critical limit is reduced in proportion to the increased volume of the mixed (diluted) composite sample used for testing.

If the composite sample test result is under the composite limit, then all the individual samples are also under the limit. If the composite sample test result is over the composite limit, then each individual sample needs to be tested to see which one(s), if any, are over the individual limit. The draft guidance has been updated to improve clarity.

Statistical aspects of microbiological criteria related to food (JEMRA series 24) provide further guidance on the pooling sample.

[2] Corrected from "seconds"

別添C3.3.3

Appendix I

PROPOSED DRAFT REVISION OF THE *CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS* (CAC/RCP 52-2003)

NEW SECTION [X] FOR FISH AT RISK FOR SCOMBROTOXIN FORMATION

(for comments at Step 3 through https://ocs.codexalimentarius.org)

SECTION [X] – HARVESTING, PROCESSING, STORAGE AND DISTRIBUTION OF FISH AND FISHERY PRODUCTS AT RISK FOR SCOMBROTOXIN (HISTAMINE) FORMATION

Preamble

This section complements other sections of the Code by providing detailed control recommendations for the prevention of scombrotoxin fish poisoning (SFP). This section only applies to specific marine finfish species (listed in Annex [Z]) at risk of developing hazardous levels of histamine. This section contains specific guidelines for preventing SFP; however, within the scope of this Code, it is not possible to provide all the appropriate controls and alternatives that may apply to every operation because these will vary with each particular operation.

Scombrotoxin fish poisoning (SFP) is a worldwide food safety challenge that, in some parts of the world, accounts for the largest proportion of fish-borne illness cases. Individuals suffering from SFP may show one or more symptoms including flushing, swelling, rash, itching, headache, heart palpitations, abdominal cramps, diarrhoea, and vomiting. In some cases, exacerbation of asthma and more serious cardiac manifestations may occur. Symptoms typically develop rapidly (from 5 minutes to 2 hours after ingestion of implicated fish), with a usual duration of 8–12 hours, although symptoms may persist for up to several days. SFP is rarely fatal.

Scombrotoxin fish poisoning is caused by the ingestion of certain species of marine fish (listed in Annex [Z]) that have been allowed to develop biogenic amines such as histamine. These species generally contain high levels of free histidine in their musculature and are more likely to form hazardous levels of histamine after death when subjected to time-temperature abuse.

Although detailed components of scombrotoxin have not been identified, it is generally accepted that biogenic amines produced by spoilage bacteria, especially histamine, play an important role in the pathogenesis of SFP. Other biogenic amines that are also produced during fish spoilage, such as cadaverine and putrescine, are thought to increase the toxicity of histamine. However, in most epidemiological studies, SFP is associated with high histamine levels in the implicated fish, and the controls used to inhibit histamine-producing bacteria and enzymes are also expected to be effective at preventing the formation of other biogenic amines. Therefore, histamine serves as a useful indicator compound for scombrotoxin, and histamine is monitored for scombrotoxin control purposes.

Histamine is produced in fish and fishery products by spoilage bacteria that are part of the natural microflora of the skin, gills, and gut of freshly caught fish. After the fish die, these bacteria migrate into the previously sterile fish musculature where they multiply if time and temperature are not controlled. When histamineproducing bacteria multiply in fish flesh, they produce histidine decarboxylase enzymes (HDC), which convert naturally present histidine into the toxic metabolite histamine.

Rapid multiplication of histamine-producing bacteria can be prevented by chilling fish immediately after death and maintaining the fish in a chilled, or frozen, state from harvest to consumption. However, once sufficient bacterial multiplication has occurred to produce histidine decarboxylase, enzymatic activity can continue to produce histamine slowly at refrigeration temperatures.

Histamine formation is effectively controlled by adherence to good manufacturing practices to

コメント [maff1]: US コメント（add.1 の P.3）
…The use of HACCP principles on any fishing boat and training crew members on HACCP is optional; however, this may not be clear.（中略）See our specific comments for suggested revisions that may clarify this issue.
→本趣旨に沿う他国コメント（主に US や NZ）については、賛成のスタンスでよいか。

コメント [t2]: そう思います

コメント [maff3]: 前回会合で、FAO/WHO の文献レビューの結果に基づきサケ科を入れるかどうか検討することになっていたが、FAO/WHO の文献レビューは CCFH までに示されるのか。どう対応するか。

コメント [t4]: 夏の終わりに draft に対するコメントを求められ、いつ open になるのか待っていたが、今日時点で CCFH メンバーに暫定版すら提出されていない

maintain hygienic quality of fish, and by using HACCP principles to control detrimental fish time-temperature exposure.

The following subsections contain technical guidance for the control of histamine formation at key steps in the food chain (harvesting, receiving, transportation, and processing operations).

The relevant guidelines in subsection X.1 (Harvest vessel operations) also apply to the harvest of aquacultured fish.

Figure X.1. Example flow chart for the production of fish at risk of scombrotoxin formation.

This flow chart is for illustrative purposes only. For implementation of HACCP principles, a complete and comprehensive flow chart has to be drawn up for each product.

X.1 Harvest vessel operations

X.1.1. Catching Fish

↓

X.1.2 Gutting and gilling (optional)

↓

X.1.3 Chilling and freezing

↓

X.1.4. Refrigerated and frozen storage (fishing vessel)

↓

X.1.5. Monitoring records (fishing vessel)

↓

X.2 Reception of fish

(receiving establishment)

X.2.1 Review of fishing vessel records (receiving establishment)

↓

X.2.2 Temperature monitoring

↓

X.2.3 Sensory evaluation

↓

X.2.4 Histamine testing

↓

X.2.5 Monitoring records (receiving establishment)

↓

X.3 Transportation X.3 Transportation

↓

X.4 Processing operations

X.4.1 Reception (processing establishment)

↓

X.4.2 Processing, time and temperature control

コメント [maff5]: 【質問】本規範の定義では、critical limit, corrective action 等の用語は、HACCP や DAP（defect action point）に使われる。これらの用語に係る内容は、GMPs only の船に適用されるのか。（今更で申し訳ありません…）

コメント [t6]: GMP　only の場合は CL はないので、適用されない

コメント [maff7]: NZ コメント（add.1 の P.7）

Delete steps in the flow chart that are not process steps e.g. X.1.5, X.2.1, X.2.2, X.2.3, X.2.4, X.2.5, X.4.6.

→賛成のスタンスでよいか。

コメント [t8]: フローから抜くけど、セクションは維持でもいい？

↓

X.4.3 Heat processing

↓

X.4.4 Processing, other technological measures

↓

X.4.5 Refrigerated and frozen storage (processing establishment)

↓

X.4.6 Monitoring records (processing establishment)]

X.1 Harvest vessel operations

Fishers use many different harvesting methods throughout the world, employing hooks, nets, and traps. Water and environmental temperatures vary depending on geographic location and season. In all cases, live retrieval or quick retrieval of dead fish, rapid chilling of the fish in a timely manner, and maintenance of the fish at cold temperatures, are critical to prevent histamine formation.

Time for histamine formation can vary substantially at the same temperature because different histamine producing bacteria with different histamine-producing activity may be present. Time-temperature critical limits should take into account the potential for histamine production under the worst case conditions for the particular operation.

The fishing vessel and equipment, and the methods used, should be designed or adapted to prevent histamine formation for the catch sizes, fish sizes, fish species, and air and water temperatures encountered. Vessel crews should be trained in hygienic practices and temperature control methods and understand their importance, and responsible crew members should be trained in HACCP principles used to control histamine formation, where possible.

Use of HACCP principles to control fish time-temperature exposure on the harvest vessel is an effective means to prevent hazardous levels of histamine formation, and provides better consumer protection than the alternative approach of testing histamine levels in fish after delivery.

X.1.1 Catching fish

- The time period that nets or hooks are left in the water, and the number and rate of fish caught, should be optimized to allow live landing of fish where practical.
- If captured fish are held in the sea for too long following death, decomposition commences, and histamine can begin to form. The warmer the seawater, the more rapid the decomposition and the greater the risk of histamine formation. Dead fish that exhibit marginalized quality attributes, consistent with exposure to time-temperature abuse, should not be retained on board the vessel, or, if retained, should be segregated and identified properly to allow testing and proper disposition when off-loaded.

  In addition, the harvesting methods should be modified in a way that no dead fish with marginal quality will be brought on board.
- Before landing fish, the deck area and equipment should be hygienically cleaned to avoid contamination of fish (see Section 3.4 Hygiene control program), and the chilling medium should be ready and at the target temperature.
- Fish should be removed from nets and hooks as quickly as possible to prevent death or to minimize the period from death until chilling of the fish.

コメント [maff9]: bullets の記載順について何かルールはあるのか。
（時系列にして、CL の設定→魚を釣る前に考慮する事項→魚を釣るときに考慮する事項→魚を釣った後に考慮する事項、という順にした方がわかりやすいのではないか、という意見がありました。）

コメント [t10]: ルールはない。仰せの通り。CRD でコメント出しますか？

コメント [maff11]: （釣るとき）

コメント [maff12]: （釣ったあと）

コメント [maff13]: （釣ったあと）

コメント [maff14]: （釣ったあと）

- Critical limits should be established for the time period between death of the fish and the start of chilling that will effectively prevent histamine production. Time of death of the fish may be the time slaughtered onboard, or where the actual time of death is not observed or truly known, an estimated time based on an observable event, such as the time of deployment of a longline when some of the fish are landed dead.
- The time period between death of fish and chilling that will effectively prevent histamine formation can vary based on the ocean and air temperatures encountered, the sizes and species of fish caught, and other relevant factors particular to the harvesting operation. See the FAO/WHO Expert Report (Section 6.1.1 Chilling)[3] for further guidance on establishing time-temperature critical limits for fish after death.
- The rate or volume of catch should not exceed the ability of the crew to quickly initiate chilling, and should not exceed the capability of the vessel's chilling system to maintain critical limits for cooling media temperature, or sufficiency of ice.
- Rough handling, overcrowding and over stacking of fish should be avoided where practical because crushing, bruising, and lacerations of the skin accelerate the spread of histamine-producing bacteria from the gut, gills, and skin into the fish musculature.

コメント [maff15]: （釣る前～釣るとき）

コメント [maff16]: （釣ったあと）

X.1.2 Gutting and gilling (optional)

- Histamine-producing bacteria are universally present in the gut, gills, and skin of fish at the point of capture. Rapid removal of guts and gills, and rinsing of the gut cavity, significantly delays histamine formation in the muscle.
- For large fish, removing the gut aids chilling by allowing chilling media (e.g. ice, refrigerated seawater) access to the visceral cavity, resulting in more rapid chilling of this bacteria-laden region of the fish.
- Care should be taken and hygienic practices should be maintained during gutting and gilling in order to minimize the spread of bacteria from the guts, gills, skin, and other contamination sources, into the muscle tissue.

X.1.3 Chilling and freezing

コメント [maff17]: bullets の記載順について何かルールはあるのか。
（CL の設定→氷冷に係る事項→冷凍に係る事項、という順にした方がわかりやすいのではないか、という意見がありました。）

Rapid chilling as soon as possible after death is the most crucial aspect of histamine control because bacterial growth and histamine formation accelerate exponentially with time under unrefrigerated conditions. Few prolific histamine-producing bacteria will grow and multiply at refrigeration temperatures, and the growth rates of those that do are much reduced.

- Sufficient ice to completely surround each fish, or preferably, ice/seawater slurries or refrigerated seawater (RSW) should be used to bring the internal temperature of fish to below 4°C as quickly as possible after death to slow bacterial growth and enzymatic activity.
- Freezing is more effective than refrigerated chilling and maintaining chilled temperatures in preventing histamine formation. It is good practice to gut the fish before freezing. Freezing to -18 °C, or below, will stop the growth of histamine-producing bacteria and will prevent any preformed histidine decarboxylase enzymes from producing additional histamine.
- Note that freezing does not detoxify preformed histamine, nor does it effectively eliminate histamineproducing bacteria and enzymes, which can become active when temperatures increase again, such as during processing or meal preparation.

[3] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.1.1 Chilling.) Link: http://www.fao.org/fileadmin/user_upload/agns/pdf/Histamine/Histamine_AdHocfinal.pdf

- Crew members responsible for chilling should provide feedback to the catching operation to assure that the rate or volume of incoming fish does not exceed the ability to rapidly chill the fish within established time-temperature critical limits and maintain the fish in a chilled state.
- Care should be taken to manage the chilling of dead fish to ensure that none are inadvertently left exposed on deck past the critical time limit for the conditions.
- Refrigeration and other chilling equipment should be in good repair, and operated in a manner that quickly chills fish without physical damage. For example, fish should be packed loosely in ice slurries, RSW, and brine tanks to allow good circulation and rapid cooling.
- Where ice is used, fishing vessels should have sufficient ice for the amount of fish that could be caught and for the potential length of the fishing trip. For further information see FAO Fisheries Technical Paper 436 (The use of ice on small fishing vessels)[4].
- For larger eviscerated fish, the belly cavity should be packed with ice, or other cooling media, for more rapid chilling of this bacteria-laden region of the fish.
- Critical limits and monitoring methods and frequencies should be established for the onboard chilling/freezing process. For example, limits may be established for maximum loading volumes and rates, maximum starting temperature for RSW and/or brine tanks, and monitoring frequencies to ensure an adequate chilling environment is maintained for the duration of the chilling operation for each harvested set[5] of fish.

X.1.4 Refrigerated and frozen storage (fishing vessel and transfer vessel)

- Fish should be stored at a temperature as close as possible to 0°C (4°C or below) until off-loading.
- Refrigerated storage at 4°C or below will inhibit growth and enzyme production for most histamineproducing bacteria, and will slow the growth of the less prolific histamine-producing bacteria that can grow at refrigerated temperatures.
- Ice, where used, should completely surround the stored fish and be regularly monitored throughout the trip and replenished as necessary.
- Refrigerated seawater and/or brine temperature should be monitored and carefully controlled in order to help maintain inhibitory temperatures.
- Continuous temperature recording devices should be used where practical in refrigerated and frozen storage compartments to enable inadequate conditions to be identified and appropriate actions taken to minimize consumer risk.

コメント [maff18]: Colombia がここを削除する提案をしていますが、device を使わなくてもレコードを取っていればいいので、ここは残しておく方が良いのではないか。

コメント [t19]: 僕も残すべきだと思います

X.1.5 Monitoring records (fishing and transfer vessel)

- Records of histamine control monitoring activities should be maintained in a way that they can be readily retrieved for trace-back to possible causes if elevated levels of histamine are detected later.
- Records should be made available to the receiving establishment that offloads the fish from the vessel to provide evidence that histamine controls were implemented properly and effectively by the fishing and transfer vessel.
- Vessel records should include documentation of actual observed activities and times

[4] *FAO Fisheries Technical Paper 436* (“The use of ice on small fishing vessels.”) Link: http://www.fao.org/docrep/006/Y5013E/y5013e00.htm#Contents

[5] A "set" means the fish from one set net, or the fish from one set long-line, etc.

pertinent to onboard controls for all histamine-forming fish harvested from each fishing set on each fishing trip.

- The records kept depend on the operation and may include:
  - Ocean water temperature and air temperature
  - Dates and times of earliest fish death, and times to get fish into appropriate chilling media
  - Initial RSW and/or brine tank temperatures
  - Brine,RSW, or storage compartment refrigeration temperature monitoring records or checks for adequacy of ice during the chilling operation and during holding of the fish for the duration of the fishing trip.
- A responsible crew member should review the monitoring records daily to confirm that critical limits were met, and that appropriate corrective actions were taken when necessary.
- Where onboard record keeping is impractical, such as for small artisanal day boats, the operation receiving the fish may be able to monitor and record all the parameters necessary to assure histamine control (e.g. time of departure and return, air and water temperature, adequacy of ice and fish internal temperature, etc.), and avoid the need to test histamine levels at receipt.
- If some of the fish stored on the vessel are at risk for histamine formation because critical limits were exceeded, then these fish should be segregated and identified in order to allow targeted testing and proper disposition at unloading.

コメント [maff20]: US コメント（add.1 の P.16）
この部分を削除し、bullet の最後に”In some cases, a day boat may need to record the time that fishing started in order to determine that there was adequate histamine control for the trip.” の一文を追加。
→賛成のスタンスでよいか。（record keeping が impractical な場合と書いてしまうと、施氷が十分かの判断もできないと考えられるため）

コメント [t21]: 御意

X.2 Reception of fish (receiving establishment)

Fish reception (at the establishment where the fish are offloaded from the fishing or transfer vessel) is an important control point for histamine because this is where vessel records, fish temperatures, signs of decomposition, and histamine levels are best monitored and decisions are made as to whether the fish are safe to accept for processing or to proceed in commerce.

Reception controls may need to be specific to both the harvest vessels as well as to any collection/transfer vessels that deliver the fish to the receiving establishment.

If deficiencies in fishing vessel controls are found at receiving, feedback should be provided to the vessel operator, and the cause(s) of the problem should be evaluated and corrected before future deliveries from the fishing vessel are considered. In addition, appropriate corrective actions regarding the delivered fish should be taken and recorded.

During offloading of fish from the harvest vessel (and at any point of transfer in the supply chain), care should be taken that the cold chain is maintained. For example, fish should be offloaded quickly, fish totes should not be left exposed to elevated temperatures, and fish should be re-iced or placed under refrigeration in a timely manner. Frozen fish should be handled in a manner to maintain the frozen state.

X.2.1 Review of fishing vessel controls and records (receiving establishment)

Review of fishing vessel histamine control systems and monitoring records, when available, is an effective method to ensure that appropriate procedures were followed to help control histamine formation in the fish while on the fishing vessel.

- Refer to Section X.1.5 Monitoring records (fishing vessel).
- Vessel records applicable to histamine control should be requested and reviewed by the

receiving personnel to determine if they are complete and reflect appropriate harvest and onboard handling practices, and that all applicable fishing vessel critical limits were met.

- If vessel records are incomplete and the receiving establishment cannot reliably ensure that the specific delivery of fish was harvested, handled, and stored in a manner that prevents histamine formation, such as by intensified histamine sampling and testing, the delivery should be rejected.
- Sometimes the impact of a critical limit deviation on the fishing vessel may be minimized if the records clearly show that only part of a delivery was affected (e.g. one brine well or one specific fishing set during the fishing trip) and if the affected fish can be effectively segregated from the rest of the delivery when the vessel is unloaded. Precautions should be taken to ensure none of the other fish in the delivery have been affected.
- Histamine testing can be used when vessel records are not available or unclear. However, this testing can be less reliable because histamine may be unevenly distributed within and between fish, and fish with high histamine are difficult to find using limited or small sample sizes. Sampling and testing that is statistically meaningful in terms of appropriate consumer protections can be resource intensive.

  Histamine testing at fishing vessel reception is therefore best used as verification of the effectiveness of a properly implemented and documented histamine control system on the fishing vessel. (Refer to Section X.2.4 Histamine testing.)

コメント [maff22]: （Section 2.4 に移すべきというコメントが出ている。→OK）

コメント [t23]: そう思う

X.2.2 Temperature monitoring

- Fish internal temperatures should be measured at reception to help ensure that fish were properly stored onboard the fishing and transfer vessel.
- For fish stored in ice, the adequacy of ice surrounding the fish should also be observed and recorded at the time of offloading the fishing vessel, along with internal temperature measurements. More fish should be monitored when the quantity or distribution of ice appears inadequate. Temperatures near the surface of exposed un-iced portions should be measured, as well as deep core temperatures of the fish, to ensure all edible portions of the fish are taken into consideration in the assessment.
- Fish should be randomly selected from throughout the fishing vessel delivery lot. The number of fish temperatures monitored and recorded should be sufficient to provide reasonable assurance that temperatures appeared to be controlled by the vessel crew. Variations in species, morphologies, and sizes of fish should be considered and captured in the selection of fish monitored for temperature.
- If an internal temperature in a sample fish exceeds 4°C, then the entire fishing vessel delivery lot should be considered at risk. Higher temperatures usually correspond to higher histamine risk, however, higher deep core temperatures may need to be accounted for when larger fish have been delivered soon after harvest such that the core temperatures have not yet chilled to 4°C or below despite implementation of appropriate chilling procedures. Cooling curves based on studies applicable to the specific fishing sector are useful to ascertain proper temperature critical limits for fish at receiving in these circumstances. If a deviation from the temperature critical limits occurs, the cause should be determined and corrected, and intensified histamine testing performed, or the vessel lot rejected.

X.2.3 Sensory evaluation

Sensory evaluation of fish at reception is a useful screening method to identify fishing vessel delivery lots that have been mishandled or subjected to time - temperature abuse and, hence, are at risk of elevated histamine levels. Neither histamine formation nor decomposition occurs in the

absence of time-temperature abuse. However, the correlation between histamine level and sensory evidence of decomposition is not absolute, and histamine formation often occurs without readily detectable sensory indicators of decomposition. Therefore, sensory evaluation should not be used as the only or final assurance that the histamine level is acceptable, and reliable vessel control records or histamine testing, along with temperature monitoring, should be part of a complete receiving control system.

- Fish for sensory evaluation should be chosen randomly from throughout the fishing vessel delivery lot. Deliveries of multiple species with different compositions, morphologies, and sizes should be taken into account in the sampling strategy. It may be appropriate to select more fish from portions of the delivery identified by vessel records or temperature examination to be at greater risk for histamine formation.
- The number of fish examined should be sufficient to provide assurance that the fishing vessel crew appear to have been vigilant about time-temperature exposures of the fish. The number of samples should be increased when conditions or fishing methods are more likely to introduce variable timetemperature exposures of fish, e.g. longlining, unusually warm weather, unusually large catch size, limited remaining ice, etc.
- Evidence of abuse that may be conducive to histamine formation is indicated when the fish sensory attributes indicate marginal quality, not only when the sensory attributes show advanced decomposition. See FAO “Sensory Assessment of Fish Quality”[6] and Codex “Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories”[7] for guidance on sensory evaluation of fish.
- If sensory evidence of decomposition is detected at reception, it indicates that controls on the fishing vessel may be inadequate and that the entire vessel lot is at risk for elevated histamine. The cause of the decomposition should be determined and the necessary procedural corrections, or equipment repairs, verified. It is justifiable to reject the entire delivery based on inadequate time-temperature control; however, if further evaluation is used to determine if some of the fish are suitable for human consumption, then intensified histamine sampling and testing should be performed on the delivery. The testing should also include the decomposed fish to determine if the decomposition was conducive to histamine formation.

X.2.4 Histamine testing

When a fishing vessel delivering fish has implemented a histamine control system based on HACCP principles, and review of vessel records is one of the controls used by the receiving establishment, then histamine testing is only used as a periodic verification procedure to assess if the vessel control system is adequate and working properly. The number and frequency of the verification tests carried out depend on the number of vessel suppliers and the type of fishery from which the receiving establishment receives fish. If verification test results signal potential lapses in care of the fish, then the frequency of verification testing should be increased until testing and other evidence suggest that the vessel operators have implemented effective corrective measures (e.g. a series of consecutive problem-free deliveries).

When a fishing vessel delivering fish uses GMPs, but has not implemented a histamine control system based on HACCP principles using monitoring and establishing its records that provide

コメント [maff24]: 複数の国からコメントが出ている。NZ や US のコメントをベースにした修正に対し、賛成のスタンスでよいか。

[6] FAO/Torry Advisory Note No. 91, “Sensory Assessment of Fish Quality.” Link: http://www.fao.org/wairdocs/tan/x5989e/x5989e00.htm

[7] CAC/GL 31-1999, “Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories.” Link: http://www.fao.org/fao-who-codexalimentarius/shproxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B31-1999%252FCXG_031e.pdf

assurance and evidence of control, then histamine testing becomes a critical control point at reception rather than a verification procedure, and testing should be applied to every vessel delivery lot. If histamine levels do not meet the required limit, the vessel should be notified and the cause determined and corrected. In addition, the affected fishing vessel delivery lot should be rejected.

The histamine testing guidance in this subsection is also applicable to periodic verification of histamine controls used during later production, storage and transportation steps, as well as for testing to determine product disposition when critical limits are exceeded.

X.2.4.1 Histamine testing, achievable histamine level

- Freshly harvested scombrotoxin-forming fish typically have histamine levels below 2 mg/kg, and food business operators that apply HACCP principles can achieve a histamine level lower than 15 mg/kg[8].
- Marginally elevated histamine levels indicate poor implementation of hygienic processes and histamine controls during harvest, chilling and/or on-vessel storage, and a significant risk that some fish in a lot will have unacceptable histamine levels.
- Histamine achievable levels at vessel reception should be lower than the achievable levels in product further along the distribution chain because the presence of histamine-forming enzymes, as evidenced by histamine levels approaching 15 mg/kg, is likely to result in additional increases with time and exposure to non-refrigerated temperatures during further processing and handling.

X.2.4.2 Histamine testing, sampling strategies

- Sampling plans for histamine should be selected based on statistical performance parameters to be effective. Statistical tables and computer programs provide the information needed to design a sampling plan based on the histamine limits, the degree of protection, and the confidence in results desired. The FAO/WHO Histamine Sampling Tool[9] is a useful application designed for this purpose.
- Determining sampling plan performance usually requires an estimate of the standard deviation of the level being measured. The standard deviation of the histamine levels can be estimated from the global data provided in the FAO/WHO Expert Report (Table 5.1)[10], or it can be estimated when appropriate data have been collected, including worst case scenarios, at the receiving location.
- Because histamine is distributed unevenly in lots (has a high standard deviation), hazardous fish are statistically difficult to find using small sample numbers. The FAO/WHO Expert Report (Section 6.2.2.2)[11] suggests using histamine accept/reject levels ("value for m") that

---

[8] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.1 Management of histamine production in fish and fishery products.)

[9] *FAO/WHO Histamine Sampling Tool*. Link: http://www.fstools.org/histamine/

[10] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Table 5.1 Parameters of the Normal distribution fitted to the logarithm of the concentration of histamine, and probability of exceeding the limit of 200 mg/kg for each survey referenced in Table 3.2.)

[11] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.2.2.2 Using the known standard deviation and the derived mean to design a sampling plan.)

are lower than the target acceptable limit in order to reduce the number of samples required to achieve a given level of confidence in the testing results.

- More sample units should be tested whenever vessel records, sensory analysis, or fish temperatures indicate possible lapses in time - temperature control that could result in elevated histamine.

X.2.4.3 Histamine testing, analytical methods

- It is best to test the raw fish material upon arrival from the fishing vessels, where individual loin sections can be identified. As the fish get processed into various market forms, or product from different vessel lots gets comingled, assessments of the suitability and safety of the fish from the individual fishing vessels becomes more difficult and less effective.
- Several reliable test methods exist for determining histamine levels in fish. The FAO/WHO Expert Report (Section 2.5 Analytical methods for histamine)[12] lists some of the available methods.
- The receiving establishment should confirm that the testing method used is properly validated for the detection limits used. The staff responsible for the sampling and testing should receive training in the procedures used.
- The part of the fish selected for testing will significantly affect the test results. Test portions should be cut from the head-end of the lower loin near the gills because that area has the highest probability of elevated histamine in abused raw fish. Sufficient representation (e.g. approximately 250 grams) of fish muscle, should be collected to prepare for analysis. For smaller fish, in addition to the lower anterior loin portion, the upper anterior loin, and the mid-section of the lower loin, in that order, can also be collected, and for very small fish, multiple fish may need to be collected to acquire a representative sample unit of fish muscle (e.g. approximately 250 grams). The entire sample unit should be thoroughly blended so that the smaller aliquot used for the analytical method is representative of the entire sample unit.
- To screen deliveries more economically, sample units from different fish can be optionally combined (composite sample) to reduce the number of histamine analyses required, provided that the histamine level critical limit is lowered proportionately. For example, after independently grinding each of 3 individual sample units, a portion (e.g. 100 grams from each of the 250 gram ground units) can be further blended together and used for a single composite sample analysis. In this case, the critical limit must be divided by 3 in order to ensure detection of one unit exceeding the critical limit within the composite sample. If the lower critical limit is exceeded, further analysis of the retained individually ground portions from each of the 3 sample units making up the composite may be performed to determine if any sample unit exceeds the non-composited critical limit. Note, the ability to composite multiple sample units is limited by the lowest histamine level that is accurately quantified by the analytical method in use.

X.2.5 Monitoring records (receiving establishment)

- Histamine control records should be maintained at the receiving establishment for trace-back to possible causes if elevated histamine is discovered further along the distribution chain.
- Receiving establishment monitoring records may include, but are not limited to:
  - Relevant information about vessel delivery lot (e.g. vessel name and type, captain's

[12] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 2.5 Analytical methods for histamine.)

コメント [maff25]: Section2.4.2（sampling strategy）に記載した方が適切ではないか。

コメント [t26]: 確かに検査法ではないですね。CRD

コメント [maff27]: US コメント（add.1 の P.29）
「e.g. 100-250 grams」と修正
→国内の試験法に照らして問題ないでしょうか？

コメント [maff28]: US コメント（add.1 の P.29）
「e.g. one third from each of the ground units」と修正
（→OK）

コメント [t29]: 御意

name, date/time of offloading, type and volume (weight) of fish off-loaded)

- Copies of the fishing vessel's monitoring records that were reviewed (refer to Section X.1.5,
- Monitoring records (fishing vessel)
- Sensory evaluation results
- Internal temperatures at the time of offloading
- Histamine test results, when applicable.

- A responsible person should examine, as a part of verification activity, the monitoring records before product release to confirm that critical limits were maintained, and that appropriate corrective actions were taken when necessary.

X.3 Transportation

- Refer to Section 20 (Transportation)
- Refer to Section X.1.4 (Refrigerated and frozen storage)
- Transport vehicles or vessels should be adequately equipped to keep fish cold by mechanical refrigeration or by completely surrounding the fish with ice or other cooling media.
- Vehicles or vessels should be pre-chilled before loading fish where applicable.
- Refrigerated compartment temperatures, or cooling media such as ice slurries, should be monitored during transportation between locations (e.g. receiving establishment, processing establishment, distributor, market, etc.) using continuous temperature recording devices (where practical), and the receiving establishment should review the temperature record from the device. Devices should be periodically calibrated for accuracy.
- At delivery, internal temperatures of a representative sample of fish, and adequacy of ice or other cooling media when applicable, should be monitored by receiving personnel as described in Section X.2.2 Temperature monitoring.
- If a temperature control critical limit is exceeded, the cause of the problem should be identified and corrected by the operator of the vehicle or vessel. The affected lot may be rejected by the receiving personnel, or the receiver may perform intensified histamine analysis on representative fish collected throughout the lot, and the lot rejected if any fish are over the histamine critical limit (See subsection X.2.4).

X.4 Processing operations

This section applies to processing on land or at sea (e.g., factory vessel, mother ship)

X.4.1 Reception (processing establishment)

- If fish are delivered directly from the fishing vessel to the processing establishment, then refer to Section X.2 Reception (receiving establishment).
- If fish are delivered by transport vehicle or vessel, then refer to Section X.3 Transportation. If the processing establishment is a secondary processor receiving product from a primary processor (e.g. receiving establishment or factory vessel), then the secondary processor

コメント [maff30]: 【質問】factory vessel の中には、GMP only の船もあるという理解でよいか。（下の EU コメントに関連）

コメント [t31]: それはない

should ensure that the primary processor uses HACCP or a similar control system designed to prevent formation of hazardous levels of histamine.

- When it is impractical for the initial receiving establishment to conduct all the appropriate histamine controls listed in subsection X.2 (i.e. vessel records review, temperature monitoring, sensory evaluation, and histamine testing), then the processing establishment should conduct these activities, and should ensure that the controls and decisions are applied to intact fishing vessel lots that are not comingled with other lots. However, fish internal temperatures (and adequacy of ice, where applicable) should always be monitored at vessel delivery (to evaluate vessel control), as well as at the processing establishment (to evaluate transport control).

コメント [maff32]: EU コメント（Add.1 の P.30）
The notion of similar control system is not defined in the document; a receiving establishment or a factory vessel should have in place a control system based on HACCP

コメント [t33]: これはどういう意図なのかわからない

X.4.2 Processing, time and temperature control

When fish undergo processing (e.g., thawing, cutting, re-chilling, salting, drying, pickling, smoking, canning) it is important that they are not held at temperatures for sufficient time that histamine-producing bacteria can grow and produce histamine to hazardous levels.

- Scientific studies and microbial growth models[13] may be used to estimate the exposure times and temperatures that result in elevated histamine levels.
- Histamine formation is quite variable and strongly depends on the previous handling of the raw material and the different species of histamine-producing bacteria that are present; therefore, the worst case scenario should be considered when establishing critical limits.
- The acceptable maximum histamine level used to establish processing time-temperature critical limits should take into consideration any further handling, processing, storage, and preparation that may lead to further histamine formation before consumption.
- The measure used for time-temperature critical limits should be the cumulative product nonrefrigerated time-temperature exposure over all processing steps.
- Processing room temperature should be maintained as cool as practical during processing operations, and product exposure times should be minimized. For example, fish should be iced, or returned to refrigerated storage, during production breaks or production flow slow-downs.
- Controlled product flow and batch monitoring is an effective strategy to ensure product is not subjected to unacceptable time-temperature exposures. For example, periodically measure the ambient temperature and the time for a marked batch to begin and complete the processing step.
- Air thawing of raw material should occur at refrigerated temperatures to prevent excessive warming of the surface of the fish. Immersion in circulating cold water or spraying with cold water may be used to shorten thawing time. For re-chilling and refreezing, see Subsection X.1.3.
- When time-temperature critical limits are exceeded, the cause should be determined and corrected. In addition, intensified histamine testing should be performed (see section X.2.4.2) before releasing affected product for human consumption. Alternatively, product should be rejected.

コメント [maff34]: 使う分だけ解凍すること、一旦解凍したものを再凍結しないことを追記すべきではないか。

「ヒスタミン食中毒予防マニュアル」（大日本水産会）の、項目４（調理施設では）に、以下の記載あり
・使う分だけを解凍し、解凍後は速やかに調理する。
・一旦解凍したものを再凍結して使用しない。

コメント [t35]: 良いコメントです。CRD で出しますか？

X.4.3 Heat processing

コメント [maff36]: 他の章と比較すると、critical limit（ヒスタミン産生菌の殺菌を達成するため）の設定など具体的な対策に関する記述が少ない印象。
（本規範の別の章でカバーしているので本 draft には詳細を書かないという整理か？）

コメント [t37]: そうです。

[13] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.1.9 Microbiological modelling.)

- Adequate heat treatment (e.g. cooking, hot smoking) can kill histamine-producing bacteria and inactivate histidine decarboxylase enzymes. *Morganella morganii* is probably the most heat resistant of the histamine-producing bacteria, and in Australian salmon/ kahawai at temperatures between 58 and 62°C, the D-values for eliminating these bacteria and their associated HDC enzymes were between 15 and 1.5 minutes (FAO/WHO 2012).
- Once formed, however, histamine itself is heat stable and is not destroyed by heat. Therefore, histamine controls during harvesting, and during other steps prior to thermal processing, are critical to prevent inclusion of previously formed histamine in the finished product.
- If the product is exposed to bacterial contamination and temperature abuse after initial heating, histamine formation may start again. Thus, for products such as hot smoked fish, care should be taken to avoid contamination after smoking. Additionally, refrigerated storage is essential unless the water activity is reduced sufficiently or some other means is used to prevent bacterial growth.
- For commercially sterile canned or pouched products, the container protects the product from bacterial recontamination, and no further histamine is produced when stored at ambient temperatures. However, once the product package is opened, histamine formation can occur again if the product is recontaminated in the absence of preventative time-temperature controls.

X.4.4 Processing, other technological measures

Time and temperature control is the recommended method for preventing histamine formation in fresh, frozen, and refrigerated processed fish products.

Some products and processes (e.g. fermenting, smoking, salting, drying, pickling, acidifying, preserving, modified atmosphere packaging) introduce other technological factors that may inhibit the introduction and/or growth of histamine-producing bacteria. The interaction of these factors is complex and often unpredictable. For example, increased salt content, or increased acidity, may decrease or increase histamine production, depending on conditions.

Thorough scientific studies, and proper establishment and validation of control parameters for each specific process and product, are imperative to ensure the safe manufacture of foods that incorporate other technological measures as an element of histamine control. (See Guidelines for the Validation of Food Safety Control Measures, CAC/GL 69 - 200.)

The safe application of any of these treatments is dependent on the rapid chilling and maintenance of chilled temperatures of the raw fish material from the time of death of the fish until the proper inhibitory or destructive control attributes contributed by the treatments have been achieved. And, depending on the treatment, the finished product may need to remain chilled until consumed to ensure safety.

X.4.5 Refrigerated and frozen storage (processing establishment)

- Refer to Section X.1.4 Refrigerated and frozen storage (fishing vessel).
- For products whose preparation does not include a heating step or other means to eliminate histamineproducing bacteria and their enzymes, the presence of histamine-producing bacteria means that refrigerated storage will continue to be a critical control point for the inhibition of histamine formation throughout the shelf-life of the products until consumed.

X.4.6 Monitoring records (processing establishment)

- Processing establishment monitoring records may include, but are not limited to:

コメント [maff38]: not limited to と書いてあるものの、加熱工程の温度・時間も例示に入れた方がよいのではないか。

コメント [t39]: そういえばそうですね。これも CRD？

- Transport vehicle or transport vessel temperature log or adequacy of ice, and fish internal temperatures
- Temperatures and exposure times of product during unrefrigerated processing steps
- Critical control point monitoring records for other validated methods used to control histamine formation in processed fish
- Refrigerated storage temperature logs.

- A responsible person should examine the monitoring records before product release to confirm that critical limits were maintained, and that appropriate corrective actions were taken when necessary.

The processing facility should use histamine testing to periodically verify that histamine controls are working properly (Refer to section X.2.4).

CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

E

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 5 **CX/FH 17/49/6**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

Forty-ninth Session

Chicago, Illinois, United States of America, 13 - 17 November 2017

PROPOSED DRAFT GUIDANCE FOR HISTAMINE CONTROL IN THE *CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS* (CAC/RCP 52-2003)

Prepared by the Electronic Working Group led by Japan and the United States of America

Codex members and Observers wishing to submit comments at Step 3 on this draft should do so as instructed in CL 2017/70-FH available on the Codex webpage/Circular Letters 2017:

http://www.fao.org/fao-who-codexalimentarius/circular-letters/en/. Comments will only be accepted through the online commenting system within the deadline indicated in CL 2017/70-FH.

Background

1. During the 48th Session of the Committee on Food Hygiene, the CCFH agreed to develop separate guidance on histamine control and to decide at a later stage on the final format in the *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003)[1].

2. The Committee agreed to establish an electronic working group (EWG), co-chaired by Japan and the United States of America, working in English, with the following terms of reference:

a. Revise control guidance of the Code of Practice for Fish and Fishery Products for the "hazard of scombrotoxin fish poisoning", using histamine as the marker biogenic amine for control, and using a GHP and HACCP-based approach, for circulation for comments at Step 3.

b. Ensure that the guidance covers the entire food chain (harvesting, storage, handling, processing, and distribution).

c. Include, where appropriate, scientific information about histamine formation with the purpose of informing on the importance of time/temperature controls.

d. Consider if any products covered by the Code of Practice for Fish and Fishery Products need specialized or revised control guidance.

e. Consider based on the review of scientific literature by FAO/WHO, the inclusion of Salmonidae in the list of susceptible species in the table which will be adopted from the FAO/WHO Table 2.3[2].

Electronic Working Group

3. 28 member countries (Argentina, Australia, Brazil, Canada, Chile, China, Costa Rica, Ecuador, France, Germany, India, Japan, Malaysia, Morocco, Mexico, New Zealand, Norway, Peru, Philippines, Poland, Portugal, Singapore, Spain, Switzerland, Thailand, United Kingdom, United States, and Uruguay), one member organization (European Union) and three international organizations (FAO, WHO and ICMSF), and one NGO (NHF) participated in the EWG. A complete list of participants is attached as Appendix II.

4. The proposed draft document was initially drafted by the co-chairs, circulated twice for participant comments, and revised twice based on comments received.

---

[1] Code of Practice for Fish and Fishery Products. Link ftp://ftp.fao.org/codex/Publications/Booklets/Practice_code_fish/CCFFP_2012_EN.pdf

[2] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome. Link: http://www.fao.org/fileadmin/user_upload/agns/pdf/Histamine/Histamine_AdHocfinal.pdf

5. The EWG did not consider Item d in the terms of reference ("Consider if any products covered by the Code of Practice for Fish and Fishery Products need specialized or revised control guidance"). This item may be better considered when aligning the existing Code with the draft section.

6. The following were significant EWG discussion points:

7. One participant commented that all content relating to the application of HACCP principles on fishing vessels should be removed from the document. In their viewpoint, fishing vessels in developing countries only box and ice fish and these are primary production activities that should be excluded. And, that the FAO/WHO Expert Meeting concluded that histamine formation and SFP can be easily controlled, and the risk from SFP is best mitigated by applying basic GHPs and, where feasible, a HACCP system. In response to these comments, several changes were made to clarify that the draft guidance applies to vessels that use basic GMPs, and to vessels that use basic GMPs and HACCP systems. The Draft recommends that when establishments receive fish from vessels that apply basic GMPs without a HACCP system (i.e. without a documented structure and monitoring records), then the receiving establishment should monitor histamine levels in the fish.

8. Several participants asked about the relationship between draft section X.2.4 (Histamine testing), and the work to be done later on sampling guidance. It was discussed that the later work was a revision of eleven Codex commodity standards that contain histamine safety limits, and that these standards were determined by CCFFP to have inconsistent, and possibly inadequate, sampling guidance for determining compliance of lots in trade with the histamine safety limit listed in the standard. *The Code of Practice for Fish and Fishery Products* serves a different purpose and contains guidance for producers on how to produce safe products with acceptable quality that will meet the end-product requirements of the Codex commodity standards.

9. One participant asked where the new histamine section would fit in the code. It was discussed that the proposed draft was designed to be a separate section within the Code, and that it is analogous to existing sections because it covers a subset of fish and fishery products, and contains control guidance at production steps. It was noted that the Introduction to the Code (How to use this Code) explains the aim and layout of the Code, and that the Proposed Draft can be added within sections 10-19 (Processing of specific fish and shellfish products).

10. One participant recommended revising an existing section of the adopted Code in order to reference the proposed draft section. It was discussed that significant editing to several sections of the existing Code will be required in order to reference the proposed draft section and to assure alignment of the existing guidance with the new guidance, and that work on aligning the existing Code should not begin until it is agreed to advance the proposed new section forward.

11. Several participants asked if the EWG was considering inclusion of Salmonidae in the table of at-risk species as listed in the terms of reference. It was noted that the FAO/WHO review was not completed, and inclusion of salmon, and the title of the table, would need to be considered after completion of the FAO/WHO review.

Recommendations

12. The working group recommends that the Committee:

a. Consider advancing the proposed draft (Appendix I) as a new section in the Code.

b. Consider when to begin an EWG for aligning the existing Code with the draft new section, taking into consideration that this work may lead to significant revisions of the adopted Code, and that it will rely on overall CCFH agreement on the content of the draft new section.

c. Regarding the table of at-risk species for the Code derived from Table 2.3 in the FAO/WHO Expert Meeting Report:

   i. Consider the inclusion of Salmonidae in the table based on the FAO/WHO review.

   ii. Consider the appropriate title for the table, which may depend on if Salmonidae are included.

   iii. Confirm where the table will be located (e.g. as a new annex in the Code).

Appendix I

PROPOSED DRAFT REVISION OF THE *CODE OF PRACTICE FOR FISH AND FISHERY PRODUCTS* (CAC/RCP 52-2003)
NEW SECTION [X] FOR FISH AT RISK FOR SCOMBROTOXIN FORMATION

(for comments at Step 3 through https://ocs.codexalimentarius.org)

SECTION [X] – HARVESTING, PROCESSING, STORAGE AND DISTRIBUTION OF FISH AND FISHERY PRODUCTS AT RISK FOR SCOMBROTOXIN (HISTAMINE) FORMATION

Preamble

This section complements other sections of the Code by providing detailed control recommendations for the prevention of scombrotoxin fish poisoning (SFP). This section only applies to specific marine finfish species (listed in Annex [Z]) at risk of developing hazardous levels of histamine. This section contains specific guidelines for preventing SFP; however, within the scope of this Code, it is not possible to provide all the appropriate controls and alternatives that may apply to every operation because these will vary with each particular operation.

Scombrotoxin fish poisoning (SFP) is a worldwide food safety challenge that, in some parts of the world, accounts for the largest proportion of fish-borne illness cases. Individuals suffering from SFP may show one or more symptoms including flushing, swelling, rash, itching, headache, heart palpitations, abdominal cramps, diarrhoea, and vomiting. In some cases, exacerbation of asthma and more serious cardiac manifestations may occur. Symptoms typically develop rapidly (from 5 minutes to 2 hours after ingestion of implicated fish), with a usual duration of 8–12 hours, although symptoms may persist for up to several days. SFP is rarely fatal.

Scombrotoxin fish poisoning is caused by the ingestion of certain species of marine fish (listed in Annex [Z]) that have been **subjected to time-temperature abuse and** allowed to develop **scombrotoxin.** ~~biogenic amines such as histamine. These species generally contain high levels of free histidine in their musculature and are more likely to form hazardous levels of histamine after death when subjected to time-temperature abuse.~~ [US]

Although detailed components of scombrotoxin have not been identified, it is generally accepted that biogenic amines produced by spoilage bacteria, especially histamine, play an important role in the pathogenesis of SFP. Other biogenic amines that are also produced during fish spoilage, such as cadaverine and putrescine, are thought to increase the toxicity of histamine. However, in most epidemiological studies, SFP is associated with high histamine levels in the implicated fish, and the controls used to inhibit histamine-producing bacteria and enzymes are also expected to be effective at preventing the formation of other biogenic amines. Therefore, histamine serves as a useful indicator compound for scombrotoxin, and histamine is monitored for scombrotoxin control purposes.

Histamine is produced in fish and fishery products by spoilage bacteria that are part of the natural microflora of the skin, gills, and gut of freshly caught fish. After the fish die, these bacteria migrate into the previously sterile fish musculature where they multiply if time and temperature are not controlled. When histamine-producing bacteria multiply in fish flesh, they produce histidine decarboxylase **(HDC)** enzymes, **that** ~~which~~ convert histidine **(naturally present in muscle tissue flesh of at risk fish)** into the toxic metabolite histamine. [US, NZ]

Rapid multiplication of histamine-producing bacteria can be prevented by chilling fish immediately after death and maintaining the fish in a chilled, or frozen, state from harvest to consumption. However, once sufficient bacterial multiplication has occurred to produce histidine decarboxylase, enzymatic activity can continue to produce histamine slowly at refrigeration temperatures.

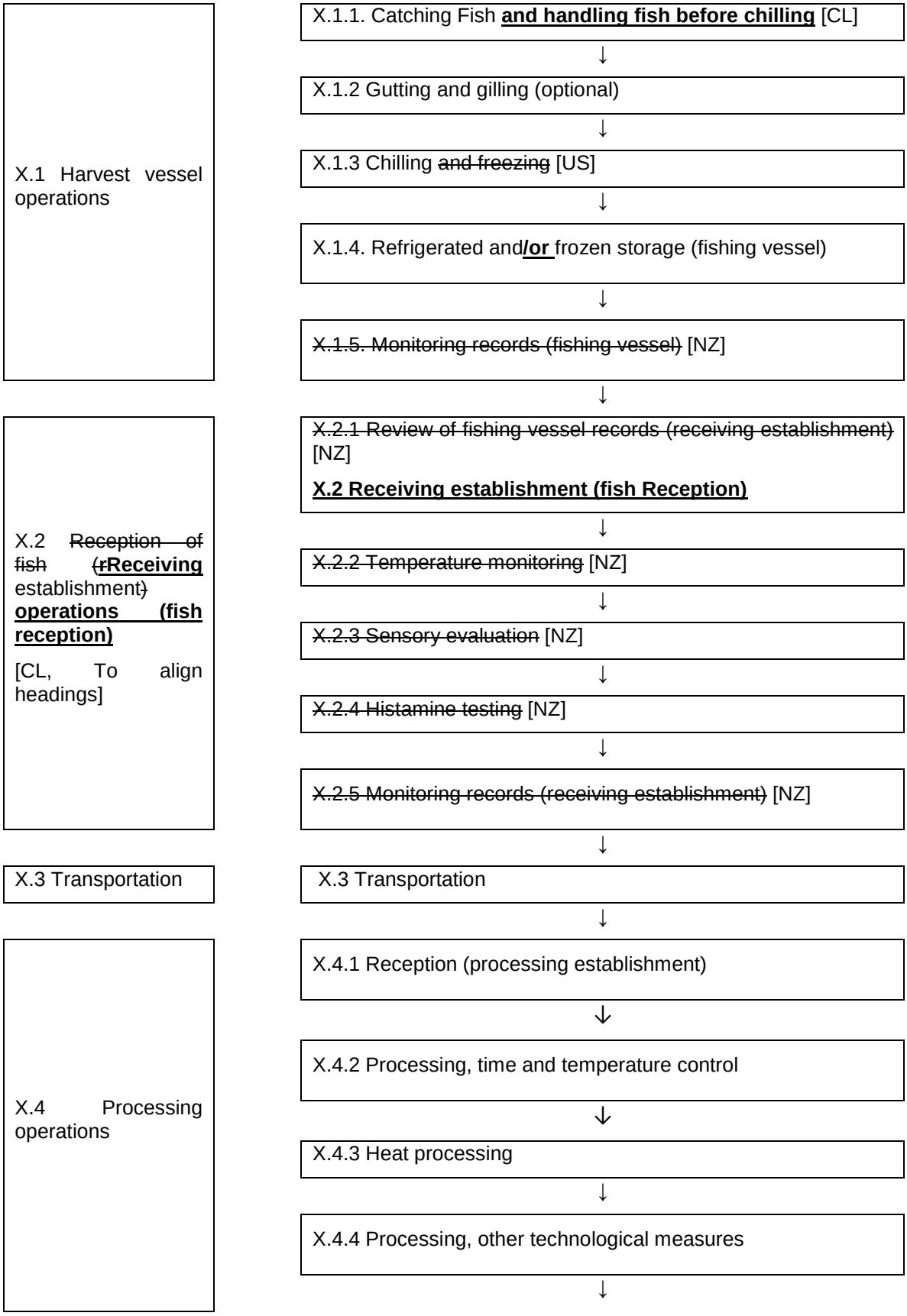
~~Histamine formation is effectively controlled by adherence to good manufacturing practices to maintain hygienic quality of fish, and by using HACCP principles to control detrimental fish time-temperature exposure.~~ [CL (co-lead), use of GMPs and HACCP is explained in “Introduction, “How to use this Code”]

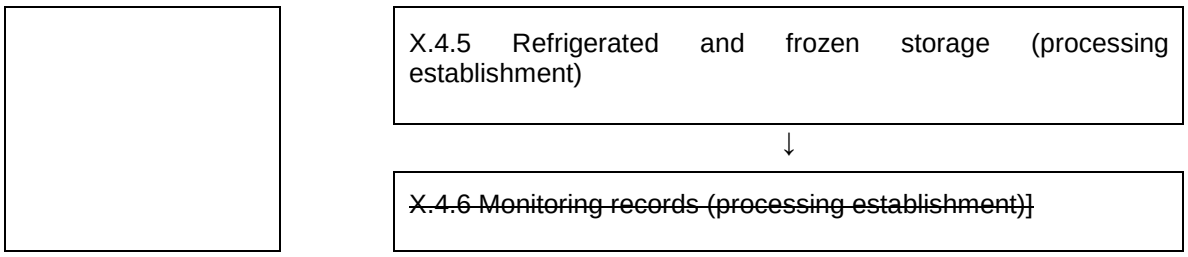
The following subsections contain technical guidance for the control of histamine formation at key steps in the food chain (harvesting, receiving, transportation, and processing operations).

The relevant guidelines in **this** section ~~X.1 (Harvest vessel operations)~~ also apply to ~~**the harvest of**~~ aquacultured fish. [NZ]

Figure X.1. Example flow chart for the production of fish at risk of scombrotoxin formation.

This flow chart is for illustrative purposes only. For implementation of HACCP principles, a complete and comprehensive flow chart has to be drawn up for each product.





X.1 Harvest vessel operations

Fishers use many different harvesting methods throughout the world, employing hooks, nets, and traps. ~~Water and environmental temperatures vary depending on geographic location and season~~. [MAR] In all cases, live retrieval or quick retrieval of dead fish, rapid chilling of the fish in a timely manner, and maintenance of the fish at cold temperatures, are critical to prevent histamine formation.

~~Time for histamine formation can vary substantially at the same temperature because different histamine-producing bacteria with different histamine-producing activity may be present. Time-temperature critical limits should take into account the potential for histamine production under the worst-case conditions for the particular operation.~~ [CL moved to X.1.1]

The fishing vessel and equipment, and the methods used, should be designed or adapted to prevent histamine formation for the catch sizes, fish sizes, fish species, and air and water temperatures encountered. Vessel crews should be trained in hygienic practices and temperature control methods and understand their importance **for histamine control**. ~~and~~ **Where HACCP principles are used, persons** responsible ~~crew members~~ **for developing HACCP documentation** should be trained in HACCP principles used to control histamine formation, ~~where possible~~. [NZ]

Traditionally, vessel operations use GMPs to control histamine, in which case the shore-based receiving establishment should perform histamine testing on each vessel delivery to monitor and document acceptable histamine levels in the raw material received. If vessel operations use a HACCP approach that provides documented evidence that histamine was controlled on the vessel, then the receiving establishment may choose to examine the vessel monitoring records as an alternative to testing each lot. [CL clarification] **The u**se of HACCP principles to control fish time-temperature exposure on ~~the~~ harvest vessel**s** ~~is an effective means to prevent hazardous levels of histamine formation, and~~ provides ~~better~~ **more reliable** consumer protection than ~~the alternative approach of~~ testing histamine levels ~~in fish~~ after delivery. [US]

X.1.1 Catching and handling fish before chilling [CL clarification of key control period, bullets rearranged in time order]

- ~~Critical l~~**L**imits should be established for the time period between death of the fish and the start of chilling that will effectively ~~prevent~~ **minimize** [NZ, CL] histamine production. The~~is~~ time period **may be adjusted according to water and air temperatures ~~encountered~~, the size and species of fish caught, and other relevant factors of the operation. The types of histamine-producing bacteria present and how rapidly they produce histamine can also change, therefore established ~~critical~~ limits should take into account the worst-case scenario. The FAO/WHO Expert Report (Section 6.1.1 Chilling)**[3] **provides examples of time-~~temperature~~ limits from fish death to chilling for medium to large fish.** [US] ~~for further guidance on establishing time-temperature critical limits for fish after death. Time of death of the fish may be the time slaughtered onboard, or where the actual time of death is not observed or truly known, an estimated time based on an observable event, such as the time of deployment of a longline when some of the fish are landed dead.~~ [US, CL]
- **Time of death of the fish may be the time slaughtered onboard, or where the actual time of death is not observed or truly known, an estimated time based on an observable event, such as the time of deployment of a longline when some of the fish are landed dead.** [US]
- The time period that nets or hooks are left in the water, and the number and rate of fish caught, should be optimized to allow live landing of fish where practical.

[3] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.1.1 Chilling.) Link: http://www.fao.org/fileadmin/user_upload/agns/pdf/Histamine/Histamine_AdHocfinal.pdf

- The rate or volume of catch should not exceed the ability of the crew to quickly initiate chilling, and should not exceed the capability of the vessel's chilling system to **achieve and** [NZ] maintain ~~critical~~ **established** limits ~~for cooling media temperature, or sufficiency of ice~~. [CL]
- Fish should be removed from nets and hooks as quickly as possible to prevent death or to minimize the period from death until chilling of the fish.
- Rough handling, overcrowding and over stacking of fish should be avoided where practical because crushing, bruising, and lacerations of the skin accelerate the spread of histamine-producing bacteria from the gut, gills, and skin into the fish **muscle** ~~musculature~~. [NZ]
- If captured fish are held in the sea for too long following death, decomposition commences, and histamine can begin to form. The warmer the seawater, the more rapid the decomposition and the greater the risk of histamine formation. Dead fish that exhibit marginalized quality attributes, consistent with exposure to time-temperature abuse, should not be retained on board the vessel, or, if retained, should be segregated and identified ~~**properly**~~ to allow ~~**testing and**~~ [NZ] proper disposition when off-loaded. In addition, the harvesting methods should be modified in a way that no dead fish with marginal quality will be brought on board **in the future**. [CL]
- Before landing fish, the deck area and equipment should be hygienically cleaned to avoid contamination of fish (see Section 3.4 Hygiene control program), and the chilling medium should be ready and at the target temperature.
- ~~The time period between death of fish and chilling that will effectively **minimize** prevent histamine formation can vary based on the ocean **water** and air temperatures encountered, the sizes and species of fish caught, and other relevant factors particular to the harvesting operation. See the FAO/WHO Expert Report (Section 6.1.1 Chilling)~~ [4] ~~for further guidance on establishing time-temperature critical limits for fish after death.~~ [US (CL) concept incorporated above]

X.1.2 Gutting and gilling (optional)

- Histamine-producing bacteria are universally present in the gut, gills, and skin of fish at the point of capture. Rapid removal of guts and gills, and rinsing of the gut cavity, significantly delays histamine formation in the muscle.
- For large fish, removing the gut aids chilling by allowing chilling media (e.g. ice, refrigerated seawater) access to the visceral cavity, resulting in more rapid chilling of this bacteria-laden ~~region~~ **part** [MAR] of the fish.
- Care should be taken and hygienic practices should be maintained during gutting and gilling in order to minimize the spread of bacteria from the guts, gills, skin, and other contamination sources, into the muscle ~~tissue~~. [CL]

X.1.3 Chilling ~~and freezing~~ [US, CL, bullets rearranged in time order]

Rapid chilling as soon as possible after death is the most crucial aspect of histamine control because bacterial growth and histamine formation accelerate exponentially with time under unrefrigerated conditions. Few prolific histamine-producing bacteria will grow and multiply at refrigeration temperatures, and the growth rates of those that do are much reduced.

- ~~Critical~~ **Temperature** limits and monitoring ~~methods and~~ frequencies should be established for the onboard chilling/freezing process. For example, limits may be established for maximum loading volumes and rates, **and** maximum starting temperature for RSW and/or brine tanks~~, and monitoring frequencies~~ to ensure an adequate chilling environment is maintained ~~for the duration of the chilling operation~~ for each harvested set[5] of fish. [NZ, MAR, CL]
- Sufficient ice to completely surround ~~each~~ **the** [MAR] fish, or preferably, ice/seawater slurries or refrigerated seawater (RSW) should be used to bring the internal temperature of fish to below 4°C as quickly as possible after death to slow bacterial growth and enzymatic activity.

[4] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.1.1 Chilling.) Link: http://www.fao.org/fileadmin/user_upload/agns/pdf/Histamine/Histamine_AdHocfinal.pdf

[5] A "set" means the fish from one set net, or the fish from one set long-line, etc.

- Where ice is used, fishing vessels should have sufficient ice for the amount of fish that could be caught and for the potential length of the fishing trip. For further information see FAO Fisheries Technical Paper 436 (The use of ice on small fishing vessels)[6].
- For larger eviscerated fish, the belly cavity should be packed with ice, or other cooling media, for more rapid chilling of this bacteria-laden **part** ~~region~~ [MAR] of the fish.
- Freezing **fish** is more effective **in preventing histamine formation** than ~~refrigerated~~ chilling and maintaining **fish near 4°C** ~~chilled temperatures **in preventing histamine formation**~~. [US,NZ] It is good practice to gut the fish before freezing. Freezing to -18 °C, or below, will stop the growth of histamine-producing bacteria and will prevent any preformed histidine decarboxylase enzymes from producing additional histamine.
- Note that freezing does not detoxify preformed histamine, nor does it effectively eliminate histamine-producing bacteria and enzymes, which can become active when temperatures increase again, such as during processing or meal preparation.
- Crew members responsible for chilling should provide feedback to the catching operation to **ensure** ~~assure~~ [US] that the rate or volume of incoming fish does not exceed the ability to rapidly chill the fish within established time-temperature ~~critical~~ [CL] limits and maintain the fish in a chilled state. (US)
- Care should be taken to manage the chilling of dead fish to ensure that none are inadvertently left exposed on deck past the ~~critical~~ [CL] time limit **established** for the **temperature** conditions. [NZ]
- Refrigeration ~~and other chilling~~ [US] equipment should be in good repair, and operated in a manner that quickly chills fish without physical damage. For example, fish should be packed loosely in ice slurries, RSW, and brine tanks to allow good circulation and rapid cooling.
- ~~Where ice is used, fishing vessels should have sufficient ice for the amount of fish that could be caught and for the potential length of the fishing trip. For further information see FAO Fisheries Technical Paper 436 (The use of ice on small fishing vessels)[7].~~
- ~~For larger eviscerated fish, the belly cavity should be packed with ice, or other cooling media, for more rapid chilling of this bacteria-laden **part** region [MAR] of the fish.~~

X.1.4 Refrigerated and/or frozen storage (fishing vessel and transfer vessel)

- **Refrigerated** ~~F~~**f**ish [US] should be stored at a temperature as close as possible to 0°C ~~(4°C or below)~~**. The storage temperature should be kept below 4°C** until off-loading. [BRA] ~~Refrigerated s~~**S**torage at ~~4°C or below~~ **these temperatures** will inhibit **or slow the** growth and enzyme production for most histamine-producing bacteria~~, and will slow the growth of the less prolific histamine-producing bacteria that can grow at refrigerated temperatures~~. [NZ]
- Ice, where used, should completely surround the stored fish and be regularly monitored throughout the trip and replenished as necessary.
- Refrigerated seawater and/or brine temperature should be **regularly** monitored **throughout the trip** and ~~carefully~~ controlled in order to ~~help~~ maintain inhibitory **storage** temperatures. [NZ]
- Continuous temperature recording devices, **or thermometers,** should be used ~~where practical~~ in refrigerated and frozen storage compartments to ~~enable~~ **ensure that** inadequate **holding** conditions ~~to be~~ **are** identified and appropriate actions taken to minimize consumer risk. [COL, NZ, US, CL]

X.1.5 Monitoring records (~~fishing and transfer~~ applicable to vessels using HACCP principles) [CL]

- Records of histamine control monitoring activities should be maintained in a way that they can be readily retrieved for trace-back to possible causes if elevated levels of histamine are detected later.
- Records should be made available to the receiving establishment that offloads the fish from the vessel to provide evidence that histamine controls were implemented ~~**properly and**~~ effectively by the ~~**fishing and transfer**~~ vessel. [NZ]

---

[6] *FAO Fisheries Technical Paper 436* ("The use of ice on small fishing vessels.") Link: http://www.fao.org/docrep/006/Y5013E/y5013e00.htm#Contents

[7] *FAO Fisheries Technical Paper 436* ("The use of ice on small fishing vessels.") Link: http://www.fao.org/docrep/006/Y5013E/y5013e00.htm#Contents

- Vessel records should include **real-time** documentation of ~~**actual**~~ observed activities ~~**and times**~~ pertinent to onboard controls for all histamine-forming fish harvested from each fishing set on each fishing trip. [NZ, CL]
- The records ~~kept~~ **of histamine control monitoring activities** [NZ] depend on the operation and may include:
  - ~~Ocean water temperature and air temperature~~ [US]
  - Dates and times of earliest fish death, and times to get fish into appropriate chilling media
  - ~~Initial RSW and/or brine tank temperatures~~ [US]
  - Brine, RSW, or storage compartment refrigeration temperature monitoring records or checks for adequacy of ice during the chilling operation and during ~~holding~~ **storage** of the fish for the duration of the fishing trip. [NZ]
  - ~~Ocean w~~**W**ater ~~temperature~~ and air temperature [NZ]
- A responsible crew member should review the monitoring records daily to confirm that critical limits were met, and that appropriate corrective actions were taken when necessary.
- ~~Where onboard record keeping is impractical, such as for small artisanal day boats, the operation receiving the fish may be able to monitor and record all the parameters necessary to assure histamine control (e.g. time of departure and return, air and water temperature, adequacy of ice and fish internal temperature, etc.), and avoid the need to test histamine levels at receipt.~~ [CL]
- If some of the fish ~~stored~~ on the vessel are **determined based on monitoring records to be** at risk for **unacceptable** histamine **levels** ~~formation because critical limits were exceeded~~, then these fish should be segregated and identified in order to allow targeted testing and**/or** proper disposition at unloading. [NZ, CL]

X.2 ~~Reception of fish (r~~ Receiving establishment~~)~~ operations (fish reception) [CL, alignment of section headings]

Fish reception (at the establishment where the fish are offloaded from the fishing or transfer vessel) is an important control point for histamine**.** ~~because t~~**T**his is where ~~vessel records,~~ fish temperatures, signs of decomposition, and histamine levels **and/or vessel records** ~~are best~~ **should be** monitored**,** ~~and decisions are made as to whether the fish are safe to accept for processing or to proceed in commerce.~~ [CL, (NZ)]

Reception controls may need to be specific to both the harvest vessels as well as to any collection/transfer vessels that deliver the fish to the receiving establishment.

If deficiencies in ~~**fishing**~~ [NZ] vessel controls are found at receiving, feedback should be provided to the vessel operator, and the cause(s) of the problem should be evaluated and corrected before future deliveries from the fishing vessel are considered. In addition, appropriate corrective actions regarding the delivered fish should be taken and recorded.

During offloading of fish from the ~~**harvest**~~ vessel (and at any point of transfer in the supply chain), care should be taken that the cold chain is maintained. For example, fish should be offloaded quickly, fish totes should not be left exposed to elevated temperatures, and fish should be re-iced or placed under refrigeration in a timely manner. Frozen fish should be ~~handled in a manner to~~ maintain**ed in** the frozen state. [NZ]

~~**X.2.1 Review of fishing vessel controls and records (receiving establishment)**~~ [CL, section moved down]

~~Review of fishing vessel histamine control systems and monitoring records, when available, is an effective method to ensure that appropriate procedures were followed to help control histamine formation in the fish while on the fishing vessel.~~

- ~~Refer to Section X.1.5 Monitoring records (fishing vessel).~~
- ~~Vessel records applicable to histamine control should be requested and reviewed by the receiving personnel to determine if they are complete and reflect appropriate harvest and onboard handling practices, and that all applicable fishing vessel critical limits were met.~~
- ~~If vessel records are incomplete and the receiving establishment cannot reliably ensure that the specific delivery of fish was harvested, handled, and stored in a manner that prevents histamine formation, such as by intensified histamine sampling and testing, the delivery should be rejected.~~

- ~~Sometimes the impact of a critical limit deviation on the fishing vessel may be minimized if the records clearly show that only part of a delivery was affected (e.g. one brine well or one specific fishing set during the fishing trip) and if the affected fish can be effectively segregated from the rest of the delivery when the vessel is unloaded. Precautions should be taken to ensure none of the other fish in the delivery have been affected.~~

- ~~Histamine testing can be used when vessel records are not available or unclear. However, this testing can be less reliable because histamine may be unevenly distributed within and between fish, and fish with high histamine are difficult to find using limited or small sample sizes. Sampling and testing that is statistically meaningful in terms of appropriate consumer protections can be resource intensive. Histamine testing at fishing vessel reception is therefore best used as verification of the effectiveness of a properly implemented and documented histamine control system on the fishing vessel. (Refer to Section X.2.4 Histamine testing.)~~

X.2.~~2~~1 Temperature monitoring

- Fish internal temperatures should be measured at reception to **ensure reception termperature limits are met, and to** help ~~ensure~~ **provide confidence** that fish were properly stored onboard the fishing and transfer vessel~~.~~ [NZ, CL]

- For fish stored in ice, the adequacy of ice surrounding the fish should ~~**also**~~ [US] be observed and recorded at the time of offloading the fishing vessel, along with internal temperature measurements. More fish should be monitored when the quantity or distribution of ice appears inadequate. Temperatures near the surface of exposed un-iced portions should be measured, as well as deep core temperatures of the fish, to ensure all edible portions of the fish are taken into consideration in the assessment.

- Fish should be randomly selected from throughout the fishing vessel delivery lot. The number of fish temperatures monitored and **results** recorded should be sufficient to provide reasonable assurance that **the** temperatures appeared to be controlled by the vessel crew. Variations in species, morphologies, and sizes of fish should be ~~considered and captured in the selection of fish monitored for temperature~~ **taken into account when taking samples**. [NZ]

- **Fish on the vessel should have been stored at a temperature as close as possible to 0°C (4°C or below).** If an internal temperature in a sample fish exceeds 4°C, **(or the established temperature limit based on elapsed time from death),** then **this indicates a lapse in histamine control. The cause of** the **deviation should be determined and corrected, and intensified histamine testing of the** entire ~~fishing~~ vessel delivery lot ~~should be considered at risk~~ **performed, or the delivery rejected**. [US]

- ~~If an internal temperature in a sample fish exceeds 4°C, then the entire fishing vessel delivery lot should be considered at risk.~~ [US] Higher temperatures usually correspond to higher histamine risk~~,~~**;** however, higher deep core temperatures may need to be ~~accounted~~ **allowed** for ~~when~~ **in** larger fish **that** have been delivered soon after harvest ~~such that the core temperatures~~ **and** have not yet chilled to 4°C or below despite implementation of appropriate chilling procedures. Cooling curves based on studies applicable to the specific fishing sector are useful to **establish** ~~ascertain~~ proper ~~temperature critical limits for~~ fish ~~at receiving~~ **reception temperatures** in these circumstances. ~~If a deviation from the temperature critical limits occurs, the cause should be determined and corrected, and intensified histamine testing performed, or the vessel lot rejected.~~ [US]

X.2.~~3~~2 Sensory evaluation

Sensory evaluation of fish at reception is a useful screening method to identify fishing vessel delivery lots that have been mishandled or subjected to time-temperature abuse and, hence, are at risk of elevated histamine levels. Neither histamine formation nor decomposition occurs in the absence of time-temperature abuse. However, the correlation between histamine level and sensory evidence of decomposition is not absolute, and histamine formation often occurs without readily detectable sensory indicators of decomposition. Therefore, sensory evaluation should not be used as the only or final assurance that the histamine level is acceptable, and reliable vessel control records or histamine testing, along with temperature monitoring, should be part of a complete receiving control system.

- Fish for sensory evaluation should be chosen randomly from throughout the ~~**fishing**~~ vessel delivery lot. Deliveries of multiple species with different compositions, morphologies, and sizes should be taken into account in the sampling ~~strategy~~ **plan**. It may be appropriate to select more fish from portions of the delivery **lot** identified by vessel records or temperature examination to be at greater risk for histamine formation. [NZ]

- The number of fish examined should be sufficient to provide assurance that the ~~fishing~~ vessel crew appear to have been vigilant about time-temperature exposures of the fish. The number of samples **taken** should be increased when conditions or fishing methods are more likely to introduce variable time-temperature exposures of fish, e.g. longlining, unusually warm weather, unusually large catch size, limited remaining ice, etc. [NZ]
- Evidence of abuse that may be conducive to histamine formation is indicated when the fish sensory attributes indicate marginal quality, not only when the sensory attributes show advanced decomposition. See FAO "Sensory Assessment of Fish Quality"[8] and Codex "Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories"[9] for guidance on sensory evaluation of fish.
- If sensory evidence of decomposition is detected at reception, it indicates that controls on the ~~fishing~~ vessel may ~~be~~ **have been** inadequate and that the entire vessel lot is at risk for elevated histamine. The cause of the decomposition should be determined and the necessary procedural ~~corrections~~ **changes**, **and improvement to facilities** or equipment ~~repairs,~~ verified. It is justifiable to reject the entire delivery **lot** based on **evidence of** inadequate time-temperature control; however, if further evaluation is used to determine if some of the fish are suitable for human consumption, then intensified histamine sampling and testing should be performed on the **entire** delivery **lot**. The testing should also include the decomposed fish **found** to determine if the **type of** decomposition **detected** was conducive to histamine formation. [NZ, CL clarification]

X.2.~~1~~3 Review of ~~fishing~~ vessel control~~s and~~ records (receiving establishment) [CL (NZ)]

If vessel operators use HACCP principles, ~~R~~**r**eview of ~~fishing~~ vessel histamine control ~~systems and monitoring~~ records, when available, is an effective **control** method **at receipt** to ensure that appropriate procedures were followed on the vessel to ~~help control~~ **minimize** histamine formation in the fish while on the fishing vessel [CL] **and is more effective than routine histamine testing.** [US]

- Refer to Section X.1.5 Monitoring records (fishing vessel).
- Vessel records applicable to histamine control should be requested and reviewed by the receiving personnel to determine if they are complete and reflect appropriate harvest and onboard handling practices, and that all applicable fishing vessel critical limits were met.
- If vessel records are **reviewed and found to be** incomplete and the receiving establishment cannot reliably ensure that the specific delivery of fish was harvested, handled, and stored in a manner that prevents histamine formation **by other means**, such as by intensified histamine sampling and testing, the delivery should be rejected. **(Refer to Section X.2.4 Histamine testing).** [NZ]
- ~~Sometimes~~ ~~t~~**T**he impact of a critical limit deviation on the fishing vessel may be minimized if the records clearly show that only part of a delivery was affected (e.g. one brine well or one specific fishing set ~~during the fishing trip~~) and ~~if~~ the affected fish ~~can be~~ **were** effectively segregated ~~from the rest of the delivery~~ when the vessel ~~is~~ **was** unloaded. ~~Precautions should be taken to ensure none of the other fish in the delivery have been affected.~~ [NZ]
- ~~Histamine testing can be used when vessel records are not available or unclear. However, this testing can be less reliable because histamine may be unevenly distributed within and between fish, and fish with high histamine are difficult to find using limited or small sample sizes. Sampling and testing that is statistically meaningful in terms of appropriate consumer protections can be resource intensive. Histamine testing at fishing vessel reception is therefore best used as verification of the effectiveness of a properly implemented and documented histamine control system on the fishing vessel. (Refer to Section X.2.4 Histamine testing.)~~ [US, MAR, NZ (moved)]

X.2.4 Histamine testing

When ~~a fishing vessel delivering fish has implemented a histamine control system based on HACCP principles, and~~ review of **fishing** vessel **histamine control** records is **used as** one of the **histamine** controls ~~used~~ by ~~the~~ **a** receiving establishment, then histamine testing ~~is only used~~ **should be performed periodically** as ~~a periodic~~ verification ~~procedure to assess if~~ **that** the ~~vessel~~ control system is ~~adequate and working properly~~ **continuing to work effectively**. [CAN] ~~The number and frequency of the verification tests carried out depend on the number of vessel suppliers and the type of fishery from which the receiving~~

[8] FAO/Torry Advisory Note No. 91, "Sensory Assessment of Fish Quality." Link: http://www.fao.org/wairdocs/tan/x5989e/x5989e00.htm

[9] CAC/GL 31-1999, "Guidelines for the Sensory Evaluation of Fish and Shellfish in Laboratories." Link: http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCAC%2BGL%2B31-1999%252FCXG_031e.pdf

~~establishment receives fish~~. [NZ] If verification test results ~~signal potential lapses in care of the fish~~ **indicate elevated histamine levels**, then **the vessel control system should be reviewed and corrected, and the** frequency of ~~verification~~ testing should be increased until testing **results** and other evidence suggest that the vessel ~~operators have~~ **control systems are being effectively** implemented ~~effective corrective measures~~ (e.g. a series of consecutive problem-free deliveries). [NZ, CL clarification]

When a fishing vessel ~~delivering fish~~ **operation** uses GMPs, but has not implemented a histamine control system ~~based on HACCP principles~~ ~~using~~ **including** monitoring and ~~establishing its records~~ **record keeping** that provide ~~assurance and~~ **documented** evidence of control, then histamine testing ~~becomes a critical control point~~ **is an important monitoring procedure** at **the** reception **critical control point, rather than a verification procedure**, and testing should be applied to every vessel delivery lot. If histamine levels ~~do not meet~~ **exceed** the ~~required~~ **established critical** limit, the vessel should be notified and the cause determined and corrected. In addition, the affected fishing vessel delivery lot should be rejected. [NZ, CL clarification]

Note that histamine testing can be less reliable than receipt of appropriate vessel control records because histamine may be unevenly distributed within and between fish, and fish with high histamine are difficult to find using limited or small sample sizes. Sampling and testing that is statistically meaningful in terms of appropriate consumer protection can be resource intensive. Histamine testing at fishing vessel reception is therefore best used as verification of the effectiveness of a properly implemented and documented histamine control system on the fishing vessel. [US, NZ]

The histamine testing guidance in this subsection ~~is~~ **can** also ~~applicable~~ **be applied** to **intensified sampling or** periodic verification of histamine controls ~~used during later production, storage and transportation steps, as well as for testing to determine product disposition when critical limits are exceeded~~ **throughout the supply chain**. [NZ]

X.2.4.1 Histamine testing, achievable histamine level<u>s</u> [CL]

- Freshly harvested scombrotoxin-forming fish typically have histamine levels below 2 mg/kg, and food business operators that apply HACCP principles can achieve a histamine level lower than 15 mg/kg[10].
- Marginally elevated histamine levels **[(e.g., > 15 mg/kg]** [for NZ] indicate poor implementation of hygienic processes and histamine controls during harvest, chilling and/or on-vessel storage, and a**n** ~~significant~~ **elevated** risk that some fish in a lot will have unacceptable histamine levels. **In addition, they indicate that histamine decarboxylase enzymes are present that can contribute to histamine formation during exposure to elevated temperatures further along the food chain, even without growth of histamine-forming bacteria.** [US]
- ~~Histamine achievable levels of at vessel reception should~~ may be lower than the achievable levels **Additional increases** in ~~product further along the distribution chain because the presence of histamine-forming enzymes, as evidenced by~~ histamine levels ~~approaching 15 mg/kg, is~~ **are** likely ~~to result in additional increases~~ with time and exposure to non-refrigerated temperatures during further processing and handling, **and this should be considered when establishing acceptable histamine levels**. [NZ, CL clarify intent]

X.2.4.2 Histamine testing, sampling strategies

- Sampling plans for **testing** histamine **levels** should be selected based on statistical performance parameters ~~to be effective~~. Statistical tables and computer programs **can** provide the information needed to design a sampling plan based on the histamine limits, the degree of protection, and the confidence in results desired. The FAO/WHO Histamine Sampling Tool[11] is ~~a useful~~ **an example of an** application designed for this purpose. [NZ]
- Determining sampling plan performance usually requires an estimate of the standard deviation of the level being measured. The standard deviation of the histamine levels can be estimated from the global data provided in the FAO/WHO Expert Report (Table 5.1)[12], or it can be estimated ~~when~~ **after** [US] appropriate data have been collected, including worst case scenarios, at the receiving location.

[10] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.1 Management of histamine production in fish and fishery products.)
[11] *FAO/WHO Histamine Sampling Tool*. Link: http://tools.fstools.org/histamine/
[12] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Table 5.1 Parameters of the Normal distribution fitted to the logarithm of the concentration of histamine, and probability of exceeding the limit of 200 mg/kg for each survey referenced in Table 3.2.)

- Because histamine is distributed unevenly in lots (has a high standard deviation), hazardous fish are statistically difficult to find using small sample numbers. The FAO/WHO Expert Report (Section 6.2.2.2)[13] suggests using histamine accept/reject levels ("value for m") that are lower than the ~~target~~ [NZ] acceptable limit in order to reduce the number of samples required to achieve a given level of confidence in the testing results.
- More sample units should be tested whenever vessel records, sensory analysis, or fish temperatures indicate possible lapses in time-temperature control that could result in elevated histamine.
- It is best to ~~test~~ **sample** the raw fish material upon arrival from the fishing vessels, where individual loin sections can be identified~~, and~~ **for trace back to vessel lots**. As the fish get processed into various market forms, or product from different vessel lots gets comingled, assessments of the suitability and safety of the fish from the individual fishing vessels becomes more difficult and less effective. [CL, moved from below with clarification]
- **Samples taken should be representative of the lot.** [NZ]

X.2.4.3 Histamine testing, analytical methods

- ~~It is best to test **sample** the raw fish material upon arrival from the fishing vessels, where individual loin sections can be identified, and **for trace back to vessel lots**. [CL] As the fish get processed into various market forms, or product from different vessel lots gets comingled, assessments of the suitability and safety of the fish from the individual fishing vessels becomes more difficult and less effective.~~ [CL moved up]
- Several reliable test methods exist for determining histamine levels in fish. The FAO/WHO Expert Report (Section 2.5 Analytical methods for histamine)[14] lists some of the available methods.
- The ~~receiving establishment should confirm that the~~ testing method used ~~is~~ **should be** properly validated for the detection limits used. The staff responsible for the sampling and ~~testing~~ **for sample analysis** should receive training in the procedures used.[NZ, CL]
- The part of the fish selected for testing ~~will~~ **can** significantly affect the test results. Test portions should be cut from the head-end of the lower loin near the gills because that area has the highest probability of elevated histamine in abused raw fish. Sufficient representation ~~(e.g. approximately 250 grams)~~ of fish muscle~~,~~ should be collected to prepare for analysis (e.g. ~~approximately~~ **100-250** grams). For smaller fish, in addition to the lower anterior loin portion, the upper anterior loin, and the mid-section of the lower loin, in that order, can also be collected**.**~~, and for~~ **For** very small fish, multiple fish may need to be collected to acquire a representative sample unit ~~of fish muscle (e.g. approximately 250 grams)~~. The entire sample unit should be thoroughly blended so that the smaller aliquot used for the analytical method is representative of the entire sample unit. [US, CAN, MAR]
- To screen deliveries more economically, sample units from different fish can be optionally combined (composite sample) to reduce the number of histamine analyses required, provided that the histamine level critical limit is lowered proportionately. ~~For example, after independently grinding each of 3 individual sample units, a portion (e.g. 100 grams from each of the 250 gram ground units) can be further blended together and used for a single composite sample analysis. In this case, the critical limit must be divided by 3 in order to ensure detection of one unit exceeding the critical limit within the composite sample. If the lower critical limit is exceeded, further analysis of the retained individually ground portions from each of the 3 sample units making up the composite may be performed to determine if any sample unit exceeds the non-composited critical limit. Note, the ability to composite multiple sample units is limited by the lowest histamine level that is accurately quantified by the analytical method in use.~~ [NZ]

X.2.5 Monitoring records (receiving establishment)

- Histamine control records should be maintained at the receiving establishment for trace-back to possible causes if elevated histamine is discovered further along the distribution chain.
- Receiving establishment monitoring records may include, but are not limited to:

---

[13] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.2.2.2 Using the known standard deviation and the derived mean to design a sampling plan.)

[14] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 2.5 Analytical methods for histamine.)

- Relevant information about vessel delivery lot (e.g. vessel name and type, captain's name, date/time of offloading, type and volume (weight) of fish off-loaded)
- ~~Copies of the fishing vessel's monitoring records that were reviewed (refer to Section X.1.5, Monitoring records (fishing vessel)~~
- Sensory evaluation results
- Internal temperatures at the time of offloading
- Histamine test results, when applicable.
- Copies of the fishing vessel's monitoring records ~~that were~~ reviewed**, when applicable** ~~(refer to Section X.1.5, Monitoring records (fishing vessel)~~ [CL (NZ)]

- A responsible person should examine, as a part of verification activity, the monitoring records before product release to confirm that critical limits were maintained, and that appropriate corrective actions were taken when necessary.

X.3 Transportation

- Refer to Section 20 (Transportation)
- Refer to Section X.1.4 (Refrigerated and frozen storage)
- Transport vehicles or vessels should be adequately equipped to keep fish cold by mechanical refrigeration or by completely surrounding the fish with ice or other cooling media.
- Vehicles or vessels should be pre-chilled before loading fish where applicable.
- Refrigerated compartment temperatures, or cooling media such as ice slurries, should be monitored during transportation between locations (e.g. receiving establishment, processing establishment, distributor, market, etc.) using continuous temperature recording devices (where practical), and the receiving establishment should review the temperature record from the device. Devices should be periodically calibrated for accuracy.
- At delivery, internal temperatures of a representative sample of fish, and adequacy of ice or other cooling media when applicable, should be monitored by receiving personnel as described in Section X.2.2 Temperature monitoring.
- If ~~a~~ **established fish reception or vehicle compartment** temperature control ~~critical~~ limit**s** ~~is~~ **are** exceeded, the cause of the problem should be identified and corrected by the operator of the vehicle or vessel. **If evidence indicates that temperarture abuse leading to elevated histamine could have occurred,** ~~The~~ **the** affected lot may be rejected by the receiving personnel, or the receiver may perform intensified histamine analysis on representative fish collected throughout the lot, and the lot rejected if any fish ~~are over~~ **exceed** the **established** histamine ~~critical~~ limit (~~See~~ **Refer to** subsection X.2.4 **Histamine testing**). [NZ]

X.4 Processing operations

This section applies to processing on land or at sea (e.g., factory vessel, mother ship)

X.4.1 Reception (processing establishment)

- If fish are delivered directly from the fishing vessel to the processing establishment, then **also** refer to Section X.2 Reception (receiving establishment). [CL]
- If fish are delivered by transport vehicle or vessel, then **also** refer to Section X.3 Transportation. [CL]
- If the processing establishment is a secondary processor receiving product from a primary processor (e.g. receiving establishment or factory vessel), then the secondary processor should ~~ensure~~ **confirm** that the primary processor uses **a** HACCP ~~or a similar control~~ system designed to prevent formation of ~~hazardous~~ unacceptable levels of histamine. [EU, NZ]
- When it is impractical for the initial receiving establishment to conduct all the ~~appropriate~~ **necessary** histamine controls listed in subsection X.2 (i.e.**,** ~~vessel records review,~~ temperature monitoring, sensory evaluation, **vessel records review**~~,~~ and**/or** histamine testing), then the processing establishment should conduct these activities, and should ensure that**, where practical,** the controls and decisions are applied to intact fishing vessel lots that are not comingled with other lots. **Note, h**owever, **that** fish internal temperatures (and adequacy of ice, where applicable) should always be monitored at vessel delivery **by the receiving establishment** (to evaluate vessel control), as well as

at **receipt to** the processing establishment (to evaluate **land-**transport**ation** control). **If lots are co-mingled and there may be unacceptable levels of histamine in fish, the entire lot must be considered when making decisions on disposition.** [NZ, CL]

X.4.2 Processing~~,~~ time and temperature control [CL - comma not needed]

When fish undergo processing (e.g., thawing, cutting, re-chilling, salting, drying, pickling, **cooking,** smoking, canning) it is important that they are not ~~held at temperatures for sufficient~~ **subjected to** time**-temperature conditions** ~~that~~ **where** histamine-producing bacteria can grow and produce histamine to ~~hazardous~~ **unacceptable** levels. [CAN, NZ]

- Scientific studies and microbial growth models[15] may be used to estimate the exposure times and temperatures that result in elevated histamine levels.
- Histamine formation is quite variable and strongly depends on the previous handling of the raw material and the different species of histamine-producing bacteria that are present; therefore, the worst case scenario should be considered when establishing critical limits.
- The acceptable maximum histamine level used to establish processing time-temperature critical limits should take into consideration **the point in the supply chain and** any further handling, processing, storage, and preparation that may lead to further histamine formation before consumption. [NZ]
- The measure used for time-temperature critical limits should be the cumulative product non-refrigerated time-temperature exposure over all processing steps.
- Processing room temperature should be maintained as cool as practical during processing operations, and product exposure times should be minimized. For example, fish should be iced, or returned to refrigerated storage, during production breaks or production flow slow-downs.
- Controlled product flow and batch monitoring is an effective strategy to ensure product is not subjected to unacceptable time-temperature exposures. For example, periodically measure the ambient temperature and the time for a marked batch to begin and complete the processing step.
- Air thawing of raw material should occur at refrigerated temperatures to prevent excessive warming of the surface of the fish. Immersion in circulating cold water or spraying with cold water may be used to shorten thawing time. For re-chilling and refreezing, see Subsection X.1.3.
- When time-temperature critical limits are exceeded, the cause should be determined and corrected. In addition, intensified histamine testing should be performed (see section X.2.4.2) before releasing affected product for human consumption. Alternatively, product should be rejected.

X.4.3 Heat processing

- Adequate heat treatment (e.g. cooking, hot smoking) can kill histamine-producing bacteria and inactivate histidine decarboxylase enzymes. *Morganella morganii* is probably the most heat resistant of the histamine-producing bacteria, and in Australian salmon/ kahawai **(*Arriis trutta*)** at temperatures between 58 and 62°C, the D-values for eliminating these bacteria and their associated HDC enzymes were between 15 and 1.5 minutes (FAO/WHO 2012). [US]
- Once formed, however, histamine itself is heat stable and is not destroyed by heat. Therefore, histamine controls during harvesting, and during other steps prior to thermal processing, are critical to ~~prevent inclusion of previously formed~~ **minimize the presence of** histamine in the finished product. [CAN]
- If the product is exposed to bacterial contamination and temperature abuse after initial heating, histamine formation may start again. Thus, for products such as hot smoked fish, care should be taken to avoid contamination after smoking. Additionally, refrigerated storage is essential unless the water activity is reduced sufficiently or some other means is used to prevent bacterial growth.
- For commercially sterile canned or pouched products, the container protects the product from bacterial recontamination, and no further histamine is produced when stored at ambient temperatures. However, once the product package is opened, histamine formation can occur again if the product is recontaminated in the absence of preventative time-temperature controls.

X.4.4 Processing, other technological measures

[15] *Joint FAO/WHO Expert Meeting on the Public Health Risks of Histamine and Other Biogenic Amines from Fish and Fishery Products*, July, 2012, Rome (Section 6.1.9 Microbiological modelling.)

Time and temperature control is the recommended method for preventing histamine formation in fresh, frozen, and refrigerated processed fish products.

Some products and processes (e.g. fermenting, smoking, salting, drying, pickling, acidifying, preserving, modified atmosphere packaging) introduce other technological factors that may inhibit the introduction and/or growth of histamine-producing bacteria. The interaction of these factors is complex and often unpredictable. For example, increased salt content, or increased acidity, may decrease or increase histamine production, depending on conditions.

Thorough scientific studies, and proper establishment and validation of control parameters for each specific process and product, are imperative to ensure the safe manufacture of foods that incorporate other technological measures as an element of histamine control. (See Guidelines for the Validation of Food Safety Control Measures, CAC/GL 69 - 200.)

The ~~safe application~~ **success** of ~~any of~~ these treatments is dependent on the rapid chilling and maintenance of chilled temperatures of the raw fish ~~material~~ from the time of death ~~of the fish~~ until the ~~proper~~ inhibitory ~~or destructive control attributes contributed by~~ **effects from** the treatments ~~have been~~ **are** achieved. ~~And~~ **In addition**, depending on the treatment, the finished product may need to remain chilled until consumed to ensure safety. [CAN]

X.4.5 Refrigerated and frozen storage (processing establishment)

- Refer to Section X.1.4 Refrigerated and frozen storage (fishing **vessel and transfer** vessel). [NZ]
- For products whose preparation does not include a heating step or other means to eliminate histamine-producing bacteria and their enzymes, ~~the presence of histamine-producing bacteria means that~~ refrigerated storage will continue to be a critical control point ~~for the inhibition of~~ **to prevent** histamine formation throughout the shelf-life of the products ~~until consumed~~. [CAN]

X.4.6 Monitoring records (processing establishment)

- Processing establishment monitoring records may include, but are not limited to:
    - Transport vehicle or ~~transport~~ vessel temperature ~~log~~ **records** or adequacy of ice, and fish internal temperatures [NZ]
    - Temperatures and exposure times of product during unrefrigerated processing steps
    - Critical control point monitoring records for other validated methods used to control histamine formation in processed fish
    - Refrigerated storage temperature logs.
- A responsible person should examine the monitoring records before product release to confirm that critical limits were maintained, and that appropriate corrective actions were taken when necessary.

The processing facility should use histamine testing to periodically verify that histamine controls are working properly (Refer to section X.2.4 **Histamine testing**). [NZ]

Appendix II

LIST OF PARTICIPANTS

Chair

Prof. Hajime Toyofuku

toyofuku@yamaguchi-u.ac.jp

Co-Chairperson

Dr. Bill Jones

William.Jones@fda.hhs.gov

Australia

Ms. Amanda Hill
Amanda.hill@foodstandards.gov.au

Australian Codex contact point
codex.contact@agriculture.gov.au

Codex Australia
codex.contact@agriculture.gov.au

Argentina

María Esther Carullo
mcarullo@senasa.gov.ar

Josefina Cabrera
josefina@anmat.gov.ar

Brazil

Mrs. Ligia Lindner Schreiner
ligia.schreiner@anvisa.gov.br

Canada

Hélène Couture
Helene.Couture@hc-sc.gc.ca

Martin Duplessis
martin.duplessis@hc-sc.gc.ca

Hussein Hussein
hussein.hussein@hc-sc.gc.ca

Chile

Ms. Constanza Vergara
constanza.vergara@achipia.gob.cl

China

Ms Lianzhu Wang
wanglz@ysfri.ac.cn

Ms Yingying Guo
guoyy@ysfri.ac.cn

Ms. Hao DING
dinghao@cfsa.net.cn

Dr Zhenxing Li
lizhenxing@ouc.edu.cn

Costa Rica

Dra. Heilyn Fernández Carvajal
hfernandez@senasa.go.cr

Lic. María Elena Aguilar Solano
maguilar@ministeriodesalud.go.cr

Lic. Amanda Lasso Cruz
alasso@meic.go.cr

Ecuador

Mónica Alexandra
monica.quinatoa@msp.gob.ec

Miguel Ortiz
miguel.ortiz@msp.gob.ec

Eduardo Solis Thompson
esolis@institutopesca.gob.ec

Fernanda Hurtado Angulo
fhurtado@institutopesca.gob.ec

European Union

Mr. Paolo Caricato
paolo.caricato@ec.europa.eu

EU Codex contact point
Sante-Codex@ec.europa.eu

France

Mrs Florence Delavouet
florence.delavouet@agriculture.gouv.fr
bpmed.sdssa.dgal@agriculture.gouv.fr

Mr Julien Landure
Julien.landure@scl.finances.gouv.fr
LABO13@scl.finances.gouv.fr

Mr. Guillaume Duflos
guillaume.duflos@anses.fr

Germany

Ms. Dr. Ute Ostermeyer
Ute.ostermeyer@mri.bund.de

Ms. Ute Schröder
Ute.schroeder@mri.bund.de

India

Shri. R.M.Mandlik
tech1@eicindia.gov.in

Shri. S.S Shaji
shaji@mpeda.gov.in

National Codex Contact Point (NCCP)
codex-india@nic.in

Japan

Ms. Mako Iioka
mako_iioka540@maff.go.jp
codex_maff@maff.go.jp

Mr. Kenji Urakami
codexj@mhlw.go.jp

Malaysia

Ms. Raizawanis Abdul Rahman
raizawanis@moh.gov.my

Mrs. Sakhiah Md Yusof
sakhiah@moh.go.my

Codex Contact Point Malaysia
ccp_malaysia@moh.gov.my

Morroco
Dr Oleya El Hariri
oleyafleur@yahoo.fr

Pr. Noureddine Bouchriti
bouchriti@gmail.com

Mr Abdellatif Hmidane
hmidane@mpm.gov.ma

Mexico

Penélope Elaine Sorchini Castro
psorchini@cofepris.gob.mx

María Guadalupe Arizmendi Ramírez
mgarizmendi@cofepris.gob.mx
codex@cofepris.gob.mx

New Zealand

Mr. Jim Sim
jim.sim@mpi.govt.nz

Norway

Åsne Sangolt
Asne.Sangolt@mattilsynet.no
codex@mattilsynet.no

Peru

Carlos Guzman
carlos.guzman@sanipes.gob.pe

Carla Villena
carla.villena@sanipes.gob.pe

Philippines

Consuelo C. Baltazar
ccb_aspcu@yahoo.com

Almueda C. David
acdavid@fda.gov.ph

Poland

Miroslaw Michalski
mmichal@piwet.pulawy.pl

Portugal

Dr. António Pedro Margarido
pmargarido@dgav.pt

Singapore

Mr. Leslie Phua
Leslie_phua@ava.gov.sg

Spain

Julian Garcia, Baena
jgbaena@magrama.es
cioa@msssi.es

Switzerland

Mrs. Christina Gut
christina.gut@blv.admin.ch

Thailand

Mr. Manat Larpphon
mlarpphon@gmail.com
manat@acfs.go.th

Ms. Virachnee Lohachoompol
virachnee@acfs.go.th
codex@acfs.go.th

United Kingdom

Theo Hawkins
heo.hawkins@foodstandards.gsi.gov.uk

United States of America

Robert Samuels
robert.samuels@fda.hhs.gov

Ronald Benner
ronald.benner@fda.hhs.gov

Jenny Scott
jenny.scott@fda.hhs.gov

Clarke Beaudry
clarke.beaudry@fda.hhs.gov

Lisa Weddig
lweddig@nfi.org

Uruguay

Maria Salhi
msalhi@dinara.gub.uy
codex-EWG@latu.org.uy

International Commission on Microbiological Specifications for Foods (ICMSF)

Dr. Tom Ross, PhD
tom.ross@utas.edu.au

National Health Federation (NHF)

Ms Birgitta Lauren
lauren@expectiongfitness.com

FAO

Sarah Cahill
Sarah.Cahill@fao.org

WHO

Dr Rei NAKAGAWA
nakagawar@who.int