Ⅱ 分担研究報告

平成 30 年度厚生労働行政推進調査事業費補助金　食品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

研究分担報告書

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 30 年度中に開催され、本研究の対象とした部会は第 24 回 CCRVDF (2018 年 4 月 23 日～27 日)第 50 回 CCFH (2087 年 11 月) 及び第 24 回 CCFICS（2018 年 10 月）であり、またてそれら部会に関連した電子的作業部会での議題を中心に報告する。

C. 研究結果及び考察

C.1　第 24 回 CCRVDF

対処方針作成までは昨年度の報告書に記載したので、今年度は部会の主な議題の要点を報告する。

議題２．コーデックス総会及びその他の部会等からの付託事項

第 40 回コーデックス総会（CAC）における CCRVDF に関連した結論及び議論の内容について報告があった。第 73 回コーデックス執行委

員会（CCEXEC）から、動物用医薬品と農薬の両方として使用する（dual use）物質の MRL を検討する際に CCRVDF とコーデックス残留農薬部会（CCPR）がより緊密に協力するようにとの勧告があった。

第 50 回 CCPR において、dual use 成分について、FAO/WHO 合同残留農薬専門家会議（JMPR）/ FAO/WHO 合同食品添加物専門家会議（JECFA）及び CCPR / CCRVDF のより良い連携のための革新的方法を考え出す必要性があることを各国代表団が支持した。第 50 回 CCPR は、その革新的方法として JMPR / JECFA 間の協力の改善（例：ハーモナイズされた MRL、指標残留の定義）及び dual use 成分の JECFA / JMPR による評価のための優先順位付けに関して、CCPR と CCRVDF 間の作業で共同に取り組むべく方策について検討する提案があった。

抗菌剤耐性に関する特別部会（TFAMR）の議長を務める韓国の Park Yong Ho 氏より、TFAMR が抗菌剤耐性を最小限に抑えるための行動規範（CXC 61-2005）の改訂と統合的な抗菌剤耐性のサーベイランスのガイドラインの新規策定を行っていること、及び国際獣疫事務局（OIE ）と協力し FAO と WHO の科学的助言を提供するために、2018 年 6 月上旬に専門家協議を行うことが伝えられた。

議題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

JECFA 事務局から、第 85 回 JECFA（2017 年、ジュネーブ）が検討を行った事項及び結果について報告があった。主な報告内容及び討議結果は以下のとおり。

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。JECFA 事務局はデータ不足を認識したうえで、包括的な文献調査を行ったが、このような追加の努力をもってしても、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。

動物用医薬品及び農薬として使用されている化合物の慢性食事暴露評価

JECFA 事務局は動物用医薬品及び農薬として使用されている化合物の慢性食事暴露評価に関する最近のレビューについて報告した。この評価は JECFA 及び JMPR によって現在使用されているモデルの比較及び 18 か国で行われた国による推定の比較によって行われた。この結果により、化合物の毒性学的特性及び曝露モデルのより良い調整が行われ、より現実的な食事暴露評価になると考えられる。

残留動物用医薬品の ARfD

JECFA 事務局は、動物用医薬品の ARfD を確立するための指針を 2017 年 5 月に公表し、JECFA によって完全に実施されたこと、及びより現実的な微生物学的 ARfD にするために、その確立するための手法を改良したとの情報を提供した。

動物組織における薬物残留物の相対的バイオアベイラビリティーおよび/または薬理学的活性の評価

JECFA 事務局は、第 85 回 JECFA において、食品中の動物用医薬品の非結合型残留物のバイオアベイラビリティーが限定的なものであることを示すための試験設計の指針を公表したことをについて情報提供した。

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

OIE から、抗菌剤耐性に関するワンヘルスの活動など最近の OIE の活動について報告がなされた。VICH アウトリーチフォーラムを通じて VICH の活動が VICH に参加していない国々に広がっていること、OIE が VICH ガイドライン 57 草案（食用動物における動物用医薬品の代謝及び残留動態を評価するための試験：水産動物の休薬期間設定のための指標残留減衰試験）ドラフトのパブリックコメントを開始したことなどの報告がなされた。

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、以下の 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。

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。

（結果）

最終文（下線部）の記載を支持する代表団（日本、EU、エジプト等）からは、JECFA が評価を行ったこと、これまで当部会により勧告された類似物質と整合すべきであることなどの意見が出された。日本からは、JECFA が

遺伝毒性及び発がん性を理由に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、最終文は加盟国がゲンチアナバイオレットの食用動物中での残留を最小限にするための最適な措置を決定する際の支障とはならない（最終文の文言には十分な柔軟性がある）、また、これまでCCRVDFが設定した同様の物質（例、マラカイトグリーン）に対するRMRとの整合性の観点から、引き続き当RMR案を支持する旨発言した。

最終文の削除を支持する代表団（米国、ジャマイカ、ペルーなど）からは、最終文は指図的と解釈され、加盟国が同じゴールを達成でき、その国にとっては最適と考える代替のリスク管理を選択する判断を制限しかねないこと、ゲンチアナバイオレットの局所使用は、マラカイトグリーンの経口投与と同じレベルのリスクをもたらさない旨のコメントがあった。

議論の結果、コンセンサスを達成するため、RMRテキストは加盟国が食品中のゲンチアナバイオレットの残留を防ぐための適切なリスク管理アプローチを選択できるという、RMRの解釈を明確にする文を報告書に含むことに合意した。フットノートを付けるという案も提案されたが、総会に採択を求める文書に、報告書を引用するフットノートを付けることはできないこと、また、すでに報告書で解釈の説明を記載していることから、フットノートをつけることは限られた支持しか得られなかった。提案されたRMRを第41回CACにステップ8で承認を求めることに合意した。この決定に対し、米国、エクアドル、ホンデュラス及びニカラグアが留保を示した。

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案について今回会合で議論を行った。

（結果）

EU、エジプト等のMRL案を支持しない代表団からは、ヒトに健康リスクをもたらす懸念があること、動物用医薬品は食品を生産する動物において治療以外の目的で使用してはならないこと、MRLを採用することでコーデックスはジルパテロールの使用を容認したというメッセージを送ることになること、を反対理由とした意見が出された。

MRL案を支持する代表団（米国、日本、豪州等）からは、JECFAの科学的評価結果はCCRVDFによって適用されるリスクアナリシスの原則に基づく妥当なものであること、動物用医薬品のコーデックスにおける定義は治療用医薬品に限定されていないこと、反対派の議論（動物衛生、動物愛護）はコーデックス委員会の権限外であること、承認がない国でも輸入食品のモニターのためにはコーデックスのMRLは有用であること（特に自身でリスク評価を行う能力のない途上国）などの意見が出された。日本からは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、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及び我が国では動物用医薬品としては承認されていないものの、インポートトレランス申請によりMRLを設定しており、貿易の支障とはならないことから、MRL原案を支持する旨発言した。

議長はMRL案のステップが進むのを支持しない代表団は手続きマニュアルの規定に従い棄権することができると提案したが、それらの代表団は議長の提案を受け入れなかった。

さらに、議長は、科学的な懸念ではなく科学以外の要因によりCCRVDFのコンセンサスが得られないことを認め、今期の部会における討論を中止し、MRL設定のステップを進めないことを提案したが、ニュージーランドは、本物質が、リスク評価の優先順位を決める基準に適合し、CCRVDFからJECFAに対し評価を勧告し、その決定は総会も承認していること、GVPに従って使用したいかなる残留も消費者のリスクにはならないというJECFAの評価結果についてはCCRVDF内で明確なコンセンサスがあること、Codex手続きマニュアルに示された“その他のlegitimate factor”を挙げた国はないこと、従ってMRL設定のステップを進めないという判断は手続きマニュアル及びCCRVDFの手続きのルールに反すること、CCRVDFの委任事項外の哲学的な理由による反対により貿易に重要なMRLのステップを進めないという判断は受入られない、ニュージーランドはCACによって明確化された決定に反するこの事例に対するアドホックな基準を適用することに反対した。日本も科学的評価に基づかない決定及びコーデックスの委任外でかつCCRVDFのルールに基づかない決定に対する遺憾の意を表明した。ニュージーランドのほか、アルゼンチン、オーストラリア、ボリビア、ブラジル、ブルキナファソ、コロンビア、コスタリカ、コートジボワール、ドミニカ共和国、エクアドル、エルサルバドル、ガーナ、グアテマラ、ホンデュラス、日本、ケニア、マリ、メキシコ、ニカラグア、ナイジェリア、パナマ、ペルー、南アフリカ共和国、タンザニア、トーゴ、米国及びザンビアの28カ国が上記の理由でMRLのステップを進めないことに対して留保した。

結論として、JECFAの評価及び提案されたMRLの安全性については一定の合意が得られたものの、コンセンサスには至らず、ステップを進めることはできず、ジルパテロールはステップ４に留まった。

この決定に対し、コーデックス事務局から、CCRVDFのこの決定はCCEXEC及びCACに対し、この問題を議論し、対策を講じるべきという強いメッセージを送ることになるとしたうえで、CCRVDFが科学を超えた因子で、基準に沿って行動をすることが出来なかったこと対し懸念を表明し、将来コーデックスへの潜在的なダメージを避けるため、適切な会合で議論が行われることを希望した。なお、このコーデックス事務局の発言を結論に書くか否かでレポート採択としては異例の小一時間を費やすことになった。

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った。

（結果）

アモキシシリン及びアンピシリン（finfishの筋肉及び切り身）のMRL案

日本からは、動物用医薬品のGVPに従った使用と調和してMRLを設定すること、MRLを動物用医薬品がGVPに従って投与される対象動物種由来の組織及び食品に設定すべきことを理由に、MRLは全てのfinfishではなく、加盟国において動物用医薬品の承認又は登録のあるグループに限ること、すなわちアモキシシリンとアンピシリンのMRLはyellowtail group（ブリを含む目）とflounder group

（ヒラメを含む目）に限定すべきと発言した。

また、第85回JECFAレポートには、アモキシシリンでナマズの切り身、タイの皮及び筋肉の残留試験データはあるものの、アンピシリンでは皮や切り身に関するデータはなく、MRLは同じ値であること、当該薬品は極性が高く皮には移行しにくいと考えられること、切り身（皮と筋肉）を一緒にホモジナイズすると筋肉の残留が希釈されてしまう可能性があること、及び一部の魚の皮はホモジナイズが難しいこと等を踏まえて、筋肉のみにMRLを設定することを提案した。JECFA事務局からは、魚は切り身と筋肉の両方で取引されていることから、それぞれについてMRLを設定する必要があること及びアモキシシリン（及びアンピシリン）は少なくとも1つの加盟国で、すべての魚　に対し承認・登録されていること、アモキシシリンの評価については提出されたデータパッケージは完全ではないが文献等から十分な情報が得られたことからリスクアセスメントが可能と判断したことについて説明があった。なお、日本の意見に賛同する代表団はおらず、上記理由を根拠にMRLは原案どおりステップ5/8で採択された。

フルメトリン（ハチミツ）のMRL案

JECFA事務局からは、第85回JECFAの成果を紹介し、ADIおよびARfDに基づいて、ハチミツについてタンデム質量分析計（LC-MS / MS）で測定した際の最も信頼性の高い分析法の定量下限値（LOQ ：3 μg/ kg）の2倍に基づいて6 μg/ kgのMRLを推奨した旨の説明があった。一部の代表団からは、提案されたMRLが厳しいものであり、途上国では容易に実施できない高感度の分析法を用いたLOQに基づいていることへの懸念、検査能力の欠如が貿易上の問題に繋がる可能性から、MRLを50 μg/ kgに引き上げるよう提案がなされた。別の代表団は、フルメトリンがワックスやハニカムに蓄積し、それらからハチミツに移行する可能性があることを指摘し、これはリスクマネジメントの決定において考慮すべきである旨発言した。一方、JECFA事務局は、フルメトリンはワックス中に蓄積するが高い親油性のためにハチミツに再分配されることはなく、GVPに従って使用すればリスクはほとんどないことを説明した。この結果、GVPに従って使用した場合には残留物はヒトの健康に対して有害となる可能性はほとんどないためMRL設定は不要とされ、ステップ5で採択された。

ルフェヌロン（サケ及びマスの切り身）のMRL案

JECFA事務局からは、ルフェヌロンが農薬としても使用されていることから、第85回JECFAの報告書では、農薬由来及び動物用医薬品由来の残留物を合わせて食事からの曝露量が推定されているとの説明があった。ルフェヌロンはマスに対して登録されていないのではないかとの懸念が示されたが、1加盟国がマスに対して登録していることを明確にしたため、MRL案はステップ5/8で採択された。

モネパンテル（牛の脂肪等）のMRL案

MRL案はステップ5/8で採択された。

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。

今回会合では、討議文書中のOption A、B及びCの違いが分かりにくいことから本会議の討議前に会期内作業部会を開催し、議長国

と共同議長国から討議文書及び討議文書において参照しているVICHガイドライン57草案に関するプレゼンテーションを行った（ノルウェーが概要とOption A、Bについて、日本がOption CとVICHガイドライン57草案について説明)。会期内作業部会における各国からの意見を踏まえ、本会議においては議長国と共同議長国がOption Cの修正案を提示し、議論が行われた。

（結果）

ノルウェー及び日本は、電子作業部会及び会期内作業部会の成果についてCCRVDFに報告した。討議文書においては、温度、塩分、系統・共通な生理および共通な行動という4つのパラメータが全て一致する魚種同士をグループとするOption A、パラメータについての十分なデータのある場合にfinfishをグループとするOption B、グルーピングはせずに各国のリスク管理に任せるOption Cが挙げられていたが、ノルウェーと日本はこれら4つのパラメータを同等に用いて魚をグループ化するための共通のアプローチを見つけることは、パラメータの組み合わせが多数になることから不可能であることに言及した。会期内作業部会においては、この点をさらに検討し、本会議においてノルウェーと日本からVICHガイドライン57草案に用いられている目ごとのグルーピングに基づくOption Cの修正案を提示したが、各国代表団は、VICHのガイドラインは動物用医薬品の登録 / 承認のためのデータの作成を目的としたものでありMRLを確立することを目的としたものではないため、VICH GL57草案に基づく目ごとの外挿をMRLにも用いることの妥当性を疑問視し、手続きが過度に複雑である、魚はマイナー種であることも考慮すべきである等の発言が相次いだ。その他、MRLの外挿は魚種のみに限定せず他の種にも適用することが望ましいことから、全ての種に外挿するためのポリシーを策定し、パイロットスタディとして既存の特定魚種のMRLを他の魚種に外挿する試みをすることが提案された。一方では、現在の手続きマニュアルのCCRVDFのリスクアナリシスの原則の「JECFAが科学的に妥当であり不確実性が明確であるとした場合にCCRVDFがMRLを1つ以上の種に外挿を勧告することができる」という記述を削除し、CCRVDFの裁量を増やすべきとの意見が提出された。

このリスクアナリシス原則の改正については、CCRVDFからCACに提出することが合意された。

また、議長から、当議題の作業部会を一旦終了してEUを議長国とする新たな電子作業部会を立ち上げることが提案され、EUはこれを了承した。

当該電子作業部会における作業内容は以下のとおり。

- リスク管理者としてCCRVDFがどのようにしてMRLを1つ以上の種に外挿することができるかについての実践的な方法について討議文書を準備する。
- Option C修正案と前述のアプローチのどちらが水生動物種の外挿に適しているかを比較する。
- 優先順位リストにおいてCCRVDFがコーデックスMRLを他の種に外挿するとしている化合物についてパイロットスタディを行う。

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が行われた。

（結果）

ケニアから討議文書に沿って説明がなされ、MRL の設定を促進するために、可食臓器の定義を行うこと、広く摂取され、貿易されている臓器を特定することの必要性について言及があった。各国代表団からは、貿易上、可食臓器の定義付けを行うことは重要である、必ずしも全ての臓器が特定の MRL を必要とするわけではない、MRL は必要に応じて可食臓器間で外挿することが可能である等の発言がなされた。さらに、提案された定義は十分に包括的であり、国や動物種によって異なる当該定義としても利用できることから用語集にも含めることができるであろうとされた。

農薬かつ動物用医薬品として使用する成分もあることから、臓器の定義を CCPR と調整しながら作業するという提案がなされ、ケニアが議長、ニュージーランドが共同議長を務める電子作業部会を開始することが合意された。この電子作業部会は、CCPR の食品と飼料の分類に関する電子作業部会と連携して MRL の調和と精緻化を目的として可食臓器と関連する他の動物組織の定義を精緻化する作業を行うこととされた。

議題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法の使用に係る規準の改訂に関する討議文書

カナダから、予期できない状況により、約束した討議文書を本会議のために作成することができなかったこと及び近い将来においても作成できない旨の説明があり、当面の間、本議題については中止することとされた。

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）

前回会合において、オブザーバーである HealthforAnimals（動物用医薬品企業の世界的な団体）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った。

（結果）

HealthforAnimals から討議文書の説明がなされ、製薬業界から JECFA と CCRVDF の作業に対する感謝の表明がなされ、彼らの考えではこの作業プロセスの改善が保証できると強調された。代表団は、各国でのレビューと並行して JECFA での評価を実施するなど、革新的なアイデアを歓迎したが、同時に、JECFA の完全性と透明性は維持されなければならないことを強調した。JECFA 事務局は、各国と JECFA の並行評価を行うことができる対象物質があれば、パイロットスタディを行うことを検討する意思があると述べ、議長もこのような試みが、国際的な MRL の設定を早い段階で行うことを促進し、貿易の促進にもつながるであろうと述べた。

CCRVDF は、カナダが主導し、オーストラリア、米国および JECFA 事務局と共に、化合物の評価を並行して行う上記のアプローチの長所と短所を検討するための討議文書を作成することに合意した。 CCRVDF はさらに、化合物が評価可能な状態になった場合に、そのような並行アプローチのパイロットプロジェクトを開始することに同意した。

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（共同議長国：米国とコスタリカ）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った。本会議に先立ち、米国とコスタリカは会期内作業部会において、この作業部会の目的、作業の内容、結果等についての説明を行い、討議により必要性と評価できる可能性の高い６物質の選定等を行った。

（結果）

会期内作業部会で選定された優先度の高い化合物及び動物種は以下の通りである。

・アモキシシリン：山羊及び家禽

・アンピシリン：牛、豚、馬、羊、山羊、魚及び家禽

・ジミナゼン：羊及び山羊

・イミドカルブ：馬

・イベルメクチン：馬、山羊、ラクダ及び家禽

・オキシテトラサイクリン：ハチ（はちみつ）、ラクダ、馬および山羊

上記の６物質のうち、アモキシシリン（家禽）はチリが、オキシテトラサイクリン（山羊）はコスタリカが、ジミナゼン（羊）はアルゼンチンが、アモキシシリンとアンピシリンはドイツが JECFA の評価のための資料を作成することとされた。

その他、本会議においては、議題７で設立することで合意された MRL の外挿の方針を策定する作業グループにおいて、外挿のパイロットスタディを行う際にこのデータベース内のいくつかの化合物が、外挿の候補になる可能性があると指摘があったことから、本データベースから 10 種類の化合物をパイロットスタディのために選定した。そしてこの問題を議題１２．のもとでさらに扱う方法を検討することに合意した。

本部会は、コスタリカと米国が中心となって、データベースを維持し続けることで合意した。なお、データベースに追加すべき化合物の提案はなかった。

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）

前回会合では、会期内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物理的作業部会を設置し、各国からの提案について、今回会合の直前に開催された物理的作業部会で検討した。

（結果）

オーストラリアは、本会議の直前に開催された物理的作業部会の議長を務め、作業部会の報告書を紹介し、優先順位リストの新しい提案及び CCRVDF の次回会合でデータの利用が可能で、継続的に JECFA の評価が可能である化合物について説明した。各化合物の整理は以下のとおり。

- Part A（新しい提案）

・フルメトリン（牛の MRL）

・ホスホマイシン（ADI 及び鶏と豚の MRL）

・イベルメクチン（羊と豚の MRL）

- Part B（次回 CCRVDF 会合でデータの入手可能性が確認される化合物）

・エトキシキン（インドとフォリピンが次回までのデータの入手可能性を確認する。）

・トリアンシノロン：評価に必要な毒性データが入手できないことから、削除する

ことに合意した。

- Part C （2016 年及び 2017 年からの JECFA の評価を継続する化合物）

・ジフルベンズロン
・エチオン
・ハルキノール
・シサプロニル
● Part D （MRL を外挿する化合物）
・アモキシシリン（反芻動物）
・ベンジルペニシリン（反芻動物）
・テトラサイクリン類（反芻動物）
・シハロスリン（反芻動物）
・シペルメスリン（反芻動物）
・デルタメスリン（反芻動物）
・モキシデクチン（反芻動物）
・スペクチノマイシン（反芻動物）
・レバミゾール（反芻動物）
・チルミコシン（反芻動物）
・デルタメトリン（魚類）
・フルメキン（魚類）
・テフルベンズロン（魚類）

CCRVDF は、優先順位リストの Part A 及び Part D について JECFA での評価または再評価のための優先順位の総会での承認を得るために、提出することに合意した。また、次回会合の直前に、オーストラリアが議長を務める物理的作業部会を開催し、評価または再評価を必要とする動物用医薬品の優先順位リストに関するコメントと情報を検討することとなった。

議題１３．その他の事項及び今後の作業

議長からは今回会合を振り返り、大きな前進があったものの、MRL の基礎となる JECFA のリスクアセスメントに必要なデータの欠如に苦しんだこと、特定のクラスの化合物に対し、国際的なコミュニティとして合意に達する難しさ、ある種のクラスの化合物に対し、科学の解釈ではなく確固たる価値観の違いがあってもコーデックス規格を作成すべきか等ついて言及された。

日本からは議題７に鑑み、手続きマニュアルから“JECFA が科学的に正当なものであることを確認しており、不確実性が明確に定義されている”旨の文言を削ることへの憂慮、科学的根拠に基づく MRL であるべきところを今の議論の中で本当に科学的根拠に基づく MRL が作れるのか、この会合の基本理念は科学に基づいたものであるはず、これから始まる電子作業部会では、その理念に則った科学的な議論を行う必要がある旨発言した。

JECFA 事務局からは、特にジルパテロールに関して、科学的な懸念とその他の懸念と明確に分けて議論したことへの感謝が表明され、明確に分けることを達成することは容易ではないが、コンセンサスを得るために重要な要素である旨の見解が述べられた。

議題１４．次回会合の日程及び開催地

議長より次回は 2 年後、CCPR と連続した日程で開催するとの発言があった。

C.2　第 49 回 CCFH 後、第 50 回 CCFH までの間に設置された EWG 及び第 50 回 CCFH

C.2.1 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

2018 年 3 月に WG 共同議長から別添１の文書が回覧され、これに対し、別添２のコメントを提出した。

C.2.2. ヒスタミンの WG

昨年度作成したヒスタミンコントロールのガイドラインを魚類　海産食品の実施規範（CAC/RCP52-2003）のどこに挿入するか、また、それに伴う実施規範全体の修正を行う作業部会、並びにサンプリング計画を作成する作業部会を共同議長として米国とともに作業部会を運営し、討議文書を作成した。さらに、CCFH50 直前に各国コメントで採用できるものを組み込んだ CRD を作成した。

C.2.3 アウトブレイク WG

別添 3 の WG 議長案に対し、別添 4 及び別添 5 のコメントを提出した。

C.2.4　アレルゲンの管理　WG

別添 6 の WG 議長案に対し、別添 7 のコメントを提出した。

C.2.3 CCFH50 前に提出したコメント

食品衛生の一般原則及び HACCP 付属文書の改訂案（CX/FH 18/50/5 に対するコメント
質問に対する回答

以下において、下線は挿入、見え消し部分は削除を意味する。

共同議長からの質問で、PRP, CCP, OPRP の比較表は維持すべきと回答した。
定義については以下のコメントを提案した。

Control measure: Any action or activity (i.e. control measures at CCP and some GHPs which need a higher level of control) that can be used to prevent or eliminate a significant food safety hazard or reduce it to an acceptable level

Food hygiene system: The combination of hygiene practices, including those that require additional attention (i.e. control measures at CCP and some GHPs which need a higher level of control) and that, when taken as a whole, ensures that food is safe and suitable for its intended use.

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP or a relevant GHP procedure is under control.
また、新規の用語"review of hazards"を創設するのに反対した。

Significant hazard: a hazard identified through a review of hazards or a comprehensive hazard analysis, as reasonably likely to occur in the absence of control measures, not to be prevented by general GHPs

Validation: Obtaining evidence that ~~a GHP or a~~ control measure or combination of ~~GHPs and/or~~ control measures, if properly implemented, are capable of controlling hazards to a specified outcome.

本文の修正提案

Food safety hazards that occur or are present at such levels that GHP procedures are not sufficient to… In the case that ~~sufficient control measures through GHPs~~ significant food safety hazards are ~~not possible~~ identified through hazard analysis even after the implementation of GHP, Potential sources of contamination from the environment should be considered… e.g. ~~using land with high heavy metal contaminants or~~ sources of contaminated water, runoff, faecal materials.
Q3: 日本は提案支持
Q5: Japan supports using the word "sanitation". It is clear that the word "sanitation" means cleaning and disinfection (refer to OBJECTIVES in the box), therefore, the definition of "sanitation" is not necessary.
Q6: Japan supports adding the concept of validation to Principle 6. Validation is required for each element in HACCP plan, not only for critical limits

GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

During hazard identification, evaluation, and subsequent operations in designing and

applying HACCP systems, consideration should be given to the impact of raw materials and other ingredients, food production practices, food manufacturing practices (including ~~whether processes control~~ whether hazards are adequately controlled under GHP or whether significant hazards remain and require control under HACCP), likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

The HACCP system should be reviewed periodically and when there is a significant change in the food business that could impact the hazard analysis or control measures… (The system should also be reviewed, and modified as appropriate, when the HACCP system has failed to produce a safe product, e.g., a pathogen is detected at an unacceptable level in a ready-to-eat product.

In some cases, it may be acceptable for a more simplified hazard analysis to be carried out by FBOs. This simplified process identifies groups of hazards (microbiological, physical, chemical) in order to control the sources of these hazards without the need for a comprehensive hazard analysis that identifies the ~~specific~~ specific/significant hazards of concern. Hazards which are of such a nature that their prevention, elimination or reduction to acceptable levels is essential to the production of safe food,… this may be achieved with the application of good hygiene practices, some of which may target a ~~specific~~ significant/specific hazard, (for example, cleaning equipment to control contamination of ready-to-eat foods with *Listeria monocytogenes*) or to prevent food allergens being transferred from one food to another food that does not contain that allergen when the two foods are processed on the same equipment. In other instances, control measures will need to be applied at critical control points. ~~An illustrative example of a decision-tree is attached at Appendix 1:~~

Q7: Inclusion of decision tree is not necessary since it is well-described in the current paras 157 and 159 that significant hazards are controlled by a control measure at CCP or by GHP with a higher level of control.

Critical control points are to be determined for each of the hazards identified as significant in the hazard analysis… Similarly, a CCP may control more than one hazard (e.g. cooking can be a CCP that addresses several microbial pathogens). ~~Determining whether or not the step at which a control measure is applied is a CCP in the HACCP system can be facilitated by the application of a decision tree (e.g., Diagram 2). Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other processes. Other approaches may be used. Training in the application of the decision tree is recommended~~

If a significant hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other step, then the product or process should be modified to include a control measure. Also, in case the step where a significant hazard occurs may differ from the step where a control measure (or combination of control measures) is applied

to eliminate the significant hazard (e.g. a metal shard, which contaminates a product at the cutting step, should be detected at the packing step), care should be taken to determine CCPs.
Establish validation, verification and review procedures (Step 11 and Priciple 6)
Ideally, verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions

アレルゲンの管理（CX/FH 18/50/7 に対するコメント）
SECTION II – SCOPE, USE AND DEFINITION
This Code covers allergen management throughout the supply chain including at primary production, during manufacturing, and at retail and food service end points. ~~It complements Good Hygiene Practice (GHP) in manufacturing and food preparation practices in food service.~~
すでにパラ 23.24 でカバーされており、文書の削除を提案
定義：Competent Authority、Food business operator の定義の削除を提案（すでに種々の Codex の文書で、定義なしに使用されているため）また、HACCP の定義を食品衛生の一般原則及び HACCP 付属文書のものに揃えることを提案した。
5.2.1.4 Monitoring and verification
Manufacturers should regularly review suppliers to ensure that multi-component ingredients (e.g. sauces, spice mixes) have not ~~changed and verify~~ changed. The verification should be carried out that precautionary allergen labelling (such as "may contain" statements) are only applied in instances where the manufacturer cannot reasonably prevent allergen cross-contact when such cross-contract could present a risk to allergic consumers.
理由：The allergen labelling should be separately stated from ingredients (1st sentence).
5.3.1
Manufacturers should have procedures/policies in place for suppliers to notify, in a timely manner, the manufacturer of any changes in the supplier's operation as necessary that could impact the allergen profile of the ingredient from the supplier
SECTION VI – ESTABLISHMENT: MAINTENANCE AND CLEANING
~~Manufacturers should develop cleaning procedures designed to remove food allergens to the extent possible~~.
削除を提案
~~Having assurance that cleaning has been effective is known as cleaning validation. Validation is the assessment of cleaning methods to ensure that they are adequate to minimise allergen cross-contac~~t. Cleaning processes should be validated through visual ~~assessment~~ check (checking that equipment is visibly clean) and, where feasible, through an analytical testing programme….
アセスメントはもっと仰々しいイメージでなので、実態に即した目視"チェック"を提案
SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE
Where necessary, food handlers should wear dedicated clothing in areas where specific allergens are handled and there is a high risk of allergen cross-contact…
提案理由：The recommendations should be applied depending on the separation of areas/ processing lines in each establishment.

SECTION IX – CONSUMER AWARENESS AND PRODUCT INFORMATION

~~All food products and ingredients should be accompanied by or bear adequate information to ensure other food manufacturers or processors and consumers can be informed whether the food is, or contains, an allergenic ingredient.~~

この文の削除を提案

All food products and ingredients should be accompanied by or bear adequate information to ensure other food manufacturers or processors and consumers can be informed whether the food contains an allergen…

提案理由：情報は消費者にも提供すべきとして挿入を提案

Section X Training

All personnel involved in the production, manufacturer, preparation, distribution, retail and service of foods should understand their role in allergen management and the food safety implications of the presence

hygienic design of facilities and equipment ~~in relation to allergens~~ preventing allergen cross-contact and minimizing allergen transfer 提案理由：より明確にするため

微生物食品由来アウトブレイク（CX/FH 18/50/8）に対するコメント

パラ 1,3,7,17 及び 32 で“foodborne disease outbreak”という表現の使用を提案

パラ 4,5,7,9.10, 11, 12, 19、22, 23, 26 , 28, 29 ,31, 34, 39, 42, 43, 48 ,55, 61 及び 67,並びに section 1、2.1 のタイトル.では”food safety emergencies”のという表現の使用を提案

Para 24, 27: central を national level へ変更を提案

Para 30: As not all diseases are mandatory to notify to the human health authorities' ~~access~~ a mechanism which allows the authorities to access information on these cases need to be established and an assessment on ~~the "business as usual"~~ the comparison between elevated and baseline level should be made

Para 32: For example, for Salmonella, the traditional way of comparing data is by using serotyping and pulsed-field gel electrophoresis(PFGE). The increasing availability of ~~such~~ molecular based tests, including whole genome sequencing and multiple-locus variable number of tandem repeat analysis(MLVA), ~~is~~ are expected to increase the number of links between single cases, and thereby the number of outbreaks. Because of greater ..... The use of databases containing comparable molecular based testing results from humans, animal, feed, food .....

- Sufficient laboratory capacity, specific equipment and trained personal
- No standard "cut off" values in terms of degree of differences between strains (single nucleotide polymorphisms (SNP) is established. The differences acceptable counted in SNPs differ between agents and depends on the agent analyzed. Interpretation of results will require bioinformatics specialists. Public databases can be used for comparing typing results and give information of related findings.
- Sharing of WGS sequences in a form that is useful for comparison between the human health and the food control authorities, e.g. multilocus sequence typing (MLST) types

- Considerations of ~~legal requirements~~ any constrains for sharing of data. If data .....

C.2.4 第 50 回 CCFH 対処方針

第 50 回 CCFH 対処方針作成時、アドバイスを提供した。主要議題の背景及び対処方針は次の通り。

仮議題 5. 食品衛生の一般原則（CXC 1-1969）及び HACCP に関する付属文書の改訂原案

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 49 回)会合においては、原案の文書そのものは議論せずに、今後の作業の前提として、「一次生産」は独立したセクションとして残すこと、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が、責務の説明に「ハザード分析」という用語は使用しないこと、全ての食品事業者は Good Hygiene Practice(GHP)を導入する必要があり業種等によってはハザード管理に GHP のみで十分な場合もあること、管理措置には３種類あること（GHP 、いわゆる OPRP 及び Critical Control Point (CCP)）等の原則に合意した。その後具体的な規定については、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にて議論してきた。

今回会合では、物理的作業部会を開催しステップ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、ステップ 5/8 で第 42 回総会に諮ることを目指している。

電子作業部会から提案されている主な論点は以下のとおり。

① 文書中に新たに加える定義、改訂、新たに参照する文書、図等についてどうするか。

② GHP、CCP に加え、その他の衛生管理手法（いわゆる OPRP＝「enhanced GHP」）を管理措置の１つとして含めるかどうか。なお、電子作業部会の議長は、enhanced GHP を含めると文書が複雑になってしまい、これは全ての事業者が活用しやすくなるように,できる限り文書を簡潔にするという CCFH で合意した作業方針に反するとの考えである。また、enhanced GHP の位置づけが明確でなく、必要に応じて、GHP についてもモニタリングの頻度を上げたり、検証や記録を行うことも可能な柔軟性のある案となっているため、修正案に enhanced GHP は含まれていない。

これまでの議論において、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潔にし、元の文書構成を保つべきであるとの立場で対処してきたところであり、我が国からの意見は概ね反映されているが、引き続き同様の立場で適宜対処ありたい。

仮議題 6. 魚類及び水産製品に関する実施規範(CXC 52-2003)の改訂：ヒスタミン管理ガイダンス文書の位置;他のセクションへの修正；ヒスタミン食品安全に関するサンプリング，検査及び分析セクションの改訂

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、魚類・水産製品部会(CCFFP)にて議論されてきたが、第 39 回総会にて、CCFFP の無期限休会に伴い CCFH の新規作業として承認され、前々回（第 48 回 CCFH）から討議を開始し、CCFFP 当時から日本及び米国が電子作業部会の共同議長を務めている。。魚類及び水産製品に関する実施規範(CXC 52-2003)の一部分として、漁獲から陸上の加工施設までのヒスタミン管理に特化したガイダンス文書が前回(第 49 回 CCFH)においてStep5/8 で第 41 回総会に諮ることに合意し、採択された。今年の電子的作業部会で

は、採択されたヒスタミン管理ガイダンス文書を既存の実施規範のどこへ追加するか、また、追加に伴って他のセクションの改訂が必要かどうか、並びに個別食品規格のヒスタミン食品安全に関するサンプリングガイダンスの作成について議論してきた。

電子作業部会では、新たに採択されたヒスタミン管理ガイダンスを既存の実施規範のセクション９（生鮮、冷凍及びミンチの魚の加工）の直後に、独立したセクションとして挿入することに合意した。サンプリングガイダンスについては、個別食品規格に対しての管理状況が不明な場合に、ロットの受け入れ可否を判断するためのものと、管理システムが適切かを評価するためのもの、２つの異なる目的に対してそれぞれサンプリングプランが示された。ロット受け入れのためのサンプリングプランに必要なサンプル数について一部の国から懸念が示されたものの、部会には電子作業部会が示したとおりのサンプリングプランが提案されている。

今回会合で電子作業部会から提案されている主な論点は以下のとおり。

①　ヒスタミン管理ガイダンス挿入にあわせた、実施規範の修正の確認

②　個別食品規格のサンプリングセクションの修正の確認

我が国としては、以上の論点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行性のあるガイダンスを作成するべきとの立場で適宜対処ありたい。

仮議題 7. 食品事業者向け食品アレルゲン管理に関する実施規範原案

前回（第 49 回）会合で豪州及び米国が、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を提案し、第 41 回総会で新規作業として承認されたもの。豪州を議長国、英国及び米国を共同議長国として立ち上げられた電子作業部会で、今回会合でステップ４として議論するための原案の作成がされた。

原案は、仮議題４で議論される食品衛生の一般原則（CXC 1-1969）に従った構成とし、範囲はサプライチェーン全体でのアレルゲン管理とし、IgE 由来及び非 IgE 由来の食品アレルギーとセリアック病等の過敏症を対象とするが、免疫反応に関わらない食品不耐症等は含めていない。また、国際的に重要な免疫反応をおこすと認知されている代表的な８種の食品は、包装食品の表示の一般規格(CXS 1-1985)と一致させた記載となっている。

電子作業部会から提案された、さらなる議論が必要である主な論点は、以下のとおり。

□　「工程管理」セクションの「モニタリングと検証」のパラ 69 において、施設が取り扱う低濃度のアレルゲンを含む可能性のある原材料について定期的に変更の有無を検証する規定を記載するのか、及び「・・を含む可能性のある(may contain)」といった予防的な(precautionary)アレルゲン表示を、施設が交差汚染を合理的に防げない場合のみに適用するのか

□　「施設（維持及び清掃)」セクションの「清掃プログラム」において、アレルゲンの交差汚染を最小限にするための清掃プロセスやその効果の検証を規定する清掃の妥当性確認についての記載を追加するかどうか。

□　「消費者意識と製品情報」セクションの「製造」において、全ての食品及び原材料にはアレルゲンが含まれているかどうかについて製造者、加工者及び消費者に情報提供する旨の記載に加え、製品がアレルゲンを含むという情報には予防的なアレルゲン表示を含むものの、そのような表示はアレルギーがある消費者が利用可能な食品を減らすことに繋がるため、体系的な使用は避けられるべきである旨の記載を追加するかどうか。

我が国としては、原案に記載されたアレルゲンの管理措置が各国で現状どのように適用されているかを参考にしつつ、消費者の健康保護のため、食品事業者にとって活用しやすく実行可能なガイダンスとなるよう、柔軟性のある記載となるよう対処ありたい。

仮議題 8. (微)生物による食品に起因する緊急事態/アウトブレイクの管理のガイダンス文書原案

前回(第 49 回)会合で EU が新規作業として提案し、WHO や複数国から本文書と既存の FAO/WHO やコーデックスの文書との重複が指摘され、本文書の新規性及び必要性について疑問が示されたが、第 41 回総会で新規作業として承認されたもの。デンマークを議長国、EU 及びチリを共同議長国として立ち上げられた電子作業部会では、改訂されたプロジェクトドキュメントを考慮して、今回会合でステップ４として議論するための原案の作成が行われた。

電子作業部会で議論された主な論点は、以下のとおり。

□　文書の構成は適当か。

□　表題の（微）生物の括弧を削除し、文書の対象を微生物による食中毒の管理のみにしてよいか。

□　EU では INFOSAN（国際食品安全当局間ネットワーク）の他に EU 地域での緊急アラートシステムがあるところ、対象範囲を国「及び地域の」としてよいか。

□　食品安全の緊急事態(Food safety emergencies)という用語を、深刻度にかかわらず全ての食中毒に使用して良いか。

□　文書と関連文書への参照のバランスは適当か。

□　さらに記載すべき関連トピックはあるか。

□　ガイドラインに図表を含めたほうがよいか。

文書の構成、「及び地域の」の追加、文書のバランスについては概ね合意が得られたが、表題の括弧の削除や、「食品安全の緊急事態(Food safety emergencies)」という用語の使用については合意に至らなかった。特に「食品安全の緊急事態(Food safety emergencies)」については、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(CXG 19-1995)で定義されているため、齟齬のないようにすべきとの意見、別の用語を使用した方が良いとの意見、また深刻度に応じたさらなるスケール分類が必要との意見等様々な意見が出された。その他、今後さらに検討すべき部分として、全ゲノムシークエンス（WGS）を適用した管理の記載について、妥当性確認の推奨や、利点だけでなく課題も記載すべき等の意見があった。

電子作業部会からの提案は、以下のとおり。

①　関連した箇所でのより詳細なガイダンスのため、他の文書を参照しつつ、単体でも読める文書となるよう発展させる目的で議論を継続すること

②　対象範囲と用語について議論すること

□　「食品安全の緊急事態(Food safety Emergency)」「食品安全事件(Food safety incident)」又は「食品安全事案(Food safety event)」のどれを使用するか、また本文書の対象として、健康被害が起きていない食品汚染事件についてどの程度含めるか。

□　表題と対象範囲について、「(微）生物学的」の代わりに「生物学的」にしてよいか。

□　食品に起因するアウトブレイク（Foodborne outbreak）の定義について、２案のうちどちらを使用するか。

□　「迅速なリスク評価」及び/又は「事件評価」の使用。

我が国は、新たな文書が既存の文書と齟齬のないように、また重複のないようにすべきとの立場である。また、米国及びブラジル等が本文書を新たなガイドラインではなくinformation documentとの位置づけとすることを提案しているところ、これを支持して差し支えない。

文書の内容に関しては、「食品安全の緊急事態(Food safety Emergency)」の用語は、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(CXG 19-1995)で定義されているため、新たに別の定義を作成すべきでなく、また、各国が参照した際に、食中毒を早期発見し、被害拡大を防止し、さらに再発を防止する観点から、必要な対応を迅速にとるために有益な内容とすべきである。したがって、緊急事態（恐れを含む）以外の全ての「食品安全事件(Food safety incident)」、「食品安全事案(Food safety event)」や健康被害のない事件等において、過度な負担とならないよう対象範囲及び内容を検討すべきとの考えで適宜対処ありたい。また、食品安全の緊急事態（Food safety Emergency）の範囲を明確化すべきとの議論になった場合は、どの程度の事案を緊急事態と認識するかは各国で解釈が異なることから、我が国としては、緊急事態の範囲を明確化すべきではないとの立場で適宜対処する。なお、我が国は、腸管出血性大腸菌感染症の遺伝子解析は全ゲノムシーケンス（WGS）ではなく、反復配列多型解析法（MLVA法）を使用している。費用面や迅速に検査を行う点においてはWGSよりMLVA法が優れている点もあり、各国がそれぞれの病因物質（微生物やウイルス）に対してどのような遺伝子解析手法を用いているかについて適宜聴取ありたい。

仮議題9. 志賀毒素産生性大腸菌(Shiga toxin-producing Escherichia coli:STEC)の今後の作業についての討議文書

米国、ウルグアイ及びチリがSTEC新規作業に関する討議文書を作成することとされていたもの。CCFHの要請に応じて2017年及び2018年に開催されたFAO/WHO専門家会合の報告書において、STECのリスクが高いとされた牛肉、未殺菌乳及び未殺菌乳から製造されたチーズ、葉物野菜、並びにスプラウト類について、STECを管理するためのガイドラインを新たに策定すること、フォーマットについては、「鶏肉におけるカンピロバクター及びサルモネラ属菌の管理のためのガイドライン（CXG 78-2011)」及び「牛肉及び豚肉における非チフス性サルモネラ属菌の管理に関するガイドライン（CXG 87-2016)」の例に倣うことが提案されている。肉類、乳類、生鮮果実･野菜については、それぞれ衛生実施規範が既に存在することから、作業の重複を避けつつ、STECに特異的かつ効果的な管理措置に関するガイドラインが策定されるよう対処ありたい。。

C.2.4 第50回CCFHの主な議論と結論

第50回CCFH（2018年11月12日（月）～11月16日（金)，パナマシティ（パナマ）にて開催された第50回CCFHの議論の概要と我が国の今後の課題についてまとめた

<u>議題3　FAO/WHO合同微生物学的リスク評価専門家会議（JEMRA）を含むFAO及びWHOの作業から提起された事項</u>

FAO及びWHO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。

<u>水質について</u>

- FAO代表から，第２回のFAO及びWHO専門家会合の結論の報告として,食品製造及び加工に使用される水によって最終製品の安全を損なうことなく、「目的に適する(fit-for-purpose)」水をリスクベースアプローチで決定すべきと述べた。また、生

鮮品及び水産食品の製造/加工に使用される水質の評価をするための決定分析ツールが作成されたので次のステップとしてこれを実際に試用して FAO/WHO の活動に協力する国を募集していること、さらに作業が必要な事項として、「目的に適する(fit-for-purpose)」水の微生物基準の設定と再利用水のための決定ツールの強化があること、が述べられた。

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

- FAO 代表から，前回会合後に更に行われた汚染源の寄与率（source attribution）に関する作業の結果として，大部分(56%)のアウトブレイクでは要因が明らかになっておらず,特定できたものでは牛肉及び生鮮野菜がそれぞれ約 30%を占めることが報告された。さらに、症例対照研究により牛肉が STEC の散発事例の要因としてさらに重要性が認識されたことから、牛肉と生鮮野菜に対する STEC 管理の作業を優先する正当性が示された、と述べられた。

その他の関連事項

- FAO 代表から，腸炎ビブリオ及びビブリオバルニフィカスのリスク評価モデルの妥当性確認/改訂、リスク評価方法の既存のガイダンス文書の更新、既存の病原菌―食品リスク評価の改訂及び食品由来 AMR における環境、植物、殺生物剤の役割に関する作業の報告があった。
- WHO 代表から，最近の INFOSAN（国際食品安全当局ネットワーク）の活動について、加盟国による活発な参加が増えている旨、報告があった。

結論

部会は FAO/WHO の貢献に感謝の意を表した。また、議長から、科学的アドバイスが必要な事項は可能な限り早く特定することが重要（通常対応するのに 15 か月は必要なため）である旨の指摘があった。

議題 4　国際獣疫事務局（OIE）からの情報

OIE 事務局が欠席のためコーデックス事務局から，　FAO/WHO/OIE の 3 者協力のメカニズムのもと基準策定や科学的助言の活動が行われていること，食品安全における獣医の役割、責任及び食品安全における獣医サービスの変化を反映して、改訂された陸性コードの 6.2 章「食品安全システムにおける獣医サービスの役割」が採択されたことが報告された。

議題 5　食品衛生の一般原則（CXC 1-1969）及び HACCP に関する付属文書の改訂原案

会合内物理的作業部会での議論を踏まえ,作業部会議長である英国が作成した報告書に基づいて議論が行われた。合意された主な事項は以下のとおり。

- 「食品原料の衛生的生産」に FAO/WHO の参照文書を含めないこと。
- 現行の食品衛生の一般原則 4.4.5 のサブセクション「温度管理」は工程のモニタリングではなく、「施設」の中の項目であることから表題の「管理」を削除すること。
- 「 Sanitaion 」 を 「 Cleaning and disinfection」に修正すること。
- 原則３及び６の項目名を現行のままとすること。
- 一般衛生管理（GHP）と HACCP の比較表及び CCP ディシジョンツリーは別添に移すこと。

また、部会では主に以下についての議論が行われた。

「導入（introduction)」のパラ４

食品事業者は自らが扱う食品に関係する危害要因を知り、これらが及ぼす消費者への健康影響を理解する必要があるとともに、適切に管理されることを確実にすべきであること。GHP はいかなる事業でも関連する危

害要因を効果的にコントロールする基礎であること。特定の事業者にとっては、GHP を効果的に実施することが食品安全に取り組む上で十分な場合もあること。

「導入」のパラ５

いわゆる OPRP の記載として、「greater attention」ではなく、「greater focus」を使用すること。

「導入」のパラ６

食品の安全性確保の観点から、GHP の実施のみでは不十分な場合（例. 複雑な工程や製品、ガス置換による保存可能期間の延長、特殊用途向け食品）もあること。危害要因分析を通じて重要な危害要因が特定された場合には、HACCP 原則が適用されるべきであること。

「水」のセクション

現行の水のサブセクションの記述を削除し、“飲用適”及び“清浄水(clean water)を“目的に適した水”に変更したうえで FAO/WHO の専門家会合の報告書が出版された時点で引用することに合意した。なお、“目的”は“意図する用途”と同意である。さらに、「必要に応じて、保管、配水及び温度管理のために適切に維持された設備からの適切な水の供給ができること。」という記載を含めることに合意した。

定義

「水」、「汚染物質」、「汚染」、「食品の適切性」、「消毒」、「食品衛生システム」については合意されたが、「許容範囲」、「食品事業者」、「行政当局」及び「適正衛生規範」については、さらに検討される。

今後の作業方針として、部会で合意された事項は、以下のとおり。

- 改訂案については、再度改訂作業を行うためにステップ２に戻すこととされた。
  これを受け，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。
- 本会合で合意された部分を除き、本会合の議論及び提出された各国コメントを踏まえ，以下を重点に置き、文書の改訂作業を行うこと。
  - （提出されたコメントを踏まえ）本会合で議論されなかったセクションの修正
  - 角括弧に入っている（合意できなかった）テキスト
  - 「一般原則」及び「経営コミットメント」のセクション、及び比較表を部会での合意内容と統一させる。

  本会合の議論を踏まえ、
- 現行文書にある図表（HACCP 適用のロジカルシークエンス、HACCP ワークシートの例及び CCP 判断図）を含めるのか、改訂の必要があるのかを検討すること。
- 次回会合前日に物理的作業部会を開催し，提出された各国コメントを検討した上で 51 回会合で議論するための修正原案を作成すること。

本議題については、電子作業部会の報告書を次回会合の３か月前以上前に送付し、ステップ３でコメントを求めることとされた。

議題 6　魚類及び水産製品に関する実施規範(CXC 52-2003)の改訂：ヒスタミン管理ガイダンス文書の位置;他のセクションへの修正；ヒスタミン食品安全に関するサンプリング,検査及び分析セクションの改訂

電子的作業部会の議長国である日本及び米国が，各国・地域から提出されたコメントを踏まえて修正した改訂案に基づき議論が行われた。

「魚類及び水産製品に関する実施規範（CXC 52-2003）」におけるヒスタミン管理ガイダンスの位置

セクション９（生鮮、冷凍及びミンチの魚の加工）の直後に、独立したセクションとして挿

入することに合意した。

ヒスタミン管理ガイダンスの挿入に伴う CXC 52-2003 の他のセクションの改訂

ヒスタミン管理ガイダンスの挿入に伴い、他のセクションにヒスタミンを潜在的な危害要因として追加するなど必要な修正が行われれた。

魚類及び水産製品に関する個別食品規格におけるサンプリングガイダンス

共同議長から、２つの目的のサンプリングプラン（①個別食品規格の適合性を判断する際、ヒスタミンの管理状況が不明の場合にロットの受入の可否の判断、②GHP 又は HACCP 管理が運用されている施設に由来するロットに係る適切な管理の検証）は、食品の安全性を確保しつつ、実用性かつ実行性を踏まえて、作成されたものである旨の説明があった。また、時間と温度管理がヒスタミンの管理には重要であることから、後者のプランの使用を主に想定しているとした。

これについて、各国・地域から様々な見解が示された。

- ①の目的で提案されている二階級サンプリングプランはヒスタミンを重篤な危害要因としているように見えるが、中等度の危害要因であることを踏まえれば、三階級サンプリングプランの方が適切である。また、59 サンプルユニットは非実用的かつ経費がかかるプランであり、生産者及び行政当局に不必要な負担となる。
- 三階級サンプリングプランは、より少ないサンプル数での運用実績があり、実用的、実行的かつ効果的である。
- ②のプランは、個別食品の安全性を確認するプランではなく、管理措置の検証のためのものであり、本作業の対象外である。

これに対して、共同議長から、ヒスタミンは中等度の危害要因であるが、米国では最も多く報告されている魚由来の疾患であること、ヒスタミンの安全限界値は症状を引き起こすレベルと近く、安全マージンはないため、7.1.1 のサンプリングプランにあるような厳しいプランを提案せざるを得ない、ヒスタミンの管理は温度と時間の管理が基本であり、GHP や HACCP が実施されている場合には柔軟なサンプリングプランの適用が可能であること、危害要因の重篤性ではなく、保護のレベル（1/20）に基づきサンプリングプランの厳しさを決定している、実行可能性及びコストはサンプル数だけではなくサンプリング計画を適用する頻度も考慮にいれるべき、迅速スクリーニング法及びサンプルを複合試料とすることでコストを低減できる、一方、あるロットについてヒスタミン管理に関する事前の情報がない、またはヒスタミン食中毒の発生施設として特定された生産者の場合には、消費者保護の観点からより厳しいサンプリングプランを適用する必要がある場合もあること等を説明した。

しかしながら、議論が収束しなかったため、共同議長は、作業を進展させることは難しいと判断し、より多くのデータが蓄積し、また分析・サンプリング部会（CCMAS）が「サンプリングに関する一般ガイドライン（CXG 50-2004）」を改訂するまで作業の延期を提案した。

改訂案の合意が得られなかったことを受け、部会は以下について合意した。

- CCMAS での「サンプリングに関する一般ガイドライン」の改訂作業が終わるまで検討を延期すること。
- 現時点において、ヒスタミンのサンプリングプランに合意することは困難である旨を総会に報告すること。
- 消費者保護、柔軟性及び実行性の間で受入可能なバランスを達成するような水産食品におけるヒスタミンのサンプリングプランの策定において部会が直面した課題について「サンプリングに関する一般ガイドライン」を改訂する

際に考慮に入れるように CCMAS に報告すること。

議題７ 食品事業者向け食品アレルゲン管理に関する実施規範原案

電子作業部会共同議長のオーストラリアから、検討を要する主な問題はアレルゲンの閾値に関する事項、リスク評価の方法、「予防的なアレルゲン表示」の用語の使用であることが述べられた後、各国から提出されたコメントをもとに共同議長が改訂した文書に基づき議論が行われた。

アレルゲン管理措置は、予防及び低減できるため、文書を通じて両方の目的を記載すること、アレルゲン交差接触の「リスク」は不明であるため交差接触の「可能性（likelihood)」と適宜書き換えること等の修正のほか、アレルギー反応をおこす食品リスト及び予防的なアレルゲン表示について、時間をかけて議論がされた。部会は食品中の表示されないアレルゲン及び意図しないアレルゲンについて、両方の状況があり得るので、危害要因の特性付けのセクションにおいて両者を含めることにした。

セクション 5.2.1.4 の原材料等の供給者の見直しについては、対象を供給者の作業及び加工助剤の供給者にまで拡大し、セクション 5.6 については、消費者によるアレルギー反応の認識及び対応は大事ではあるがアレルゲン管理ではないことから削除し、セクション 5.8.1 については措置を講じることが大事であり、表題を“消費者からの苦情”から“消費者からの苦情及び必要な措置”へ変更した。

アレルギー反応を起こす食品リストは、グルテンを含む穀類（小麦、ライ麦、えん麦、大麦、スペルト小麦又はこれらの交雑種及びこれらの製品)、甲殻類、卵、魚類、乳、ピーナッツ、大豆、木の実となっている。共同議長から、食品表示部会(CCFL)の文書「包装食品の表示に関するコーデックス一般規格（CXS1-1985)」に記載された過敏症の要因リストと合わせたこと、えん麦はグルテンを含まないが、グルテンを含む穀物と同じ場所で生産され交差接触が生じることから脚注をつけている旨の説明があった。本リストは CCFL へ助言を求めることとした。

予防的なアレルゲン表示については、必要な場合があるかもしれないが、この表示がアレルゲンの存在を防止・低減するための措置の実施に代わるものではないということを部会として認識した上で、共同議長から、予防的なアレルゲン表示の一般的な説明及び関連したリスク評価/閾値の使用についての記載を作成し挿入した旨の説明があった。閾値については、科学に基づいた閾値の使用が食品アレルギーのある消費者へのリスクを測定するツールとなること、閾値の使用により予防的なアレルゲン表示の使用を減らし、実際に使用する場合に表示を消費者にとってより意味のあるものとすることができる、との記載となっている。これらに加え、予防的なアレルゲン表示の定義、製造者が商品を仕入れる際の表示の検証、表示の使用等の表示に関するパラについて現在は角括弧にいれることとし、CCFL へ助言を求めることにした。

アレルゲン管理に関する決定をサポートするための、リスク評価の使用に関する食品事業者へのアドバイスを含めるため、リスク評価のアプローチについて FAO/WHO へ科学的助言を求めることとした。また、リスク評価については、食品事業者に負荷となる作業を意図するものではなく、食品事業者が予防的な表示の使用よりもアレルゲン管理の手順を見直しを行う重要性を強調するものであることを確認した。

結論として、部会は本原案をステップ５で総会に諮ることに合意した。

CCFL には、食品表示に関する記載（パラ 158,159）承認及び下記２点について助言を求めることとした。

・予防的なアレルゲン表示の使用の適切性(REP19/FH の Appendeix III のパラ 14,28,72,152,160,161)及びその定義

・アレルギー反応を起こす食品リスト(パラ 9)
また、FAO/WHO に、科学的助言を提供するための専門家会議を開催すること及びこれを CCFL に情報提供することを求めた。食品アレルゲンのリスク管理に関する FAO/WHO 専門家会議のへの付託事項は以下のとおり。

① 重要なアレルゲン(グルテンを含む穀類、甲殻類、卵、魚類、乳、ピーナッツ及び木の実)について、アレルギーがある消費者のほとんどが反応を起こさない閾値はどこか。
② 食品事業者がどのように閾値を使って、以下の事項を決定できるか。
   - どの程度の清掃方法により、アレルギーがあるほとんどの消費者に対して、アレルゲン交差汚染によるリスクを防止または低減するレベルまでアレルゲンを除去できるのか
   - 低濃度のアレルゲンを含む原材料(例:予防的なアレルゲン表示がされた原材料)の使用にあたり、アレルゲン交差接触の防止または低減するための管理が必要となるのか
③ 優先的なアレルゲンについて、食品及び接触表面の試験のための適切な分析方法
④ 食品事業者が下記を決定するために、利用できる方法/ツールは何か。
   - 清掃手順の後に、食品にアレルゲン交差接触が合理的に発生する可能性は高いか
   - 異なるアレルゲンプロファイルの食品に使用した器具から、アレルゲン交差接触が合理的に発生する可能性が高いか
   - 交差接触の結果おきる食品中のアレルゲンのレベル

議題 8. (微)生物による食品に起因する緊急事態/アウトブレイクの管理のガイダンス文書原案

電子作業部会議長のデンマークから、文書の対象範囲及び FAO/WHO 文書の参照、用語について議論を行うことの提案がされ、各国から提出されたコメントをもとに共同議長が改訂した文書に基づき議論が行われた。

FAO/WHO 文書の参照

コーデックス事務局から、文書の参照についてコーデックスとして特別なルールはないものの、外部文書の参照は最低限にとどめ挿入はケースバイケースで検討されるべき、最終文書で参照を削除するために関連情報を文書原案に組み込むこともできるとの説明があった。これを受け、可能な範囲で、参照文書からの関連情報を原案に組み込むこととした。

対象範囲

共同議長から、対象範囲は人の症例発生のない食品汚染は含まず、症例のあるアウトブレイクのみとし、タイトルに入れていたクライシスについても主観的であるために外す提案がされた。WHO から、食品の輸出入に伴い症例が発生していない国でも対応が必要な場合があったり、人の症例が出てから原因食品が明らかになるまでに時間がかかる散発事例があったりするので、対象範囲についてはより広いアプローチが必要との発言があった。日本から追加で、CCFICS の「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(CXG 19-1995)」で定義されている「食品緊急事態(emergency)」のほうが適当ではないかと発言した。各国から Emergency の用語を支持する発言はなく、共同議長からアウトブレイク管理に関連するのでそれらの一部の観点は含まれるとの説明があり、対象範囲は「食品由来のアウトブレイク」とし、タイトルの「クライシス」は削除することとした。

「食品由来アウトブレイク」の定義

共同議長から、WHO「食品由来疾病アウトブ

レイク」での定義[1]と米国 CDC の定義[2]を組み合わせた定義が提案された。日本から、WHO の定義をそのまま使用する方が良いのではないかと発言したところ、カナダから、カナダでは CDC の定義に含まれるとおり、疫学調査によりあきらかになることが必要である旨述べた。合意した定義は以下のとおり。

「食品由来である可能性のある特定の疾病の観察された症例数が期待される数を超える場合、又は、共通の食品の飲食による同様の食品由来疾病の症例発生が２以上あり、疫学的な分析により特定の食品がその疾病の要因であると推察されるもの」

「生物的」または「(微) 生物的」の用語の使用

括弧を外し「生物的」の用語を選択し、米国からの提案により例示を限定した。合意した「生物的危害要因」の定義は以下のとおり。

「生物的危害要因とは、ヒトに害を与える力のある微生物を含む、生物的な要因。例:細菌、ウイルス及び寄生虫、を含む。」

「迅速なリスク評価」かつ/または「アウトブレイク評価」の用語の使用

「迅速なリスク評価」を選択し、合意した定義は以下のとおり。

「迅速なリスク評価とは、食品由来アウトブレイクにおける利用可能な情報に基づくリスク評価で、(暫定的な)リスク管理措置を迅速にサポートするため至急行う必要のあるものであるから、標準的なリスク管理の４手順の完全な進行を必ずしも含むものではない。」

ガイダンス中への図の使用

共同議長から、今後図を使用した説明を用いて、国、地域及び国際間のネットワークのつながりを示す例を入れる旨の説明があった。

結論として、部会は本原案をステップ２に戻し、再起草することに合意した。引き続き、デンマークを議長、チリ及び EU を共同議長とする電子的作業部会をたちあげ、本会合での議論及び合意事項、提出されたコメントをもとに文書の見直し、改訂、次回会合で検討する改訂版を準備を行うこととした。

議題９　牛肉、未殺菌乳及び未殺菌乳から製造されたチーズ、葉物野菜、並びにスプラウト類における志賀毒素産生性大腸菌(Shiga toxin-producing *Escherichia coli*:STEC)の管理

新規作業として議論されたため、議題１０の結果に記載。

議題 10　その他の事項及び今後の作業

新規作業/今後の作業計画

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

新規作業（牛肉、未殺菌乳及び未殺菌乳から製造されたチーズ、葉物野菜、並びにスプラウト類における志賀毒素産生性大腸菌(Shiga toxin-producing *Escherichia coli*:STEC)の管理）

ガイダンス作成は段階別アプローチとし、牛肉及び葉物野菜を第１優先とすること、文書の構成はまず一般的なガイダンスを記載し、その後に食品別ガイダンスとするのが適当であること、「未殺菌乳」という用語は加熱処理をした乳も含まれうるので「生乳」とすること等の

[1] a) The observed number of cases of a particular disease exceeds the expected number.
b) The occurrence of two or more cases of a similar foodborne disease resulting from the ingestion of a common food.

[2] A foodborne outbreak is an incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiologic analysis implicates the food as the source of the illness

議論がされた。これらの議論をもとに、部会として電子作業部会の議長国であるチリ及び米国に、本部会での議論を踏まえ（タイムラインの修正を含む）たプロジェクトドキュメントの改訂を求めた。

結論として、新規作業を開始することに合意し、改訂したプロジェクトドキュメントを総会に提出し新規作業の承認を諮ることとした。総会の承認を前提として、チリ及び米国を共同議長とする電子作業部会を立ち上げ、次回会合にてステップ３でコメント募集、検討するための原案を作成することとした。

今後の作業計画

今後の作業計画の表に下記の改訂を行った。

・STEC に関する文書は次回総会に承認を求めるため削除

・食品製造中の水の安全な使用の原則は、評価が行われたことから、点数を記載（合計 25）として、最優先事項とする

・南アフリカ提案で、2017 年のリステリアアウトブレイクの情報から、リステリア文書の見直しを表に追加

・穀物の保存の衛生実施規範のプロジェクトドキュメントを探しやすいよう、脚注に情報を追加

部会は、食品加工における安全な水の使用の原則に関する討議文書を作成する必要性を認識し、ホンジュラスがチリ、EU, インド及びデンマークのサポートを得て次回会合での討議に向け討議文書を起草するという申し出を歓迎した。

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第次回会合時に CCFH における作業の優先順位に関する物理的作業部会（議長国：米国）を開催することで合意された。

議題 11. 次回会合の日程及び開催地

次回会合は 2019 年 11 月 4～8 日に米国で開催される予定。

C.4 第 24 回コーデックス食品輸出入検査・認証制度部会（CCFICS）

C.4.1 PWG エジンバラ

5 月 28 日-31 日、イギリスのエジンバラでシステム同等性 2 日、第 3 者認証 2 日 WG が開催され、起草作業が行われた。

C.4.2 第 24 回 CCFICS 前コメント作成

〇第三者認証

文書の理解を深めるための、第三者認証の情報/データを実際に使用している good practice を、information document 等で例示することを提案。

〇システム同等性

次の内容を提案する。

１．文書の文言に一貫性をもたせること

２．文書と図表の言葉を一致させること。文の主語を明確にすること

３．ステップ１（最初の協議）は、輸入国の他の食品安全に係る状況（緊急時対応、他のシステム同等性、リソース）やそのインパクトを考慮に入れ、優先順位をつけて実施されるようにすること

Specific comments

定義

Japan proposes to delete the definition "Equivalence" because this guidance intends to provide clear recommendation for developing and implementing systems equivalence and therefore this could contradict such concept.

Decision Criteria: those factors used to determine whether the exporting country's NFCS or relevant part is capable of ~~reliably~~ adequately meeting the objectives of the

importing country's NFCS or the relevant part for the products under consideration.
(理由：Japan proposes to replace "reliably" with "adequately" for clarification.)

Process steps:
10 The process steps related to consideration, assessment, ~~recognition~~ determination and maintenance of the equivalence of NFCSs include the following[8] and are expanded in the following subsections and illustrated as a simplified flow chart at Figure 1:
Japan proposes to change "recognition" into "determination" for consistency with GL53.

Step1
Prior to countries formally requesting consultations, initial discussions should occur to determine whether to commence a system equivalence assessment and whether any preliminary considerations a~~re met~~ should have been sufficiently performed. The countries should then agree the potential scope of the assessment and identify the gaps in existing experience, knowledge and confidence relating to that scope.Once the decision to commence and the associated scope has been discussed the exporting country should formalise its request.

Step 5:Assessment process
Japan proposes to insert "process" for consistency with Step 6.
Importing country assesses the submission to determine where the exporting country's NFCS or relevant part meets the objectives of the importing country'sNFCS.The assessment process should be transparent, evidence-based and focus on assessing whether the exporting country's NFCS in whole or the relevant part as described meets the decision criteria.

理由：Japan proposes to add this sentence because it sould be clarified who is responsible for this action.

Step 6:Decision process を"Judgement process"への変更を提案
理由： GL53 section 8 のタイトル"judgement"と一貫性をとるため.

~~The decision process~~ Importing country should ~~be~~ ensure the judgement process is transparent and the result of the assessment documented with the results should be discussed with the exporting country prior to finalisation.
理由：Japan proposes to modify this paragraph for clarification on who ensures the transparency of the process.

Step 7:Formalization and maintenance of the ~~recognition~~ determination
理由：Japan proposes to change "recognition" into "determination" for consistency with GL53.
~~Recognitions~~ Determinations of system equivalence should be documented and subject to regular review.
パラ 11 の上にセブセクションタイトルとして initial discussions を図と一致させるため挿入することを提案
パラ 13 の後に次の文の挿入を提案
In the initial discussions, consideration should be given to allow the importing country to prioritize the equivalence of system recognition with other food safety issues already in place.
理由： system equivalence の作業が他の緊急な食品安全関連の作業を滞られるべきではないから
14 Relevant matters relating to preliminary considerations by importing country and the likelihood of success may include
下線部挿入を提案

15 It is important that exporting countries engage in ~~preliminary~~ initial discussions on the potential scope of any equivalence of systems assessment.The scope may relate to an entire NFCS or only to that part of a NFCS relevant to the products that are currently or intended to be traded between the two countries
パラ 18The importing country decision to commence an equivalence of systems assessment may involve a determination that:
19 Once the decision to commence and the associated scope has been discussed between importing country and importing country, the exporting country should formalise its request to the importing country for an equivalence of systems recognition.The two countries should then agree on a plan for progressing the assessment which may include for example milestones, timeframes and if necessary priorities
パラ 20
Where the preliminary considerations are not sufficiently ~~met~~ performed both (or importing and exporting) countries may wish to consider working jointly toward identifying possible technical assistance that could support a future arrangement to reduced impediments to trade and duplication of control activities

5.6 STEP 6: DECISION PROCESS
日本は"decision(process)" を "judgement process" へ変更を提案。理由： GL53 section 8 titled "judgement".と一貫性を持たすため
STEP 7: FORMALIZATION AND MAINTENANCE OF THE RECOGNITION
日本は"recognition" を "determination" に変更を提案。理由： GL53 と一貫性を持たすため
Regarding the figure1 - Preliminary discussion should be replaced with preliminary consideration so as to be sonsistent with para13. For consistency with Step2 of the text, the title(Document Decision criteria for comparison) should be "Decision criteria for comparison. For consistency with Step4 of the text, the title(Develop and present case for equivalent in line with importing country objectives and Desicion Criteria) should be "Dexcription

C.4.3 第 24 回 CCFICS 対処方針作成

第 24 回 CCFICS 対処方針作成時、アドバイスを提供した。主要議題の経緯と対処方針は次の通り

仮議題 4 システム同等性の使用に関するガイドライン原案

（経緯）
本作業は、輸出入時の監視の不必要な重複を減少させると同時に、消費者の健康保護及び食品貿易の公正な取引の保証に効果的な手段として、輸出国と輸入国の間の食品安全制度（システム）の同等性の適切な利用を支援するための
ガイドラインを作成しようとするもの（提案国：ニュージーランド)。
第 21 回会合（2014）において、討議文書を作成することが合意され、第 22 回会合（2016）において、ニュージーランドを議長国として、討議文書を改訂するための電子作業部会を立ち上げることで合意された。その後、前回作業部会第 23 回会合（2017）において、電子作業部会を踏まえて修正が行われた文書を基に議論され、新規作業として第 40 回総会での承認を求めることで合意され、第 40 回総会にて承認された。
今次会合では、２回の物理作業部会を経て作成された本ガイドライン原案を基に検討を行う。
（概要）
システムの同等性とは、輸出入国の食の健康を保護すること、食品貿易における公正な取引を保証することに関して、同じ水準、目的を達成できる能力をいう。

目的：システム同等性の検討、評価、認識、維持の過程に関して、実用的なガイダンスを提供すること。
範囲：消費者の健康保護、食品貿易の公正な取引の保証に関係する、輸入される食品に関する NFCS。NFCS に輸出入時の検査や証明のシステムを含む。
概要：システム同等性を検討するに当たっての原則及び評価する際の手順について示されている。
ステップ１：評価開始前の協議及び評価開始の決定（両国）
ステップ２：システムの比較のための判断基準の提供（輸入国）
ステップ３：輸入国の NFCS の目的の説明（輸入国）
ステップ４：輸出国の NFCS の説明（輸出国）
ステップ５：評価の実施（輸入国）
ステップ６：評価結果の決定（輸入国）
最終決定前の協議（輸出国）
ステップ７：NFCS が同等であることの認識の文書化と維持（両国）
（対処方針）
輸入国が主導権をもって協議の開始を決定できる枠組みが維持されるよう、議論の内容に留意しつつ、適宜対処したい。

仮議題 5 電子証明書のペーパーレス使用に関するガイドライン原案（CXG 38-2001 の改訂）
（経緯）
本作業は、「一般公的証明書の設計、作成、発行及び使用に関するガイドライン」（CXG 38-2001）について、ペーパーレスでの使用を踏まえた改訂をしようとするもの（提案国：オランダ）。
第 21 回会合（2014）において、討議文書の作成について合意され、第 22 回会合（2016）、電子作業部会を経て、第 23 回会合において、CXG 38-2001 を改訂する新規作業を開始すること、電子作業部会を立ち上げること、新規作業として第 40 回総会での承認を求めることが合意され、第 40 回総会にて承認された。
電子作業部会において、主に次の観点から改訂された。
・電子証明書を使用していない国のために、紙での証明書の使用を除外しない
・電子証明書、電子署名、シングルウィンドウの定義
・責任、要件、データモデルの説明

今次会合では、電子作業部会を経て改訂された本ガイドライン原案を基に検討を行う。
（対処方針）
議論の内容に留意しつつ、慎重に対処したい。

仮議題 6 食品安全及び食品貿易の公正な取引の分野での第三者認証スキームへの規制アプローチに関するガイドライン原案
（経緯）
本作業は、NFCS に第三者認証スキームの情報を取り入れる方法について、ガイドラインを作成しようとするもの。（提案国：カナダ）。
第 22 回会合（2016）において提案され、前回第 23 回会合（2017）において、新規作業を開始すること、物理作業部会を立ち上げること、新規作業として第 40 回総会での承認を求めることが合意され、第 40 回総会にて承認された。
今次会合では、２回の物理作業部会を経て作成された本ガイドライン原案を基に検討を行う。
（概要）
第三者認証とは、国家の規制要件または、国際的な規制要件を利用する規格を所有している、非政府組織の制度または自主的な制度をいう。

目的：第三者認証制度の情報を NFCS に使用するための、ガイダンスを提供すること。
範囲：消費者の健康保護、食品貿易の公正な取引の保証に関係する NFCS の目的と一致する、第三者認証制度。なお、規制当局によって管理されている公的な検査システム、証明システム、規制基準を検査、証明する認証機関には適用されない。
概要：関係者の役割及び責任、第三者認証プログラムの評価基準、第三者認証の情報を使用するための規制当局のアプローチ等について示されている。
（対処方針）
第三者認証プログラムが管轄当局と同等のチェック機能を有しているか等に留意しつつ、慎重に対処したい。

仮議題 7 食品の清廉性／信憑性に関する討議文書

（経緯）
本作業は、食品偽装に対処するため、食品の清廉性／信憑性に関する管轄当局が取り組むための方法論を確立させ、原則とガイドラインを作成しようとするもの（提案国：イラン）。
第 22 回会合（2016）において、新規作業の提案がなされ、前回第 23 回会合（2017）にて、次の事項を目的とした電子作業部会を実施することが合意された。
・「food integrity」、「food authenticity」、「food fraud」、「economically motivated adulteration (EMA)」 の定義を明確にし、CCFICS の文書を評価するための作業範囲を示す。
・CCFICS の文書を評価し、食品偽装に対処するための基準があるか、それらの基準における食品の清廉性／信憑性の取扱い方にギャップがあるかを確認する。
・評価の結果を踏まえ、更なる作業もしくは新規作業に関する討議文書を作成する。
今次会合では、作成された討議文書を基に、第 24 回会合にて新規作業として議論するための検討を行う。
（概要）
本討議文書では、「food integrity」、「food authenticity」、「food fraud」、「economically motivated adulteration (EMA)」の定義が示され、CCFICS の既存の文書ついて評価されている。なお、本討議文書では、新規作業の検討が提案されている。
・food integrity（食品の清廉性）：安全性、品質、栄養などの期待される特
性に関して、本物であり、変更されていない食品の状態
・food authenticity（食品の信憑性）：食品の本質、起源、固有性などに偽
りがない品質
・food fraud（食品偽装）：不当な利益を得るために、食品の清廉性に関して、他人を欺く意図的な行為
・economically motivated adulteration (EMA)（経済的な動機による不純物の混入） ：食品偽装のひとつ。経済的な利益を得るため、製品の見た目上の価値を増やすこと、もしくはコストを減らすことを目的として、製品中の
物質を意図的に置き換えること。
（対処方針）
各国の意見を十分に聴取し、仮に新規作業を行う場合、コーデックスの役割及び CCFICS の付託事項（ToR: Terms of Reference）に合致していることを確認した上で、作成されるガイドラインがどのような性格を持つものか、またその目的、対象に留意しつつ、適宜対処したい。

仮議題８ 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

（経緯）
本作業は、会合での戦略的で、将来を見据えた議論を容易にし、定期的に、CCFICS の

作業を精査し、将来の課題に着手することを目指すもの。

第 20 回会合（2013）において、新たな世界規模の課題が、継続的に食品安全管理に関連する技術に影響を与えるとし、戦略的なアプローチをとるため討議文書を要望し、第 21 回会合(2014)において、討議文書を議論し、この討議文書は常設の議題とし、各部会前に更新することで合意された。

第 22 回会合 (2015)において、予備評価と優先する分野の特定に関する枠組みを含めて討議文書を発展させることとし、 第 23 回会合 (2017)において、付録Ａ（CCFICS の作業に関連する新たな世界規模の課題）と付録Ｂ（CCFICS の予備評価と優先する分野の特定に関する枠組の概要）が示された。

今次会合にあたっては、各国の意見を聴取して付録Ａを更新し、付録Ｂの改訂を行う。

（対処方針）

我が国から提案する課題はないことを踏まえ、各国の意見を聴取し、作業の提案等がなければ、会合を開催する頻度を低くするなど、CCFICS の今後の方向性について適宜提案したい。

仮議題９ 物理作業部会の試験的アプローチの評価

（経緯）

本議題は、2017 年 12 月のチリ及び 2018 年５月の英国で実施された物理作業部会での、インターネットを通じた参加の取組について報告するもの。

第 23 回会合 (2017)において、議長によって、NFCS のような複合的な問題を抱える議題の解決にあっては、物理作業部会がなお効果的であるとして、「システム同等性」及び「第三者認証」に関する物理作業部会が提案されたが、一部の国から、発展途上国の参加が困難であることが指摘された。そこで、議長から、物理作業部会の開催時に、リアルタイムで、インターネットを通じた物理作業部会への参加が可能となるシステムを準備することが提案された。

本議題では、第 42 回総会で、CCFICS の物理作業部会でのインターネットを通じた試験的アプローチが成功したこと、他の部会でも物理作業部会を開催する時にはインターネットを通じたアプローチを検討するよう勧告することを推奨する。

（対処方針）

本取組において、同時通訳の準備、回線の切断、時差による開催時間の違いに問題があったとの報告があることから、これらの問題を解決した上で、現実的なインターネットを通じた物理作業部会の開催について勧告することを提案

したい。

仮議題 10.1 同等性の使用に係るガイダンスの統合及び近代化の提案に関する

討議文書

（経緯）

本部会において、仮議題４を含む同等性に関する CCFICS の文書について統合及び近代化することを提案するもの。

仮議題４には、既存のコーデックスガイドラインと重複する概念が含まれているため、特定の状況ごとにどの文書を適用するかの判断に混乱を招くおそれがあるとし、既存のガイドライン（CXG 34-1995 及び CXG 53-2003 ※）と仮議題４のガイドラインを見直し、評価し、統合及び近代化することが提案されている。

（対処方針）

討議文書に示された提案を支持する方向で適宜対処したい。

※CXG 34-1995：Guidelines for the Development of Equivalence Agreements Regarding Food Imports and Export Inspection and Certification Systems

※CXG 53-2003：Guidelines on the Judgement of Equivalence of Sanitary

Measures associated with Food Inspection and Certification Systems

C.4.4. 第 24 回コーデックス食品輸出入検査・認証制度部会（CCFICS）報告

平成 30（2018）年 10 月 22 日（月）から 10 月 26 日（金）にかけて、ブリスベン（豪）において開催された会合の概要は以下のとおり。

議題４　システム同等性の使用に関するガイダンス原案（ステップ３）

本作業は、輸出入時の監視の不必要な重複を減少させると同時に、消費者の健康保護及び食品貿易の公正な取引の保証に効果的な手段として、輸出国と輸入国の間の食品安全制度（システム）の同等性の適切な利用を支援するためのガイドラインを作成しようとするもの（提案国：ニュージーランド)。

電子作業部会の議長国であるオランダから、ガイダンス原案について説明がなされた。

議長から、初めに、提案されたガイダンス文書原案を検討し、その後、同等性に係る既存文書に関する勧告（議題 10.1）について議論することが提案された。

[主な議論]

セクション３：定義

・既存の CCFICS の定義を使用すること、新しい定義は簡潔にし、セクション４の原則から削除すること。

・「Equivalence」及び「System Equivalence」という用語を使用する必要性についてさらに検討する。

セクション４：原則

・本原則は、国家食品管理システム（以下、NFCS）間の同等性の認識に向けて良いロードマップになっている。

・過去の文書(CXG 82-2013 及び CXG 89-2916)と矛盾してはならない。

セクション５：プロセスステップ

・日本から、輸出国と輸入国の協議において、他の食品安全に係る状況（緊急時対応等）等、他に優先すべき課題がある場合は、輸入国はこれらの課題の優先順位を考慮して協議に入ることができるようにすべきであると要請した。これに対し、SPS 協定第４条において、同等性について輸出国から輸入国が求められた場合は、協議に応ずることが義務づけられている点に言及があった。

・用語（例えば、SPS 協定で使用されている recognition と GL 53 で使用されている determination、initial discussion と preliminary consideration）に関して、明確でかつ一貫性があるべきで、更なる説明が必要なものもある。

・全てのステップで、どちらの国が主導するのか明確にすべき。

・Decision criteria は、輸入国と輸出国との間で協調的に確立されるべきである。

・Decision criteria については、FAO/WHO 食品管理システム評価ツールを検討することができ、個別のアンケート様式を追加することもありえる。

・例示やその他の点（例えば指標）について、どのように使用すべきか指摘された。一般原則部会（CCGP）がコーデックス文書中での例示の使用方法について整理した指針に従うべき。

・decision-making process は、透明性があり、異なる国の発展レベルを考慮に入れるべき。

・特に、NFCS の目的が達成している証拠を提供するために、輸入国に大きな負担をかけてはならない。

・フロー図は、本分の改定後に修正すべきで、本分のステップと一致させるべき。

・既存の同等性に関連する２つのガイドライン(CAC/GL 34- 1999 及び CAC/GL 53- 2003)との整理が必要。

・同等性に関連する既存のガイドラインを統合する新規作業について、討議文書原案を

作成するために、今次会合中に作業部会を実施することに合意した。
[結論]
・今次会合で提出された意見を踏まえて改訂するため、ステップ２に戻し、ステップ３として回付し、CCFICS25 にて検討する。
・同等性に関連するガイドラインの更新と統合に関する新規作業を開始し、CAC42 で承認を受けるべく討議文書を提出する。2019 年の第 42 回総会で了承された場合、CCFICS 会合を３または４回程度経て、第 46 回総会までの採択を目指す方針とする。
・電子作業部会を設立する。なお、CCFICS25 直前を含め物理作業部会を開催する可能性がある。

議題５　電子証明書のペーパーレス使用に関するガイダンス原案　　（ステップ３）

本作業は、「一般公的証明書の設計、作成、発行及び使用に関するガイドライン」（CXG 38-2001）について、ペーパーレスでの使用を踏まえた改訂をしようとするもの（提案国：オランダ）。
電子作業部会の議長国であるオランダから、ガイダンス原案について説明がなされ、初めに、附属書Ⅱの原案について議論し、続いて本文の改正案について議論することが提案された。
[主な議論]
・一貫性と明確さを確保し、繰り返しをなくすため、コーデックスの体裁に沿って改訂されるべき。
・一般的な原則を強調し、過度の技術的な記載を避け、利用者が容易に理解できる言葉で書かれるべき。
・紙からペーパーレスへの移行、証明書の真正性の検証、データの保護、機密保持、輸出入での拒否、転送などの状況での取扱、無効な証明書の取扱などについて明確にする規定が必要。
・関連する WCO の作業とツールについて、付属書Ⅱに追記する。
・国家間の異なるシステムに対処することが必要。そのための、柔軟性をもたらすようなシステムに関する追加の詳細が必要。
・定義を追加することを検討。
・電子証明書のガイドライン作成、及びペーパーレスの促進することにつながる問題解決に焦点を当てるべき。
[結論]
・今次会合で提出された意見を踏まえて改訂するため、ステップ２に戻し、ステップ３として回付し、次回第 25 回 CCFICS 会合にて検討する。
・電子作業部会を設立する。また、次回第 25 回 CCFICS 会合直前の物理作業部会を開催する。

議題６　食品安全及び食品貿易の公正な取引の分野での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原案（ステップ３）

本作業は、NFCS に第三者認証スキームの情報を取り入れる方法について、ガイドラインを作成しようとするもの。（提案国：カナダ）。
電子作業部会の議長国である英国から、ガイダンス原案について説明がなされ、部会は、一般的な議論を行い、続いて、提案されたガイダンス原案に関する予備的な技術的議論を行った。
[主な議論]
・日本から、物理作業部会や今次会合のサイドイベントで得られた第三者認証スキームの使用に関するプレゼンテーションを、委員会での議論に役立てるために、コーデックスの情報文書として保管するよう要請した。
・第三者認証スキームの使用によって、管轄当局のリスク管理を強化することができると認識するが、政府の公的検査に代わるべき

ものでも、使用が義務づけられるべきものでもない。

・情報管理のための具体的な方法を明確にすることによってガイダンス原案を改善できる。

・第三者認証スキームの使用によって作成されたデータは、食品事業者に帰属するが、第三者認証プログラムの所有者によってその後に作成されたデータは、NFCS に貴重な情報を伝えることができる。

・技術的な議論の後、部会は、会期中の作業部会を設立し、今次会合で提出された意見を踏まえて改訂することに合意した。

・会期中の作業部会によって改訂されたガイダンス原案を検討し、明確かつ一貫性を持たせるための更なる改訂を行った。

[結論]

・ほとんどの問題が解決され、検討が必要な部分が限定されていることから、準備が整ったとして、本ガイダンス案をステップ５で次回第 42 回総会に採択を求めるよう諮ることで合意された。

・今次会合で提出された意見を含む、未解決の問題と、ステップ 6 で提出されるコメントを検討するため、電子作業部会を設立する。なお、次回第 25 回 CCFICS 会合直前を含めに物理作業部会を開催する可能性がある。

議題７　食品の清廉性／信憑性に関する討議文書

本作業は、食品偽装に対処するため、食品の清廉性／信憑性に関する管轄当局が取り組むための方法論を確立させ、原則とガイドラインを作成しようとするもの（提案国：イラン）。

電子作業部会の議長国であるイランが今次会合に参加していないため、電子作業部会の共同議長国である EU から、討議文書について説明がなされた。

[主な議論]

・既存のコーデックスのテキストが既に関連する問題に取り組んでいるため、新たなガイダンスの必要性については慎重に検討すべき。

・将来の CCFICS の作業は、既存のテキストとの重複を避けるべきで、CCFICS の任務の中に明確に定義されるべき。

・関連する定義は、更なる検討が必要。

・他のコーデックスの部会が、どのような知見を有しているかを含めて、コーデックス委員会に助言を求めることができる。

・CCFICS は、制御プログラムを設計する際に管轄当局が考慮すべきリスクの種類、国家間及び国際レベルでの異なる当局間の情報交換及び協力、食品偽装事件に関するステークホルダーと一般市民とのコミュニケーション、食糧偽装を対象とした行政措置を含むガイダンスの範囲について言及することができる。

[結論]

・食品偽装の問題に取り組む際に、CCFICS が果たすべき役割について更に検討する。

・関連するコーデックス文書が CCFICS やその他の部会で存在していることに留意して、他の部会の管轄との重複作業を避けるため、CCFICS 内外の関連する既存のコーデックス文書を包括的に分析する。

・電子作業部会を設立する。

議題８　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

本作業は、部会での戦略的で、将来を見据えた議論を容易にし、定期的に、CCFICS の作業を精査し、将来の課題に着手することを目指すもの。

オーストラリアから、討議文書について説明がなされた。

[主な議論]

・優先順位付けの基準は更に明確化する必要がある。また、使用された情報を更新する必要性がある。

・付属書 A（CCFICS をとりまく新たな世界規模の問題）は、最新の状態にしておくべきであり、作成されたときのバージョンを示すべき。

・付属書 B（優先順位付けツール）は、特に、複数の提案があった場合における、低、中、高の区別が明確ではない。

・付属書 B 及び C（新規作業提案書ひな形）は、優先順位付けを支援することのみを意図しており、その使用は義務ではないこと、複数の提案があった場合に使うことができることが示された。

[結論]

・付属書 A を、基本の文書とし、管理は部会のメンバーで会合ごとに持ち回りとする。

・付属書 A に記載されているリストについて、次回第 25 回 CCFICS 会合）にて見直す。

・付属書 B 及び C を試験的に使用し、次回第 25 回 CCFICS 会合で再検討する。

・CCFICS での優先順位付けに着手する前に、第 50 回食品衛生部会（CCFH）（2018）における「guidance on the management of (micro)biological foodborne crises/outbreaks」の議論の結果を待つ。

議題９　物理作業部会の試験的アプローチの評価

本議題は、2017 年 12 月のチリ及び 2018 年５月の英国で実施された物理作業部会での、インターネットを通じた参加の取組について報告するもの。

オーストラリアから、本議題について説明がなされ、物理作業部会の共同議長であるチリは、遠隔参加した国が予想よりも少なかったこと、データと情報の収集を通じていくつかの問題（例えば、接続が成功した国/人数、接続の継続時間、接続しない/参加しなかった理由）を更に検討する必要があること、スペイン語チャンネルでの一時的な中断等の技術的課題があることを指摘した。

[主な議論]

・物理作業部会でのインターネットを通じた参加の取組は、一般的に参加者が増え、将来の会議のための有用なツールとして役立つ可能性がある。

・本取組を評価するためには、経験を通じて指摘された課題の全てが本文書に反映されるべきではないか。

・技術的な問題、インターネットでの参加者が休憩時における非公式の議論の機会を逃すこと、状況を把握しづらいこと、時差の問題、作業部会が長時間に渡ること等の課題がある。

・インターネットでの参加者が期待されていたほど多くなかった理由は不明。

[結論]

・物理作業部会でのインターネットを通じた参加の取組は、参加者を増やす可能性がある。

・本取組の使用を検討する際は、経験を通じて指摘された課題を考慮する。

・参加する際の障壁と、その解決策を分析する必要がある。

・部会は、本取組を続けていくことを勧告した。

議題 10　その他の事項及び今後の作業

議題 10.1　同等性の使用に係るガイダンスの統合及び近代化の提案に関する討議文書

今次会合において、仮議題４を含む同等性に関する CCFICS の文書について統合及び近代化することを提案するもの。

仮議題４とあわせて検討された。

議題 11　次回の開催日時及び開催地

第 25 回食品輸出入検査・認証制度部会は 2020 年４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。

D. 研究発表

1. 論文発表

(1)豊福　肇. 小規模食品施設における一般衛生管理のポイントとHACCP導入　HACCP7原則の弾力的運用　月刊HACCP, 24(4), p24-30, 2019

(2) 小島三奈、多田剛士、豊福肇. 第23回食品輸出入検査・認証制度部会(CCFICS)、食品衛生研究. 68巻2号、p.23-32

(3)大城直正、登田美桜、石川輝、鈴木穂高、豊福肇. 熱帯性魚類食中毒シガテラのリスク評価のための研究、食品衛生研究. 68巻5号、p.15-37

(4)豊福肇. 第17回世界食品安全会議　参加報告①、食品衛生研究. 68巻7号、p.25-35

(5)豊福肇. 第17回世界食品安全会議　参加報告②、食品衛生研究. 68巻12号、p.33-38

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、及びCCFICSに関する６つの講義、計９時間を担当。

E. 知的財産権の出願・登録状況

特になし

PROPOSED DRAFT REVISION OF THE *GENERAL PRINCIPLES OF FOOD HYGIENE*
(CAC/RCP 1-1969)

1. During the planetary session at CCFH49 following the Physical Working Group, the Committee agreed to:

- consider the points in CRD2 as a basis for the further development of CXC 1-1969;
- establish an EWG, chaired by the United Kingdom and co-chaired by France, Ghana, India, Mexico and United States of America, working in English, French and Spanish to:
- continue revision of the three parts of the document (Introduction, GHPs, HACCP) taking into account the discussions at CCFH49 and the written comments submitted;
- clarify the relationship of the three types of control measures: GHPs, control measures essential for safety that are applied at Critical Control Points (CCPs), and control measures essential for safety that are not applied at CCPs, using examples; and
- clarify how food business operators come to understand the hazards associated with their business and determine the types of control measures needed to control the hazards.

2. Following the meeting, we have been reviewing the comments received from members in conjunction with the draft text and discussions on the fundamental principles at CCFH49. You will recall that there were some areas where a consensus was not reached by the PWG or the Plenary, including the inclusion of an additional category of controls referred to as 'enhanced GHPs' or OPRPs.

3. Given the range of opinions, we are recommending that the concept of 'enhanced GHPs' should not be included in the revised document. We believe this is consistent with the initial brief for the revisions to GPFH (CCFH47) which was to simplify the text as far as possible and for it to be useful for a global audience and all types of business. In our view, including this concept adds a level of complexity without adding value or clarity and this is not consistent with the original direction from CCFH. Full justification for our recommendation is included on page 1 of the revised document.

4. We note that the EWG was also tasked by CCFH47 to examine the need for a class of controls where management as CCPs presents a challenge and this led to the consideration of the concept of 'enhanced GHPs. We believe it would be reasonable to consider this task has been completed as it has been examined and discussed by 3 EWGs and 3 plenary sessions.

5. Based on discussions in Chicago, and further consideration amongst Co-Chairs we believe further efforts to reach a consensus amongst the EWG are unlikely to be successful and will delay development of the revised guidance. CCFH Chair indicated in his comments in Chicago that is was acceptable to conclude that no consensus could be reached if an issue has been considered thoroughly and there is no majority opinion. We are therefore seeking EWG agreement to the recommendation that concept of 'enhanced GHPs' should not be included in the revised document to allow the work to progress. Our intention would be to clarify the explanation of GHP and HACCP-based controls by adapting the text taking into account relevant comments from members and including examples from different types of businesses.

6. A revised text is attached for your consideration. We are still working on this but it would be helpful to receive your comments on the suggested amendments to the text (including the drafting notes**/**comments) and examples which can be used to illustrate the text). As you will see, throughout the text there are a number of boxes (shaded blue for ease of reference) which highlight areas where would be grateful for your input. In particular, we would welcome your comments/agreement on the following points:-

   - conclusion that enhanced GHPs should not be included in the document; and

   - terminology used for enhanced GHPs – suggestion the control measure should only be used for HACCP and alternative terminology (hygiene intervention, hygiene measure) should be used when referring to GHPs

7. We would be grateful for your comments by Monday 30 April 2018 so that we can continue to develop the document.

Thank you for your help.

Best wishes

Chair and Co-Chairs

UK, France, Ghana, India, Mexico and the United States of America

March 2018

Appendix I

PROPOSED DRAFT REVISION OF THE *GENERAL PRINCIPLES OF FOOD HYGIENE* (CAC/RCP 1-1969)

(for comments at Step 3 through CL2017/69-FH)

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

Note: Revised text on General Principles of Food Hygiene has been developed by the EWG following direction provided by CCFH49 and the PWG (November 2017). Notes have been included to provide explanation for major changes to the text and highlight areas where further discussions are required.

The EWG has been tasked with examining whether it is appropriate to include a category of control measures termed 'enhanced GHPs' in the document following original direction (CCFH) to consider controls where management through CCPs is challenging.

Co-Chairs have concluded that the concept of 'enhanced GHPs' should not be included in the document and the text has been amended accordingly. Instead we recommend changes to the text to highlight that some GHPs may warrant additional attention (e.g., monitoring, verification and records).

Justification

This issue has been discussed extensively by the EWG and 3 CCFH meetings and there is no consensus on whether the concept of enhanced GHPs should be included in the revised GPFH.

Different approaches for including the concept of enhanced GHPs and an explanation of relationships between CCPs, enhanced GHPs and GHPs have been presented. It is extremely challenging to provide a clear and simple explanation and examples provided can be considered either GHPs or CCPs and none of the proposed approaches have been acceptable to the EWG or CCFH.

In the absence of an agreed and simple explanation which includes enhanced GHPs as a category of control measures, we are of the view that this adds a layer of complexity which is not consistent with the original direction from CCFH that GPFH should be simplified as far as possible and accessible to all types of business.

There is also no consensus on whether enhanced GHPs would be applied within either a GHP-based or HACCP-based system and practical examples provided also show they could be included in either.

The need for increased attention to some GHPs due to their impact on safety can be included in the text and supported by recommendations for increased monitoring and verification as needed. The text as drafted now provides flexibility for FBOs to incorporated food safety controls as either GHPs or HACCP CCPs as appropriate.

Given the absence of majority opinion and clear examples that demonstrate the need for an additional category of controls it will be very difficult to reach a consensus and continued consideration will delay development of the revised guidance.

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 at best unpleasant and, in some circumstances, can be severe or fatal or have a negative impact on human health over the long term. Furthermore, outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation. Food spoilage is wasteful, costly, threatens food security and can adversely affect trade and consumer confidence.

2. International food trade and 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 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, importers, manufacturers and processors, food warehouse/logistics operators, food handlers, retailers, and consumers, has a responsibility to assure that food is safe and suitable for consumption. All businesses must be aware of and understand the biological, chemical and physical hazards associated with the food they produce and the measures required to manage those hazards so that food produced is safe and suitable for use

Note to EWG – paragraph amended to emphasise FBO responsibilities

3. This document outlines the general principles that should be understood and followed by food business operators (FBOs) at all stages of the food chain and that provide a basis for competent authorities to oversee food safety and suitability. Taking into account the point in the food chain; the nature of the business; the relevant contaminants; and whether the relevant contaminants adversely affect safety, suitability or both; these principles will enable food businesses, to develop their own food hygiene practices and necessary food safety control measures, while complying with requirements set by competent authorities. While it is the food business operator's responsibility to provide safe food, this may be as simple as ensuring that the "4Cs" (namely, Chilling, Cooking, Cleaning and Cross-contamination) are adequately controlled.

Note to EWG – text (para 4a from CX/FH 17/49/5 deleted as it was agreed that all businesses should be aware of and understand the hazards associated with their business.

4. Prerequisite Programmes (PRPs), which include Good Hygiene Practices (GHPs), Good Manufacturing Practices (GMPs) and Good Agricultural Practices (GAPs) as appropriate must be applied, to lay the foundation for producing safe and suitable food. GHPs maintain the hygiene of a process, are essential for ensuring safety and suitability of food and apply broadly to all food businesses. **[**It should be noted that for some GHPs a higher level of control (e.g. increased monitoring and verification) may be required to provide safe and suitable food and thus the level of control and the frequency of monitoring and verification will need to be applied appropriately. For example, the cleaning of equipment and surfaces which come in contact with food may warrant a greater level of control and frequency of monitoring than, say, the cleaning of walls and ceilings.**]** or **[**In implementing GHPs, specific activities (e.g. cleaning of food contact surfaces) if not properly checked or supervised could lead to direct contamination of food. Such activities demand extra responsibilities and monitoring to assure the safety and suitability of food.**]**

Note to EWG: text added above to highlight increased attention to some GHP's due to their impact on food safety Views requested on whether first or second text in square brackets should be used.

4b. In some cases(e.g a business assembling sandwiches to order by consumers, a warehouse, cold storage facility or retailers selling fresh vegetables or RTE products) GHPs alone may be sufficient to control hazards within a business, while in others additional controls may be required to manage significant hazards which have been identified by a site-specific hazard analysis by application of control measures at critical control points (CCPs) within a Hazard Analysis and Critical Control Point (HACCP) system (see GHP and CCP Comparison Table below).

Note to EWG: The decision tree has been removed as it was added to support understanding of enhanced GHPs which we have now decided not to use in the document.

Note to EWG: text added in para 4c to reflect the outcome of CCFH49 discussions. Includes 2 terms [hazard analysis] [review of hazards] to reflect differences in understanding of what is required for Hazard Analysis and in opinion on whether all businesses should be required to carry out a hazard analysis. Views are requested on preferred terminology

4c. All businesses should be aware of the hazards associated with their type of business to ensure that they are managed, this could be achieved by undertaking a [hazard analysis][by reviewing hazards]. The complexity of the review can be adapted to the nature and size of the business. At a simple level this might require an awareness that ingredients/raw material could be contaminated by food pathogens and

potential risks should be controlled using basic hygiene measures such as cooking, chilling, preventing cross contamination and effective cleaning (as appropriate to the business) but in larger, more complex businesses, this could require more comprehensive analysis and a detailed understanding of specific hazards involved and the appropriate risk management interventions (e.g., the application of HACCP principles, as described in Chapter 2). In reviewing operations and potential hazards, including a hazard analysis conducted within the HACCP framework, consideration should be given to GHPs that are being, or that have been, established. This will indicate whether GHPs are sufficient to control the hazards associated with the operation or whether HACCP-based controls are required. FBOs without the resources to carry out a site specific hazard analysis/review of hazards may use external resources such as existing models, references, standards, regulations, or Codes of Practice and adapt these to the site.

Note to EWG – in paragraph below, second sentence deleted as covered elsewhere in text. New text added it reflect flexibility in application of HACCP. May need to be developed further – there is also a suggestion to move last two sentence of para 5 to the bottom of para 4c. Views are requested.

5. [Chapter One] of this document describes GHPs, which are the basis of all food hygiene systems to support the production of safe and suitable food. [Chapter Two] describes HACCP. Although it is not generally feasible to apply HACCP at primary production, some of the principles can be applied. Those that can should be encouraged throughout the food chain from primary production to final consumption and their implementation should be guided by scientific evidence of risks to human health. It is recognised that implementation of HACCP may be challenging for some businesses. HACCP principles can be applied flexibly in individual operations and businesses may use external resources or adapt a generic HACCP plan provided by the competent authority or food industry [1] to the specific site circumstances

Note to EWG: A comparison table has been introduced as requested by CCFH to support understanding of the relationship between GHP and HACCP.

6. The following comparison table shows the relationship of GHPs applied for food safety and suitability and HACCP control measures applied to enhance food safety.

[1] FAO/WHO guidance to governments on the application of HACCP in small and/or less developed food businesses ISSN 0254-4725

Note to EWG: Table revised to remove reference to enhanced GHPs and now focusses on explanation of differences between GHPs and CCPs. Text amended to assist understanding of the differences in the controls. Co-Chairs are still developing this Table. Comments and examples are requested

Comparison of GHPs, and HACCP Control Measures

	Good Hygiene Practices (GHPs)	**Control Measures at Critical Control Points (CCPs)**
Scope	General conditions and activities for maintaining hygiene, including creating the environment (external and internal to the food business) so as to ensure production of safe and suitable food. Not specific to any hazard but results in reduction of likelihood of hazards occurring and in some prevention of contaminants.	Specific to a product or group of products. Controls at production steps that are critical to reduce significant hazards in foods to an acceptable level.
When identified?	Before or during review of hazards and in certain situations after a detailed hazard analysis.	After Hazard analysis for control measures at CCPs
Validation of the effectiveness of the hygiene measure	Where needed, generally not carried out by FBOs themselves, e.g. effectiveness of cleaning products/equipment will be validated for effective use by manufacturer and it is sufficient for the FBO to use cleaning products/equipment according to manufacturer's instructions.	Yes, validation should be carried out (*Guidelines for the Validation of Food Safety Control Measures* CAC/GL 69-2008)
Criteria	Some aspects of GHPs may be measurable or observable e.g. hand washing or equipment cleaning and may require an evaluation of the impact on product (e.g., frequency of cleaning complex equipment such as meat slicers). [could be used to highlight measures for which increases attention is needed]	Critical limit which separates acceptable <u>products</u> from unacceptable • measurable (e.g. temperature, pH, a_w), or • observable (e.g. visual checks, appearance, texture).

Monitoring	Yes, where relevant, to ensure procedures and practices are applied properly. Usually non-continuous; Frequency dependent on the operation and sufficiency.	Yes, to ensure CCP is in control • in [real][actual[time/continuous], or • if not continuous, at appropriate frequency
Corrective actions when loss of control is indicated	• For procedures and practices: Yes, [where relevant]. • For products: Usually not necessary. Corrective action should be considered on a case by case basis as failure to apply some GHPs, such as failure to clean between products with different allergen profiles, not rinsing after cleaning and/or disinfecting [or post maintenance equipment checks indicating loose machinery parts], may result in action on product. Other examples could include:- I. Vegetables not properly disinfected so not suitable for raw consumption if FBO can decide to either disinfect again, throw away or cook it; or II. If during maintenance work on equipment, loosened parts (bolts, nuts etc) can fall into the food product,	• For products: Yes. Pre-determined actions for products. • For procedures and practices: Yes, corrective actions if necessary to restore control and prevent recurrence.
Verification	Yes, where relevant, usually scheduled (e.g., visual observation that equipment is clean before use)	Yes. Scheduled verification of implementation of control measures [e.g. through record review, testing, internal and external audit]
Record keeping (e.g. monitoring records)	Yes, where relevant	Yes
Documentation (e.g. documented procedures)	Yes, where relevant	Yes

OBJECTIVES

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

- provide principles and guidance on the application of good hygiene practices applicable throughout the food chain to provide food that is safe and suitable for consumption;
- provide guidance on the application of HACCP principles;

Note for EWG: sentence deleted as not required in the "Objectives". *How* this relationship is established should become apparent from the document.

- clarify the relationship between GHPs and HACCP; and
- provide the basis on which sector- and product-specific codes of practice are established.

SCOPE

Note to EWG: Text amended to remove emphasis on the manufacturing sector and re-enforce message that GPFH applies throughout the food chain

8. This document provides a framework of general principles for producing safe and suitable food for human consumption by outlining necessary hygiene and food safety conditions to be implemented in production of food and recommending, where appropriate, specific food safety control measures at certain steps throughout the food chain.

USE

General

Note to EWG: Additional text added following discussions at CCFH49

9. 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. It is generally applicable to food businesses and to competent authorities that provide oversight, and provides flexibility to meet the needs of different types of food businesses in the context of international food trade. However, it should be noted that it is not possible for the document to provide specific guidance for all situations and specific types of food businesses and the nature and extent of food safety risk associated with individual circumstances.

10. There will be situations where some of the specific requirements contained in this document are not applicable. The fundamental question for each food business operator in every case is "what is necessary and appropriate to control the hazards associated with the operation and ensure 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 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 knowledge of the operation and hazards including available scientific information. 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 operations and 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 unsafe food;
- provide an effective control system to ensure food is safe and suitable for human consumption;
- maintain confidence in domestically and internationally traded food; and
- provide information that 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, implement and review processes that provide food that is safe and suitable for its intended use;
- ensure food handlers are competent as appropriate to their job activities;
- cultivate a strong food safety culture by demonstrating their commitment to providing safe and suitable food and encouraging appropriate food safety practices;
- 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 food correctly; and

- contribute to maintaining confidence in domestically and internationally traded food.

Note for EWG: Should reference to consumers be retained as this is outside remit of the document – views are requested.

14. Consumers should play their role by following relevant guidance and instructions for food preparation and applying appropriate food hygiene measures to ensure that their food is safe and suitable for consumption.

Note for EWG: section below developed to reflect amendments in previous text and direction from CCFH49

GENERAL PRINCIPLES

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

(ii) GHPs should ensure that food is produced in a sanitary environment in order to minimise the presence of contaminants. In some cases, GHPs may be sufficient to manage hazards associated with an operation.

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

(iv) Some GHPs require more attention than others as they have a greater impact on food safety.

(v) [Review of hazards and if required] a comprehensive hazard analysis, whether undertaken by the FBO itself or not, should identify all potential hazards associated with the raw materials and other ingredients, the production process and its related environment (e.g. people, equipment and facility) and determine the significant hazards that should be controlled to ensure food safety.

(vi) Hazards are controlled by GHPs and/or CCPs. While recognising the importance of CCPs in controlling specific hazards, some GHPs may also require more attention than others as they have a greater impact on food safety. Significant hazards not controlled by GHPs are controlled by specific control measures.

(vii) Control measures that are critical to achieve an acceptable level of food safety should be scientifically validated[2]

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

[2] *Guidelines for the Validation of Food Safety Control measures* (CAC/GL 69-2008)

(ix) 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.

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

Management Commitment

15. Management commitment to incorporate food safety into the business objectives of the food business and to communicate the importance of producing safe food, both for the consumer and the business is fundamental to the success of any food hygiene system.

Note for EWG – text deleted below as if a system is effective you may not need to improve this. However, businesses should be aware of advances in knowledge and technology so bullet added to cover continuous improvement.

16. Managers should ensure effectiveness of the food hygiene systems 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 system when changes are planned and implemented;
- verifying that controls are working and documentation is up to date;
- ensuring the appropriate training and supervision are in place for personnel;
- ensuring compliance with relevant regulatory requirements;
- encouraging continuous improvement taking into account of developments in knowledge and technology; and
- enabling a strong food safety culture by demonstrating commitment to providing safe and suitable food and encouraging appropriate food safety behaviours.

Definitions

Note to EWG: Section to be developed based on terms used in Parts 2 and 3; include here the definitions that already exist in the RCP-1, Section 2.3 to facilitate discussion on them.

Food hygiene system - The combination of hygiene practices and control measures that, when taken as a whole, ensures that food is safe and suitable for its intended use.

Food safety control system[3] **-** The combination of control measures that, when taken as a whole, ensures that food is safe for its intended use.

Control measure

Note to EWG – square brackets used around Hazard control measures as not yet clear if this term will be needed

[Hazard control measures]

Significant hazard - a hazard identified through a hazard analysis as reasonably likely to occur in the absence of control and needing specific control measures, and/or at places other than CCPs

Note to EWG: definition of basic hazard analysis deleted as CCFH agreed using additional terms in to describe hazard analysis was confusing

Note to EWG: decision tree deleted as term enhanced GHP no longer being included

[3] *Guidelines for the Validation of Food Safety Control measures* (CAC/GL 69-2008)

[CHAPTER ONE]

GOOD HYGIENE PRACTICES

Introduction

17. The development, implementation and maintenance of GHPs provide the conditions and activities that are necessary to support the production of safe and suitable food at all stages of the food chain from primary production through to handling of the final product. Applied generally, they assist in controlling food safety hazards in food products in the work environment.

Note to EWG: This section needs to be expanded or an annex. UK to draft to provide simplified language.

18. As previously noted a review of the operation and its hazards may indicate that GHPs alone are sufficient to manage the hazards associated with an operation.

19. An appropriate location, layout, design, construction and maintenance of premises and facilities are essential for implementation of GHPs to be effective. Knowledge of the food and its production process is also essential. This [Chapter] provides guidance for effective implementation of GHPs and should be applied in conjunction with sector and product-specific codes.

20. Where this Chapter refers to food business operators, this includes primary production settings.

PRIMARY PRODUCTION

Note to EWG: Original text reinserted following discussions in the PWG and the agreement at the Plenary session. Needs further development including appropriate examples which can be added to the text in the relevant sections. Examples to be added into the text are requested

OBJECTIVES:

Primary production should be managed in a way that ensures that food is safe and suitable for its intended use. Where necessary, this will include:

− avoiding the use of areas where the environment poses a threat to the safety of food;
− controlling contaminants, pests and diseases of animals and plants in such a way as not to pose a threat to food safety;
− adopting practices and measures to ensure food is produced under appropriately hygienic conditions.

RATIONALE:

To reduce the likelihood of introducing a contaminant which may adversely affect the safety of food, or its suitability for consumption, at later stages of the food chain.

ENVIRONMENTAL HYGIENE

21. Potential sources of contamination from the environment should be considered. In particular, primary food production should not be carried on in areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in food.

HYGIENIC PRODUCTION OF FOOD SOURCES

22. The potential effects of primary production activities on the safety and suitability of food should be considered at all times. In particular, this includes identifying any specific points in such activities where a high probability of contamination may exist and taking specific measures to minimize that probability. The HACCP-based approach may assist in the application of such measures - see Chapter 2.

Producers should as far as practicable implement measures to:

• control contamination from air, soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production;

• control plant and animal health so that it does not pose a threat to human health through food consumption, or adversely affect the suitability of the product; and

• protect food sources from faecal and other contamination.

In particular, care should be taken to manage wastes, and store harmful substances appropriately. On-farm programmes which achieve specific food safety goals are becoming an important part of primary production and should be encouraged.

HANDLING, STORAGE AND TRANSPORT

23. Procedures should be in place to:

• sort food and food ingredients to segregate material which is evidently unfit for human consumption;

• dispose of any rejected material in a hygienic manner; and

• Protect food and food ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling, storage and transport.

Care should be taken to prevent, so far as reasonably practicable, deterioration and spoilage through appropriate measures which may include controlling temperature, humidity, and/or other controls.

CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

24. Appropriate facilities and procedures should be in place to ensure that:

• any necessary cleaning and maintenance is carried out effectively; and

• an appropriate degree of personal hygiene is maintained

SECTION I: ESTABLISHMENT DESIGN AND FACILITIES

OBJECTIVES:

Depending on the nature of the operations and the associated risks, 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 and minimises airborne 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 contaminants to be effectively controlled.

Location of establishment

25. Establishments should not be located anywhere where there is a threat to food safety or suitability and hazards cannot be controlled by reasonable measures. The location of a food establishment including temporary/mobile establishments should not introduce any hazards from the environment that cannot be controlled. In particular, unless sufficient safeguards are provided, food 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;
    - areas prone to infestations of pests; and
    - areas where wastes, either solid or liquid, cannot be removed effectively.

26. Landscaping near a food facility should be properly designed to minimise attracting and harbouring pests. Where necessary, experts should be consulted for advice on appropriate plants for use in landscaping.

Equipment

Note to EWG: original text from CAC/RPC1–1969 has been incorporated into subsequent sections.

Hygienic design and layout of food establishment [and equipment]

27. The internal design and layout of food establishments and equipment should permit good food hygiene practices, permit adequate maintenance and cleaning, protect from cross-contamination and facilitate, if feasible, linear flux of operations.

28. The clean and dirty areas should be separated to minimize cross-contamination through measures such as physical separation (e.g. walls, partitions) and/or location (e.g. distance), traffic flow (e.g. one-directional production flow), airflow, and separation in time, with suitable cleaning and disinfection between uses.

Internal structures and fittings

29. Structures within food establishments should be soundly built of durable materials, which are easy to maintain, clean and where appropriate easy to disinfect. They should be constructed of non-toxic and inert materials according to intended use and normal operating conditions. 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;
    - 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 (e.g. lighting) 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;
    - doors should have smooth, non-absorbent surfaces, be easy to clean and, where necessary, disinfect;
    - 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, materials unless food business operators can satisfy the competent authority the other materials used are appropriate. Some work surfaces in contact with the products can be made of material which do not satisfy these requirements but are essential for technological reasons (i.e. wood in milk curdling of some cheeses which will enrich the milk with flora).

Temporary/mobile food establishments and vending machines

30. Establishments and structures covered here include market stalls, street vending vehicles and temporary premises such as tents and marquees.

31. Such premises and structures should be located, designed and constructed to avoid, as far as reasonably practicable, the contamination of food and the harbouring of 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

Note to EWG: Original text from CAC/RPC1–1969 has been moved to the section on water. This should be considered further when the document is more developed as agreement has not been reached on the appropriate location for the text.

Drainage and waste disposal

32. Adequate drainage and, waste disposal systems and facilities should be provided and well maintained. They should be designed and constructed so that the risk of contaminating food or the potable or clean water supply is avoided. It is important that drainage does not flow from highly contaminated areas to areas where finished food is exposed to the environment]

33. Waste should be collected, disposed of by trained personnel and, where appropriate, disposal records maintained. The waste disposal site should be located away from the food establishment to prevent pest infestation. Containers for waste, by-products and inedible or hazardous substances, should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material.

34. Containers used to hold hazardous substances prior to disposal should be identified and, where appropriate, be lockable to prevent malicious or accidental contamination of food.

Cleaning facilities

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

Personnel hygiene facilities and toilets

36. Adequate personnel hygiene facilities and toilets should be available in order that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food. Such facilities should be suitably located and designated. They should include:

    - adequate means of washing and drying hands, including soap, wash basins and [where appropriate], a supply of hot and cold (or suitably temperature controlled) water;
    - lavatories of an appropriate hygienic design with taps not be operated by hands (where this is not possible a disposable paper towel can be used to turn the taps off);
    - adequate changing facilities for personnel; and
    - where necessary, separate sinks should be available for hand washing and food washing.

Temperature control

Note for EWG: We intend to add a paragraph to discuss monitoring of temperature of premises, equipment and food.

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

Air quality and ventilation

38. 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 (e.g. to prevent an increase in moisture of dried foods that would allow growth of microorganisms and production of toxic metabolites).

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

Lighting

40. 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 fittings should, where appropriate, be protected to ensure that food is not contaminated by breakages

Storage

41. Adequate and, where necessary, separate 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.

42. Where appropriate, food storage facilities should be designed and constructed to:

i. permit adequate maintenance and cleaning;

ii. avoid pest access and harbourage;

iii. enable food to be effectively protected from contamination during storage; and

iv. where necessary, provide an environment which minimizes the deterioration of food (such as by temperature and humidity control).

43. 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

44. Equipment and containers coming into contact with food, should be suitable for food contact, designed and constructed and located to ensure that they can be adequately cleaned (other than those which are single-use only) and disinfected (where necessary) and maintained to avoid the contamination of food, according to hygienic design principles. Equipment and containers should be made of materials that are non-toxic according to intended use. Where

necessary, equipment should be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection and to facilitate inspection for pests.

Food control and monitoring equipment

45. Equipment used to cook, heat, 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. Where appropriate, equipment should be calibrated to ensure that food processes are monitored consistently and accurately

46. 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 characteristics likely to have a detrimental effect on the safety or suitability of food.

SECTION II: CONTROL OF OPERATION

Note to EWG: Text in Section II will be revised as the document develops. Some changes have been made but further amendments will be required to ensure clarity and consistency and reflect agreed structure. Objectives and rationale should also be revised.

OBJECTIVES:

To produce food that is safe and suitable for human consumption by:

- formulating design requirements with respect to raw materials and other ingredients, composition/formulation, 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 contaminants.

Note to EWG: Further consideration is required to reach agreement on whether additional sections on product description, process description and monitoring procedures should be included or whether they are adequately addressed in other parts of the text. If agreement is reached these paragraphs 28 to 33 should be developed to ensure the appropriate level of detail is provided. Views requested.

[Product description

Note to EWG on point 47 – need to consider expanding to include some addition guidance to what is needed here. Views requested.

47. An FBO that is producing or preparing a food should provide a description of the food. Products may be described individually or in groups in a manner that will not compromise the identification and analysis of food safety hazards or other factors such as suitability of product. Grouping of food products should be based on having similar inputs and ingredients, process steps and intended purpose.

48. For some FBOs, the descriptions may be basic, e.g., primary production could describe products as “fresh vegetables,” “cattle,” “milk,’ etc, restaurants could describe products as “sandwiches,” “hot meals,” “cold salads,” etc.

49. The description should identify, as appropriate,

    - the intended use of the food, e.g., whether it is ready-to-eat or whether it is intended for further processing either by consumers or another business, for example cooking raw seafood;
    - any specific consumer groups e.g.: infants, elderly, immuno-compromised individuals;

- any relevant specifications or important characteristics associated with the food, such as any allergens present; and
- any relevant acceptable hazard levels required for the food by the competent authority, or set by the FBO.
- Instructions provided for further use for example keep frozen until cooking

Process description

Note to EWG: This is relatively easy for a processor or manufacturer, but more difficult, if not nearly impossible, for some operators such as restaurateurs and primary producers. Depending on the detail of a process description, this could be relatively easy for primary producers who simply grow crops or raise animals. And restaurant could group processes/steps – heat, cool, assemble, store. Suggested amendments to reflect challenges for SLDBs. This may need expanding. Views requested.

50. The FBO producing a food should consider all steps in the operation for a specific product. It may be helpful to develop a flow diagram which could also be used for a number of similar products (see product description above) that are produced using similar processing steps to ensure all steps are captured. The process steps should be confirmed as accurate by checking against the actual process. For example, for restaurants the flow diagram could be based on the activities that are generics from the reception of ingredients/raw material, conservation (cold storage, frozen, room temperature), and preparation before use (washing, disinfection, defrosting) and cooking or preparation.

Monitoring procedures

Note for EWG: Consider moving this text after control of food hazards and key aspects of food hygiene systems. Views and examples for inclusion in paras 51-53 requested.

51. The FBO should develop and implement procedures for monitoring control measures as relevant to the business and as applicable to the hazard being controlled. Procedures could include responsible personnel, method of monitoring (including frequency and sampling regime if applicable) and monitoring records to be kept. The frequency of monitoring should be appropriate to ensure consistent process control. See Chapter 2 for additional information on monitoring at CCPs.

Activity	**Procedure**	**Relevant information**
Reception of raw materials	Specifications or criteria of acceptance or rejection	Characteristic that the product should meet for being accepted (e.g. temperature, records, certificate)

		Frequency of monitoring (e.g. each reception)

Corrective actions

52. The FBO should develop corrective action procedures as relevant to the business that are implemented when a non-compliance is identified. Procedures could include:

    - who is responsible;
    - immediate action to be taken;
    - any product disposition to be considered;
    - any escalating response needed to competent authority;
    - any action to prevent reoccurrence; and
    - records to be kept.

Verification of GHP

53. The FBO should develop verification procedures as relevant to the business, which ensure that GHP procedures have been implemented effectively, monitoring is occurring and that appropriate corrective actions are taken when requirements are not met. Procedures could include:

    - who is responsible;
    - review of GHP procedures, monitoring, corrective actions and records;
    - review when any changes occur to the product, process and other operations associated with the business; and
    - the verification records to be kept.

MANAGEMENT OF FOOD HAZARDS

Note for EWG Management of food hazards is central to everything so consider re-ordering section I so this moves to after the primary production section. Need to include examples from primary production and retail in paras below text amended to delete references to enhanced GHPs not being included. Include key points in Annex on [hazard analysis] or [hazard review]. Points should be adapted so they are more applicable to all businesses. This text is similar to the HACCP requirements at the moment though agree that Control of Food Hazards belongs in Control of Operations. Appropriate examples and views requested.

Note to EWG: CCFH49 agreed that guidance on carrying out a [hazard analysis][review of hazards] should be developed and included in the guidance to support this section

54. GHPs manage many food hazards which could contaminate food products, e.g. persons who handle food at harvest, during manufacturing and during preparation; raw materials and other ingredients purchased from suppliers; cleaning and maintaining the work environment; storage and display. As stated earlier all businesses should review operations and potential hazards to determine whether the application of GHPs is sufficient to manage the food hazards associated with the operation.

55. Where hygienic interventions are determined as being unable to reduce the food hazard to an acceptable level, a food safety control system based on HACCP should be implemented and this is discussed further in [Chapter 2].

KEY ASPECTS OF FOOD HYGIENE SYSTEMS

Note for EWG This section needs development. Some of the references are closer to HACCP than GHP. Text should be more general and remove words like 'critical'? Also need to include examples. e.g. storing raw materials and ingredients according to instructions, or (for primary production) appropriate chill temperatures. Could also add an overarching comment about monitoring devices in monitoring and validation as this applies to all devices not just temperature recording devices. Examples and views requested.

Note: title may need amending in line with text as it develops. Restructuring of sections and additional sections on Humidity control and control of air have been suggested and should be discussed further

Time and temperature control

56. Inadequate food temperature control is one of the most common hygiene failures. This allows survival or growth of microorganisms that are 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 impacts the safety and suitability of food.

57. 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 microorganisms such as pathogenic and spoilage microflora;
- 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.

58. Such systems should also specify tolerable limits for time and temperature variations. Temperature control systems that impact safety and suitability of food should be monitored. Temperature monitoring and recording devices should be checked for accuracy and calibrated as needed.

Specific process steps

Note to EWG: Original text from CAC/RPC1–1969 has been deleted as this is covered in specific codes.

Formulation

59. The composition of a food, e.g. adding preservatives such as acids, salts or sugars, can be useful in preventing growth and toxin production by microorganisms. When formulation is used to control foodborne pathogens (e.g., adjusting the pH or water activity to a level that prevents growth), systems should be in place to ensure that the product is formulated correctly.

Microbiological[4], Chemical and Physical Contamination

Note for EWG: Consider expanding to indicate how specifications can help with GHP e.g. setting specifications for ingredients. Further discussions required to reach agreement on the Title and text at para 61. Para 62 – use of the work 'Particularly' high may be misleading and lead to FBOs not applying appropriate controls. Views requested.

60. Where microbiological, chemical or physical specifications are used in the control of food safety or suitability, such specifications should be based on sound scientific principles and state, where appropriate, monitoring procedures, analytical methods and acceptable limits. Specifications can help ensure that raw materials and other ingredients are fit for purpose and contaminants have been minimized to the extent possible.

Microbiological cross-contamination

61. Microbiological contamination occurs thorough the transfer of microorganisms from one food to another, either by direct contact or indirectly by food handlers, or by contact with surfaces, from cleaning equipment, or via splashing or airborne particles. Raw, unprocessed food, which could pose a contamination risk, should be effectively separated from ready-to-eat foods, either physically or by time, with effective intermediate cleaning and where appropriate disinfection.

[4] Refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CAC/GL 21- 1997).

62. In some food operations, access to processing areas may need to be restricted or controlled for food safety purposes. Where risks are high, access to processing areas should be only via a changing facility. Personnel may be required to put on clean protective clothing (which may be of a differentiating colour from other parts of the facility), including footwear and wash their hands before entering.

63. Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and where necessary disinfected after raw food preparation, particularly when raw materials with a high microbiological load such as meat and poultry and fish have been handled or processed.

Physical contamination

Note for EWG: The needs section to be developed as physical contamination is not only an issue for manufacturing and processing. It can also be an issue at all stages of the food chain e.g. bale twine being carried through production, rodents or insect infestation in produce/raw materials). Need to add a comment about choking.

64. Systems should be in place to prevent contamination of foods by extraneous materials, especially any hard or sharp object(s) e.g. glass, metal shards, bone(s), rubber plastic. In manufacturing and processing, suitable prevention strategies such as maintenance and regular inspection and detection or screening devices should be used where necessary. Procedures should be in place for food handlers to follow in the case of breakage (e.g., breakage of glass or plastic containers, metal equipment.

Chemical contamination

Note to EWG: Text to be developed to give equal prominence to chemical contamination and guidance on control of chemicals used in premises, additives, veterinary residues and checks on incoming materials etc. Views requested.

65. Systems should be in place to prevent contamination of foods by harmful chemicals, e.g. cleaning materials, non-food grade lubricants, etc. Toxic cleaning compounds, disinfectants, and pesticide chemicals should be identified, stored and used in a manner that protects against contamination of food, food contact surfaces, and food packaging materials. Food additives that may be harmful if used improperly should be controlled so they are only used as intended.

Allergenic Contamination

Note for EWG: New text has been proposed in response to CCFH comments. Text should be developed further e.g. considering the examples of allergens, references to precautionary labelling and supplier management programmes and verification through audit to ensure consistency with sections on other contamination. This text should be developed including stages of the food chain to address in the hazard review/analysis e.g. agricultural cross contamination, storage of ingredients the COP for allergens under CCFH will be covering primary production]. CCFH is developing guidance on management of food allergens to complement this section of the GPFH. We recommend leaving the details of allergen management to that document. Depending on the timing of the document, we may be able to

cross-reference it here.

66. Hazard identification should take into account the allergenic nature of some foods. Presence of allergens e.g. nuts, milk, eggs and cereals containing gluten (not an inclusive list) should be identified in raw materials, other ingredients and products. A system of allergen management should be in place starting from receipt of foods that are or that contain allergens, during processing, and during storage of food products. Controls should be put in place to prevent their presence in foods where they are not labelled. Controls to prevent cross-contamination from foods containing allergens to other foods should be implemented e.g. separation either physically or by time (with intervening cleaning between foods with different allergen profiles. Where cross-contamination cannot be prevented despite well-implemented GHPs, consumers should be informed.

INCOMING MATERIALS

Note for EWG: Include examples here e.g. seeds for sprouting or planting RTE crops. Also add reference to setting specifications and verifying that these are being met either by assurances from the supplier or own checks Sprouts are adequately covered by the Code of Hygienic Practice for Fresh Fruits and Vegetables and its Sprouts Annex. Views and examples requested.

67. Only raw materials and other ingredients that are fit for purpose should be used. Incoming materials including food ingredients should be procured according to specifications and their compliance with food safety and suitability specifications should be verified where necessary. Incoming raw materials or other ingredients should, where appropriate, be inspected and sorted before processing. Where necessary, laboratory tests should be conducted to verify food safety and suitability of raw materials or ingredients. These tests may be conducted by a supplier that provides a Certificate of Analysis, the purchaser, or both. No incoming material should be accepted by an establishment if it is known to contain chemical, physical or microbiological contaminants which would not be reduced to an acceptable level by controls applied during sorting and/or where appropriate processing. Stocks of raw materials and other ingredients should be subject to effective stock rotation.

PACKAGING

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

WATER

Note: EWG has developed the Original text from CAC/RPC1–1969 in paras 51 to 58. However. it should be further developed taking account of information from FAO/WHO consideration of water e.g. reference could be made to FAO/WHO guidance as far as possible and basic information provided here with references to specific commodity codes.

Water supply

69. An adequate supply of potable water and/or clean water with appropriate facilities for its storage, distribution and temperature control, should be available whenever necessary to ensure the safety and suitability of food. Potable water should meet the requirements as specified in the latest edition of WHO Guidelines for Drinking Water Quality, or water of a higher standard.

70. Non-potable water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food), should have a separate system. Non-potable and clean water systems should be identified and should not connect with, or allow reflux into, potable water systems.

Water in contact with food

71. The quality of water used in primary production should be suitable for its intended purpose. For additional information on water for primary production see relevant codex texts e.g. the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003) and *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

72. Only potable water should be used in food handling and processing, except in certain food processes, e.g. chilling, and in food handling areas, where this does not constitute a hazard to the safety and suitability of food (e.g. the use of clean sea water or clean water).

73. [Clean] water recirculated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use. The treatment process should be effectively monitored. 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

74. Potable water should be used to avoid food contamination. The potable water may be treated where this is required by the production process.

Ice and steam in direct contact with food

Note to EWG – need to consider ice made from sea water. Views requested.

75. Ice [in direct contact with food] should be made from potable water. Ice should be produced, handled and stored so they are protected from contamination.

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

MANAGEMENT AND SUPERVISION

Note to EWG: Original text from CAC RPC1-1969 from this section has been moved to training and management

DOCUMENTATION AND RECORDS

77. Appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf-life of the product or as determined by the Competent Authority. Documentation can enhance the credibility and effectiveness of the food hygiene system and demonstrate that all reasonable care and due diligence has been taken to protect the health of consumers

RECALL PROCEDURES

Note for EWG: Expanded to add link to deviation from controls and indicate that failure to apply GHP effectively can result in food recalls.

78. Managers should ensure effective procedures are in place to respond to any deviation from GHP controls. Failure to apply the controls effectively should be assessed for the impact on food safety or suitability. Procedures should enable the comprehensive, rapid and effective recall of any food from the market that may pose a risk to public health. Where a product has been recalled because of an immediate health hazard, other products which are produced under similar conditions which may also present a hazard to public health should be evaluated for safety and may need to be recalled. The need for public warnings should be considered.

79. Provision should be made so recalled products can 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 reduce the hazard to an acceptable level.

SECTION III: ESTABLISHMENT MAINTENANCE, SANITATION AND PEST CONTROL

Note to EWG: Further discussion is required to determine whether a definition should be provided for 'Sanitation' to clarify that this includes cleaning and where appropriate disinfection

OBJECTIVES:

To establish effective systems that:

- ensure adequate sanitation i.e cleaning and if necessary disinfection;
- ensure adequate pest control
- ensure waste management

monitor effectiveness of sanitation, pest control and waste management procedures

RATIONALE:

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

General

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

    • facilitate all sanitation (i.e., cleaning and, where appropriate, disinfection) procedures;

    • function as intended; and

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

81. Cleaning should remove food residues and dirt which may be a source of contamination, including with allergens. The necessary cleaning methods and materials will depend on the nature of the food business, the food type and surface to be cleaned. Disinfection may be necessary after cleaning.

82. 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 during cleaning operations. Cleaning products suitable for food contact surfaces should be used in food preparation areas.

83. Cleaning and disinfection chemicals should be handled and used carefully and in accordance with manufacturers' instructions, for example, using the correct dilutions and contact times, and stored, where necessary, separated from food, in clearly identified containers to avoid the risk of contaminating food.

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

Sanitation procedures and methods

85. Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow and vacuum cleaning or other methods that avoid the use of water, and chemical methods using solutions of detergents, alkalis or acids. Dry cleaning or other appropriate methods for removing and collecting residues and debris may be needed in some operations and/or food processing areas where water enhances the risk of microbiological contamination. Care should be taken to ensure cleaning procedures do not lead to contamination of food e.g. spray from pressure washing can spread contamination from dirty areas such as floors and drains over a wide area and contaminate food contact surfaces or exposed food.

86. Cleaning procedures will involve, where appropriate:

- removing gross visible debris from surfaces;
- applying a detergent solution to loosen soil and bacterial film (cleaning); and
- rinsing with water (hot water where appropriate) to remove loosened soil and residues of detergent.

Where necessary, cleaning should be followed by chemical disinfection with subsequent rinsing unless the manufacturer's instructions indicate on scientific basis that rinsing is not required. Concentrations of chemicals used for disinfection should be appropriate for use and applied according to manufacturers' instructions.

Sanitation (Cleaning and Disinfection) Procedures

87. Cleaning and disinfection procedures should ensure that all parts of the establishment are appropriately clean, and should include the cleaning of cleaning equipment. Where appropriate, programmes should be drawn up in consultation with relevant specialist expert advisors

88. Where written cleaning and disinfection programmes are used, they should specify:

- areas, items of equipment and utensils to be cleaned, and, where appropriate, disinfected;
- responsibility for particular tasks;
- method and frequency of sanitation and, where appropriate, disinfection; and
- monitoring and verification activities.

Monitoring Effectiveness

Note for EWG: Add in text about periodic review with suppliers to make sure cleaning agents continue to be appropriate. Text amended to reflect requirements for SLDBs. Microbiological

sampling and testing is an unreasonable expectation for some businesses and in some cases unnecessary. This can be expanded with more examples e.g. including rapid testing kits. Need to consider redrafting following discussion.

89. Application of sanitation procedures should be monitored for effectiveness and periodically verified by means such as audits and visual inspections to ensure they are applied. properly. The type of monitoring of sanitation programmes will depend on the nature of the procedures, but could include pH, water temperature, conductivity, cleaning agent concentration, disinfectant concentration, and other parameters important to ensuring the programme is being implemented as designed. Microorganisms can develop resistance to cleaning agents and the food production environment can change over time so periodic review with cleaning agent suppliers will help ensure cleaning agents used are effective and appropriate. While effectiveness of cleaning agents and instructions for use will be validated by cleaning agent manufacturers, microbiological sampling and testing of the environment and food contact surfaces can help verify that sanitation programmes are effective and being applied properly. Microbiological sampling and testing may not be appropriate in all cases and an alternative approach might include observation of cleaning procedures to make sure protocols are being followed. Sanitation and maintenance procedures should be regularly reviewed and adapted to reflect any changes in circumstances and documented as appropriate.

PEST CONTROL SYSTEMS

General

90. Pests (e.g. birds, rodents, insects etc.) 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 building design, layout and location, sanitation, inspection of incoming materials and good monitoring can minimize the likelihood of infestation and thereby limit the need for pesticides.

Preventing access

91. 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

92. 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, unused equipment should be removed.

Monitoring and detection

Note: Consideration should be given to expanding the text to include more details on monitoring and detection including where this is outsourced e.g. attention to key areas of infestation, main pests and trends.

93. Establishments and surrounding areas should be regularly examined for evidence of infestation. Detectors and traps [e.g. insect light traps, baits stations] should be designed and located so as to prevent potential contamination of materials, products or facilities.

Eradication

94. 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

95. Suitable provision should be made for the removal and storage of waste. Waste [should as far as possible be collected in covered containers and should] 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.

96. Waste stores should be kept appropriately clean and free of pests and be resistant to pest infestation].

MONITORING EFFECTIVENESS

Note: Original text from CAC RPC-1 1969 has been moved to section on cleaning

SECTION IV: PERSONAL HYGIENE

OBJECTIVES:

To ensure that those who come directly or indirectly into contact with food:

- Maintain appropriate personal health;
- maintain an appropriate degree of personal cleanliness; and
- behave and operate in an appropriate manner.

Note to EWG – para 97 Added to clarify expectations.

97. Food businesses should establish policies and procedures for personal hygiene and ensure all personnel are aware of the importance of personal hygiene and expectations of controls that need to be applied.

Health Status

Note for EWG: Para 97 - Develop the text to provide some more guidance to the business what to do when the personnel report illness. E.g. some injuries can be protected with suitable dressings/covering. Although this addressed in para 100). Also for gastro-intestinal illness workers should generally be excluded/prevented from handling RTE foods for foods for [48hrs] after symptoms stop and some may need additional restrictions. This may be too prescriptive but there should at least be a general requirement indicating action should be based on medical advice. Relevant to para 100 too, however the time restrictions are complicated and depend on the type of illness; this would be too prescriptive for a Codex document. We may be able to craft some general text. Views requested

97. People known, or suspected to be suffering from or to be a carrier of a disease or illness [communicable disease] 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.

98. . For some illnesses, it may be necessary for food handlers to get medical clearance before returning to work.

Illness and Injuries

99. 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.

100. Cuts and wounds, where personnel are permitted to continue working, should be covered by suitable waterproof dressings.

Personal Cleanliness

101. Food handlers should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head and beard covering, and footwear. Measures should be implemented to prevent cross-contamination by food handlers through adequate hand washing and, where necessary, wearing gloves. If gloves are worn, appropriate measures will also need to be applied to ensure the gloves do not become a source of contamination.

102. Personnel, including those wearing gloves, should clean their hands regularly, especially when personal cleanliness may affect food safety, in particular:

- at the start of food handling activities;
- immediately after using the toilet; and
- after handling any contaminated material, such as waste or raw and unprocessed foods where this could result in contamination of other food items

103.. In order to clean the hands, it is recommended to was them with soap and water by wetting hands with water and applying sufficient soap to cover all surfaces. Rinse hands with clean, running water and dry thoroughly with a single-use towel or other method that does not re-contaminate hands. Multiple use cloth drying towels should not be used. Hand sanitizers should not replace hand washing and should be used only after hands have been washed.

Personal Behaviour

104. 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.

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

Visitors

106. Visitors to food businesses, and in particular, to food manufacturing, processing or handling areas, should, where appropriate, wear protective clothing and adhere to the other personal hygiene provisions in paras 79-87.

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 hygiene practices are taken during transport, even where adequate hygiene practices have been taken earlier in the food chain.

General

107. Food should 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

108. 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 unsafe or unsuitable for consumption; and
- allow any necessary temperature, humidity and other conditions to be checked.

Use and Maintenance

109. 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.

110. 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.

SECTION VI: PRODUCT INFORMATION AND CONSUMER AWARENESS

Note: Consideration should be given to expanding the Objectives and Rational to include allergens

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;
- allergic consumers can identify allergens present in foods; and
- the lot or batch can be easily identified and recalled if necessary.

Consumers should be given enough knowledge of food hygiene to enable them to:

- be aware of the importance of reading and understanding the label.
- 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. Insufficient product information about the allergens in food can also result in allergic consumers becoming ill.

Lot identification

111.. 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. The *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) applies.

112. 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 recall of the products, where necessary.

Product Information

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

Product Labelling

114. 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. This should also include information that identifies food allergens in the product as ingredients or where cross-contact cannot be excluded. The *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) applies.

Consumer Education

Note for EWG: Consider whether we need this section as it seems a little out of place in comparison to the rest of the document – could paras 114 and 115 be merged?

115.. 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; foodborne illness and the presence of allergens.

SECTION VII: TRAINING

OBJECTIVE:

All those engaged in food operations in contact with food or in proximity should understand food hygiene to ensure competence 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

116. 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.

Training Programmes

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

- the nature and risk of the food, in particular its ability to sustain growth of pathogenic or spoilage microorganisms;
- 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.

Instruction and Supervision

118. 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/or 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.

119. 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. Personnel tasked to monitor the equipment used in food control should be trained adequately to ensure that they are competent to perform their tasks and are aware of the impact of their tasks to the safety and suitability of the food.

Refresher Training

120. 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.

[CHAPTER TWO]

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

PREAMBLE

121. The first part of this [Chapter] sets out the seven principles of the Hazard Analysis and Critical Control Point (HACCP) system. The second part provides general guidance for the application of the system while recognizing that the details of application may vary and a more flexible approach to application may be appropriate depending on the circumstances and the capabilities of the food operation.

122. The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention of hazards rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

Note to EWG: Para 123 – need to seek views on to what extent HACCP can be applied to primary production

123. HACCP can 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. As well as enhancing food safety, implementation of HACCP can provide other significant benefits, such as more efficient processes based on a thorough analysis of capability, more effective use of resources by focusing on critical areas, and fewer recalls through identification of problems before product is released. In addition, the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

124. The successful application of HACCP requires the full [strong] commitment and involvement of management and the work force. It also requires a multidisciplinary approach; this multidisciplinary approach should include, when appropriate, expertise in agronomy, veterinary health, production, microbiology, public health, food technology, environmental health, chemistry and engineering, according to the particular application. The application of HACCP is the system of choice in the management of food safety within such systems.

Note to EWG: Text has been added introduce flexibilities for small businesses. This should be developed further and supported by examples of adaptations that can be made and by drawing on existing guidance. Views and examples requested

125. Barriers to the application of HACCP in small and less developed businesses (SLDBs) have been acknowledged and flexible approaches to the implementation of HACCP in such businesses, are described in the FAO/WHO Guidance to governments on the application of HACCP in SLDBs[5]. It provides ways to adapt the HACCP approach to assist competent authorities in supporting SLDBs, for example, development of a HACCP-based system which is consistent with the seven principles of HACCP but does not conform to the layout or steps described in this section.

DEFINITIONS

Note to EWG: Consideration should be given to moving all definitions to a single section in the document. Definitions to be developed as drafting progresses.

Control (verb): To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control (noun): The state wherein correct procedures are being followed and criteria are being met.

Control measure: Any action and activity that can be used to maintain compliance with GP and HACCP procedures

Note for EWG: Given the previous 2 definitions, a 'control measure' must have compliance criteria. – Further discussion needed on Hazard control measure below. Views requested

[***Hazard control measure***]: (to be developed) [suggestion that this be "a control measure for a significant hazard, [may not longer be needed following drafting changes]

Corrective action: Any action taken when a deviation occurs in order to correct a problem and minimize the potential for it to reoccur.

Critical Control Point (CCP): A step at which a control measure is essential against a significant(s) hazard(s). can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical limit: A criterion which separates acceptability from unacceptability.

Deviation: Failure to meet a critical limit.

[5] FAO/WHO. Guidance to governments on the application of HACCP in small and/or less-developed food businesses. FAO Food and Nutrition Paper 86. 2006.

Flow diagram: A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

HACCP: A system which identifies, evaluates, and controls hazards which are significant for food safety.

HACCP 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.

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

Hazard analysis: The process of collecting and evaluating information on hazards identified in the environment, in the process or in the food, and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Step: A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

Validation: Obtaining evidence that hazard control measures, if properly implemented, are capable of controlling hazards to an acceptable level.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine whether a control measure has been operating as intended.

PRINCIPLES OF THE HACCP SYSTEM

The HACCP system consists of the following seven principles:

PRINCIPLE 1

Conduct a hazard analysis.

PRINCIPLE 2

Determine the Critical Control Points (CCPs).

PRINCIPLE 3

Establish critical limit(s).

PRINCIPLE 4

Establish a system to monitor control of the CCP.

PRINCIPLE 5

Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

PRINCIPLE 6

Establish procedures for verification to confirm that the HACCP system is working effectively.

PRINCIPLE 7

Establish documentation concerning all procedures and records appropriate to these principles and their application.

GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

Note to EWG: The text in paras 6-45 has been developed to some extent but further consideration is required to clarify the relationship between the 12 step plan and GHP as some of the steps are also applicable to a lesser extent GHP-based systems. It is likely that some text will move into the Introduction or [Chapter 1]. Also, further discussions are required on whether the 12 step flow chart is still appropriate, and how to incorporate flexibilities for SLDBs.

INTRODUCTION

126. Prior to application of HACCP to any sector of the food chain, that sector should have in place GHPs according to Chapter I of this document, the appropriate product and sector-specific Codex Codes of Practice, and appropriate food safety requirements set by competent authorities. These prerequisite programmes to HACCP, including training, should be well established, fully operational and verified in order to facilitate the successful application and implementation of the HACCP system. HACCP application will not be effective without prior implementation of GHPs.

127. For all types of food business, management awareness and commitment are necessary for implementation of an effective HACCP system. The effectiveness will also rely upon management and employees having the appropriate HACCP knowledge and skills.

128. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration should be given to the impact of raw materials and other ingredients, food production practices, food manufacturing practices (including whether manufacturing processes control hazards or result in hazards requiring control), likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

129. HACCP is a systematic approach that enhances control of specific food safety hazards, where necessary, over that achieved by the GHPs that have been applied by the establishment. The intent of the HACCP system is to focus control at Critical Control Points (CCPs). Redesign of the operation should be considered if a [food safety] hazard which must be controlled is identified but no control measures are found. As described in the GHP Section, food hazards may be controlled adequately by GHP-based control measures.

130. HACCP should be applied to each individual operation separately. CCPs identified in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a different nature.

131. The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step.

Flexibility for small and/or less developed food businesses

132. The application of the HACCP principles should be the responsibility of each individual business. However, it is recognised by competent authorities and FBOs that there may be obstacles that hinder the effective application of the HACCP principles by individual businesses. This is particularly relevant in small and/or less developed businesses. While it is recognized that when applying HACCP, flexibility appropriate to the business is important, all seven principles should be applied in the HACCP system. This flexibility should take into account the nature [and size] of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints, as well as the risk associated with the produced food.

133. Small and/or less developed businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP plan. In such situations, expert advice should be obtained from other sources, which may include: trade and industry associations, independent experts and competent authorities. HACCP literature and especially sector-specific HACCP guides can be valuable. HACCP guidance developed by experts relevant to the process or type of operation may provide a useful tool for businesses in designing and implementing a HACCP plan. Where businesses are using expertly developed HACCP guidance, it is essential that it is specific to the foods and/or processes under consideration.[6]

[6] FAO/WHO Guidance to governments on the application of HACCP in SLDBs.

134. The efficacy of any HACCP system will nevertheless rely on management and employees having the appropriate HACCP knowledge and skills, therefore ongoing training is necessary for all levels of employees and managers, as appropriate to the food business.

APPLICATION

135. The application of HACCP principles consists of the following tasks as identified in the [Logical Sequence for Application of HACCP] (Diagram 1).

Assemble HACCP Team (Step 1)

136. The food business operator should assure that the appropriate product specific knowledge and expertise are available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team that includes individuals conducting different activities within the operation, e.g., production, maintenance, sanitation.

137. Where such expertise is not available on site, expert advice should be obtained from other sources, such as trade and industry associations, independent experts, competent authorities, HACCP literature and HACCP guidance (including sector-specific HACCP guides). It may be possible that a well-trained individual with access to such guidance is able to implement HACCP in-house. Generic HACCP-based systems developed externally may be used by FBOs where appropriate but should be tailored to the food operation.

138. The HACCP team should identify the scope of the HACCP system and are responsible for writing the HACCP plan. The scope should describe which segment of the food chain is involved and the general classes of hazards (biological, chemical, physical) to be addressed (e.g. does it cover all classes of hazards or only selected classes).

Describe product (Step 2)

139. A full description of the product should be drawn up, including relevant safety information such as composition, physical/chemical characteristics (including a_w, pH, preservatives etc.), microbiocidal/static treatments (heat-treatment, freezing, brining, smoking, etc.), packaging, durability/shelf life, 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 limits already established for food safety hazards should be considered and accounted for in the HACCP plan, e.g. limits for food additives, regulatory microbiological criteria, maximum allowed veterinary

medicines residues and times and temperatures for heat treatments prescribed by competent authorities.

Identify intended use (Step 3)

140. The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. institutional feeding, may have to be considered.

Construct flow diagram (Step 4)

141. The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the operation for a specific product. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation. The flow diagram should indicate all the flows, including those of ingredients, personnel, water and air.

On-site confirmation of flow diagram (Step 5)

142. Steps should be taken to confirm the processing activity against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.

List all potential hazards associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards (Step 6 and Principle 1)

Note to EWG: This section needs to be developed following further discussions on the extent to which all businesses need to carry out a hazard analysis and should build on text provided in the GHP Section. This should draw on guidance in existing Codex documents e.g. CAC/GL 63 2007

143. Hazard analysis consists of identifying potential hazards and evaluating these hazards to determine which hazards are significant for the specific food business operation. The HACCP team should list all of the potential hazards that may be reasonably expected to occur at each step according to the scope of the food business operation. To identify potential hazards that may be associated with ingredients, “receiving” the ingredients can be considered as the step.

144. The HACCP team should next evaluate the hazards to identify which of these potential hazards are of such a nature that their prevention or reduction to acceptable levels is

essential to the production of safe food (i.e., determine the significant hazards that need to be addressed in a HACCP plan.

145. In conducting the hazard analysis (i.e., hazard identification and hazard evaluation) to determine whether there are significant hazards, wherever possible the following should be considered:

a. hazards historically associated with the type of food or its ingredients (e.g., from surveys or sampling and testing of hazards in the food chain, from recalls, or from information in the scientific literature);

- adverse health effects (including their severity) historically associated with the hazards in the type of food or its ingredients;[7]
- the likely occurrence of hazards;
- the nature of the equipment used in making a food product

b. survival or multiplication of microorganisms of concern;

c. production or persistence in foods of toxins (e.g., mycotoxins), chemicals (e.g., pesticides, drug residues) or physical agents (e.g., glass, metal); and,

d. conditions leading to the above.

The hazard analysis should consider not only the intended use, but also any known unintended use (e.g., a soup mix intended to be mixed with water and cooked but known to be used without a heat treatment in flavouring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan

Note to EWG – para 26 and 27 requires review and revision and should maybe be included in Chapter 1. Views requested.

146. In some cases, it may be acceptable for a more simplified hazard analysis to be carried out by FBOs which identifies groups of hazards (microbiological, physical, chemical) in order to control the sources of these hazards without the need for a hazard analysis that identifies the specific hazards of concern. Generic HACCP-based tools and guidance documents provided externally, for example, by industry or regulators, are designed to assist with this step.

[7] *Principles and Guidelines for the Conduct of Microbiological Risk Management* CAC/GL 63-2007.

147. Hazards which are of such a nature that their elimination or reduction to acceptable levels is essential to the production of safe food (because they are reasonably likely to occur in the absence of control) should be identified and controlled by [control measures][hygienic intervention] designed to prevent or reduce them to an acceptable level. This may be achieved with the application of good hygiene practices, some of which may target a specific hazard, [(for example, cleaning equipment to control contamination of ready-to-eat foods with *Listeria monocytogenes*) or to prevent food allergens being transferred from one food to another food that does not contain that allergen when the two foods are processed on the same equipment. In other instances, hazard control measures will need to be applied at critical control points.]

148. Consideration should be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure. For example, to control *L. monocytogenes*, a heat treatment may be needed to kill the organism in the food and cleaning and disinfection may be needed to prevent transfer from the processing environment; a heat treatment can control both *Salmonella* and *E. coli* O157:H7 that present a hazard in raw meat.

Determine Critical Control Points (Step 7 and Principle 3)

[8]

Note to EWG: It has agreed that the current decision tree applied to identify CCPs should be reviewed.

149. There may be more than one CCP at which control is applied to address the same hazard. Similarly, a CCP may control more than one hazard. Determining if the step at which a [control measure][hygienic intervention] must be applied is a CCP in the HACCP system can be facilitated by the application of a decision tree (e.g., Diagram 2), which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. Other approaches may be used. Training in the application of the decision tree is recommended.

[8]Since the publication of the decision tree by Codex, its use has been implemented many times for training purposes. In many instances, while this tree has been useful to explain the logic and depth of understanding needed to determine CCPs, it is not specific to all food operations, e.g. slaughter, and therefore it should be used in conjunction with professional judgement, and modified in some cases.

150. If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

Establish critical limits for each CCP (Step 8 and Principle 3)

151. Critical limits that separate acceptable procedures and products from unacceptable ones should be specified for each Critical Control Point. In some cases more than one critical limit will be elaborated at a particular step (e.g., heat treatments commonly include critical limits for both time and temperature). Criteria often used include minimum or maximum values for critical parameters associated with the control measure such as measurements of temperature, time, moisture level, pH, a_w, available chlorine, contact time, conveyor belt speed, and ,where appropriate, sensory parameters which can be observed, such as a pump setting.

Note to EWG – there is a suggestion to add a para about the ability of control measures to comply with the criterial limits has to be scientifically validated – if not by the fbo by the external expert. Views requested

152. 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.[9] 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.

153. Where HACCP guidance developed by experts, instead of the HACCP team, has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, product or groups of products under consideration. These critical limits should be measurable or observable.

[9] *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008).

Establish a monitoring system for each CCP (Step 9 and Principle 4)

154. 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. 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.

155. If monitoring is not continuous, then the amount or frequency of monitoring should be sufficient to ensure the CCP is in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are usually preferred to microbiological testing because they may be done rapidly and can often indicate the control of microbial hazards associated with the product.

156. The personnel doing the monitoring should be instructed on appropriate steps to take when monitoring indicates the need to take action. Data derived from monitoring should be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.

157. All records and documents associated with monitoring CCPs should be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company as a verification of control (see Step 11).

Establish corrective actions (Step 10 and Principle 5)

158. Specific written corrective actions should be developed for each CCP in the HACCP system in order to effectively deal with deviations when they occur.

159. The corrective actions should ensure that the CCP has been brought under control. Actions taken should include segregating the affected product and analysing the safety of the product to ensure proper disposition of the affected product. External experts may be needed to conduct such evaluations. In some cases, the evaluation may indicate that the product is safe and can be released into commerce. In other cases it may be determined that the product could be reprocessed (e.g., re-pasteurized); in other situations the product may need to be destroyed (e.g., contamination with *Staphylococcus* enterotoxin). A root cause analysis should be conducted where possible to identify and correct the source of the deviation in order to minimize the potential for the deviation to reoccur. Details of the corrective actions, including the cause of the deviation and product disposition procedures should be documented in the

HACCP record keeping. Periodic review of corrective actions should be undertaken to identify trends and to ensure corrective actions are effective.

Establish verification procedures (Step 11 and Principle 6)

Note to EWG: Further discussion is required on Validation and Verification to allow this text to be developed further so that appropriate text is included under Principle 1 and here.

160. Establish procedures for individual control measures, as well as the HACCP system as a whole. Verification includes validation, i.e., obtaining scientific and technical evidence that hazard control measures are capable of controlling a hazard, as well as activities to verify on an ongoing basis that the hazard control measures are being implemented as intended (i.e., in accordance with the HACCP plan). Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur.

161. Validation is performed during development of the HACCP plan, and, in addition to obtaining the evidence that the control measures are capable of controlling the hazard, includes obtaining evidence in operation during the initial implementation of the HACCP system to show that control can be achieved consistently under production conditions. Validation is applied during the establishment of critical limits to ensure that the appropriate values are chosen. This could include a review of scientific literature, using mathematical models, conducting validation studies, or using safe harbours developed by authoritative sources. Validation is also done on a periodic basis when the plan is reanalysed and when changes indicate the need for re-validation. Validation is described more fully in the *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69 – 2008).

162. After validation, verification activities should be performed on an ongoing basis to ensure the HACCP system functions as intended and continues to operate effectively. Verification, which includes observations, auditing, calibration, sampling and testing, and records review, can be used to determine if the HACCP system is working correctly. Examples of verification activities include:

- Review of monitoring records to confirm that CCPs are kept under control;
- Review of corrective action records, including specific deviations, product dispositions and any analysis to determine the root cause of the deviation;
- Calibration or checking the accuracy of instruments used for monitoring and verification;

- Observation that control measures are being conducted in accordance with the plan;
- Sampling and testing, e.g., for microorganisms[10] or chemical hazards such as mycotoxins to verify product safety;
- Sampling and testing the environment for microbial contaminants such as *Listeria*; and
- Review of the HACCP system, including the hazard analysis and the HACCP plan (e.g., internal or third-party audits).

163. Verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties.

164. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Verification of the implementation of hazard control measures should be conducted with sufficient frequency to determine that the HACCP plan is being implemented properly.

165. Where possible, verification activities should include a comprehensive review (e.g., reanalysis or an audit) of the HACCP system periodically, as appropriate, or when changes occur to confirm the efficacy of all elements of the HACCP system. This review of the HACCP system should confirm that the appropriate hazards have been identified, that hazard control measures and critical limits are adequate to control the hazards, that monitoring and verification activities are occurring in accordance with the plan and are capable of identifying deviations, and that corrective actions are appropriate for deviations that have occurred. This review can be carried out by individuals within a food business or by external experts.

Establish documentation and record keeping (Step 12 and see Principle 7)

166. Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to

[10] *Principles and guidelines for the establishment and application of microbiological criteria related to food* (CAC/GL21-1997.

verify that the HACCP controls are in place and being maintained. Expertly developed HACCP guidance materials (e.g. sector-specific HACCP guides) may be utilised as part of the documentation, provided that those materials reflect the specific food operations of the business.

167. Examples of documentation include

- HACCP team composition
- Hazard analysis;
- CCP determination;
- Critical limit determination;
- Validation of [[hazard] control measures] [hygienic intervention] ; and
- Modifications made to the HACCP plan.

168. Examples of records include:

- CCP monitoring activities;
- Deviations and associated corrective actions; and

169. • Verification procedures performed. An example of a HACCP worksheet for the development of a HACCP plan is attached as Diagram 3. [see Diagram 3 of CAC/RCP 1-1969]

170. A simple record-keeping system can be effective and easily communicated to employees. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperatures.

TRAINING

171. Training of personnel in industry, government and academia in HACCP principles and applications is an essential element for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the operating personnel to in charge of each Critical Control Point.

172. Cooperation between primary producer, industry, trade groups, consumer organisations, and responsible authorities is vitally important. Opportunities should be provided for the joint training of industry and competent authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

PROPOSED DRAFT[Japan1] **REVISION OF THE *GENERAL PRINCIPLES OF FOOD HYGIENE* (CAC/RCP 1-1969)**

1. During the planetary session at CCFH49 following the Physical Working Group, the Committee agreed to:

- consider the points in CRD2 as a basis for the further development of CXC 1-1969;
- establish an EWG, chaired by the United Kingdom and co-chaired by France, Ghana, India, Mexico and United States of America, working in English, French and Spanish to:
- continue revision of the three parts of the document (Introduction, GHPs, HACCP) taking into account the discussions at CCFH49 and the written comments submitted;
- clarify the relationship of the three types of control measures: GHPs, control measures essential for safety that are applied at Critical Control Points (CCPs), and control measures essential for safety that are not applied at CCPs, using examples; and
- clarify how food business operators come to understand the hazards associated with their business and determine the types of control measures needed to control the hazards.

2. Following the meeting, we have been reviewing the comments received from members in conjunction with the draft text and discussions on the fundamental principles at CCFH49. You will recall that there were some areas where a consensus was not reached by the PWG or the Plenary, including the inclusion of an additional category of controls referred to as 'enhanced GHPs' or OPRPs.

3. Given the range of opinions, we are recommending that the concept of 'enhanced GHPs' should not be included in the revised document. We believe this is consistent with the initial brief for the revisions to GPFH (CCFH47) which was to simplify the text as far as possible and for it to be useful for a global audience and all types of business. In our view, including this concept adds a level of complexity without adding value or clarity and this is not consistent with the original direction from CCFH. Full justification for our recommendation is included on page 1 of the revised document.

4. We note that the EWG was also tasked by CCFH47 to examine the need for a class of controls where management as CCPs presents a challenge and this led to the consideration of the concept of 'enhanced GHPs. We believe it would be reasonable to consider this task has been completed as it has been examined and discussed by 3 EWGs and 3 plenary sessions.

5. Based on discussions in Chicago, and further consideration amongst Co-Chairs we believe further efforts to reach a consensus amongst the EWG are unlikely to be successful and will delay development of the revised guidance. CCFH Chair indicated in his comments in Chicago that is was acceptable to conclude that no consensus could be reached if an issue has been considered thoroughly and there is no majority opinion. We are therefore seeking EWG agreement to the recommendation that concept of 'enhanced GHPs' should not be included in the revised document to allow the work to progress. Our intention would be to clarify the explanation of GHP and HACCP-based controls by adapting the text taking into account relevant comments from members and including examples from different types of businesses.

6. A revised text is attached for your consideration. We are still working on this but it would be helpful to receive your comments on the suggested amendments to the text (including the drafting notes**/**comments) and examples which can be used to illustrate the text). As you will see, throughout the text there are a number of boxes (shaded blue for ease of reference) which highlight areas where would be grateful for your input. In particular, we would welcome your comments/agreement on the following points:-

   - conclusion that enhanced GHPs should not be included in the document; and

   - terminology used for enhanced GHPs – suggestion the control measure should only be used for HACCP and alternative terminology (hygiene intervention, hygiene measure) should be used when referring to GHPs[Japan2]

7. We would be grateful for your comments by Monday 30 April 2018 so that we can continue to develop the document.

Thank you for your help.

Best wishes

Chair and Co-Chairs

UK, France, Ghana, India, Mexico and the United States of America

March 2018

Appendix I

PROPOSED DRAFT REVISION OF THE *GENERAL PRINCIPLES OF FOOD HYGIENE* (CAC/RCP 1-1969)

(for comments at Step 3 through CL2017/69-FH)

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

Note: Revised text on General Principles of Food Hygiene has been developed by the EWG following direction provided by CCFH49 and the PWG (November 2017). Notes have been included to provide explanation for major changes to the text and highlight areas where further discussions are required.

The EWG has been tasked with examining whether it is appropriate to include a category of control measures termed 'enhanced GHPs' in the document following original direction (CCFH) to consider controls where management through CCPs is challenging.

Co-Chairs have concluded that the concept of 'enhanced GHPs' should not be included in the document and the text has been amended accordingly. Instead we recommend changes to the text to highlight that some GHPs may warrant additional attention (e.g., monitoring, verification and records).

Justification

This issue has been discussed extensively by the EWG and 3 CCFH meetings and there is no consensus on whether the concept of enhanced GHPs should be included in the revised GPFH.

Different approaches for including the concept of enhanced GHPs and an explanation of relationships between CCPs, enhanced GHPs and GHPs have been presented. It is extremely challenging to provide a clear and simple explanation and examples provided can be considered either GHPs or CCPs and none of the proposed approaches have been acceptable to the EWG or CCFH.

In the absence of an agreed and simple explanation which includes enhanced GHPs as a category of control measures, we are of the view that this adds a layer of complexity which is not consistent with the original direction from CCFH that GPFH should be simplified as far as possible and accessible to all types of business.

There is also no consensus on whether enhanced GHPs would be applied within either a GHP-based or HACCP-based system and practical examples provided also show they could be included in either.

The need for increased attention to some GHPs due to their impact on safety can be included in the text and supported by recommendations for increased monitoring and verification as needed. The text as drafted now provides flexibility for FBOs to incorporated food safety controls as either GHPs or HACCP CCPs as appropriate.

Given the absence of majority opinion and clear examples that demonstrate the need for an additional category of controls it will be very difficult to reach a consensus and continued consideration will delay development of the revised guidance.

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 at best unpleasant and, in some circumstances, can be severe or fatal or have a negative impact on human health over the long term. Furthermore, outbreaks of foodborne illness can damage trade and tourism, and lead to loss of earnings, unemployment and litigation. Food spoilage is wasteful, costly, threatens food security and can adversely affect trade and consumer confidence.

2. International food trade and 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 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, importers, manufacturers and processors, food warehouse/logistics operators, food handlers, retailers, and consumers, has a responsibility to assure that food is safe and suitable for consumption. All businesses must be aware of and understand the biological, chemical and physical hazards associated with the food they produce and the measures required to manage those hazards so that food produced is safe and suitable for use

Note to EWG – paragraph amended to emphasise FBO responsibilities

3. This document outlines the general principles that should be understood and followed by food business operators (FBOs) at all stages of the food chain and that provide a basis for competent authorities to oversee food safety and suitability. Taking into account the point in the food chain; the nature of the business; the relevant contaminants; and whether the relevant contaminants adversely affect safety, suitability or both; these principles will enable food businesses, to develop their own food hygiene practices and necessary food safety control measures, while complying with requirements set by competent authorities. While it is the food business operator's responsibility to provide safe food, this may be as simple as ensuring that "WHO 5 keys for safer food" is adequately implemented[m3].

Note to EWG – text (para 4a from CX/FH 17/49/5 deleted as it was agreed that all businesses should be aware of and understand the hazards associated with their business.

4. Prerequisite Programmes (PRPs), which include Good Hygiene Practices (GHPs), Good Manufacturing Practices (GMPs) and Good Agricultural Practices (GAPs) as appropriate should be applied, to lay the foundation for producing safe and suitable food. GHPs maintain the hygiene of a process, are essential for ensuring safety and suitability of food and apply broadly to all food businesses. **[**It should be noted that for some GHPs a higher level of control (e.g. increased monitoring and verification) may be required to provide safe and suitable food and thus the level of control and the frequency of monitoring and verification will need to be applied appropriately. For example, the cleaning of equipment and surfaces which come in contact with food may warrant a greater level of control and frequency of monitoring than, say, the cleaning of walls and ceilings.**]**[Japan4] or **[**In implementing GHPs, specific activities (e.g. cleaning of food contact surfaces) if not properly checked or supervised could lead to direct contamination of food. Such activities demand extra responsibilities and monitoring to assure the safety and suitability of food.**]**

Note to EWG: text added above to highlight increased attention to some GHP's due to their impact on food safety Views requested on whether first or second text in square brackets should be used.

4b. In some cases (e.g a business assembling sandwiches to order by consumers, a warehouse, cold storage facility or retailers selling fresh vegetables or RTE products) GHPs alone may be sufficient to control hazards within a business, while in others additional controls may be required to manage significant hazards which have been identified by a site-specific hazard analysis by application of control measures at critical control points (CCPs) within a Hazard Analysis and Critical Control Point (HACCP) system (see GHP and CCP Comparison Table below).

Note to EWG: The decision tree has been removed as it was added to support understanding of enhanced GHPs which we have now decided not to use in the document.

Note to EWG: text added in para 4c to reflect the outcome of CCFH49 discussions. Includes 2 terms [hazard analysis] [review of hazards] to reflect differences in understanding of what is required for Hazard Analysis and in opinion on whether all businesses should be required to carry out a hazard analysis. Views are requested on preferred terminology

4c. All businesses should be aware of the hazards associated with their type of business to ensure that they are managed, this could be achieved by undertaking a [hazard analysis][~~by reviewing hazards~~[HT5]]. The complexity of the analysis can be adapted to the nature and size of the business. At a simple level this

might require an awareness that ingredients/raw material could be contaminated by foodborne pathogens and potential risks should be controlled using basic hygiene measures such as cooking, chilling, preventing cross contamination and effective cleaning (as appropriate to the business) but in larger, more complex businesses, this could require more comprehensive analysis and a detailed understanding of specific hazards involved and the appropriate risk management interventions ~~(e.g., the application of HACCP principles, as described in Chapter 2[m6]).~~ In reviewing operations and potential hazards, including a hazard analysis conducted within the HACCP framework, consideration should be given to GHPs that are being, or that have been, established. This will indicate whether GHPs are sufficient to control the hazards associated with the operation or whether HACCP-based controls are required. FBOs without the resources to carry out a site specific hazard analysis/ of hazards may use external resources such as existing models, guidelines, references, standards, regulations, or Codes of Practice and adapt these to the site.

Note to EWG – in paragraph below, second sentence deleted as covered elsewhere in text. New text added it reflect flexibility in application of HACCP. May need to be developed further – there is also a suggestion to move last two sentence of para 5 to the bottom of para 4c. Views are requested.

5. [Chapter One] of this document describes GHPs, which are the basis of all food hygiene systems to support the production of safe and suitable food. [Chapter Two] describes HACCP. Although it is not generally feasible to apply HACCP at primary production, some of the principles can be applied. Implementation of HACCP can be encouraged throughout the food chain from primary production to final consumption and should be guided by scientific evidence of risks to human health[HT7]. It is recognised that implementation of HACCP may be challenging for some businesses. HACCP principles can be applied flexibly in individual operations and businesses may use external resources or adapt a generic HACCP plan provided by the competent authority or food industry[1] to the specific site circumstances

Note to EWG: A comparison table has been introduced as requested by CCFH to support understanding of the relationship between GHP and HACCP.

6. The following comparison table shows the relationship of GHPs applied for food safety and suitability and HACCP control measures applied to enhance food safety.

[1] FAO/WHO guidance to governments on the application of HACCP in small and/or less developed food businesses ISSN 0254-4725

Note to EWG: Table revised to remove reference to enhanced GHPs and now focusses on explanation of differences between GHPs and CCPs. Text amended to assist understanding of the differences in the controls. Co-Chairs are still developing this Table. Comments and examples are requested

Comparison of GHPs, and HACCP Control Measures

	Good Hygiene Practices (GHPs)	**Control Measures at Critical Control Points (CCPs)**
Scope	General conditions and activities for maintaining hygiene, including creating the environment (external and internal to the food business) so as to ensure production of safe and suitable food. Not specific to any hazard but results in reduction of likelihood of hazards occurring and in some prevention of contaminants.	Specific to a product or group of products. Controls at production steps that are critical to reduce significant hazards in foods to an acceptable level.
When identified?	Before or during review of hazards and in certain situations after a detailed hazard analysis.	After Hazard analysis for control measures at CCPs
Validation of the effectiveness of the hygiene measure	Where needed, generally not carried out by FBOs themselves, e.g. effectiveness of cleaning products/equipment will be validated for effective use by manufacturer and it is sufficient for the FBO to use cleaning products/equipment according to manufacturer's instructions.	Yes, validation should be carried out (*Guidelines for the Validation of Food Safety Control Measures* CAC/GL 69-2008)
Criteria	Some aspects of GHPs may be measurable or observable e.g. hand washing or equipment cleaning and may require an evaluation of the impact on product (e.g., frequency of cleaning complex equipment such as meat slicers). [could be used to highlight measures for which increases attention is needed]	Critical limit which separates acceptable products from unacceptable • measurable (e.g. temperature, pH, a_w), or • observable (e.g. visual checks, appearance, texture).

Monitoring	Yes, where relevant, to ensure procedures and practices are applied properly. Usually non-continuous; Frequency dependent on the operation and sufficiency.	Yes, to ensure CCP is in control • in [time/],[Japan8] or • if not continuous, at appropriate frequency
Corrective actions when loss of control is indicated	• For procedures and practices: Yes, [where relevant]. • For products: Usually not necessary. Corrective action should be considered on a case by case basis as failure to apply some GHPs, such as failure to clean between products with different allergen profiles, not rinsing after cleaning and/or disinfecting [or post maintenance equipment checks indicating loose machinery parts], may result in action on product. Other examples could include:- I. Vegetables not properly disinfected so not suitable for raw consumption if FBO can decide to either disinfect again, throw away or cook it; or II. If during maintenance work on equipment, loosened parts (bolts, nuts etc) can fall into the food product,	• For products: Yes. Pre-determined actions for products. • For procedures and practices: Yes, corrective actions if necessary to restore control and prevent recurrence.
Verification	Yes, where relevant, usually scheduled (e.g., visual observation that equipment is clean before use)	Yes. Scheduled verification of implementation of control measures [e.g. through record review, testing, internal and external audit]
Record keeping (e.g. monitoring records)	Yes, where relevant	Yes
Documentation (e.g. documented procedures)	Yes, where relevant	Yes

OBJECTIVES

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

- provide principles and guidance on the application of good hygiene practices applicable throughout the food chain to provide food that is safe and suitable for consumption;
- provide guidance on the application of HACCP principles;

  Note for EWG: sentence deleted as not required in the "Objectives". *How* this relationship is established should become apparent from the document.

- clarify the relationship between GHPs and HACCP; and
- provide the basis on which sector- and product-specific codes of practice are established.

SCOPE

Note to EWG: Text amended to remove emphasis on the manufacturing sector and re-enforce message that GPFH applies throughout the food chain

8. This document provides a framework of general principles for producing safe and suitable food for human consumption by outlining necessary hygiene and food safety conditions to be implemented in production of food and recommending, where appropriate, specific food safety control measures at certain steps throughout the food chain.

USE

General

Note to EWG: Additional text added following discussions at CCFH49

9. 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. It is generally applicable to food businesses and to competent authorities that provide oversight, and provides flexibility to meet the needs of different types of food businesses in the context of international food trade. However, it should be noted that it is not possible for the document to provide specific guidance for all situations and specific types of food businesses and the nature and extent of food safety risk associated with individual circumstances.

10. There will be situations where some of the specific requirements contained in this document are not applicable. The fundamental question for each food business operator in every case is "what is necessary and appropriate to control the hazards associated with the operation and ensure 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 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 knowledge of the operation and hazards including available scientific information. 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 operations and 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 unsafe food;
- provide an effective control system to ensure food is safe and suitable for human consumption;
- maintain confidence in domestically and internationally traded food; and
- provide information that 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, implement and review processes that provide food that is safe and suitable for its intended use;
- ensure food handlers are competent as appropriate to their job activities;
- cultivate a strong food safety culture by demonstrating their commitment to providing safe and suitable food and encouraging appropriate food hygienic system;
- 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 food correctly; and

- contribute to maintaining confidence in domestically and internationally traded food.

Note for EWG: Should reference to consumers be retained as this is outside remit of the document – views are requested[HT9].

14. Consumers should play their role by following relevant guidance and instructions for food preparation and applying appropriate food hygiene measures to ensure that their food is safe and suitable for consumption.

Note for EWG: section below developed to reflect amendments in previous text and direction from CCFH49

GENERAL PRINCIPLES

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

(ii) GHPs should ensure that food is produced in a sanitary environment in order to minimise the presence of contaminants. In some cases, GHPs may be sufficient to manage hazards associated with an operation.

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

(iv) Some GHPs require more attention than others as they have a greater impact on food safety.

(v) a hazard analysis, whether undertaken by the FBO itself or not and whether simple or comprehensive depending on the operation, should identify all potential hazards associated with the raw materials and other ingredients, the production process and its related environment (e.g. people, equipment and facility) and determine the significant hazards that should be controlled to ensure food safety.

(vi) Hazards are controlled by GHPs and/or CCPs. While recognising the importance of CCPs in controlling specific significant hazards, some GHPs may also require more attention than others as they have a greater impact on food safety. Significant hazards not controlled by GHPs are controlled by specific control measures.

(vii) Control measures that are critical to achieve an acceptable level of food safety should be scientifically validated[2]

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

[2] *Guidelines for the Validation of Food Safety Control measures* (CAC/GL 69-2008)

(ix) 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.

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

Management Commitment

15. Management commitment to incorporate food safety into the business objectives of the food business and to communicate the importance of producing safe food, both for the consumer and the business is fundamental to the success of any food hygiene system.

Note for EWG – text deleted below as if a system is effective you may not need to improve this. However, businesses should be aware of advances in knowledge and technology so bullet added to cover continuous improvement.

16. Top management [Japan10]should ensure effectiveness of the food hygiene systems 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 system when changes are planned and implemented;
- verifying that controls are working as intended and documentation is up to date;
- ensuring the appropriate training and supervision are in place for personnel;
- ensuring compliance with relevant regulatory requirements;
- encouraging continuous improvement taking into account of developments in knowledge and technology; and
- enabling a strong food safety culture by demonstrating commitment to providing safe and suitable food and encouraging appropriate food safety behaviours.

Definitions

Note to EWG: Section to be developed based on terms used in Parts 2 and 3; include here the definitions that already exist in the RCP-1, Section 2.3 to facilitate discussion on them.

Food hygiene system - The combination of hygiene practices and control measures that, when taken as a whole, ensures that food is safe and suitable for its intended use.

Food safety control system[3] **-** The combination of control measures that, when taken as a whole, ensures that food is safe for its intended use.

Control measure

Note to EWG – square brackets used around Hazard control measures as not yet clear if this term will be needed

[Hazard control measures[HT11]**]**

Significant hazard - a hazard identified through a hazard analysis as reasonably likely to occur in the absence of control and needing specific control measures, and/or at places other than CCPs

Note to EWG: definition of basic hazard analysis deleted as CCFH agreed using additional terms in to describe hazard analysis was confusing

Note to EWG: decision tree deleted as term enhanced GHP no longer being included

[3] *Guidelines for the Validation of Food Safety Control measures* (CAC/GL 69-2008)

[CHAPTER ONE]

GOOD HYGIENE PRACTICES

Introduction

17. The development, implementation and maintenance of GHPs provide the conditions and activities that are necessary to support the production of safe and suitable food at all stages of the food chain from primary production through to handling of the final product. Applied generally, they assist in controlling food safety hazards in food products in the work environment.

Note to EWG: This section needs to be expanded or an annex. UK to draft to provide simplified language.

18. As previously noted a review of the operation and its hazards may indicate that GHPs alone are sufficient to manage the hazards associated with an operation.

19. An appropriate location, layout, design, construction and maintenance of premises and facilities are essential for implementation of GHPs to be effective. Knowledge of the food and its production process is also essential. This [Chapter] provides guidance for effective implementation of GHPs and should be applied in conjunction with sector and product-specific codes.

20. Where this Chapter refers to food business operators, this includes primary production settings.

PRIMARY PRODUCTION

Note to EWG: Original text reinserted following discussions in the PWG and the agreement at the Plenary session. Needs further development including appropriate examples which can be added to the text in the relevant sections. Examples to be added into the text are requested[HT12][Japan13]

OBJECTIVES:

Primary production should be managed in a way that ensures that food is safe and suitable for its intended use. Where necessary, this will include:

− avoiding the use of areas where the environment poses a threat to the safety of food;
− controlling contaminants, pests and diseases of animals and plants in such a way as not to pose a threat to food safety;
− adopting practices and measures to ensure food is produced under appropriately hygienic conditions.

RATIONALE:

To reduce the likelihood of introducing a contaminant which may adversely affect the safety of food, or its suitability for consumption, at later stages of the food chain.

ENVIRONMENTAL HYGIENE

21. Potential sources of contamination from the environment should be considered. In particular, primary food production should not be carried on in areas where the presence of potentially harmful substances would lead to an unacceptable level of such substances in food.

HYGIENIC PRODUCTION OF FOOD SOURCES

22. The potential effects of primary production activities on the safety and suitability of food should be considered at all times. In particular, this includes identifying any specific points in such activities where a high probability of contamination may exist and taking specific measures to minimize that probability. The HACCP-based approach may assist in the application of such measures - see Chapter 2.

Producers should as far as practicable implement measures to:

• control contamination from air, soil, water, feedstuffs, fertilizers (including natural fertilizers), pesticides, veterinary drugs or any other agent used in primary production;

• control plant and animal health so that it does not pose a threat to human health through food consumption, or adversely affect the suitability of the product; and

• protect food sources from faecal and other contamination.

In particular, care should be taken to manage wastes, and store harmful substances appropriately. On-farm programmes which achieve specific food safety goals are becoming an important part of primary production and should be encouraged.

HANDLING, STORAGE AND TRANSPORT

23. Procedures should be in place to:

• sort food and food ingredients to segregate material which is evidently unfit for human consumption;

• dispose of any rejected material in a hygienic manner; and

• Protect food and food ingredients from contamination by pests, or by chemical, physical or microbiological contaminants or other objectionable substances during handling, storage and transport.

Care should be taken to prevent, so far as reasonably practicable, deterioration and spoilage through appropriate measures which may include controlling temperature, humidity, and/or other controls.

CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

24. Appropriate facilities and procedures should be in place to ensure that:

• any necessary cleaning and maintenance is carried out effectively; and

• an appropriate degree of personal hygiene is maintained

SECTION I: ESTABLISHMENT DESIGN AND FACILITIES

OBJECTIVES:

Depending on the nature of the operations and the associated risks, 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 and minimises airborne 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 contaminants to be effectively controlled.

Location of establishment

25. Establishments should not be located anywhere where there is a threat to food safety or suitability and hazards cannot be controlled by reasonable measures. The location of a food establishment including temporary/mobile establishments should not introduce any hazards from the environment that cannot be controlled. In particular, unless sufficient safeguards are provided, food 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;
    - areas prone to infestations of pests; and
    - areas where wastes, either solid or liquid, cannot be removed effectively.

26. Landscaping near a food facility should be properly designed to minimise attracting and harbouring pests. Where necessary, experts should be consulted for advice on appropriate plants for use in landscaping.

Equipment

Note to EWG: original text from CAC/RPC1–1969 has been incorporated into subsequent sections.

Hygienic design and layout of food establishment [and equipment]

27. The internal design and layout of food establishments and equipment should permit good food hygiene practices, permit adequate maintenance and cleaning, protect from cross-contamination and facilitate, if feasible, linear flux of operations.

28. The clean and dirty areas should be separated to minimize cross-contamination through measures such as physical separation (e.g. walls, partitions) and/or location (e.g. distance), traffic flow (e.g. one-directional production flow), airflow, and separation in time, with suitable cleaning and disinfection between uses.

Internal structures and fittings

29. Structures within food establishments should be soundly built of durable materials, which are easy to maintain, clean and where appropriate easy to disinfect. They should be constructed of non-toxic and inert materials according to intended use and normal operating conditions. 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;
    - 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 (e.g. lighting) 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;
    - doors should have smooth, non-absorbent surfaces, be easy to clean and, where necessary, disinfect;
    - 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, materials unless food business operators can satisfy the competent authority the other materials used are appropriate. Some work surfaces in contact with the products can be made of material which do not satisfy these requirements but are essential for technological reasons (i.e. wood in milk curdling of some cheeses which will enrich the milk with flora).

Temporary/mobile food establishments and vending machines

30. Establishments and structures covered here include market stalls, street vending vehicles and temporary premises such as tents and marquees.

31. Such premises and structures should be located, designed and constructed to avoid, as far as reasonably practicable, the contamination of food and the harbouring of 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

Note to EWG: Original text from CAC/RPC1–1969 has been moved to the section on water. This should be considered further when the document is more developed as agreement has not been reached on the appropriate location for the text.

Drainage and waste disposal

32. Adequate drainage and, waste disposal systems and facilities should be provided and well maintained. They should be designed and constructed so that the risk of contaminating food or the potable or clean water supply is avoided. It is important that drainage does not flow from highly contaminated areas to areas where finished food is exposed to the environment]

33. Waste should be collected, disposed of by trained personnel and, where appropriate, disposal records maintained. The waste disposal site should be located away from the food establishment to prevent pest infestation. Containers for waste, by-products and inedible or hazardous substances, should be specifically identifiable, suitably constructed and, where appropriate, made of impervious material.

34. Containers used to hold hazardous substances prior to disposal should be identified and, where appropriate, be lockable to prevent malicious or accidental contamination of food.

Cleaning facilities

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

Personnel hygiene facilities and toilets

36. Adequate personnel hygiene facilities and toilets should be available in order that an appropriate degree of personal hygiene can be maintained and to avoid contaminating food. Such facilities should be suitably located and designated. They should include:

    - adequate means of washing and drying hands, including soap, wash basins and [where appropriate], a supply of hot and cold (or suitably temperature controlled) water;
    - lavatories of an appropriate hygienic design with taps not be operated by hands (where this is not possible a disposable paper towel can be used to turn the taps off);
    - adequate changing facilities for personnel; and
    - where necessary, separate sinks should be available for hand washing and food washing.

Temperature control

Note for EWG: We intend to add a paragraph to discuss monitoring of temperature of premises, equipment and food.

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

Air quality and ventilation

38. 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 (e.g. to prevent an increase in moisture of dried foods that would allow growth of microorganisms and production of toxic metabolites).

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

Lighting

40. 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 fittings should, where appropriate, be protected to ensure that food is not contaminated by breakages

Storage

41. Adequate and, where necessary, separate 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.

42. Where appropriate, food storage facilities should be designed and constructed to:

i. permit adequate maintenance and cleaning;

ii. avoid pest access and harbourage;

iii. enable food to be effectively protected from contamination during storage; and

iv. where necessary, provide an environment which minimizes the deterioration of food (such as by temperature and humidity control).

43. 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

44. Equipment and containers coming into contact with food, should be suitable for food contact, designed and constructed and located to ensure that they can be adequately cleaned (other than those which are single-use only) and disinfected (where necessary) and maintained to avoid the contamination of food, according to hygienic design principles. Equipment and containers should be made of materials that are non-toxic according to intended use. Where necessary, equipment should be durable and movable or capable of being disassembled to allow for maintenance, cleaning, disinfection and to facilitate inspection for pests.

Food control and monitoring equipment

45. Equipment used to cook, heat, 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. Where appropriate, equipment should be calibrated to ensure that food processes are monitored consistently and accurately

46. 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 characteristics likely to have a detrimental effect on the safety or suitability of food.

SECTION II: CONTROL OF OPERATION

Note to EWG: Text in Section II will be revised as the document develops. Some changes have been made but further amendments will be required to ensure clarity and consistency and reflect agreed structure. Objectives and rationale should also be revised.

OBJECTIVES:

To produce food that is safe and suitable for human consumption by:

- formulating design requirements with respect to raw materials and other ingredients, composition/formulation, 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 contaminants.

Note to EWG: Further consideration is required to reach agreement on whether additional sections on product description, process description and monitoring procedures should be included or whether they are adequately addressed in other parts of the text. If agreement is reached these paragraphs 28 to 33 should be developed to ensure the appropriate level of detail is provided. Views requested.

[Product description

Note to EWG on point 47 – need to consider expanding to include some addition guidance to what is needed here. Views requested.

47. An FBO that is producing or preparing a food should provide a description of the food. Products may be described individually or in groups in a manner that will not compromise the identification and analysis of food safety hazards or other factors such as suitability of product. Grouping of food products should be based on having similar inputs and ingredients, process steps and intended purpose.

48. For some FBOs, the descriptions may be basic, e.g., primary production could describe products as “fresh vegetables,” “cattle,” “milk,’ etc, restaurants could describe products as “sandwiches,” “hot meals,” “cold salads,” etc.

49. The description should identify, as appropriate,

- Ingredients/raw materials,
- the intended use of the food, e.g., whether it is ready-to-eat or whether it is intended for further processing either by consumers or another business, for example cooking raw seafood;
- any specific consumer groups e.g.: infants, elderly, immuno-compromised individuals;

- any relevant specifications or important characteristics associated with the food, such as pH, Aw, and any allergens present; and
- any relevant acceptable hazard levels required for the food by the competent authority, or set by the FBO.
- Instructions provided for further use for example keep frozen until cooking

Process description

Note to EWG: This is relatively easy for a processor or manufacturer, but more difficult, if not nearly impossible, for some operators such as restaurateurs and primary producers. Depending on the detail of a process description, this could be relatively easy for primary producers who simply grow crops or raise animals. And restaurant could group processes/steps – heat, cool, assemble, store. Suggested amendments to reflect challenges for SLDBs. This may need expanding. Views requested.

50. The FBO producing a food should consider all steps in the operation for a specific product. It may be helpful to develop a flow diagram which could also be used for a number of similar products (see product description above) that are produced using similar processing steps to ensure all steps are captured. The process steps should be confirmed as accurate by checking against the actual process. For example, for restaurants the flow diagram could be based on the activities that are generics from the reception of ingredients/raw material, conservation (cold storage, frozen storage, room temperature storage), and preparation before use (washing, disinfection, defrosting) and cooking or preparation.

Monitoring procedures

Note for EWG: Consider moving this text after control of food hazards and key aspects of food hygiene systems. Views and examples for inclusion in paras 51-53[Japan14] requested.

51. The FBO should develop and implement procedures for monitoring control measures as relevant to the business and as applicable to the hazard being controlled. Procedures could include responsible personnel, method of monitoring (including frequency and sampling regime if applicable) and monitoring records to be kept. The frequency of monitoring should be appropriate to ensure consistent process control. See Chapter 2 for additional information on monitoring at CCPs.

Activity	**Procedure**	**Relevant information**
Reception of raw materials	Specifications or criteria of acceptance or rejection	Characteristic that the product should meet for being accepted (e.g. temperature, records, certificate)

		Frequency of monitoring (e.g. each reception)

Corrective actions

52. The FBO should develop corrective action procedures as relevant to the business that are implemented when a non-compliance is identified. Procedures could include:

    - who is responsible;
    - immediate action to be taken;
    - any product disposition to be considered;
    - any escalating response needed to competent authority;
    - any action to prevent reoccurrence; and
    - records to be kept.

Verification of GHP

53. The FBO should develop verification procedures as relevant to the business, which ensure that GHP procedures have been implemented effectively, monitoring is occurring and that appropriate corrective actions are taken when requirements are not met. Procedures could include:

    - who is responsible;
    - review of GHP procedures, monitoring, corrective actions and records;
    - review when any changes occur to the product, process and other operations associated with the business; and
    - the verification records to be kept.

MANAGEMENT OF FOOD HAZARDS

Note for EWG Management of food hazards is central to everything so consider re-ordering section I so this moves to after the primary production section. Need to include examples from primary production and retail in paras below text amended to delete references to enhanced GHPs not being included. Include key points in Annex on [hazard analysis] or [hazard review]. Points should be adapted so they are more applicable to all businesses. This text is similar to the HACCP requirements at the moment though agree that Control of Food Hazards belongs in Control of Operations. Appropriate examples and views requested.

Note to EWG: CCFH49 agreed that guidance on carrying out a [hazard analysis][review of hazards] should be developed and included in the guidance to support this section

54. GHPs manage many food hazards which could contaminate food products, e.g. persons who handle food at harvest, during manufacturing and during preparation; raw materials and other ingredients purchased from suppliers; cleaning and maintaining the work environment; storage and display. As stated earlier all businesses should review operations and potential hazards to determine whether the application of GHPs is sufficient to manage the food hazards associated with the operation.

55. Where GHP is determined as being unable to reduce the food hazard to an acceptable level, a food safety control system based on HACCP should be implemented and this is discussed further in [Chapter 2].

KEY ASPECTS OF FOOD HYGIENE SYSTEMS

Note for EWG This section needs development. Some of the references are closer to HACCP than GHP. Text should be more general and remove words like 'critical'? Also need to include examples. e.g. storing raw materials and ingredients according to instructions, or (for primary production) appropriate chill temperatures. Could also add an overarching comment about monitoring devices in monitoring and validation as this applies to all devices not just temperature recording devices. Examples and views requested.[Japan15]

Note:[Japan16] title may need amending in line with text as it develops. Restructuring of sections and additional sections on Humidity control and control of air have been suggested and should be discussed further

Time and temperature control

56. Inadequate food temperature control is one of the most common hygiene failures. This allows survival or growth of microorganisms that are causes of foodborne illness or food spoilage. Such controls include time and temperature control during cooking, cooling, processing and storage. Systems should be in place to ensure that time and temperature is controlled effectively where it impacts the safety and suitability of food.

57. Time and 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 microorganisms such as pathogenic and spoilage microflora;
- 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.

58. Such systems should also specify tolerable limits for time and temperature variations. Temperature control systems that impact safety and suitability of food should be monitored. Temperature monitoring and recording devices should be checked for accuracy and calibrated as needed.

Specific process steps

Note to EWG: Original text from CAC/RPC1–1969 has been deleted as this is covered in specific codes.

Formulation

59. The composition of a food, e.g. adding preservatives such as acids, salts or sugars, can be useful in preventing growth and toxin production by microorganisms. When formulation is used to control foodborne pathogens (e.g., adjusting the pH or water activity to a level that prevents growth), systems should be in place to ensure that the product is formulated correctly.

Microbiological[4], Chemical and Physical Contamination

Note for EWG: Consider expanding to indicate how specifications can help with GHP e.g. setting specifications for ingredients. Further discussions required to reach agreement on the Title and text at para 61. Para 62 – use of the work 'Particularly' high may be misleading and lead to FBOs not applying appropriate controls. Views requested.

60. Where microbiological, chemical or physical specifications are used in the control of food safety or suitability, such specifications should be based on sound scientific principles and state, where appropriate, monitoring procedures, analytical methods and acceptable limits. Specifications can help ensure that raw materials and other ingredients are fit for purpose and contaminants have been minimized to the extent possible. FBOs should consider that when the initial contamination level in raw material is low (e.g. 10^3 cfu/g), the required degree of heat treatment (in this care, for example, 5 log reduction) is also low

Microbiological cross-contamination

61. Microbiological contamination occurs thorough the transfer of microorganisms from one food to another, either by direct contact or indirectly by food handlers, or by contact with surfaces, from cleaning equipment, or via splashing or airborne particles. Raw, unprocessed food, which could pose a contamination risk, should be effectively separated from ready-to-eat foods, either physically or by time, with effective intermediate cleaning and where appropriate disinfection.

[4] Refer to the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CAC/GL 21- 1997).

62. In some food operations, access to processing areas may need to be restricted or controlled for food safety purposes. Where risks are high, access to processing areas should be only via a clothes and shoes changing facility. Personnel may be required to put on clean protective clothing (which may be of a differentiating colour from other parts of the facility), including footwear and wash their hands before entering.

63. Surfaces, utensils, equipment, fixtures and fittings should be thoroughly cleaned and where necessary disinfected after raw food preparation, particularly when raw materials with a high microbiological load such as meat and poultry and fish have been handled or processed.

Physical contamination

Note for EWG: The needs section to be developed as physical contamination is not only an issue for manufacturing and processing. It can also be an issue at all stages of the food chain e.g. bale twine being carried through production, rodents or insect infestation [Japan17] in produce/raw materials). Need to add a comment about choking [Japan18]. [Japan19]

64. Systems should be in place to prevent contamination of foods by extraneous materials, especially any hard or sharp object(s) e.g. glass, metal shards, bone(s), rubber plastic. In manufacturing and processing, suitable prevention strategies such as maintenance and regular inspection and detection or screening devices should be used where necessary. Procedures should be in place for food handlers to follow in the case of breakage (e.g., breakage of glass or plastic containers, metal equipment.

Chemical contamination

Note to EWG: Text to be developed to give equal prominence to chemical contamination and guidance on control of chemicals used in premises, additives, veterinary residues and checks on incoming materials etc. Views requested [Japan20].

65. Systems should be in place to prevent contamination of foods by harmful chemicals, e.g. cleaning materials, non-food grade lubricants, etc. Toxic cleaning compounds, disinfectants, and pesticide chemicals should be identified, stored and used in a manner that protects against contamination of food, food contact surfaces, and food packaging materials. Food additives that may be harmful if used improperly should be controlled so they are only used as intended.

Allergenic Contamination

Note for EWG: New text has been proposed in response to CCFH comments. Text should be developed further e.g. considering the examples of allergens, references to precautionary labelling and supplier management programmes and verification through audit to ensure consistency with sections on other contamination. This text should be developed including stages of the food chain to address in the hazard review/analysis e.g. agricultural cross contamination, storage of ingredients the COP for allergens under CCFH will be covering primary production]. CCFH is developing guidance on management of food allergens to complement this section of the GPFH. We recommend leaving the details of allergen

management to that document. Depending on the timing of the document, we may be able to cross-reference it here.[Japan21]

66. Hazard identification should take into account the allergenic nature of some foods. Presence of allergens e.g. nuts, milk, eggs and cereals containing gluten (not an inclusive list) should be identified in raw materials, other ingredients and products. A system of allergen management should be in place starting from receipt of foods that are or that contain allergens, during processing, and during storage of food products. Controls should be put in place to prevent their presence in foods where they are not labelled. Controls to prevent cross-contamination from foods containing allergens to other foods should be implemented e.g. separation either physically or by time (with intervening cleaning between foods with different allergen profiles. Where cross-contamination cannot be prevented despite well-implemented GHPs, consumers should be informed.

INCOMING MATERIALS

Note for EWG: Include examples here e.g. seeds for sprouting or planting RTE crops. Also add reference to setting specifications and verifying that these are being met either by assurances from the supplier or own checks Sprouts are adequately covered by the Code of Hygienic Practice for Fresh Fruits and Vegetables and its Sprouts Annex. Views and examples requested.[Japan22]

67. Only raw materials and other ingredients that are fit for purpose should be used. Incoming materials including food ingredients should be procured according to specifications and their compliance with food safety and suitability specifications should be verified where necessary. Incoming raw materials or other ingredients should, where appropriate, be inspected (e.g. visual check of damages of packages during transportation, or temperature for refrigerated and frozen foods, use by date, and declared allergens) and sorted before processing. Where necessary, laboratory tests should be conducted to verify food safety and suitability of raw materials or ingredients (e.g. the compliance against specifications). Microbiological sampling and testing of incoming materials should be performed based on the principles and guidelines in the CAC GL 21, PRINCIPLES AND GUIDELINES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA RELATED TO FOODS , These tests may be conducted by a supplier that provides a Certificate of Analysis, the purchaser, or both. No incoming material should be accepted by an establishment if it is known to contain chemical, physical or microbiological contaminants which would not be reduced to an acceptable level by controls applied during sorting and/or where appropriate processing. Stocks of raw materials and other ingredients should be subject to effective stock rotation.

PACKAGING

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

WATER

Note: EWG has developed the Original text from CAC/RPC1–1969 in paras 51 to 58. However. it should be further developed taking account of information from FAO/WHO consideration of water e.g. reference could be made to FAO/WHO guidance as far as possible and basic information provided here with references to specific commodity codes[HT23].

Water supply

69. An adequate supply of potable water and/or clean water with appropriate facilities for its storage, distribution and temperature control, should be available whenever necessary to ensure the safety and suitability of food. Potable water should meet the requirements as specified in the latest edition of WHO Guidelines for Drinking Water Quality, or water of a higher standard.

70. Non-potable water (for use in, for example, fire control, steam production, refrigeration and other similar purposes where it would not contaminate food), should have a separate system. Non-potable and clean water systems should be identified and should not connect with, or allow reflux into, potable water systems.

Water in contact with food

71. The quality of water used in primary production should be suitable for its intended purpose. For additional information on water for primary production see relevant codex texts e.g. the *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003) and *Code of Practice for Fish and Fishery Products* (CAC/RCP 52-2003).

72. Only potable water should be used in food handling and processing, except in certain food processes, e.g. chilling, and in food handling areas, where this does not constitute a hazard to the safety and suitability of food (e.g. the use of clean sea water or clean water).

73. [Clean] water recirculated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use. The treatment process should be effectively monitored. 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

74. Potable water should be used to avoid food contamination. The potable water may be treated where this is required by the production process.

Ice and steam in direct contact with food

Note to EWG – need to consider ice made from sea water. Views requested.[Japan24]

75. Ice [in direct contact with food] should be made from potable water. Ice should be produced, handled and stored so they are protected from contamination.

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

MANAGEMENT AND SUPERVISION

Note to EWG: Original text from CAC RPC1-1969 from this section has been moved to training and management

DOCUMENTATION AND RECORDS

77. Appropriate records of processing, production and distribution should be kept and retained for a period that exceeds the shelf-life of the product or as determined by the Competent Authority. Documentation can enhance the credibility and effectiveness of the food hygiene system and demonstrate that all reasonable care and due diligence has been taken to protect the health of consumers

RECALL PROCEDURES

Note for EWG: Expanded to add link to deviation from controls and indicate that failure to apply GHP effectively can result in food recalls.

78. Managers should ensure effective procedures are in place to respond to any deviation from GHP controls. Failure to apply the controls effectively should be assessed for the impact on food safety or suitability. Procedures should enable the comprehensive, rapid and effective recall of any food from the market that may pose a risk to public health. Where a product has been recalled because of an immediate health hazard, other products which are produced under similar conditions which may also present a risk to public health should be evaluated for safety and may need to be recalled. The need for public warnings should be considered.78 bis, Recall procedures should be documented

and maintained, and modified where necessary based on the findings of periodic field trials etc. [Japan25]

79. Provision should be made so recalled products can 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 reduce the hazard to an acceptable level.

SECTION III: ESTABLISHMENT MAINTENANCE, SANITATION AND PEST CONTROL

OBJECTIVES:

To establish effective systems that:

- ensure adequate sanitation i.e cleaning and if necessary disinfection;
- ensure adequate pest control
- ensure waste management

monitor effectiveness of sanitation, pest control and waste management procedures

RATIONALE:

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

General

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

    • facilitate all sanitation (i.e., cleaning and, where appropriate, disinfection) procedures;

    • function as intended; and

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

81. Cleaning should remove food residues and dirt which may be a source of contamination, including with allergens. The necessary cleaning methods and materials will depend on the nature of the food business, the food type and surface to be cleaned. Disinfection may be necessary after cleaning.

82. 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 during cleaning operations. Cleaning products suitable for food contact surfaces should be used in food preparation areas.

83. Cleaning and disinfection chemicals should be handled and used carefully and in accordance with manufacturers' instructions, for example, using the correct dilutions and contact times, and stored, where necessary, separated from food, in clearly identified containers to avoid the risk of contaminating food.

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

Sanitation procedures and methods

85. Cleaning can be carried out by the separate or the combined use of physical methods, such as heat, scrubbing, turbulent flow and vacuum cleaning or other methods that avoid the use of water, and chemical methods using solutions of detergents, alkalis or acids. Dry cleaning or other appropriate methods for removing and collecting residues and debris may be needed in some operations and/or food processing areas where water enhances the risk of microbiological contamination. Care should be taken to ensure cleaning procedures do not lead to contamination of food e.g. spray from pressure washing can spread contamination from dirty areas such as floors and drains over a wide area and contaminate food contact surfaces or exposed food.

86. Cleaning procedures will involve, where appropriate:

    - removing gross visible debris from surfaces;
    - applying a detergent solution to loosen soil and bacterial film (cleaning); and
    - rinsing with water (hot water where appropriate) to remove loosened soil and residues of detergent.

Where necessary, cleaning should be followed by chemical disinfection with subsequent rinsing unless the manufacturer's instructions indicate on scientific basis that rinsing is not required. Concentrations of chemicals used for disinfection should be appropriate for use and applied according to manufacturers' instructions.

Sanitation (Cleaning and Disinfection) Procedures

87. Cleaning and disinfection procedures should ensure that all parts of the establishment are appropriately clean, and should include the cleaning of cleaning equipment. Where appropriate, programmes should be drawn up in consultation with relevant specialist expert advisors

88. Where written cleaning and disinfection programmes are used, they should specify:

- areas, items of equipment and utensils to be cleaned, and, where appropriate, disinfected;
- responsibility for particular tasks;
- method and frequency of sanitation and, where appropriate, disinfection; and
- monitoring and verification activities.

Monitoring Effectiveness

Note for EWG: Add in text about periodic review with suppliers to make sure cleaning agents continue to be appropriate. Text amended to reflect requirements for SLDBs. Microbiological sampling and testing is an unreasonable expectation for some businesses and in some cases unnecessary. This can be expanded with more examples e.g. including rapid testing kits. Need to consider redrafting following discussion.[Japan26]

89. Application of sanitation procedures should be monitored for effectiveness and periodically verified by means such as audits and visual inspections to ensure they are applied. properly. The type of monitoring of sanitation programmes will depend on the nature of the procedures, but could include pH, water temperature, conductivity, cleaning agent concentration, disinfectant concentration, and other parameters important to ensuring the programme is being implemented as designed. Microorganisms can develop resistance to cleaning agents and the food production environment can change over time so periodic review with cleaning agent suppliers will help ensure cleaning agents used are effective and appropriate. While effectiveness of cleaning agents and instructions for use will be validated by cleaning agent manufacturers, microbiological sampling and testing of the environment and food contact surfaces can help verify that sanitation programmes are effective and being applied properly. Microbiological sampling and testing may not be appropriate in all cases and an alternative approach might include observation of cleaning procedures to make sure protocols are being followed. Sanitation and maintenance procedures should be regularly reviewed and adapted to reflect any changes in circumstances and documented as appropriate.

PEST CONTROL SYSTEMS

General

90. Pests (e.g. birds, rodents, insects etc.) 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 building design, layout and location, sanitation, inspection of incoming materials and good monitoring can minimize the likelihood of infestation and thereby limit the need for pesticides.

Preventing access

91. 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

92. 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, unused equipment should be removed.

Monitoring and detection

Note: Consideration should be given to expanding the text to include more details on monitoring and detection including where this is outsourced e.g. attention to key areas of infestation, main pests and trends.

93. Establishments and surrounding areas should be regularly examined for evidence of infestation. Detectors and traps [e.g. insect light traps, baits stations] should be designed and located so as to prevent potential contamination of raw materials, products or facilities. Even monitoring and detection are outsourced, FBO should review the report of monitoring, if necessary, take corrective action (e.g. eradication of pests, elimination of harbour sites, or invasion routes) by the FBO or designated pest control operators.

Eradication

94. 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

95. Suitable provision should be made for the removal and storage of waste. Waste [should as far as possible be collected in covered containers and should] 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.

96. Waste stores should be kept appropriately clean and free of pests and be resistant to pest infestation].

MONITORING EFFECTIVENESS

Note: Original text from CAC RPC-1 1969 has been moved to section on cleaning

SECTION IV: PERSONAL HYGIENE

OBJECTIVES:

To ensure that those who come directly or indirectly into contact with food:

- Maintain appropriate personal health;
- maintain an appropriate degree of personal cleanliness; and
- behave and operate in an appropriate manner.

Note to EWG – para 97 Added to clarify expectations.

97. Food businesses should establish policies and procedures for personal hygiene and ensure all personnel are aware of the importance of personal hygiene and expectations of controls that need to be applied.

Health Status

Note for EWG: Para 97 - Develop the text to provide some more guidance to the business what to do when the personnel report illness. E.g. some injuries can be protected with suitable dressings/covering. Although this addressed in para 100). Also for gastro-intestinal illness workers should generally be excluded/prevented from handling RTE foods for foods for [48hrs] after symptoms stop and some may need additional restrictions. This may be too prescriptive but there should at least be a general requirement indicating action should be based on medical advice. Relevant to para 100 too, however the time restrictions are complicated and depend on the type of illness; this would be too prescriptive for a Codex document. We may be able to craft some general text. Views requested

97. People known, or suspected to be suffering from or to be a carrier of a disease or illness [communicable disease] 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.

98. . For some illnesses, it may be necessary for food handlers to get medical clearance before returning to work.

Illness and Injuries

99. 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.

100. Cuts and wounds, where personnel are permitted to continue working, should be covered by suitable waterproof plaster and hand gloves[HT27].

Personal Cleanliness

101. Food handlers should maintain a high degree of personal cleanliness and, where appropriate, wear suitable protective clothing, head and beard covering, and footwear. Measures should be implemented to prevent cross-contamination by food handlers through adequate hand washing and, where necessary, wearing gloves. If gloves are worn, appropriate measures will also need to be applied to ensure the gloves do not become a source of contamination.

102. Personnel, including those wearing gloves, should clean their hands regularly, especially when personal cleanliness may affect food safety, in particular:

- at the start of food handling activities;
- immediately after using the toilet; and

• after handling any contaminated material, such as waste or raw and unprocessed foods where this could result in contamination of other food items

103.. In order to clean the hands, it is recommended to was them with soap and water by wetting hands with water and applying sufficient soap to cover all surfaces. Rinse hands with clean, running water and dry thoroughly with a single-use towel or other method that does not re-contaminate hands. Multiple use cloth drying towels should not be used. Hand sanitizers should not replace hand washing and should be used only after hands have been washed.

Personal Behaviour

104. 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.

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

Visitors

106. Visitors to food businesses, and in particular, to food manufacturing, processing or handling areas, should, where appropriate, wear protective clothing and adhere to the other personal hygiene provisions in paras 79-87.

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 hygiene practices are taken during transport, even where adequate hygiene practices have been taken earlier in the food chain.

General

107. Food should 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

108. 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 unsafe or unsuitable for consumption; and
- allow any necessary temperature, humidity and other conditions to be checked.

Use and Maintenance

109. 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.

110. 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.

SECTION VI: PRODUCT INFORMATION AND CONSUMER AWARENESS

Note: Consideration should be given to expanding the Objectives and Rational to include allergens

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;
- allergic consumers can identify allergens present in foods; and
- the lot or batch can be easily identified and recalled if necessary.

Consumers should be given enough knowledge of food hygiene to enable them to:

- be aware of the importance of reading and understanding the label.
- 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. Insufficient product information about the allergens in food can also result in allergic consumers becoming ill.

Lot identification

111.. 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. The *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) applies.

112. 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 recall of the products, where necessary.

Product Information

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

Product Labelling

114. 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. This should also include information that identifies food allergens in the product as ingredients or where cross-contact cannot be excluded. The *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) applies.

Consumer Education

Note for EWG: Consider whether we need this section as it seems a little out of place in comparison to the rest of the document – could paras 114 and 115 be merged?

115.. 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; foodborne illness and the presence of allergens.

SECTION VII: TRAINING

OBJECTIVE:

All those engaged in food operations in contact with food or in proximity should understand food hygiene to ensure competence 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

116. 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.

Training Programmes

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

- the nature and risk of the food, in particular its ability to sustain growth of pathogenic or spoilage microorganisms;
- 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.

Instruction and Supervision

118. 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/or 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.

119. 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. Personnel tasked to monitor the equipment used in food control should be trained adequately to ensure that they are competent to perform their tasks and are aware of the impact of their tasks to the safety and suitability of the food.

Refresher Training

120. 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.

[CHAPTER TWO]

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

PREAMBLE

121. The first part of this [Chapter] sets out the seven principles of the Hazard Analysis and Critical Control Point (HACCP) system. The second part provides general guidance for the application of the system while recognizing that the details of application may vary and a more flexible approach to application may be appropriate depending on the circumstances and the capabilities of the food operation.

122. The HACCP system, which is science based and systematic, identifies specific hazards and measures for their control to ensure the safety of food. HACCP is a tool to assess hazards and establish control systems that focus on prevention of hazards rather than relying mainly on end-product testing. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments.

Note to EWG: Para 123 – need to seek views [Japan28]on to what extent HACCP can be applied to primary production

123. HACCP can be applied throughout the food chain from primary production to final consumption with certain flexibility as necessary and its implementation should be guided by scientific evidence of risks to human health. As well as enhancing food safety, implementation of HACCP can provide other significant benefits, such as more efficient processes based on a thorough analysis of capability, more effective use of resources by focusing on critical areas, and fewer recalls through identification of problems before product is released. In addition, the application of HACCP systems can aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety.

124. The successful application of HACCP requires the strong commitment and involvement of management and the work force. It also requires a multidisciplinary approach; this multidisciplinary approach should include, when appropriate, expertise in agronomy, veterinary health, production, microbiology, public health, food technology, environmental health, chemistry and engineering, according to the particular application. The application of HACCP is the system of choice in the management of food safety within such systems.

Note to EWG: Text has been added introduce flexibilities for small businesses. This should be developed further and supported by examples of adaptations that can be made and by drawing on existing guidance. Views and examples requested

125. Barriers to the application of HACCP in small and less developed businesses (SLDBs) have been acknowledged and flexible approaches to the implementation of HACCP in such businesses, are described in the FAO/WHO Guidance to governments on the application of HACCP in SLDBs[5]. It provides ways to adapt the HACCP approach to assist competent authorities in supporting SLDBs, for example, development of a HACCP-based system which is consistent with the seven principles of HACCP but does not conform to the layout or steps described in this section, e.g. recording only noncompliance monitoring records instead of every monitoring results to reduce unnecessary heavy burden of record keeping for certain types of FBOs[HT29] .

DEFINITIONS

Note to EWG: Consideration should be given to moving all definitions to a single section in the document. Agree Definitions to be developed as drafting progresses.

Control (verb): To take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

Control (noun): The state wherein correct procedures are being followed and criteria are being met.

Control measure: Any action and activity that can be used to maintain compliance with GHP, if necessary, and HACCP procedures

Note for EWG: Given the previous 2 definitions, a 'control measure' must have compliance criteria. [Japan30] –Further discussion needed on Hazard control measure below. Views requested

[***Hazard control measure***[Japan31]]: (to be developed) [suggestion that this be "a control measure for a significant hazard, [may not longer be needed following drafting changes]

Corrective action: Any action taken when a deviation occurs in order to correct a problem and minimize the potential for it to reoccur.

[5] FAO/WHO. Guidance to governments on the application of HACCP in small and/or less-developed food businesses. FAO Food and Nutrition Paper 86. 2006.

Critical Control Point (CCP): A step at which a control measure is essential against a significant(s) hazard(s). can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical limit: A criterion which separates acceptability from unacceptability.

Deviation: Failure to meet a critical limit.

Flow diagram: A systematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

HACCP: A system which identifies, evaluates, and controls hazards which are significant for food safety.

HACCP 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.

Hazard: [Japan32]A biological, chemical or physical agent in [, or condition of,] food with the potential to cause an adverse health effect.

Hazard analysis: The process of collecting and evaluating information on hazards identified in the environment, in the process or in the food, and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan.

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Step: A point, procedure, operation or stage in the food chain including raw materials, from primary production to final consumption.

Validation: Obtaining evidence that hazard control measures, if properly implemented, are capable of controlling hazards to an acceptable level.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring to determine whether a control measure has been operating as intended.

PRINCIPLES OF THE HACCP SYSTEM

The HACCP system consists of the following seven principles:

PRINCIPLE 1

Conduct a hazard analysis.

PRINCIPLE 2

Determine the Critical Control Points (CCPs).

PRINCIPLE 3

Establish critical limit(s).

PRINCIPLE 4

Establish a system to monitor control of the CCP.

PRINCIPLE 5

Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

PRINCIPLE 6

Establish procedures for verification to confirm that the HACCP system is working effectively.

PRINCIPLE 7

Establish documentation concerning all procedures and records appropriate to these principles and their application.

GUIDELINES FOR THE APPLICATION OF THE HACCP SYSTEM

Note to EWG: The text in paras 6-45 has been developed to some extent but further consideration is required to clarify the relationship between the 12 step plan and GHP as some of the steps are also applicable to a lesser extent GHP-based systems. It is likely that some text will move into the Introduction or [Chapter 1]. Also, further discussions are required on whether the 12 step flow chart is still appropriate, and how to incorporate flexibilities for SLDBs.

INTRODUCTION

126. Prior to application of HACCP to any sector of the food chain, that sector should have in place GHPs according to Chapter I of this document, the appropriate product and sector-specific Codex Codes of Practice, and appropriate food safety requirements set by competent authorities. These prerequisite programmes to HACCP, including training, should be well established, fully operational and verified in order to facilitate the successful application and implementation of the HACCP system. HACCP application will not be effective without prior implementation of GHPs.

127. For all types of food business, management awareness and commitment are necessary for implementation of an effective HACCP system. The effectiveness will also rely upon management and employees having the appropriate HACCP knowledge and skills.

128. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration should be given to the impact of raw materials

and other ingredients, food production practices, food manufacturing practices (including whether manufacturing processes control hazards or result in hazards requiring control), likely end-use of the product, categories of consumers of concern, and epidemiological evidence relative to food safety.

129. HACCP is a systematic approach that enhances control of specific food safety hazards, where necessary, over that achieved by the GHPs that have been applied by the establishment. The intent of the HACCP system is to focus control at Critical Control Points (CCPs). Redesign of the operation should be considered if a [food safety] hazard which must be controlled is identified but no control measures are found. As described in the GHP Section, food hazards may be controlled adequately by GHP-based control measures.

130. HACCP should be applied to each individual operation separately. CCPs identified in any given example in any Codex Code of Hygienic Practice might not be the only ones identified for a specific application or might be of a different nature.

131. The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step.

Flexibility for small and/or less developed food businesses

132. The application of the HACCP principles should be the responsibility of each individual business. However, it is recognised by competent authorities and FBOs that there may be obstacles that hinder the effective application of the HACCP principles by individual businesses. This is particularly relevant in small and/or less developed businesses. While it is recognized that when applying HACCP, flexibility appropriate to the business is important, all seven principles should be applied in the HACCP system. This flexibility should take into account the nature [and size] of the operation, including the human and financial resources, infrastructure, processes, knowledge and practical constraints, as well as the risk associated with the produced food.

133. Small and/or less developed businesses do not always have the resources and the necessary expertise on site for the development and implementation of an effective HACCP plan. In such situations, expert advice should be obtained from other sources, which may include: trade and industry associations, independent experts and competent authorities. HACCP literature and especially sector-specific HACCP guides can be valuable. HACCP guides developed by experts relevant to the process or type of operation may provide a useful tool for businesses in designing and implementing a HACCP plan. Where businesses are

using expertly developed HACCP guides, it is essential that it is specific to the foods and/or processes under consideration.[6]

134. The efficacy of any HACCP system will nevertheless rely on management and employees having the appropriate HACCP knowledge and skills, therefore ongoing training is necessary for all levels of employees and managers, as appropriate to the food business.

APPLICATION

135. The application of HACCP principles consists of the following tasks as identified in the [Logical Sequence for Application of HACCP] (Diagram 1).

Assemble HACCP Team (Step 1)

136. The food business operator should assure that the appropriate product specific knowledge and expertise are available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team that includes individuals conducting different activities within the operation, e.g., production, maintenance, sanitation.

137. Where such expertise is not available on site, expert advice should be obtained from other sources, such as trade and industry associations, independent experts, competent authorities, HACCP literature and HACCP guides (including sector-specific HACCP guides). It may be possible that a well-trained individual with access to such guidance is able to implement HACCP in-house. Generic HACCP plan developed externally may be used by FBOs where appropriate but should be tailored to the food operation.

138. The HACCP team should identify the scope of the HACCP system and are responsible for writing the HACCP plan. The scope should describe which segment of the food chain is involved and the general classes of hazards (biological, chemical, physical) to be addressed (e.g. does it cover all classes of hazards or only selected classes).

Describe product (Step 2)

139. A full description of the product should be drawn up, including relevant safety information such as composition, physical/chemical characteristics (including a_w, pH, preservatives etc.), microbiocidal/static treatments (heat-treatment, freezing, brining, smoking, etc.), packaging, durability/shelf life, 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

[6] FAO/WHO Guidance to governments on the application of HACCP in SLDBs.

the purpose of development of the HACCP plan. Any limits already established for food safety hazards should be considered and accounted for in the HACCP plan, e.g. limits for food additives, regulatory microbiological criteria, maximum allowed veterinary medicines residues and times and temperatures for heat treatments prescribed by competent authorities.

Identify intended use (Step 3)

140. The intended use should be based on the expected uses of the product by the end user or consumer. In specific cases, vulnerable groups of the population, e.g. institutional feeding, may have to be considered.

Construct flow diagram (Step 4)

The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the operation for a specific product. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation. The flow diagram should indicate all the flows, including those of ingredients, personnel, water and air. The flow diagrams should be used when conducting the hazard analysis as a basis for evaluating the possible occurrence, increase, decrease or introduction of food safety hazards[HT33]. Flow diagrams should be clear, accurate and sufficiently detailed to the extent needed to conduct the hazard analysis. Flow diagrams should, as appropriate, include but not limited to the following:

a) the sequence and interaction of the steps in the operation;

b) any outsourced processes;

c) where raw materials, ingredients, processing aids, packaging materials, utilities and intermediate products enter the flow;

d) where reworking and recycling take place;

e) where end products, intermediate products, by-products and waste are released or removed.

On-site confirmation of flow diagram (Step 5)

141. Steps should be taken to confirm the processing activity against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. The confirmation of the flow diagram should be performed by a person or persons with sufficient knowledge of the processing operation.

List all potential hazards associated with each step, conduct a hazard analysis to identify the significant hazards, and consider any measures to control identified hazards (Step 6 and Principle 1)

Note to EWG: This section needs to be developed following further discussions on the extent to which all businesses need to carry out a hazard analysis and should build on text provided in the GHP Section. This should draw on guidance in existing Codex documents e.g. CAC/GL 63 2007

142. Hazard analysis consists of identifying potential hazards and evaluating these hazards to determine which hazards are significant for the specific food business operation therefore to be controlled[HT34]. The HACCP team should list all of the potential hazards that may be reasonably expected to occur at each step according to the scope of the food business operation. To identify potential hazards that may be associated with ingredients, "receiving" the ingredients can be considered as the step.

143. The HACCP team should next evaluate the hazards to identify which of these potential hazards are of such a nature that their prevention or reduction to acceptable levels is essential to the production of safe food (i.e., determine the significant hazards that need to be addressed in a HACCP plan.

144. In conducting the hazard analysis (i.e., hazard identification and hazard evaluation) to determine whether there are significant hazards, wherever possible the following should be considered:

a. hazards historically associated with the type of food or its ingredients (e.g., from surveys or sampling and testing of hazards in the food chain, from recalls, or from information in the scientific literature);

- adverse health effects (including their severity) historically associated with the hazards in the type of food or its ingredients;[7]
- the likely occurrence of hazards;
- the nature of the equipment used in making a food product

b. survival or multiplication of microorganisms of concern;

c. production or persistence in foods of toxins (e.g., mycotoxins), chemicals (e.g., pesticides, drug residues) or physical agents (e.g., glass, metal); and,

d. conditions leading to the above.

[7] *Principles and Guidelines for the Conduct of Microbiological Risk Management* CAC/GL 63-2007.

The hazard analysis should consider not only the intended use, but also any known unintended use (e.g., a soup mix intended to be mixed with water and cooked but known to be used without a heat treatment in flavouring a dip for chips) to determine the significant hazards to be addressed in the HACCP plan

Note to EWG – para 26 and 27 requires review and revision and should maybe be included in Chapter 1. Views requested.

145. In some cases, it may be acceptable for a more simplified hazard analysis to be carried out by FBOs which identifies groups of hazards (microbiological, physical, chemical) in order to control the sources of these hazards without the need for a hazard analysis that identifies the specific hazards of concern. Generic HACCP-based tools and guidance documents provided externally, for example, by industry or regulators, are designed to assist with this step.

146. Hazards which are of such a nature that their elimination or reduction to acceptable levels is essential to the production of safe food (because they are reasonably likely to occur in the absence of control) should be identified and controlled by [control measures] designed to prevent or reduce them to an acceptable level. This may be achieved with the application of good hygiene practices, some of which may target a specific hazard, (for example, cleaning equipment to control contamination of ready-to-eat foods with *Listeria monocytogenes*) or to prevent food allergens being transferred from one food to another food that does not contain that allergen when the two foods are processed on the same equipment. In other instances, control measures will need to be applied at critical control points.

147. Consideration should be given to what control measures, if any exist, can be applied to each hazard. More than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure. For example, to control *L. monocytogenes*, a heat treatment may be needed to kill the organism in the food and cleaning and disinfection may be needed to prevent transfer from the processing environment; a heat treatment can control both *Salmonella* and *E. coli* O157:H7 that present a hazard in raw meat.

Determine Critical Control Points (Step 7 and Principle 3)

[8]

Note to EWG: It has agreed that the current decision tree applied to identify CCPs should be reviewed.

148. There may be more than one CCP at which control is applied to address the same hazard. Similarly, a CCP may control more than one hazard. Determining if the step at which a [control measure] should be applied is a CCP in the HACCP system can be facilitated by the application of a decision tree (e.g., Diagram 2), which indicates a logic reasoning approach. Application of a decision tree should be flexible, given whether the operation is for production, slaughter, processing, storage, distribution or other. Other approaches may be used. Training in the application of the decision tree is recommended.

149. If a hazard has been identified at a step where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

Establish critical limits for each CCP (Step 8 and Principle 3)

150. Critical limits that separate acceptable procedures and products from unacceptable ones should be specified for each Critical Control Point. In some cases more than one critical limit will be elaborated at a particular step (e.g., heat treatments commonly include critical limits for both time and temperature). Criteria often used include minimum or maximum values for critical parameters associated with the control measure such as measurements of temperature, time, moisture level, pH, a_w, available chlorine, contact time, conveyor belt speed, and ,where appropriate, sensory parameters which can be observed, such as a pump setting.

Note to EWG – there is a suggestion to add a para about the ability of control measures to comply with the criterial limits has to be scientifically validated – if not by the fbo by the external expert. Views requested

151. 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.[9] FBOs may not always need to commission studies themselves to validate control measures.

[8]Since the publication of the decision tree by Codex, its use has been implemented many times for training purposes. In many instances, while this tree has been useful to explain the logic and depth of understanding needed to determine CCPs, it is not specific to all food operations, e.g. slaughter, and therefore it should be used in conjunction with professional judgement, and modified in some cases.

[9] *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69-2008).

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.

152. Where HACCP guides developed by experts, instead of the HACCP team, has been used to establish the critical limits, care should be taken to ensure that these limits fully apply to the specific operation, product or groups of products under consideration. These critical limits should be measurable or observable.

Establish a monitoring system for each CCP (Step 9 and Principle 4)

153. 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. 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.

154. If monitoring is not continuous, then the amount or frequency of monitoring should be sufficient to ensure the CCP is in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes and there will not be time for lengthy analytical testing. Physical and chemical measurements are usually preferred to microbiological testing because they may be done rapidly and can often indicate the control of microbial hazards associated with the product.

155. The personnel doing the monitoring should be instructed on appropriate steps to take when monitoring indicates the need to take action. Data derived from monitoring should be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated.

156. All records and documents associated with monitoring CCPs should be signed by the person(s) doing the monitoring and by a responsible reviewing official(s) of the company as a verification of control (see Step 11).

Establish corrective actions (Step 10 and Principle 5)

157. Specific written corrective actions should be developed for each CCP in the HACCP system in order to effectively deal with deviations when they occur.

158. The corrective actions should ensure that the CCP has been brought under control. Actions taken should include segregating the affected product and analysing the safety of the product to ensure proper disposition of the affected product. External experts may be needed to conduct such evaluations. In some cases, the evaluation may indicate that the product is safe and can be released into commerce. In other cases it may be determined that the product could be reprocessed (e.g., re-pasteurized); in other situations the product may need to be destroyed (e.g., contamination with *Staphylococcus* enterotoxin). A root cause analysis should be conducted where possible to identify and correct the source of the deviation in order to minimize the potential for the deviation to reoccur. Details of the corrective actions, including the cause of the deviation and product disposition procedures should be documented in the HACCP record keeping.

Periodic review of corrective actions should be undertaken to identify trends and to ensure corrective actions are effective.

Establish verification procedures (Step 11 and Principle 6)

Note to EWG: Further discussion is required on Validation and Verification to allow this text to be developed further so that appropriate text is included under Principle 1 and here.

159. Establish procedures for individual control measures, as well as the HACCP system as a whole. Verification includes validation, i.e., obtaining scientific and technical evidence that control measures are capable of controlling a hazard, as well as activities to verify on an ongoing basis that the hazard control measures are being implemented as intended (i.e., in accordance with the HACCP plan). Verification also includes reviewing the adequacy of the HACCP system periodically and, as appropriate, when changes occur.

160. Validation is performed during development of the HACCP plan, and, in addition to obtaining the evidence that the control measures are capable of controlling the hazard, includes obtaining evidence in operation during the initial implementation of the HACCP system to show that control can be achieved consistently under production conditions. Validation is applied during the establishment of critical limits to ensure that the appropriate values are chosen. This could include a review of scientific literature, using mathematical models, conducting validation studies, or using safe harbours developed by authoritative sources. Validation is also done on a periodic basis when the plan is reanalysed and when changes indicate the need for re-validation. Validation is described more fully in the *Guidelines for the Validation of Food Safety Control Measures* (CAC/GL 69 – 2008).

161. After validation, verification activities should be performed on an ongoing basis to ensure the HACCP system functions as intended and continues to operate effectively. Verification, which includes observations, auditing, calibration, sampling and testing, and records review, can be used to determine if the HACCP system is working correctly. Examples of verification activities include:

- Review of monitoring records to confirm that CCPs are kept under control;
- Review of corrective action records, including specific deviations, product dispositions and any analysis to determine the root cause of the deviation;
- Calibration or checking the accuracy of instruments used for monitoring and verification;

- Observation that control measures are being conducted in accordance with the plan;
- Sampling and testing, e.g., for microorganisms[10] or chemical hazards such as mycotoxins to verify product safety;
- Sampling and testing the environment for microbial contaminants such as *Listeria*; and
- Review of the HACCP system, including the hazard analysis and the HACCP plan (e.g., internal or third-party audits).

162. Where possible, verification should be carried out by someone other than the person who is responsible for performing the monitoring and corrective actions. Where certain verification activities cannot be performed in house, verification should be performed on behalf of the business by external experts or qualified third parties.

163. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Verification of the implementation of hazard control measures should be conducted with sufficient frequency to determine that the HACCP plan is being implemented properly.

164. Where possible, verification activities should include a comprehensive review (e.g., reanalysis or an audit) of the HACCP system periodically, as appropriate, or when changes occur to confirm the efficacy of all elements of the HACCP system. This review of the HACCP system should confirm that the appropriate hazards have been identified, that hazard control measures and critical limits are adequate to control the hazards, that monitoring and verification activities are occurring in accordance with the plan and are capable of identifying deviations, and that corrective actions are appropriate for deviations that have occurred. This review can be carried out by individuals within a food business or by external experts.

Establish documentation and record keeping (Step 12 and see Principle 7)

165. Efficient and accurate record keeping is essential to the application of a HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation and sufficient to assist the business to

[10] *Principles and guidelines for the establishment and application of microbiological criteria related to food* (CAC/GL21-1997.

verify that the HACCP controls are in place and being maintained. Externally developed HACCP guides (e.g. sector-specific HACCP guides) may be utilised as part of the documentation, provided that those materials reflect the specific food operations of the business.

166. Examples of documentation include

- HACCP team composition
- Hazard analysis;
- CCP determination;
- Critical limit determination;
- Validation of [control measures] [] ; and
- Modifications made to the HACCP plan.

167. Examples of records include:

• CCP monitoring activities;

• Deviations and associated corrective actions; and

168. • Verification procedures performed. An example of a HACCP worksheet for the development of a HACCP plan is attached as Diagram 3. [see Diagram 3 of CAC/RCP 1-1969]

169. A simple record-keeping system can be effective and easily communicated to employees. It may be integrated into existing operations and may use existing paperwork, such as delivery invoices and checklists to record, for example, product temperatures.

TRAINING

170. Training of personnel in industry, government and academia in HACCP principles and applications is an essential element for the effective implementation of HACCP. As an aid in developing specific training to support a HACCP plan, working instructions and procedures should be developed which define the tasks of the operating personnel to in charge of each Critical Control Point.

171. Cooperation between primary producer, industry, trade groups, consumer organisations, and responsible authorities is vitally important. Opportunities should be provided for the joint training of industry and competent authorities to encourage and maintain a continuous dialogue and create a climate of understanding in the practical application of HACCP.

別添 3

Guideline on the management of (micro)biological foodborne outbreaks/crisis

Indhold

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1. Introduction

1. Codex Alimentarius has issued several guidelines on hygienic practice for food businesses on how to ensure food safety. These guidelines focus on e.g. prevention, monitoring and corrective actions in case of deviations in the production processes. Despite all effort to ensure a high level of hygiene it happens that companies fail to comply with the requirements and foodborne outbreaks occur.

2. An increase in the globalized food trade in recent years, extensive production often involving many sites and a complex supply chain all contribute toward an increased number of microbiological food safety breaches and resulting outbreaks. Moreover, the volume of international food trade increases yearly.

3. Foodborne outbreaks can lead to huge socio-economic cost related to e.g. medical treatment, hospitalization and workday losses. For food business companies the consequences can be lost markets, loss of consumer demand, litigation and in the end company closures. Foodborne outbreaks can cause impediments to domestic consumption and international trade.

4. In order to be able to efficiently handle food safety emergencies a cross country and cross institutional network of efficient national and global preparedness against foodborne diseases with standardised methods and standardised interpretation and exchange of results is essential.

5. The principles for risk analysis including risk assessment, risk management and risk communication as described by Codex Alimentarius should form the framework/basis for the establishment of a system for preparedness and management of food safety emergencies.

6. Molecular analytical methods contribute to link clusters of human cases and the food source. The use of more specific genomic methods (e.g. whole genome sequencing) allows earlier detection of outbreaks, an improved management of such incidents and enables to, better narrow the identification of involved batches, and hence reduce the impact of actions taken. It is expected to lead to the reporting of more outbreaks in the future and the need for enhanced preparedness.

7. The phrase “food safety emergency” is used for simplicity throughout the document and covers foodborne outbreaks (regardless of size), crises and emergencies. The decision to categorize an outbreak as a crisis or an emergency is in the remit of the competent authority.

8. This document collects existing guidance for preparedness and management of foodborne outbreaks/crisis with cross-references to relevant documents and includes the use of new technologies in outbreak investigation.

2. Scope

9. The guideline provides guidance to competent authorities on the management of food safety emergencies, including the communication between national [and regional] programmes with INFOSAN. The guidance addresses preparedness, detection, response and recovery with

the intent of limiting the extent of such events. The scope is limited to (micro)biological hazards.

10. Furthermore the document defines the role of competent authorities and collaboration with food business operators and other stakeholders during food safety emergencies.

3. Use

11. The guideline used in conjunction with FA/WHO guidelines gives guidance to competent authorities on preparedness for food safety emergencies and on their management in a coordinated approach with public health authorities.

12. A similar effect can be expected from the World Organization for Animal Health (OIE) standards for the prevention, detection and control of zoonotic agents at the primary production stage.

13. A number of FAO/WHO documents are specifically relevant for the current guideline and should be used in conjunction:
    - Principles and Guidelines for an exchange of information in food safety emergency situations (CAC/GL 19-1995),
    - Principles and guidelines for the conduct of microbiological risk assessment (CAC/GL-30-1999),
    - The FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies[1],
    - The WHO "Foodborne disease outbreaks: Guidelines for investigation and controls"[2],
    - The FAO training handbook on "Enhancing Early Warning Capacities and Capacities for Food Safety"[3],
    - The FAO/WHO framework for developing national food safety emergency response plans[4],
    - The FAO/WHO "Risk Communication applied to food safety handbook"[5],
    - The WHO "Outbreak Communication. Best practices for communicating with the public during an outbreak"[6],
    - The FAO "Food Traceability Guidance"[7],
    - The draft Template for INFOSAN/IHR communication: National protocol for information sharing with national and international partners during food safety events and outbreaks of foodborne illness[8],
    - FAO/WHO guide for development and improving national food recall systems[9].

[1] http://apps.who.int/iris/bitstream/10665/44739/1/9789241502474_eng.pdf?ua=1
[2] http://www.who.int/foodsafety/publications/foodborne_disease/outbreak_guidelines.pdf
[3] http://www.fao.org/3/a-i5168e.pdf
[4] http://www.fao.org/docrep/013/i1686e/i1686e00.pdf
[5] http://www.fao.org/3/a-i5863e.pdf
[6] http://www.who.int/csr/resources/publications/WHO_CDS_2005_32web.pdf
[7] http://www.fao.org/3/a-i7665e.pdf
[8] Not published yet.
[9] http://www.who.int/foodsafety/publications/recall/en/

14. These documents are referred to in the most relevant section(s) of the current guideline, providing more detailed recommendations on specific aspects, but mostly not specific for the prevention and management of food safety emergencies.

4. Definitions

15. Microbiological hazards include bacteria, viruses, yeast, moulds, algae, parasitic protozoa, microscopic parasitic helminths, and their toxins and metabolites.

16. Foodborne outbreak[10]
    a) The observed number of cases of a particular disease exceeds the expected number.
    b) The occurrence of two or more cases of a similar foodborne disease resulting from the ingestion of a common food.

17. Food safety emergency covers foodborne outbreaks (regardless of size), crises and emergencies. Foodborne outbreaks caused by (micro)biological agents can be categorized according to the severity of the outbreak. Criteria for such categorization could be the number of cases and spread of the outbreak; the pathogenicity of the microorganism or if unknown agent; the distribution pattern and volumes of the food and trade implications. The risk management measures chosen will vary according to the situation.

5. Food safety emergency – preparedness system

a. Creation of formalized networks at local and national levels

18. Food safety emergencies happen all the time and vary greatly in size and severity from local outbreaks restricted to a single location to national or international outbreaks.

19. National systems and structures should be in place in order to early detect and effectively manage food safety emergencies and should have sufficient capability and capacity. The system should not be developed in isolation but be based on existing structures in the public health sector and food and veterinary control systems taking into account e.g. surveillance programmes for humans and food, laboratory networks and conditions for food production and distribution.

20. The system and structures need to be described in detail and agreed upon by the participants to ensure cooperation in mutual respect of the competences of each participating authority and agency and allowing for an incident to be managed at the lowest possible administrative level. Advice on how to perform this task is given in more detail in the FAO/WHO framework for developing national food safety emergency response plans.

21. For the system and structures to be operational it is necessary that they are well known by the participants and part of the "daily routines". Depending on the national structures of competent authorities a set of contact points should be appointed at the different levels of administration.

[10] Foodborne outbreak is defined in WHO Foodborne Disease Outbreaks: Guidelines for Investigation and Control, 2008.

- At local level permanent networks between the contact points from the different authorities/agencies should be formed ensuring the exchange of information and management of the incident within and between the networks. The networks should where relevant cooperate with stakeholders and food business operators.
- At central national level a permanent network should be established with senior personnel with experience in the management of food safety emergencies representing their respective authorities/agencies. Inspiration on the composition of such a network can be found in the description of the multiagency coordination group (MACG) described in the FAO/WHO guideline on the framework for developing national food safety emergency response plans. The role of the network should include both the coordination of large food safety emergencies through the network structure and assessing information received from the other levels and participants of the network. The central network may also be the forum where new tools and ways to handle outbreaks can be developed.
- Communication vertically between the local networks and horizontally between the local and central networks is crucial. Communication structures and practices should be included specifically in the description of the system and procedures for the network and should include the following issues:
  - The information is distributed to and understood by all parties in a timely manner and at the same time.
  - There is only one emissary and receptor in each of the participating agencies and interested parties of official information.
  - All parties know and respect the established formal information channels and these have been previously proven effective.
  - If external groups of experts are used from the agencies and stakeholders to validate the recommendations it is necessary to keep them within their domain of expertise.

b. International alert networks for food and human incidents and exchange of information with them

22. Food safety emergencies do not respect borders either by area of distribution or by origin of the source. What seem a national or regional incident may in fact be a multinational food safety emergency.

23. Regional alert networks for both food and human incidences exist in some regions alongside the International Food Safety Authorities Network (INFOSAN). The central national level of the network should include this issue in their work and actively include the national emergency contact points for these alert networks in their work both for gathering and compiling information and for submitting coordinated information concerning active food safety emergencies.

24. Principles and guidelines for the exchange of information are described in more details in the Codex document CAC/GL 19-1995 as amended and in the Template for INFOSAN/IHR communication (not yet published).

c. Monitoring systems (human, food, establishment environment) and their use in food safety emergencies

25. Most (micro)biological food safety emergencies are triggered by monitoring data from humans since they are linked to (several) human cases, hospitalisations or even deaths and therefore might attract the attention of people (e.g. medical staff) and potentially the press. Monitoring systems should therefore focus on the evaluation of human data. However data from monitoring of animals, food and the environment, including equipment of food businesses may also indicate an enhanced risk and are at least substantial for the detection of the source of the food safety emergency.
    Both types of monitoring are needed to continuously improve food safety along the whole food chain continuum.

26. In order to detect a food safety emergency there is a need for continuous:
    - Monitoring of the "baseline" or "business as usual" situation of (micro)biological hazards in humans;
    - Quick centralisation and distribution of information through early warning systems; disease notification by medical practitioners to competent authorities must be made mandatory to the extent possible.
    - Regular (at least weekly) analyses of the data in order to detect an enhanced number of detections.

27. Unless in case of very rare diseases; there might be a need for molecular testing data of the isolates to detect and demonstrate a link between different cases. The increasing availability of such tests, including genome sequencing, is expected to increase the number of links between cases, and thereby the number of outbreaks, requiring improved preparedness for outbreak management.

28. The use of molecular testing, such as whole genome sequencing, allows the finding of very similar specific molecular profiles (cluster). It may create the suspicion of outbreaks and should trigger further investigations to possibly confirm also an epidemiological link (e.g. common food consumed).

29. The use of databases with information on molecular testing and containing comparable results from human, animal, food and environmental sampling facilitates the detection of outbreaks and the search for the source of the contamination.

30. These monitoring systems are essential tools for detecting foodborne outbreaks. It is necessary to establish structures to exchange information between public health and food safety authorities. These should be used both rutinely and during food safety emergencies and may include:
    - Regular exchange of information between human health sector, competent food authorities and laboratories. The information should include information on new signals from both sectors and follow-up on ongoing outbreaks.
    - Tools for sharing surveillance data and epidemiological information such as databases or data-sharing-sites.

- In order to share surveillance data, it is necessary that data collected are comparable between sectors. Tools for comparing and presenting data, such as phylogenetic tree which can be used if surveillance data is based on genetic methods.
- Sufficient epidemiological data to evaluate the relevance of the source and to make trace back.

31. More details in the FAO “Enhancing Early Warning Capabilities and Capacities for Food Safety, Cap 3 Food Safety Surveillance”

32. More details in the WHO "Foodborne disease outbreaks: Guidelines for investigation and controls".

d. Risk assessment – structures for rapid risk assessment

33. Reference is made to the "Principles and Guidelines for the Conduct of Microbiological Risk Assessment" (CAC/GL 30-1999).

34. A risk assessment in a food safety emergency will improve the quality of the communication and provide a sound scientific basis for the actions to be taken. In a number of cases a ready-to-use risk assessment will be available, however adaptations to the specific outbreak will be required (under time pressure) based on the information from the outbreak investigations. Having structures in place to allow such (rapid) risk/outbreak assessment are therefore an essential part of outbreak preparedness. They include:
    - Lists of risk assessors available with their area of competence;
    - Clearly prepared instructions what is expected for these risk assessors taking into account that short deadline for the assessment;
    - Structure to ensure the direct and immediate submission of information from the outbreak investigations and the possibility to ask additional clarification to the investigators and/or involved food business operators.
    - Availability of information analysis tools e.g. to detect hot spots.

e. Risk communication system/strategy

35. In the context of a microbiological food safety emergency, risk communication will be the exchange of information on the microbiological risk among stakeholders (Government, Academia, Industry, Public, Mass Media and International Organizations) outside the formalized network structure, with the aim to inform and motivate to action.

36. According to the FAO/WHO effective communication is essential and requires preparation in advance of an emergency, and this should include exchange of information with all stakeholders.

37. In terms of risk communication, the preparedness should at least consider;

    - Identify all the Government agencies that may be involved in the response at some level and establish and designated official channels of communication within a food safety emergency.
    - Establish a communication strategy among participating agencies and designate an official spokesperson from the government or central network to the public. Where it

is possible, the jurisprudence of each of the government agencies should be taken into account to set the roles of each one in the risk communication strategy.

- Establish appropriate channels of communication when the agencies have local or regional offices within the country for centralization of the information. This channel should be constantly informed and tested at local and central level.
- Identify all the types of organizations that may be involved and make alliances and partnerships with them to ensure that they will speak in a coordinated manner (using one voice).
- Draft initial messages; specific details can be filled in later. Consider that each population group may have its own characteristics that affect how they perceive risks (Ex. religious belief, traditions), so understanding your audience and test messages to ensure they are culturally and demographically appropriate is important.
- Test established communication strategies in a regular basis to evaluate their efficiency.

6. Food safety emergency - management

a. Identifying and investigating a food safety emergency – human health side

38. Careful description and characterization of the outbreak is an important first step in any epidemiological investigation. Descriptive epidemiology provides a picture of the outbreak in terms of the three standard epidemiological parameters – time, place and person. Further elaboration is described in details in WHOs guideline for outbreak investigation.

39. A foodborne outbreak can be identified by
    - the national surveillance system when a cluster of human cases occur with identical or closely related type of infection and related in type or,
    - the food control authorities when they are informed about illness related to specific products or companies.

40. Depending on the information available a case definition should be created. Cases that fall within the definition should be interviewed to obtain as much information concerning food items consumed prior to illness, place of purchase, etc. If possible, standard epidemiological study methods such as case-control and cohort studies should be used to obtain information in a structured way.

41. Creation of standard questionnaires for this purpose may be performed electronically using one of the internet based free of charge opportunities. Data can then be analyzed electronically in a standard statistical software program. Some of these programs can be downloaded from the internet free of charge.

42. These investigations are described in WHO Guidelines for investigation and control of foodborne outbreaks.

b. Substantiate suspicions and/or handling of a food safety emergency – food safety side

43. Food safety emergencies where a food source or a location has been identified during the epidemiological investigations should be followed by a thorough investigation on site covering all aspects of the production and distribution to substantiate if it is possible that the food source or the location is actually the source of the outbreak. If possible the cause of contamination should be identified and verification by sampling and analyses should be attempted. These investigations are described in WHO Guidelines for investigation and control of foodborne outbreaks.

44. Food safety emergencies where the source of the outbreak is not yet known are challenging. Even if the epidemiological investigations do not reveal a possible source an indication of what could be a possible group of food items causing the outbreak may be possible to establish based on historical outbreak data and the information from the cases concerning food preferences and trade patterns. In these situations further investigation based on the knowledge of especially production, distribution and consumer preferences may be helpful in an attempt to narrow down the possible sources or locations causing the situation.

45. Tracing a food item both backwards and forwards in the food chain is an essential tool in the investigation. The process enables the investigators to see the full distribution of the food item or products made in a single production site. However this possibility is also very resource consuming and should be used only when there is either no other option or when it can be limited to a single food item preferably a few batches of the food item. The information gathered should be compared with the epidemiological information and analytical evidence of the outbreak.

46. If the overall evidence is strong enough that the source of the food safety emergency has been identified the same procedures of tracing back and forward in the food chain should be used recalling the food item/batches of the food item from the consumers thus removing the source of the emergency.

47. Guides for both food business operators and authorities on traceability systems and food recall systems are available in FAO and FAO/WHO guides on the subject.

c. Comparing epidemiological and analytical data (DK)

48. Management of outbreaks requires the human and the food and veterinary sectors to be able to share and compare relevant analytical surveillance data in order to reveal match. It is therefore essential that analytical data are either analyzed with similar methods or analysis results are comparable. For example, for Salmonella, the traditional way of comparing data is by using the Kaufmann-White classification for serotyping. In case of a match in serotypes, supplementary analysis is necessary to determine the probability of relationship. Typing methods often used are pulsed-field gel electrophoresis (PFGE) and multiple-locus variable number of tandem repeat analysis (MLVA).
49. In recent years, genetic based methods like Whole Genome Sequencing (WGS) has become widespread worldwide as a microbial typing tool. These methods have several advantages over traditional typing methods. WGS reveals the entire bacterial genome and provides very

accurate information which makes it possible to determine when isolates are identical and hereby enhances the possibility to identify the source of the emergency.

50. Enough data to ensure traceability of the product sampled should be collected and this should include species, product type, and sampling facility.

51. Food safety emergencies cannot be solved solely based on analytical data but must always be linked to epidemiological data for confirmation.

52. Descriptive epidemiological data such as structured information on food consumed, disease onset, symptoms, duration etc must me collected as part of the food-borne surveillance. If possible an epidemiological study should be performed (cohort or case-control study). Knowledge of epidemiological data in relation to outbreaks is relevant once there is a match.

53. Other tools that can be used together to determine the source of attribution in case of a food safety emergency are sample monitoring, surveillance data, source attribution studies and mathematical modelling. More information on epidemiological tools appear from the WHO guideline on outbreak investigation.

54. Robust epidemiological evidence is strong evidence and may be conclusive of the food safety emergency even without analytical evidence. Analytical evidence can support the epidemiology but will only be conclusive if the result is supported by at least the descriptive epidemiological information obtained from the patients.

d. Risk assessment

55. In most cases, a risk assessment or adaptation of an existing risk assessment to the emergency specific situation should be carried out. Since corrective action is needed urgently, a classical risk assessment might not be possible, but a simplified "outbreak assessment" must be aimed at. It includes:
    - Historical information on the prevalence of the hazard in different food, in particular if the source of the ongoing food safety emergency is not confirmed yet
    - Results from epidemiological and microbiological investigations of human outbreak cases, considering severity, possible mortality, spread of cases and affected subgroups (e.g. elderly).
    - Results from microbiological and epidemiological (including tracing back) investigations
    - Risk characterisation/threat assessment linked to the outbreak
    - Recommendations to the consumers and to competent authorities how to mitigate the risk.

56. Since such risk assessment is likely to be carried out at the beginning of an outbreak, intense interaction should be ensured between the risk assessors and the outbreak investigators (on human cases and on food investigations):
    - To ensure that most recent information is available to the risk assessors
    - To formulate targeted questions
    - To allow the risk assessors to point investigators to gaps of information or hot spots detected, guiding further investigations.

57. More detailed guidance can be found in the FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies.

e. Risk communication

58. This section should be read in conjunction with the FAO/WHO Risk Communication applied to food safety Handbook.

59. Food safety emergencies, start in one country but travel rapidly around the world and requires rapid and clear response in terms of communication.

60. At the beginning of a crisis there will be confusion and intense public and media interest. Ideally, risk communication pursues to provide all the stakeholders outside the formalized network structure with the information they need to make informed decisions.

61. Some good practices that should be considered when elaborating the risk communication message to the public are;
    - Have only one official communicator to the population.
    - Information should be simple and use plain language since public may have limited familiarity with scientific language.
    - Acknowledge the uncertainty and make the recommendations provisional. If there is a need to change the recommendations in the future, it is important to remind the public that earlier recommendations were provisional and to explain why it was changed.
    - Explanation of who the recommendation applies to and who it does not apply to and why.
    - Avoid withholding information just because it is upsetting. If not all the information exists or cannot be released, an explanation of the cause and what is being done to address this situation is important.
    - If it is possible assembly a group of experts to validate the recommendations and keep them within their domain of expertise.
    - Repeat information constantly and try to be timely.
    - Monitor effectiveness of communications and adjust as necessary

f. Documentation of the outbreak

62. It is important to collect and save sufficient information to be able to document all relevant steps in the outbreak both when it is ongoing and afterwards. During the emergency a record should be kept which includes relevant trace back information and descriptive epidemiology, hypothesis and status of the situation. The record must be updated while the food safety emergency is ongoing. When it is over, the record can be finalized to include conclusions and can serve as an outbreak report. Examples of reports and how to prepare them is further described in WHO "Foodborne disease outbreaks: Guidelines for investigation and controls.

63. For the documentation to be of future use to the institutions involved in food safety emergency management they should be kept in a structured way and accessible at all times

for the personnel involved in the work. This could be in the form of a database structure or in a shared file system accessible only to the relevant personnel/competent authorities.

64. Information from the shared system should be reviewed regularly by the competent authorities. The information can be valuable for the food control authorities in targeting official control efforts.

65. Outbreak of special interest should be considered published as scientific publications.

g. Post outbreak monitoring/surveillance

66. In order to evaluate the effect of actions taken and to reassure confidence of consumers and trade partners, enhanced monitoring, rapid centralisation and evaluation of data, in particular of human cases, should be continued until the baseline level has been reach, taking into account:
    - The delays in analysis and reporting;
    - Possible seasonal effect

7. Maintenance of the networks

a. Review of existing preparedness

67. Countries should continuously monitor, evaluate, improve and strengthen their existing network to ensure that it is functioning effectively and efficient. This should include ongoing strategic planning and review of objectives, priorities, needs, gaps, opportunities and challenges, including both internal processes and interagency/ inter-stakeholder relations. The results of such review should be documented and areas pointed out should be addressed to support capability and capacity of the system in place.

68. Evaluation of the local and national network structures can be facilitated by joint training or joint exercises, to focus on specific objectives, priorities, needs, gaps, opportunities and challenges.
    To include actual food safety emergencies structures an “after action review system” need to be implemented into the network.

69. Evaluation of the national permanent network, the member entities of the network and the efficiency of the network should be done on a regularly basis. Restructuring and development in governance system must be reflected in the network.

b. Joint training on food safety emergencies

70. A key part of capability and capacity building is the training of experts and professionals. The training should be expanded across different competent authorities and key stakeholders. The purpose should be to develop a common understanding of the entire system of local national,and international preparedness. As part of the capability and capacity building joint simulation exercises should be put in place.

71. The exercises can aim at control/verification or learning/ development.
    - Control/verification exercises are primarily aimed at testing the participants' skills, for example an expert or professional handling a particular type of method or a procedure in the contingency plan. These exercises should not be notified prior to the execution and can vary in both complexity, length in time and size of organization in number of participants.
    - With learning/development the exercises are more organized with the focus on the participants being required to achieve new competences and capabilities. It may involve roles and responsibilities or development and test of new procedural concepts and plans. Joint simulation exercises is a proven concept in this setting. Learning/ development exercises can be notified and thereby giving the participants the opportunity to prepare, which can optimize the overall outcome and learning.

72. The organization should vary the use of exercise types to include exercises focusing on procedural exercises, dilemma exercises and crisis management exercises. The different type of exercises can achieve different objectives, both in a control/ verification setting and in a learning/ development setting. The exercises can be done both in a live environment like a laboratory or in a table top form.

73. Regardless of type of joint training or exercise it is important that the activity is put into a strategic perspective and that lessons learned are captured and put into a structured reworking of the system.

c. Implementation of lessons learns

74. The evaluation of national preparedness systems can include “after action reviews” of major, serious or rare food safety emergencies. The evaluation should include both competent authorities and agencies and if possible also comments from relevant stakeholders like food business operators. The review should focus on commitment in participation, the use of resources, the sharing of information, and other essential issues. The review should be used to build a stronger system or network on national level.
    The review need to be disseminated in order to spread the lessons learned more broadly within the system. It could be to share information like:

    - What was the most notable success in the management of the emergency that other may learn from?
    - What was some of the most difficult challenges faced and how were they overcome?
    - What changes to the national structure, procedures or analytical methods is recommended?
    - What was not overcome to your satisfaction and what could be done differently next time?

75. The lessons learnt should be included in the ongoing development of capacity and capabilities of the national and local system.

1. Is the structure of the document appropriate?

Yes. We checked if the structure of the current document covers the proposed area described in the table in the project document and found that the basic structure is appropriate. However, some elements (e.g. "outbreak communication") are to be further improved (see the table attached and the answer for Question 5).

2. Should the parenthesis in the headline be deleted so the document only covers management of microbiological foodborne outbreaks?

Yes.

3. Would it be acceptable to add the words "and regional" in "Scope" to acknowledge that some regions e.g. Europe has regional alert systems for communicating both outbreaks and other food crises besides Infosan?

Yes.

4. Is the use of the term "food safety emergencies" for all type of outbreaks feasible regardless of their severity?

No.

We suggest using the existing definition for "food safety emergency" set out in CAC/GL 19-1995.

The scope of this document should be expanded to include not only "food safety emergencies" defined in the GL 19-1995, but also sporadic cases which could trigger diffuse outbreaks that may eventually be categorized as emergency as a result of the investigation. We suggest calling such cases as "potential cases" and giving a new definition for this term in the section.

We propose to amend the title, replacing "crisis/outbreaks" with "food safety emergency and potential cases" which covers emergencies and sporadic cases which could trigger diffuse outbreaks.

5. Is the balance between text and references to underlying documents appropriate?

No.

The new document just picks up the surface of each element and readers need to go back to the original, existing documents. It is not user friendly.

The table in the project document (CX/CAC 18/41/8, Annex IV) can be provided as annex since this table would help the eWG/committee to understand the link between existing FAO/WHO documents and the proposed draft. The fate of the table (i.e. to keep in the

final draft or to delete from the final draft) can be discussed at the later stage.

6. Are there relevant topics that we should address and which do not appear from the document now?

To give better guidance on the application of whole genome sequencing (WGS) in the management of food safety emergency, Japan proposes addressing potential drawbacks and challenges of WGS as well as benefits (see para 6, 27-29 and 49). According to the *Technical background paper: Applications of Whole Genome Sequencing in food safety management* (FAO, 2016), such drawbacks/challenges include cost, data handling, interpretation of data, legal issues *etc*.

http://www.fao.org/documents/card/en/c/61e44b34-b328-4239-b59c-a9e926e327b4/

7. Should we introduce graphic explanations/diagrams in the guideline although this is not normal praxis in codex text e.g. description of the network structures and monitoring?

The introduction of any graphic explanations/diagrams, which are not included in the existing documents and help readers to understand this new guideline, is more than welcome.

Guideline on the management of food safety emergency and potential cases associated with [HT1] (micro)biological hazards~~foodborne outbreaks/crisis~~

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1. Introduction

1. Codex Alimentarius has issued several guidelines on hygienic practice ~~for~~ [m2] ~~food businesses~~ on how to ensure food safety. These guidelines focus on e.g. prevention, monitoring and corrective actions in case of deviations in the production processes. Despite all effort to ensure a high level of hygiene it happens that companies fail to comply with the requirements and foodborne outbreaks occur.

2. An increase in the globalized food trade in recent years, extensive production often involving many sites and a complex supply chain all contribute toward an increased number of microbiological food safety breaches and resulting outbreaks. Moreover, the volume of international food trade increases yearly.

3. Foodborne outbreaks can lead to huge socio-economic cost related to e.g. medical treatment, hospitalization and workday losses. For food business companies the consequences can be lost markets, loss of consumer demand/confidence, litigation and in the end company closures. Foodborne outbreaks can cause impediments to domestic consumption and international trade.

4. In order to be able to efficiently handle food safety emergencies a cross country and cross institutional network of efficient national and global preparedness against foodborne diseases with standardised methods and standardised interpretation and exchange of results is essential.

5. The principles for risk analysis including risk assessment, risk management and risk communication as described by Codex Alimentarius should form the framework/basis for the establishment of a system for preparedness and management of food safety emergencies.

6. Molecular analytical methods [m3] contribute to link clusters of human cases and the food source. The use of more specific genomic methods (e.g. whole genome sequencing) allows earlier detection of outbreaks, an improved management of such incidents and enables to~~,~~ better narrow the identification of involved batches, and hence reduce the impact of actions taken. It is expected to lead to the reporting of more outbreaks in the future and the need for enhanced preparedness.

7. The term~~phrase~~ "food safety emergency" [m4] is defined in CAC/GL 19-1995.~~is used for simplicity throughout the document and covers foodborne outbreaks (regardless of size), crises and emergencies.~~ The decision to categorize an outbreak as a crisis or an emergency is in the remit of the competent authority [m5].

8. This document collects ~~existing~~ guidance for preparedness and management of foodborne outbreaks/crisis with cross-references to relevant documents and includes the use of new technologies in outbreak investigation.

2. Scope

9. The guideline provides guidance to competent authorities on the management of food safety emergencies, including the communication between national [and regional] programmes with INFOSAN. This guideline ~~intends to~~ provides a supplement and a link to documents

developed by FAO/WHO and Codex texts, as appropriate.[m6] The guidance addresses preparedness, detection, response and recovery with the intent of limiting the extent of such events. The scope is limited to (micro)biological hazards.

10. Furthermore the document defines the role of competent authorities and collaboration with food business operators and other stakeholders during food safety emergencies.

3. Use

11. The guideline used in conjunction with FAO/WHO guidelines gives guidance to competent authorities on preparedness for food safety emergencies and on their management in a coordinated approach with public health authorities.

12. A similar[m7] ~~effect can be expected from the World Organization for Animal Health (OIE) standards for the prevention, detection and control of zoonotic agents at the primary production stage.~~

13. A number of FAO/WHO documents are specifically relevant for the current guideline and should be used in conjunction:
    - Principles and Guidelines for an exchange of information in food safety emergency situations (CAC/GL 19-1995),
    - Principles and guidelines for the conduct of microbiological risk assessment (CAC/GL-30-1999),
    - The FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies[1],
    - The WHO "Foodborne disease outbreaks: Guidelines for investigation and controls"[2],
    - The FAO training handbook on "Enhancing Early Warning Capacities and Capacities for Food Safety"[3],
    - The FAO/WHO framework for developing national food safety emergency response plans[4],
    - The FAO/WHO "Risk Communication applied to food safety handbook"[5],
    - The WHO "Outbreak Communication. Best practices for communicating with the public during an outbreak"[6],
    - The FAO "Food Traceability Guidance"[7],
    - The draft Template for INFOSAN/IHR communication: National protocol for information sharing with national and international partners during food safety events and outbreaks of foodborne illness[8],
    - FAO/WHO guide for development and improving national food recall systems[9].

[1] http://apps.who.int/iris/bitstream/10665/44739/1/9789241502474_eng.pdf?ua=1
[2] http://www.who.int/foodsafety/publications/foodborne_disease/outbreak_guidelines.pdf
[3] http://www.fao.org/3/a-i5168e.pdf
[4] http://www.fao.org/docrep/013/i1686e/i1686e00.pdf
[5] http://www.fao.org/3/a-i5863e.pdf
[6] http://www.who.int/csr/resources/publications/WHO_CDS_2005_32web.pdf
[7] http://www.fao.org/3/a-i7665e.pdf
[8] Not published yet.
[9] http://www.who.int/foodsafety/publications/recall/en/

14. These documents are referred to in the most relevant section(s) of the current guideline, providing more detailed recommendations on specific aspects[HT8], ~~but mostly not specific for the prevention and management of food safety emergencies~~.

4. Definitions

15. Microbiological hazards include bacteria, viruses, yeast, moulds, algae, parasitic protozoa, microscopic parasitic helminths, and their toxins and metabolites.

16. Foodborne outbreak[10]
    a) The observed number of cases of a particular disease exceeds the expected number.
    b) The occurrence of two or more cases of a similar foodborne disease resulting from the ingestion of a common food.

17. ~~F~~[m9]~~ood safety emergency covers foodborne outbreaks (regardless of size), crises and emergencies. Foodborne outbreaks caused by (micro)biological agents can be categorized according to the severity of the outbreak. Criteria for such categorization could be the number of cases and spread of the outbreak; the pathogenicity of the microorganism or if unknown agent; the distribution pattern and volumes of the food and trade implications. The risk management measures chosen will vary according to the situation.~~

5. Food safety emergency – preparedness system

a. Creation of formalized networks at local and national levels

18. ~~F~~[m10]~~ood safety emergencies happen all the time and vary greatly in size and severity from local outbreaks restricted to a single location to national or international outbreaks.~~

19. National systems and structures should be in place in order to early detect and effectively manage food safety emergencies and should have sufficient capability and capacity. The system should not be developed in isolation but be based on existing structures in the public health sector and food and veterinary control systems taking into account e.g. surveillance programmes for humans and food, laboratory networks and conditions for food production and distribution.

20. The system and structures need to be described in detail and agreed upon by the participants to ensure cooperation in mutual respect of the competences of each participating authority and agency and allowing for an incident to be managed at the lowest possible administrative level. Advice on how to perform this task is given in more detail in the FAO/WHO framework for developing national food safety emergency response plans.

21. For the system and structures to be operational it is necessary that they are well known by the participants and part of the "daily routines". Depending on the national structures of

[10] Foodborne outbreak is defined in WHO Foodborne Disease Outbreaks: Guidelines for Investigation and Control, 2008.

competent authorities a set of contact points should be appointed at the different levels of administration.

The national structures of competent authorities may include[m11]:

- At local level permanent networks between the contact points from the different authorities/agencies should be formed ensuring the exchange of information and management of the incident within and between the networks. The networks should where relevant cooperate with stakeholders and food business operators.
- At central national level a permanent network should be established with senior personnel with experience in the management of food safety emergencies representing their respective authorities/agencies. Inspiration on the composition of such a network can be found in the description of the multiagency coordination group (MACG) described in the FAO/WHO guideline on the framework for developing national food safety emergency response plans. The role of the network should include both the coordination of large food safety emergencies through the network structure and assessing information received from the other levels and participants of the network. The central network may also be the forum where new tools and ways to handle outbreaks can be developed.
- Communication vertically between the local networks and horizontally between the local and central networks is crucial. Communication structures and practices should be included specifically in the description of the system and procedures for the network and should include the following issues:
  - The information is distributed to and understood by all parties in a timely manner ~~and at the same time~~.
  - There is only one emissary and receptor in each of the participating agencies and interested parties of official information.
  - All parties know and respect the established formal information channels and these have been previously proven effective.
  - If external groups of experts are used from the agencies and stakeholders to validate the recommendations it is necessary to keep them within their domain of expertise.[m12]

b. International alert networks for food and human incidents and exchange of information with them

22. Food safety emergencies may occur across ~~do not respect~~ borders either by area of distribution or by origin of the source. What seem a national or regional incident may in fact be a multinational food safety emergency.

23. Regional alert networks for both food and human incidences exist in some regions alongside the International Food Safety Authorities Network (INFOSAN). The central national level of the network should include this issue in their work and actively include the national emergency contact points for these alert networks in their work both for gathering and compiling information and for submitting coordinated information concerning active food safety emergencies.

24. Principles and guidelines for the exchange of information are described in more details in the Codex document CAC/GL 19-1995 as amended and in the Template for INFOSAN/IHR communication (not yet published)[HT13].

c. Monitoring or surveillance systems (human, animal, food, ~~establishment~~ environment[m14]) and their use in food safety emergencies

25. Most ~~(~~micro~~)~~biological food safety emergencies are triggered by monitoring or surveillance data from humans since they are linked to (several) human cases, hospitalisations or even deaths and therefore might attract the attention of people (e.g. medical staff) and potentially the press. Monitoring or surveillance systems should therefore focus on the evaluation of human data. However data from monitoring of animals, food and the environment, including equipment of food businesses may also indicate an enhanced risk and are at least substantial for the detection of the source of the food safety emergency.
    Both types of monitoring or surveillance are needed to continuously improve food safety along the whole food chain continuum.

26. In order to detect a food safety emergency there is a need for continuous:
    - Surveillance ~~Monitoring~~ of the "baseline" or "business as usual" of human cases potentially ~~situation~~ associated with~~of~~ ~~(~~micro~~)~~biological hazards in food~~in~~ ~~in human~~ ;
    - Quick centralisation and distribution of information through early warning systems; disease notification by medical practitioners to competent authorities should~~must~~ be made mandatory to the extent possible.
    - Regular (e.g.~~at least~~ weekly) analyses of the data in order to detect an enhanced number of detections.

27. Unless in case of very rare diseases; there might be a need for molecular testing data of the isolates to detect and demonstrate a link between different cases. The increasing availability of such tests, including genome sequencing, is expected to increase the number of links between cases, and thereby the number of outbreaks, requiring improved preparedness for outbreak management.

28. The use of molecular testing, such as whole genome sequencing, allows the finding of very similar specific molecular profiles (cluster). It may create the suspicion of outbreaks and should trigger further investigations to possibly confirm also an epidemiological link (e.g. common food consumed).

29. The use of databases with information on molecular testing and containing comparable results from human, animal, food and environmental sampling facilitates the detection of outbreaks and the search for the source of the contamination.[HT15]

30. These monitoring or surveillance systems are essential tools for detecting foodborne outbreaks. It is necessary to establish structures to exchange information between public health and food safety authorities. These should be used both routinely and during food safety emergencies and may include:

- Regular exchange of information between human health sector, competent food authorities and laboratories. The information should include information on new signals from both sectors and follow-up on ongoing outbreaks.
- Tools for sharing surveillance data and epidemiological information such as databases or data-sharing-sites.
- In order to share surveillance data, it is necessary that data collected are comparable between sectors. Tools for comparing and presenting data, such as phylogenetic tree which can be used if surveillance data is based on genetic methods.
- Sufficient epidemiological data to evaluate the relevance of the source and to make trace back.

31. More details in the FAO training handbook on "Enhancing Early Warning Capabilities and Capacities for Food Safety", Cap 3 Food Safety Surveillance."

32. More details in the WHO "Foodborne disease outbreaks: Guidelines for investigation and controls".

d. Risk assessment – structures for rapid risk assessment

33. Reference is made to the FAO[m16]/WHO guide for application of risk analysis principles and procedures during food safety emergencies ~~"Principles and Guidelines for the Conduct of Microbiological Risk Assessment" (CAC/GL 30-1999)~~.

34. A risk assessment in a food safety emergency will improve the quality of the communication and provide a sound scientific basis for the actions to be taken. In a number of cases a ready-to-use risk assessment will be available, however adaptations to the specific outbreak will be required (under time pressure) based on the information from the outbreak investigations. Having structures in place to allow such (rapid) risk/outbreak assessment are therefore an essential part of outbreak preparedness. They include:
    - Lists of risk assessors available with their area of competence;
    - Clearly prepared instructions what is expected for these risk assessors taking into account that short deadline for the assessment;
    - Structure to ensure the direct and immediate submission of information from the outbreak investigations and the possibility to ask additional clarification to the investigators and/or involved food business operators.
    - Availability of information analysis tools e.g. to detect hot spots.

e. Risk communication system/strategy

35. In the context of a microbiological food safety emergency, risk communication will be the exchange of information on the microbiological risk among stakeholders (Government, Academia, Industry, Public, Mass Media and International Organizations) outside the formalized network structure, with the aim to inform and motivate to action.

36. According to the ~~FAO/~~WHO "Outbreak Communication. Best practices for communicating with the public during an outbreak", effective communication is essential and requires preparation in advance of an emergency, and this should include exchange of information with all stakeholders.

37. In terms of risk communication, the preparedness should at least consider;

- Identify all the ~~C~~c[HT17]ompetent authorities~~Government agencies~~ that may be involved in the response at some level and establish and designated official channels of communication within a food safety emergency.
- Establish a communication strategy among participating agencies and designate an official spokesperson from the government or central network to the public. Where it is possible, the jurisprudence of each of the competent authorities~~government agencies~~ should be taken into account to set the roles of each one in the risk communication strategy.[m18]
- Establish appropriate channels of communication when the agencies have local or regional offices within the country for centralization of the information. This channel should be constantly informed and tested at local and central level.
- Identify all the types of organizations that may be involved and make alliances and partnerships with them to ensure that they will speak in a coordinated manner (using one voice).
- Draft initial messages; specific details can be filled in later. Consider that each population group may have its own characteristics that affect how they perceive risks (Ex. religious belief, traditions), so understanding your audience and test messages to ensure they are culturally and demographically appropriate is important.
- Test established communication strategies in a regular basis to evaluate their efficiency.

6. Food safety emergency - management

a. Identifying and investigating a food safety emergency – human health side

38. Careful description and characterization of the outbreak is an important first step in any epidemiological investigation. Descriptive epidemiology provides a picture of the outbreak in terms of the three standard epidemiological parameters – time, place and person. Further elaboration is described in details in the WHO " Foodborne Disease Outbreaks: Guidelines for investigation and control"~~s guideline for outbreak investigation~~.

39. A foodborne outbreak can be identified by
    - the national surveillance system when a cluster of human cases occur with identical or closely related type of infection and related in type or,
    - the food control authorities when they are informed about illness related to specific products or companies.

40. Depending on the information available a case definition should be created. Cases that fall within the definition should be interviewed to obtain as much information concerning food items consumed prior to illness, place of purchase, etc. If possible, standard epidemiological study methods such as case-control and cohort studies should be used to obtain information in a structured way.

41. ~~Creation of~~ Developing standard questionnaires for this purpose and data analyzing may be performed according to the WHO "Foodborne disease outbreaks: Guidelines for investigation and controls"~~electronically using one of the internet based free of charge opportunities. Data can then be analyzed electronically in a standard statistical software program. Some of these programs can be downloaded from the internet free of charge.~~

42. ~~T~~[m19]~~hese investigations are described in WHO Guidelines for investigation and control of foodborne outbreaks.~~

b. Substantiate suspicions and/or handling of a food safety emergency – food safety side

43. Food safety emergencies where a food source or a location has been identified during the epidemiological investigations should be followed by a thorough investigation on site covering all aspects of the production and distribution to substantiate if it is possible that the food source or the location is actually the source of the outbreak. If possible the cause of contamination should be identified and verification by sampling and analyses should be attempted. These investigations are described in the WHO "Foodborne disease Outbreaks: Guidelines for investigation and controls~~ of foodborne outbreaks~~".

44. Food safety emergencies where the source of the outbreak is not yet known are challenging. Even if the epidemiological investigations do not reveal a possible source an indication of what could be a possible group of food items causing the outbreak may be possible to establish based on historical outbreak data and the information from the cases concerning food preferences and trade patterns. In these situations further investigation based on the knowledge of especially production, distribution and consumer preferences may be helpful in an attempt to narrow down the possible sources or locations causing the situation.

45. Tracing a food item both backwards and forwards in the food chain is an essential tool in the investigation. The process enables the investigators to see the full distribution of the food item or products made in a single production site. However this possibility is also very resource consuming and should be used only when there is either no other option or when it can be limited to a single food item preferably a few batches of the food item. The information gathered should be compared with the epidemiological information and analytical evidence of the outbreak.

46. If the overall evidence is strong enough that the source of the food safety emergency has been identified the same procedures of tracing back and forward in the food chain should be used recalling the food item/batches of the food item from the consumers thus removing the source of the emergency.

47. Guides for both food business operators and authorities on traceability systems and food recall systems are available in FAO and FAO/WHO guides on the subject.

c. Comparing epidemiological and analytical data[m20] ~~(DK)~~

48. Management of outbreaks requires the human and the food and veterinary sectors to be able to share and compare relevant analytical surveillance data in order to reveal match. It is

therefore essential that analytical data are either analyzed with similar methods or analysis results are comparable. For example, for Salmonella, the traditional way of comparing data is by using the Kaufmann-White classification for serotyping. In case of a match in serotypes, supplementary analysis is necessary to determine the probability of relationship. Typing methods often used are pulsed-field gel electrophoresis (PFGE) and multiple-locus variable number of tandem repeat analysis (MLVA).

49. In recent years, genetic based methods like Whole Genome Sequencing (WGS) has become widespread worldwide as a microbial typing tool. These methods have several advantages over traditional typing methods. WGS reveals the entire bacterial genome and provides very accurate information which makes it possible to determine when isolates are identical and hereby enhances the possibility to identify the source of the emergency.

50. Enough data to ensure traceability of the product sampled should be collected and this should include species, product type, and sampling facility.

51. Food safety emergencies cannot be solved solely based on analytical data but ~~must~~should always be linked to epidemiological data for confirmation.

52. Descriptive epidemiological data such as structured information on food consumed, disease onset, symptoms, duration etc ~~m~~should~~ust~~ be~~me~~ collected as part of the food-borne surveillance. If possible an analytical epidemiological study should be performed (i.e. cohort or case-control study). Knowledge of epidemiological data in relation to outbreaks is relevant once there is a match.

53. Other tools that can be used together to determine the source of attribution in case of a food safety emergency are sample monitoring, surveillance data, source attribution studies and mathematical modelling. More information on epidemiological tools appear from the WHO "Foodborne disease outbreaks: Guidelines for investigation and controls"~~guideline on outbreak investigation~~.

54. Robust epidemiological evidence is strong evidence and may be conclusive of the food safety emergency even without analytical evidence. Analytical evidence can support the epidemiology but will only be conclusive if the result is supported by at least the descriptive epidemiological information obtained from the patients.

d. Risk assessment

55. In most cases, a risk assessment or adaptation of an existing risk assessment to the emergency specific situation should be carried out. Since corrective action is needed urgently, a classical risk assessment might not be possible, but a simplified "outbreak assessment" ~~must~~should be aimed at. It includes:
    - Historical information on the prevalence of the hazard in different food, in particular if the source of the ongoing food safety emergency is not confirmed yet
    - Results from epidemiological and microbiological investigations of human outbreak cases, considering severity, possible mortality, spread of cases and affected subgroups (e.g. elderly).
    - Results from microbiological and epidemiological (including tracing back) investigations

- Risk characterisation/threat assessment linked to the outbreak
- Recommendations to the consumers and to competent authorities how to mitigate the risk.

56. Since such risk assessment is likely to be carried out at the beginning of an outbreak, intense interaction should be ensured between the risk assessors and the outbreak investigators (on human cases and on food investigations):
    - To ensure that most recent information is available to the risk assessors
    - To formulate targeted questions
    - To allow the risk assessors to point investigators to gaps of information or hot spots detected, guiding further investigations.

57. More ~~detailed~~general [HT21] guidance can be found in the FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies.

e. Risk communication

58. This section should be read in conjunction with the FAO/WHO Risk Communication applied to food safety h~~H~~andbook".

59. Food safety emergencies, start in one country but travel rapidly around the world and requires rapid and clear response in terms of communication.

60. At the beginning of a crisis there will be confusion and intense public and media interest. Ideally, risk communication pursues to provide all the stakeholders outside the formalized network structure with the information they need to make informed decisions.

61. Some good practices that should be considered when elaborating the risk communication message to the public are;
    - Have only one official communicator to the population.
    - Information should be simple and use plain language since public may have limited familiarity with scientific language.
    - Acknowledge the uncertainty and make the recommendations provisional. If there is a need to change the recommendations in the future, it is important to remind the public that earlier recommendations were provisional and to explain why it was changed.
    - Explanation of who the recommendation applies to and who it does not apply to and why.
    - Avoid withholding information just because it is upsetting. If not all the information exists or cannot be released, an explanation of the cause and what is being done to address this situation is important.
    - If it is possible assembly a group of experts to validate the recommendations and keep them within their domain of expertise.
    - Update~~Repeat~~ information constantly and try to be timely.
    - Monitor effectiveness of communications and adjust as necessary

f. Documentation of the outbreak

62. It is important to collect and save sufficient information to be able to document all relevant steps in the outbreak both when it is ongoing and afterwards. During the emergency a record should be kept which includes relevant trace back information and descriptive epidemiology, hypothesis and status of the situation. The record should~~must~~ be updated while the food safety emergency is ongoing. When it is over, the record can be finalized to include conclusions and can serve as an outbreak report. Examples of reports and how to prepare them is further described in the WHO "Foodborne disease outbreaks: Guidelines for investigation and controls".

63. For the documentation to be of future use to the institutions involved in food safety emergency management they should be kept in a structured way and accessible at all times for the personnel involved in the work. This could be in the form of a database structure or in a shared file system accessible only to the relevant personnel/competent authorities.

64. Information from the shared system should be reviewed regularly by the competent authorities. The information can be valuable for the food control authorities in targeting official control efforts.

65. Outbreak of special interest should be considered published as scientific publications.

g. Post outbreak monitoring/surveillance

66. In order to evaluate the effect of actions taken and to reassure confidence of consumers and trade partners, enhanced monitoring, rapid centralisation and evaluation of data, in particular of human cases, should be continued until the baseline level has been reached, taking into account:
    - The delays in analysis and reporting;
    - Possible seasonal effect

7. Maintenance of the networks

a. Review of existing preparedness

67. ~~Countries~~Competent authorities should continuously monitor, evaluate, improve and strengthen their existing network to ensure that it is functioning effectively and efficient. This should include ongoing strategic planning and review of objectives, priorities, needs, gaps, opportunities and challenges, including both internal processes and interagency/ inter-stakeholder relations. The results of such review should be documented and areas pointed out should be addressed to support capability and capacity of the system in place.

68. Evaluation of the local and national network structures can be facilitated by joint training or joint exercises, to focus on specific objectives, priorities, needs, gaps, opportunities and challenges.
    To include actual food safety emergencies structures an “after action review system” need to be implemented into the network.

69. Evaluation of the national permanent network, the member entities of the network and the efficiency of the network should be done on a regularly basis. Restructuring and development in governance system should~~must~~ be reflected in the network.

b. Joint training on food safety emergencies

70. A key part of capability and capacity building is the training of experts and professionals. The training should be expanded across different competent authorities and key stakeholders. The purpose should be to develop a common understanding of the entire system of local national, and international preparedness. As part of the capability and capacity building joint simulation exercises should be put in place.

71. The exercises can aim at control/verification or learning/ development.
    - Control/verification exercises are primarily aimed at testing the participants' skills, for example an expert or professional handling a particular type of method or a procedure in the contingency plan. These exercises should not be notified prior to the execution and can vary in both complexity, length in time and size of organization in number of participants.
    - With learning/development the exercises are more organized with the focus on the participants being required to achieve new competences and capabilities. It may involve roles and responsibilities or development and test of new procedural concepts and plans. Joint simulation exercises is a proven concept in this setting. Learning/ development exercises can be notified and thereby giving the participants the opportunity to prepare, which can optimize the overall outcome and learning.

72. The organization should vary the use of exercise types to include exercises focusing on procedural exercises, dilemma exercises and crisis management exercises. The different type of exercises can achieve different objectives, both in a control/ verification setting and in a learning/ development setting. The exercises can be done both in a live environment like a laboratory or in a table top form.

73. Regardless of type of joint training or exercise it is important that the activity is put into a strategic perspective and that lessons learned are captured and put into a structured reworking of the system.

c. Implementation of lessons learneds~~s~~

74. The evaluation of national preparedness systems can include “after action reviews” of major, serious or rare food safety emergencies. The evaluation should include both competent authorities and agencies and if possible also comments from relevant stakeholders like food business operators. The review should focus on commitment in participation, the use of resources, the sharing of information, and other essential issues. The review should be used to build a stronger system or network on national and local [m22] level.
    The review need to be disseminated in order to spread the lessons learned more broadly within the system. It could be to share information like:

- What was the most notable success in the management of the emergency that other may learn from?
- What was some of the most difficult challenges faced and how were they overcome?
- What changes to the national structure, procedures or analytical methods is recommended?
- What was not overcome to your satisfaction and what could be done differently next time?

75. The lessons learnt should be included in the ongoing development of capacity and capabilities of the national and local system.

Background

Food allergens are food safety hazards and food businesses are expected to consider allergen management in the growing, harvesting, transport, storage and production of food. While food hypersensitivity does not feature as a public health concern in all countries, it has an impact on trade with countries that have requirements related to control of food allergens.

At the 49th CCFH meeting, the Committee agreed to establish an Electronic Working Group (EWG), chaired by Australia and co-chaired by the United Kingdom and the United States of America, working in English only, to prepare, subject to the approval of the Commission, the proposed draft Code of Practice on allergen management for food business operators (Code) for circulation for comments at Step 3 and consideration at CCFH50 (November 2018).

While food hypersensitivity such as food allergy may affect a relatively small proportion of the population (the WHO suggest 1-3% of adults and 4-6% in children), an allergic reaction can be life threatening or fatal. With the increasing health burden posed by food allergy, comes the expectation that food business operators and competent authorities take steps to manage contamination from allergens.

In a global market it is crucial that there is international understanding of this issue and of the measures required to address it. Many food business operators may not be aware of control measures for allergens other than labelling their deliberate use as ingredients and processing aids.

An internationally developed guidance document for best practice allergen management will facilitate awareness and good practice.

The draft Code of Practice

The co-chairs have prepared the draft Code of Practice (Code) for discussion and consideration of the EWG participants. In developing this draft, the co-chairs have considered:

Scope of the Code - Food Supply chain

The proposed scope is to cover allergen management, including controls to prevent cross-contact, throughout the supply chain from food production and manufacturing through to retail and food service. Food manufacturers have identified agricultural practices such as crop rotation, to be a potential source of allergen contamination in a final food product.

Good allergen management guidance can help manage and minimise allergen contamination and spread this practice more widely across the industry to cover agricultural practices, transport, and storage operators, as well as processors. The principles for allergen controls are slightly different from microbiological controls in that cleaning but not sanitation are critical and physical segregation and accurate food information are key to success.

Additionally, food preparation practices at retail and in food service are critical in managing the risks of allergen exposure. The key principles for allergen management in food service are less defined in guidance. Controlling cross-contact in less-controlled food preparation areas with potentially many more allergens being present is more challenging. In many instances safety depends on conveying accurate information verbally to the consumer.

The draft document has therefore included hygiene controls across the food supply chain.

Scope of the Code - Immunological response/ Food intolerances

The proposed scope will be to cover Ig-E-mediated and non Ig-E-mediated food allergies and **will not cover** intolerances such as lactose intolerance and sulphite sensitivity which can generally be addressed by labelling strategies alone.

The majority of Ig-E mediated and non Ig-E mediated food allergies on a global basis are caused by eight foods/food groups. These include:

- Milk
- Egg
- Crustacea
- Fish
- Peanut
- Soybean
- Tree nuts
- Cereals containing gluten

The draft document has therefore included the top eight immunological response associated food groups/types as allergens of concern and practices to address the management of these allergens. We note that there may be additional/varying foods identified by specific countries which need allergen controls. However, the controls outlined in the Code would be similar and food business operators should apply these as appropriate to their own business requirements.

Because of the critical nature of allergen labelling, the CCFH allergen EWG will liaise closely with the CCFL EWG on the drafting of any text relating to labelling controls for food allergens. The specific allergen-labelling requirements are the purview of the CCFL, but controls to ensure the correct label is applied should be within the scope of the Code.

Thresholds and intended use

During the development of the Code, the use of allergen reference doses/thresholds and cleaning validation to inform risk assessment and risk management decisions will be explored. We note that there are varying principles currently being used by the food industry globally and that there are continuing scientific developments in this area.

Allergen testing

Allergen testing is an important aspect of cleaning validation and verification, and guidance will be included in the Code on when testing may be appropriate and the purpose of validation/verification and using appropriate methods for different matrices.

We are not proposing to cover interpreting test results and confidence intervals.

The role of competent authorities

An annex for Competent Authorities has been developed as part of this Code which may assist with investigating consumer complaints and incidents of undeclared food allergens supplementary to standard food investigation protocols.

CODE OF PRACTICE ON ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS

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INTRODUCTION

Food allergies are an increasing food safety issue globally and have emerged as a major public and personal health burden. While food allergies may affect a relatively small proportion of the population, an allergic reaction can be life threatening or fatal.

Allergens are an ongoing food safety concern for both allergic consumers, those who have people with food allergy in their care, and food business operators.

With the increasing health burden posed by food allergens, comes the expectation that food business operators and competent authorities take steps to manage allergen contamination. In a global market it is crucial that there is international understanding of this issue and of the measures required to address it. Allergen management practices should be part of good hygiene practices (GHPs) in manufacturing, retail and food service.

Most food allergies are caused by an adverse immune reaction (hypersensitivity) to certain food proteins. Allergy to food can be classified by their immune mechanism:

- immunoglobulin E (IgE)-mediated (immediate hypersensitivity),
- non-IgE mediated (cell-mediated, or delayed hypersensitivity), and
- mixed IgE and non-IgE mediated.

IgE-mediated symptoms develop within minutes to 1-2 hours of ingesting the food, non–IgE-mediated and mixed IgE- and non–IgE-mediated food allergies present with their symptoms several hours after the ingestion of the food. Symptoms may include itching around the mouth, hives, swelling of lips and eyes, difficulties in breathing, diarrhoea to anaphylaxis and where left untreated may result in death.

While many foods can cause allergic reactions, the most common causes of allergic reactions are milk, peanut, egg, soybean, crustaceans, tree nuts, fish and cereal containing gluten. The most common allergic reactions from tree nuts involve almonds, Brazil nuts, cashews, hazelnuts, macadamias, pecans, pistachios and walnuts. In addition, gluten, present in grains such as wheat, barley and rye, can cause adverse reactions in persons with celiac disease, a serious autoimmune disorder. While these are the most common, other allergens such as sesame are recognized as important in many countries. The controls outlined in this Code would be similar for other allergens, and food business operators should apply these as appropriate to their own business requirements.

Treatments lethal for microbial pathogens, such as heating, high pressure processing, etc. do not destroy allergens. Processes that degrade proteins, such as enzymatic or acid hydrolysis, may be effective, but this should be validated.

A variety of risk factors are associated with exposure of allergic individuals to undeclared allergens. These include the following:

For packaged food manufacturing facilities:

- labelling errors and allergen cross-contact issues due to in-process or post-process cross-contact,
- errors in handling of rework,
- improper production sequences that result in one product contaminating a subsequent product, and
- insufficient or ineffective equipment cleaning/sanitation procedures at product changeover.

For retail and food service establishments:

- failure of food allergic individuals in making their allergies known,
- lack of understanding of the serious nature of food allergy,
- lack of information recorded to know which ingredients or foods contain which allergens
- inability of service personnel to clearly communicate allergen information, and
- absence of proper food preparation procedures to avoid allergen cross-contact.

Cross contact can occur at multiple points in the food chain. Potential points where cross contact may occur are outlined in relevant sections within this Code.

Food business operators should be encouraged to have documented allergen management policies and procedures. Having allergen management policies and procedures in place allows a business to demonstrate it is taking all necessary steps to prevent the likelihood of food being unintentionally contaminated with an allergen. Documented policies and procedures and compliance with these also provides an opportunity for businesses to demonstrate adequate skills and knowledge in allergen management and reduces the risk of an allergen incident occurring.

SECTION I - OBJECTIVES

This Code of Practice (Code) provides guidance to food business operators and competent authorities to manage allergens in all areas of food production, including controls to prevent cross-contact and to ensure the correct label is applied to prepackaged foods.

The management tools and guidance in this Code, if adhered to, are a proactive approach for effectively managing allergens in food production and reducing risk for consumers, rather than a reactive response once a food safety hazard is identified.

Food allergen management also involves allergen labelling which is addressed by the *General Standard for Labelling of Prepackaged Foods* (CODEX STAN 1-1985).

SECTION II – SCOPE, USE AND DEFINITION

2.1 SCOPE

This Code provides guidance to food business operators and competent authorities to manage allergens in all areas of food production, including controls to prevent cross-contact and to ensure the correct label is applied to prepackaged foods.

The management tools and guidance in this Code, if adhered to, are a proactive approach for effectively managing allergens in food production and reducing risk for consumers, rather than a reactive response once a food safety hazard is identified.

Food allergen management also involves allergen labelling, which is addressed by the *General Standard for Labelling of Prepackaged Foods* (CODEX STAN 1-1985). This Code covers IgE-mediated and non Ig-E-mediated food allergies (e.g., celiac disease) that can be provoked by low doses of the offending food (thus requiring attention to GHPs in addition to labelling).

The Code does not cover intolerances such as lactose intolerance and sulphite-sensitivity, which can generally be addressed by labelling strategies alone. Food intolerance adverse reactions usually result from a non-immune mediated reaction to food such as a lack of enzyme to process foods effectively e.g. the absence of lactase in those with lactose intolerance.

This Code covers allergen management throughout the supply chain including during manufacturing, as well as at retail and food service end points. It provides good hygiene practice (GHP) in manufacturing and food preparation practices in food service.

2.2 USE[LK1]

This Code follows the format of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and should be used in conjunction with it, as well as with other applicable codes and standards such as the *General Standard for Labelling of Prepackaged Foods* (CODEX STAN 1-1985 (Rev. 1-1991).

The provisions in this document should be applied as appropriate, with consideration of the diversity of ingredients, processes, and control measures of the products and various degrees of risk involved in managing allergenic ingredients/foods.

2.3 DEFINITIONS[LK2]

For the purpose of this Code, the following expressions have the meaning stated:

Allergen Profile - The food allergens present in a food

Allergenic contamination (e.g., "cross-contact") - Unintentional incorporation of a food allergen into another food.

SECTION III – PRIMARY PRODUCTION

3.1 ENVIRONMENTAL HYGIENE

Growers should know the history of the field, i.e., what has been grown in the fields previously. When possible and practical, prepare the seed bed for each new crop by ploughing under or by destroying or removing old seed heads and stalks to minimize the potential for an allergen from a prior crop (e.g., soybeans) to be harvested with a subsequent crop that is different (e.g., corn).

When considering planting a new crop, signpost where the crop will be planted so it is clear which plants are planted where. This can help avoid planting allergenic crops such as soybeans directly next to wheat, thereby reducing the risk of cross contact.

3.2 HYGIENIC PRODUCTION OF FOOD SOURCES

Prior to harvest ensure that equipment used for harvesting and storage of crops is functional. Ensure that equipment is clear of visible plant debris and signs of previous crops/ food material.

3.3 HANDLING, STORAGE AND TRANSPORT

Freshly harvested cereals should be cleaned to remove foreign matter. To remove foreign grains – sifting via size can remove foreign matter such as plant debris and foreign grains/pulses/seeds. To minimise the risk of cross contamination, storage facilities must be visually inspected and thoroughly cleaned if necessary to prevent allergen cross-contact before use and between different commodities. When handling multiple commodities such as grains/pulses/seeds ensure that physical segregation is in place to prevent cross contact. Having a clear "allergen map" of the storage facility will show where allergenic crops enter and are kept so the risk of cross contact is managed.

Where bagging of the commodity is required, ensure that bags are clean, dry and stacked on pallets. Bags that have been used for an allergenic commodity should not be reused for a different commodity. Where allergenic grains or pulses are bagged and stored together, store allergens on the bottom so spillages can be easily managed from the perspective of preventing contamination of non-allergenic commodities.

Transportation of food stuff should be carried out using a clean transport vehicle in order to minimize the potential for allergen cross-contact. Food transport containers should be dry and free of the previous load. As necessary, transport containers should be cleaned before use. At unloading, transport containers containing allergenic commodities should be emptied of all cargo and cleaned as appropriate to minimize the potential for allergen cross-contact of the next commodity. For more detail on transportation refer to Section 8.

3.4 CLEANING, MAINTENANCE AND PERSONNEL HYGIENE AT PRIMARY PRODUCTION

Refer to the *General Principles for Food Hygiene*.

In addition, ensure that the area where crops are dried is clean and physical barriers are in place to prevent spillage and cross contact. Materials or containers used to lay, hang or bag crops should be cleaned to remove foreign matter and allergenic contaminants. For example avoid the re-use of jute / canvas bags for allergenic commodities for ones that do not contain that allergen, e.g., using bags that have been used for peanuts for cocoa.

Ensure designated storage areas and storage materials are clearly labelled or colour coded to prevent unintentional mix of commodities.

SECTION IV – ESTABLISHEMENT: DESIGN AND FACILITIES

4.1 LOCATION

4.1.1 Establishments

Manufacturers producing food at more than one site should consider whether it is feasible to consolidate production of products containing like allergens at one location.

4.1.2 Equipment

Where feasible, manufacturers should use dedicated processing lines for processing foods with and without a particular allergen (e.g., separate lines for dark chocolate and milk chocolate; separate lines for milk-based beverages and soy-based beverages). This may be the only way to prevent cross-contact for some foods that are viscous or sticky and thus difficult to completely remove from equipment during cleaning.

If separate production lines are used for foods with different allergen profiles (e.g., for foods that do not contain a particular allergen and for foods that do), manufacturers should provide sufficient separation to minimize the potential for cross-contact from one line to another and eliminate cross-over points or provide a means to contain food (e.g., closed pipes, enclosed conveyors) to prevent food spilling from one line to another.

Retail and food service operators should, where feasible, use equipment dedicated to foods with a particular allergen (e.g., use a separate slicer for cheese, which contains milk, and for meats that do not contain milk).

4.2 PREMISES AND ROOMS

Where feasible, manufacturers, as well as retail and food service operators, should provide a dedicated production area within the establishment for the preparation of foods that do not contain allergens, or provide dedicated production areas for foods with different allergen profiles. For example, an establishment that handles different types of tree nuts could dedicate separate rooms or other areas for handling each type of nut. One that handles different types of protein powders such as soy protein and whey powder could dedicate separate areas for handling these powders.

Manufacturers should consider providing barriers (e.g., walls, partitions, curtains) when necessary to prevent allergen cross-contact when foods with different allergen profiles are processed at the same time.

Food manufacturing premises and rooms should be designed to mitigate the risk of airborne allergen contamination throughout the processing area, especially when powdered allergens such as dried milk powder, soy protein, etc. are used.

4.3 EQUIPMENT

4.3.1 Manufacturing

Equipment and containers (other than once-only use containers and packaging) contacting foods that contain allergens should be designed and constructed to ensure that allergens can be removed during cleaning. To prevent allergen cross-contact, they should not contain areas where allergens, especially allergens that are particles (e.g., peanuts, tree nuts), could get caught in crevices such that they are not removed by the cleaning procedures applied. Welds should be smooth, seals and hoses should not contain cracks, and "dead ends" or other areas where pockets of foods containing allergens can accumulate should be eliminated.

Containers used to hold foods that contain allergens should, where possible, be dedicated to holding a specific allergen and be marked, tagged, or color-coded to identify the allergen.

4.3.2 Retail and Food Service

Retail and food service operators should use equipment and containers (other than once-only use containers and packaging) contacting foods that contain allergens that have been designed and constructed to ensure that allergens can be removed during cleaning.

Containers used to hold foods that contain allergens should, where possible, be dedicated to holding a specific allergen and be marked, tagged, or color-coded to identify the allergen.

4.4 FACILITIES

Food Business Operators should place hand wash basins in appropriate areas to prevent allergen cross-contact from personnel. Having convenient hand wash basins will encourage employees to wash hands between handling foods that have different allergen profiles. Food business operators should also consider facilities to enable cleaning and change of protective clothing especially when moving from particular areas within the factory

SECTION V – CONTROL OF OPERATION

5.1 CONTROL OF FOOD HAZARDS

Food business operators should control allergens by preventing allergen cross-contact and by ensuring that the correct label identifying the allergens in a food are applied to packaged foods.

5.1.1 Manufacturing

Manufacturers should:

- identify any steps in their operations which are critical to preventing allergen cross-contact;
- implement effective procedures to control allergen cross-contact at those steps;
- monitor control procedures to ensure their continuing effectiveness; and
- review allergen control procedures periodically, and whenever the operations change.

5.1.2 Retail and Food Service

Retail and food service operators should:

- identify any steps in their operations that pose a risk of allergen cross-contact;
- implement effective procedures to control allergen cross-contact at those steps;
- monitor control procedures to ensure their continuing effectiveness; and
- review allergen control procedures periodically, and whenever the operations change.

5.2 KEY ASPECTS OF HYGIENE CONTROL SYSTEMS

5.2.1 Manufacturing

5.2.1.1 Preventing cross-contact during processing

If the same production area is used for foods with different allergen profiles, manufacturers should, where feasible, implement production scheduling to separate by time the manufacture of products with different food allergen profiles, e.g., process foods that do not contain allergens before foods with allergens. Production schedules could be established in some cases whereby products that do not contain allergens are handled at the beginning of the schedule and different products containing the same food allergen profile could be run sequentially before products with different allergen profiles to reduce the potential for allergen cross-contact (e.g., all frozen desserts containing only milk are run before those containing both milk and egg). Where possible, allergenic ingredients should be added as late in the production process as possible, and as far downstream as possible in the processing line (e.g., closest to the filling and packaging equipment), to minimize the amount of equipment in the production area that comes in contact with the allergen. This will help control allergen cross-contact.

Manufacturers should develop traffic flow of allergen-containing ingredients, packaging supplies and employees during the manufacture of foods to minimize the potential for allergen cross-contact. Where feasible, employees working on processing lines that contain an allergen should be restricted from working on lines that do not contain the allergen. Manufacturers should consider a system to clearly identify employees working on lines manufacturing foods containing different allergen profiles, e.g., different coloured uniform/hair net.

Manufacturers should provide shielding, permanent and/or temporary partitions, covers, and catch pans to protect exposed unpackaged product from allergen cross-contact. Dry ingredients should be physically contained by covering specific equipment, such as conveying equipment, hoppers, storage silos, shakers, and size graders. Where feasible, manufacturers should dedicate utensils and tools for processing lines with different food allergen profiles; these utensils and tools should be distinguishable (e.g., through marking, tagging or color-coding) to minimize the potential for allergen cross-contact.

Allergen-containing ingredients should be opened and weighed in designated areas before being transferred in covered or closed containers to the processing line. Dry ingredients that are, or contain, a food allergen should be added in a manner that minimizes the potential for unintentional dispersion by dust. For example, the formation and dispersion of dust can be minimized by adding liquid ingredients to mixers at the same time as powders, using dust collection systems (e.g., local exhaust, ventilation systems and/or vacuum systems), controlling surrounding dust sources, and/or covering equipment.

Cooking media, such as water or oil, should be dedicated for foods with specific allergen profiles to prevent allergen cross-contact. For example, different tree nuts should not be roasted in the same oil.

Spills that contain food allergens should be cleaned up immediately.

5.2.1.2 Rework

Rework that contains allergens should be stored in sturdy containers with secure covers in designated, clearly marked areas. The rework should be appropriately labelled. Manufacturers should implement a policy for rework to be added back to same finished product (i.e., “exact into exact”) whenever feasible. Alternatively, rework can be added to another product with the same food allergen profile. Allergen-containing rework should be used as soon as possible to minimize the potential for the rework to be incorporated into the wrong product.

5.2.1.3 Application of Labels

Manufacturers should implement procedures to ensure and verify that correct product labels are used on the production line when packaging/labelling products. Labels and labelled containers should be removed at the end of the production run. Manufacturers should implement procedures to destroy or re-label food products that have been labelled incorrectly.

5.2.1.4 Monitoring and verification

Regular internal audits of production systems should be conducted to verify that allergen cross-contact controls are properly implemented, that the product formulation matches the records of allergenic ingredient use, and that the final product matches the ingredients specified on the label.

Manufacturers should use allergen-specific testing procedures where necessary and feasible to identify sanitation failures or possible allergen cross-contact.

5.2.1.5 Product development and change

When developing new products or changing formulations, manufacturers should, where feasible, avoid introducing a new allergen into the establishment or a processing line. Procedures for preventing

cross-contact may need to be reviewed and revised to address a new product or formulation with a different allergen profile. Product labels should be developed and verified to match the formulation before the new product or changed formulation is produced, and product and label specifications that are no longer used should be destroyed or archived in a manner that prevents accidental use.

5.2.2 Retail and Food Service[LK3]

5.2.2.1 Preventing cross-contact during Preparation

Retail and food service operators should know the allergenic ingredients contained in their products, as well as the risks of allergen cross-contact from the processes followed in the preparation of food items. Cross contact during preparation primarily occurs through the following ways:

- Food to food, e.g., by foods touching or one food dripping onto another food.
- Food to hand to food, e.g., handling by cooking staff, front service staff.
- Food to equipment/utensils/surface to food, e.g., sharing of utensils, for example, using a whisk to stir a milk-based sauce and then using the same whisk to stir eggs, without thoroughly washing and drying the whisk between procedures, or using the same cutting board or other surface to prepare fish and shellfish.
- Food to cooking media, e.g., shared fryers for cooking food.

Preparation processes should be designed to prevent allergen cross-contact during food preparation, e.g., separate equipment and utensils that are used for foods with different allergen profiles, dedicate utensils/equipment for allergen-containing products, or clean equipment, utensils and preparation surfaces thoroughly between use for foods with different allergen profiles. Food preparation staff should only use ingredients listed in the recipe, and not replace one ingredient with another unless the ingredient is known not to contain an allergen. Operators should not use foods for which the allergen profile is unknown, and should never guess or assume that an allergen is not present. Cooking media, such as water or oil, should be dedicated for foods with specific allergen profiles to prevent allergen cross-contact. For example, oil used to fry fish should not be used to fry potatoes.

Foods displayed for consumer purchase should be protected from cross-contact during display, e.g., by wrapping or by separation that could include plastic barriers. Designated serving utensils should be provided to handle foods with different allergen profiles, where feasible, or the utensils should be cleaned between use for foods with different allergen profiles. Personnel handling product at display and consumer purchase, as well as servers in restaurants and other food service operations, should be knowledgeable about the allergens in products, especially when the food does not contain labelling that identifies the allergens.

5.2.2.2 Rework

Retail and food service operators should follow procedures similar to those recommended for manufacturers if they use rework.

5.2.2.3 Application of Labels

In retail and food service operations that package and label foods sold directly to consumers, the label is usually generated on site, and often at the point of purchase. Retail and food service operators should implement procedures to ensure that correct product labels are selected when packaging/labelling products. They should implement procedures to destroy or re-label food products that have been labelled incorrectly.

5.2.2.4 Monitoring and verification

Supervisors of food production in retail and food service operations should periodically verify that employees are following the procedures established to prevent cross-contact and inform the consumer about allergens in foods, including applying the appropriate label to packaged foods. Regular review of ingredients and recipes to ensure accuracy of allergen information should also be undertaken.

5.2.2.5 Product development and change

When introducing a new product or formulation with a different allergen profile, procedures for preventing cross-contact may need to be reviewed and revised. Employees that handle these foods, in particular those who have direct interaction with customers, should be made aware of the changes.

5.3 INCOMING MATERIAL REQUIREMENTS

5.3.1 Manufacturing

The source of an undeclared allergen in a finished product may be an ingredient obtained directly from a supplier or an ingredient manufactured by a third-party supplier. Manufacturers should establish specifications for their suppliers that address allergen controls. Suppliers should have good allergen management practices to minimise the risk of cross contact between foods with different allergen profiles. Suppliers should also ensure that all allergens, including allergens in ingredients they use to manufacture another product, are listed on the label. Manufacturers should have programs in place to assess the allergen control programs of suppliers when necessary, e.g., a supplier questionnaire/survey and/or an audit to assess the allergen profile of foods produced at the supplier's site and the supplier's allergen management plan, including cross contact controls and cleaning schedules. Manufacturers should have procedures/policies in place for suppliers to notify the manufacturer of any changes in the supplier's operation that could impact the allergen profile of the ingredient from the supplier (e.g., the introduction of a new allergen into the supplier's establishment, particularly if that allergen will be used on the same line as the ingredient provided to the manufacturer). Manufacturers should have a procedure/policy for ensuring that any change in supplier is accompanied by a review of the product with respect to that supplier's allergen control program.

Incoming foods that are, or that contain, allergens should be labelled to identify the allergens that are present. Manufacturers should review labels on, and documents accompanying, shipments of ingredients (including minor ingredients such as spice blends and flavours) to confirm that the ingredient contains only the expected food allergen(s).

Manufacturers should inspect allergen-containing ingredients upon receipt to ensure that the containers are intact and that the contents have not leaked or spread. If containers have leaks, tears, or other defects, manufacturers should inspect nearby containers for evidence of allergen cross-contact. Manufacturers should reject (or properly dispose of) ingredients when a container is not intact or there is evidence of allergen cross-contact, or handle damaged containers in a manner that prevents allergen cross-contact (e.g., place a damaged container inside another container, or move the contents of the damaged container to a different container).

Manufacturers should clearly identify allergen-containing ingredients using a system that adequately distinguishes between ingredients with different food allergen profiles (e.g., tags or colour coding of cases/pallets/bags) to alert personnel that these materials are subject to special precautions and handling procedures throughout the establishment.

Secure, closable containers should be used to store allergen-containing ingredients. Manufacturers should segregate allergen-containing ingredients from ingredients that do not contain allergens – e.g., in a dedicated storage room or area of the establishment, or in separate bays or areas of a storage room. When this is not feasible, store ingredients that contain allergens below those that do not contain allergens to prevent allergen cross-contact in the event of a spill or leak.

5.3.2 Retail and Food Service

Retail and food service operators should purchase ingredients for which the allergen profile is known, e.g., packaged foods that list all ingredients. For example, if a bag of dried porcini mushroom and herb risotto mix does not list all the contents, then the product should not be used. The labels of incoming packaged ingredients used in the preparation of foods should be reviewed for allergens to ensure knowledge about the allergens present in the final prepared food.

5.4 PACKAGING

Food business operators should have procedures in place to review and approve all proposed product labels of all foods to ensure they are accurate with respect to allergens. There should be a procedure for destroying old packaging and labels when recipes/formulations have been changed to avoid allergen label errors.

5.5 WATER

Water that has come in to contact with a food that is or that contains an allergen should not be recirculated for use on a food that does not contain that allergen.

5.6 MANAGEMENT AND SUPERVISION

Food Business Operator managers and supervisors should have enough knowledge of allergen control principles and practices to be able to judge potential risks and determine the need for new or revised procedures to prevent allergen cross-contact or the need to take corrective action when allergen control procedures are not properly implemented.

5.7 DOCUMENTATION AND RECORDS[LK4]

5.7.1 Manufacturing

5.7.2 Retail and Food Service

5.8 RECALL PROCEDURES

Refer to the *General Principles of Food Hygiene*.

SECTION VI – ESTABLISHEMENT: MAINTENANCE AND SANITATION

6.1 MAINTENANCE AND CLEANING

6.1.1 Manufacturing

Equipment and preparation areas should be adequately cleaned between preparing foods with different allergen profiles to prevent cross contact. Cleaning procedures to remove allergen residues depend on the nature of the food residue, the food contact surface, the nature of the cleaning (e.g., dry cleaning or wet cleaning) and the equipment, tools and materials used for cleaning. Equipment may need to be disassembled to adequately remove allergen residues.

When wet cleaning, low pressure water hoses should be used instead of high pressure water hoses for removing food residues from wet processing areas, since high pressure water hoses could spread and aerosolize food allergen residues during cleaning. When removing dry food residue from difficult-to-clean areas, vacuums should be used, rather than compressed air, since compressed air can disperse food allergen residues from one area to another. If vacuums cannot remove such residues and it is not practical to disassemble equipment for cleaning food residue, manufacturers should take precautions to contain food residues that are removed by the compressed air.

Bins, totes, and containers used for ingredients that are, or contain, a food allergen should be cleaned as soon as possible after being emptied to avoid being a source of cross-contact.

Where feasible, cleaning tools, cloths, sponges, and cleaning solutions should be designated for foods with specific allergen profiles and used in a manner that does not result in cross-contact. For example, freshly prepared cleaning solutions should be used rather than reusing cleaning solutions that have been used for foods with different allergen profiles to prevent recontamination of surfaces with allergenic food residues.

6.1.2 Retail and Food Service

Equipment, utensils, containers and preparation areas should be adequately cleaned immediately after the preparation of allergen-containing foods to prevent allergen cross-contact.

6.2 CLEANING PROGRAMMES

6.2.1 Manufacturing[LK5]

Manufacturers should develop cleaning procedures designed to remove food allergens. These procedures should specify the equipment, utensil, or area of the establishment to be cleaned using the procedures; the tools and cleaning materials to be used; the sequence of steps to be followed, any disassembly required; the monitoring activities, and any actions to be taken if the procedures have not been followed or if food residues have not been adequately removed. The procedures should be validated, where feasible, to demonstrate that if the procedures are followed, allergens are effectively removed. Manufacturers should periodically conduct tests (e.g., rapid ATP (adenosine triphosphate) or protein swabs or test kits) to detect food residues that remain after cleaning as verification that the cleaning procedures have been appropriately implemented and are effective. Where feasible, these tests should include using an allergen-specific test kit (if one is available for the food allergen(s) of interest in the food matrix). If a manufacturer uses Clean in Place (CIP) systems to clean pipe work,

equipment and machinery, there should be verification that the CIP system is effectively removing allergens (e.g., testing rinse samples or swabs).

Because introducing water into some facilities and equipment can result in microbial problems, some production procedures includes a “push-through” technique in which the subsequent product, an inert ingredient (such as sugar or salt), or an allergen-containing ingredient (such as flour) that will be an ingredient in the subsequent product is pushed through the system to remove traces of food residue. Test kits should be used to evaluate “push-through” material, or the first product through the line, to demonstrate that a food allergen from a previous production run has been removed by this process.

Manufacturers should develop allergen clean up procedures for the manufacturing line in the event of spills of allergen-containing ingredients.

Manufacturers should maintain cleaning records and review them to verify that cleaning procedures have been conducted.

6.2.2 Retail and Food Service

Retail and food service operators should develop allergen clean up procedures for the food service preparation area and in the event of spills involving allergen-containing foods.

6.3 PEST CONTROL SYSTEMS

Refer to the *General Principles of Food Hygiene*.

6.4 WASTE MANAGEMENT

Food Business Operators should place waste materials that contain food allergens in covered bins, totes, or containers that are identified as holding allergen-containing waste.

6.5 MONITORING EFFECTIVENESS

Equipment should be inspected after each cleaning to determine whether it is visibly clean. Manufacturers should periodically confirm the results of cleaning and visual inspection through analytical tests (e.g., general tests for any food residue or specific tests for residues of food allergens).

SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE

Food business operators should consider the potential for cross contact of products with allergenic materials via food handlers. For example, food handlers may become a vector for cross contact if food allergens on their skin or clothing are transferred directly to foods. Allergens present as dry products (powders) are more likely to be transferred than non-volatile liquids containing allergens.

7.1 MANUFACTURING

- Manufacturers should consider additional measures to prevent cross contact: Restrict the movement of food handlers between lines processing foods with different allergen profiles. It may be appropriate to visually identify which personnel work on processing lines with different allergen profiles (e.g. different coloured clothing such as hair net etc.)
- Food handlers should wear dedicated clothing in high risk areas where specific allergens are handled. The wearing of this clothing should be restricted to those areas.
- Personnel should not be permitted to bring food or drink into areas where product, ingredients or primary packaging is exposed.

7.2 RETAIL AND FOOD SERVICE

In retail and food service operations when handling allergens such as deveining prawns, consider where feasible, assigning one individual to prepare an allergenic food. Where that is not feasible, ensure that hands and preparation surfaces are thoroughly cleaned before handling another food. When making meals which don’t contain allergens, ensure these are prepared before other foods to prevent cross contact from food handlers clothing.

SECTION VIII - TRANSPORTATION

8.1 GENERAL

FBOs should only distribute foods that are have appropriate allergen labelling and/or be able to provide appropriate documentation (unpacked foods for catering purposes) to determine the allergen status of the food.

Foods that are being distributed should be adequately contained or packaged to protect against allergen contamination.

FBOs should consider whether the foods products are being distributed to other manufacturing / retail / food service facilities. If so, they should ensure allergen managment is considered all along the transportation chain.

8.2 REQUIREMENTS

Foods should be arranged for transport in such a way that unpackaged products with incompatible allergen profiles are transported separately. If this is not possible, consider adding an additional layer of protection by inserting a pallet cover (i.e. big plastic bag used to cover the entire pallet) to reduce the risk of cross contamination, or to consider double bagging of food item. Ensure appropriate barriers and packaging are applied. Try to minimise unnecessary movement of materials.

The haulier/transporter should demonstrate a clear understanding of the food goods they carry and ensure staff can identify potential allergen cross-contamination situations.

8.3 USE AND MAINTENANCE[LK6]

Vehicles, equipment and load carrying areas should be inspected and, if necessary, cleaned to remove any residue of the previous load and allowed to dry internally before loading.

A record should be made when a vehicle has been inspected even if cleaning is not required.

Spillages of foods containing allergens that occur during transportation should be cleaned up as soon as possible to ensure that there is no subsequent allergen cross-contamination.

If any incident [LK7]occurs during loading, transportation or unloading which could result in allergen contamination, the circumstances should be reported to the owner of the goods or customer, and work should not proceed until actions to be taken have been confirmed by them. If the owner of the goods or customer is unwilling to confirm this then the haulier should at least be able to prove that the owner of the goods or customer has been informed of the incident.

If there are any excess goods left on the vehicle due to the bulk facility being full, this must not be put into any other bulk facility unless directed by the recipient. If this occurs, the driver must note what has happened on the delivery receipt note which will be returned to the owner of the goods or customer and the delivery note left with the recipient.

SECTION IX – CONSUMER AWARENESS AND PRODUCT INFORMATION

9.1 LOT IDENTIFICATION

Refer to the *General Principles for Food Hygiene*.

The *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) applies.

9.2 PRODUCT INFORMATION

Refer to the *General Principles for Food Hygiene*.

9.2.1 Manufacturing

All food products and ingredients should be accompanied by or bear adequate information to ensure other food manufacturing or processors can be informed whether the food contains an allergen. This including any applicable “advisory” statements (e.g., “may contain”).

Manufacturers should have in place controls to ensure that food is labelled appropriately, as per section 9.3.

9.2.3 Retail and food service

All food products and ingredients should be accompanied by or bear adequate information to ensure customers can be informed whether a food contains an allergen.

Where the FBO cannot ensure whether a food contains an allergen, this should be clearly communicated to the customer.

Self-serve areas where consumers handle unpackaged food products may pose a particular risk for cross contact. Provision of information on the risk of contamination should be considered in these instances.

9.3 LABELLING

Refer to the *General Principles for Food Hygiene*.

The *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985) applies.

Labelling is an important risk management and risk communication tool for food allergens. The *General Standard for the Labelling of Prepackaged Foods* lists foods known to cause hypersensitivity in 90% of cases. Substances or products causing allergies, as well as ingredients and processing aides originating from a substance or products causing allergies should be declared.

9.4 CONSUMER EDUCATION

Refer to the *General Principles for Food Hygiene*.

SECTION X - TRAINING

10.1 AWARENESS AND RESPONSIBILITIES

All personnel involved in the production, distribution and service of foods should understand the food safety implications of the presence of food allergens and their role in allergen management.

10.2 TRAINING PROGRAMMES

Individuals (e.g. top management, marketing, internal auditors, product developers, design engineers, plant personnel and contractors, employees handling consumer complaints) should receive training specific to their job responsibilities. so they are aware of the measures needed to minimize the risk of allergen cross-contact. All appropriate personnel should be encouraged to take immediate action, if any risk of contamination is suspected.

Training programs should include, as appropriate to the person's duties:

- General allergen awareness including the nature and possible consequences of their unintended or undeclared presence in products from a consumer perspective
- Awareness of the hazards and allergen risks identified at each stage of the food supply chain, including production, storage, transport and/or distribution processes and the corrective measures, the preventative measures and documentation procedures applicable in the individual's business
- Good hygiene practices for example, clothing, hand washing, and hand contact with foods to prevent allergen cross-contact
- Hygienic design of facilities and equipment in relation to allergens
- Cleaning of premises, equipment and tools and its importance in preventing allergen cross-contact
- Handling of re-work materials to prevent unintended allergens being incorporated into a food
- Waste management, for example how waste should be labelled and kept separate to prevent allergen cross-contact
- Situations where potential cross contact can occur between products, production lines or equipment, and prevention measures.
- Procedures for people traffic patterns around the site to minimize allergen transfer from one area to another, for example people changing production line or site, movement to the canteen and of visitors.
- Equipment movement around the site, for example, maintenance tools, food trays, etc to minimize allergen transfer from one area to another
- Production order and handling in order to ensure that ingredients with known allergen profiles are obtained
- Labelling and the awareness of allergen presence in raw materials, semi-finished goods and finished products
- Sources of allergen information, e.g. supplier specifications, supplier audit records.

10.3 INSTRUCTION AND SUPERVISION

Refer to the *General Principles for Food Hygiene*.

10.4 REFRESHER TRAINING

Refer to the *General Principles for Food Hygiene*.

ANNEX I – THE ROLE OF COMPETENT AUTHORITIES IN ALLERGEN INVESTIGATION

Competent authorities should have procedures in place for collecting and triaging information and complaints about undeclared allergens in foods. That procedure should cover collecting all relevant initial details including:

- name, address and phone number of the complainant;
- information on the complaint including the circumstances of the event or product;
- food product in question including date marks/batch number, contact details of manufacturer listed on the label, customer order; or food ordered and how that order was made;
- whether any product or left-over food is available for analysis;
- the location, date and time of purchase;
- other people involved in the incident;
- any other relevant information.

Due to the potential risk to health and safety, allegations of an undeclared allergen in food should be initially assessed as a serious (high risk) complaint. The aim of any such investigation should be to address two key questions urgently:

- Is there a risk to public health and safety? and
- Has appropriate action been taken to address that risk?

The complaint particulars should then be evaluated and a decision made as to what action to take. The decision on action will consider the potential risk identified along with the timeliness, motivation and plausibility of the complaint.

Investigations for manufactured products

The investigation should focus on traceback to identify the product in question and the labelling used for the batch in question.

Possible ways an allergen incident may have occurred:

- Labelling – allergen containing food not properly labelled (e.g., incorrect packaging used);
- Poor process control measures (e.g. cross-contact of allergens during manufacture or storage, not following labelling approval procedures for new or re-worked products)
- Inadequate or incorrect labelling from supplier
- Changes in recipe and/or ingredients

Investigations for retail and food service

The investigation should focus on whether the consumer received the food demanded (e.g. analyse a sample for nuts if the consumer requested a nut free product).

Possible ways an allergen incident may have occurred:

- Labelling and disclosure – allergen containing food not properly labelled (e.g., incorrect packaging used) or information not given to customer when requested;
- Miscommunication between staff (e.g. waiting staff did not communicate the customer requirement to the kitchen)
- Miscommunication between consumer and waiting staff or service provider
- Poor process control measures (e.g. cross-contact of allergens during preparation, storage)
- Inadequate or incorrect labelling from supplier
- Changes in recipe and/or ingredients
- Lack of skills and knowledge

Competent Authorities should also recognise during their investigations, that the source of allergen contamination (undeclared allergen) may be food supplied or manufactured by a third party supplier. Competent Authorities should always conduct further investigations at suspected food businesses in a timely manner to prevent further incidents occurring.

Competent Authorities may develop a set of checklists to be used in a food product allergen investigation to be used as a tool by the authorised officer to audit individual food products suspected of containing undeclared allergens.

The prime objective of an investigation into undeclared allergens in a food is to ensure that public health and safety is protected and the incident will not re-occur. The action plan depends on the outcome of the investigation. Action should always be taken in a timely manner to ensure further incidents do not occur, and public health and safety is protected.

CODE OF PRACTICE ON FOOD ALLERGEN MANAGEMENT FOR FOOD BUSINESS OPERATORS

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INTRODUCTION

Food allergies are an increasing food safety issue globally and have emerged as a major public and personal health burden. While food allergies may affect a relatively small proportion of the population, an allergic reaction can be fatal. Furthermore, it is increasingly apparent that people with food allergies experience a very significant reduction in quality of life, some of which could be mitigated by a harmonised approach to allergens in the food chain.

Allergens are an ongoing food safety concern for allergic consumers, those who have people with food allergy in their care, growers, transporters, Food Business Operators (FBOs) and Competent Authorities.

With the increasing health burden posed by food allergens, comes the expectation that FBOs ~~and Competent Authorities~~[HT1] take steps to manage unintended allergen presence. In a global market it is crucial that there is international understanding of this issue and of the measures required to address it. Allergen management practices should be part of good hygiene practices (GHPs) in manufacturing, retail and food service.

Allergens need to be managed throughout the supply chain and production process. Treatments lethal for microbial pathogens, such as heating, high pressure processing, etc. do not destroy allergenic proteins. Processes that degrade proteins, such as enzymatic or acid hydrolysis, may be effective, but these treatments should be validated for effectiveness in addressing an allergen hazard.

Hazard characterization

The allergenic nature of some foods should be identified as a hazard for susceptible individuals. Food allergies are caused by an adverse immune reaction (hypersensitivity) to certain food proteins. Allergies to food can be classified by their immune mechanism:

- immunoglobulin E (IgE)-mediated (immediate hypersensitivity),
- non-IgE mediated (cell-mediated, or delayed hypersensitivity), e.g., celiac disease, and
- mixed IgE and non-IgE mediated.

IgE-mediated symptoms develop within minutes to 1-2 hours of ingesting the food, non–IgE-mediated and mixed IgE- and non–IgE-mediated food allergies present with their symptoms several hours after the ingestion of the food. Symptoms may include itching around the mouth, hives, swelling of lips and eyes, difficulties in breathing, drop in blood pressure, diarrhoea. drop in blood pressure, and, In its most severe form to anaphylaxis; and where left untreated may result in death.

While many different foods can cause allergic reactions to susceptible individuals, the majority of food allergies on a global basis are caused by a variety of proteins in eight foods/ food groups (and products of these). These include:

- crustaceans
- egg
- fish
- milk
- peanut
- soybean
- tree nuts
- wheat and other cereals containing gluten (and their derivatives)

The most common allergic reactions from tree nuts involve almonds, brazil nuts, cashews, hazelnuts, macadamias, pecans, pistachios and walnuts. In addition, cereal grains such as wheat, barley and rye contain gluten, which can cause adverse reactions in persons with celiac disease, a serious autoimmune, non-IgE-mediated, food allergic disorder and those with specific allergies to those cereals.

While these are the most common, other allergens such as sesame and lupin [can add some others here if members want them in the list] are recognized as important in many countries and there is the potential for additional major allergens to be identified in the future. The controls outlined in this Code would be similar for any other allergens, and FBOs should apply these as appropriate to their own business requirements and applicable legislation.

Poor allergen management (including insufficient or inaccurate labelling) can result in undeclared allergens, which can vary in amount. The doses that provoke reactions vary among individuals. The risk for severe allergic reactions among a larger proportion of the population increases with increasing concentration of undeclared allergen. FBOs should familiarise themselves with the allergens of most significance to their business in terms of the customers that may purchase their food products, including food service personnel being aware of the allergenic profile of the foods they are handling and take steps to manage any potential cross-contact.

Milk, peanut, egg, soybean, tree nuts, and wheat are common ingredients in compound foods and several types of grains are grown and harvested in such a way that the grains of one variety could potentially contaminate another.

Factors contributing to exposure

A variety of situations may result in exposure of allergic individuals to undeclared allergens. These include the following:

For growing, harvesting, handling, storage and transportation:

- insufficient or ineffective cleaning of foreign grains, bags, pallets and transport vehicle;
- insufficient physical separation; and
- insufficient employee training/education on managing food allergens.

For packaged food manufacturing facilities:

- labelling errors (label misprints, outdated labels, label in a foreign language, product in the wrong package);
- allergen cross-contact issues due to in-process or post-process cross-contact;
- inappropriate design of the establishment in terms of separation of areas, location of equipment, traffic patterns, ventilation system, among others;
- errors in handling of rework;
- production sequences (scheduling) that result in one product contaminating a subsequent product;
- insufficient or ineffective equipment cleaning/sanitation procedures at product changeover;
- lack of change management for changes in formulation, ingredient supply and documentation, processes;
- improper use of an allergen-containing ingredient;
- undeclared allergen in a supplier ingredient; and
- insufficient or lack of employee training/education on managing food allergens;

For retail and food service establishments:

- lack of understanding of the serious nature of food allergy by foodservice employees;

- lack of accessible information recorded by FBOs to know which ingredients or foods contain which allergens;
- lack of mechanisms to ensure information recorded by the FBO to know which ingredient or foods contain which allergens is current and accurate
- failure of food allergic individuals in making their allergies known;
- lack of adequate storage or preparation areas;
- insufficient employee training/education on managing food allergens;
- inappropriate flow of operations or improper equipment lay-out;
- inability of FBOs to clearly communicate allergen information;
- absence of, or inadequate, food preparation and service procedures to avoid allergen cross-contact; and
- failure of the establishment to receive accurate ingredient information from supply chain.

Cross contact can occur at many points in the food chain. Potential points where cross contact may occur are outlined in relevant sections within this Code.

FBOs are encouraged to have documented allergen management policies and procedures specific to the food business. Having allergen management policies and procedures in place, and compliance with these, allows a business to demonstrate it is taking all necessary steps to reduce the likelihood of an allergen being inadvertently present in a food. Documented policies and procedures, and compliance with these, also provides an opportunity for businesses to demonstrate adequate skills and knowledge in allergen management and reduces the risk of an allergen incident occurring.

SECTION I - OBJECTIVES

This Code of Practice (Code) provides guidance to FBOs, including primary producers, to develop policies and procedures to identify allergens in all areas of food production, preparation and service, and then implement allergen management practices, including controls to:

- minimise the potential for cross-contact that is of risk to the allergic consumer
- ensure the correct allergen label is applied to pre-packaged foods, and
- that accurate information can be provided to consumers at point of sale.

The management tools and guidance in this Code, if adhered to, are a proactive approach for effectively managing allergens in food production and reducing risk for consumers, rather than a reactive response once a food safety hazard is identified.

Once a food safety hazard is identified, the Code provides some guidance on actions which can be taken by FBOs to mitigate the risk associated with the food allergen hazard.

Food allergen management also involves allergen labelling, which is addressed by the *General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985) and the *Standard for Foods for Special Dietary Use for Persons Intolerant to Gluten* (CODEX STAN 118-1979).

SECTION II – SCOPE, USE AND DEFINITION

2.1 Scope[LK2]

This Code covers allergen management throughout the supply chain including at primary production, during manufacturing, and at retail and food service end points. ~~It provides Good Hygiene Practice (GHP) in manufacturing and food preparation practices in food service.~~[福島3]

This Code covers IgE-mediated and non Ig-E-mediated food allergies (e.g., celiac disease) that can be triggered by small amounts of the offending food allergen (thus requiring attention to GHPs in addition to labelling).

This Code does not cover hypersensitivities with a non-immunological aetiology such as lactose intolerance and sulphite-sensitivity. Food intolerance adverse reactions usually result from a non-immune mediated reaction to food such as a lack of an enzyme to process foods effectively e.g. the absence or deficit of lactase in those with lactose intolerance. While intolerances are not mentioned in the following text, the nature of the controls should provide sufficient management to protect those with intolerances

2.2 Use[LK4]

This Code follows the format of the *General Principles of Food Hygiene* (CAC/RCP 1-1969) and should be used in conjunction with it, as well as with other applicable codes and standards such as the *General Standard for Labelling of Pre-packaged Foods* (CODEX STAN 1-1985 (Rev. 1-1991)) and *Code of Hygienic Practice for the Transport of Food in Bulk and Semi-packed Food*, (CAC/RCP 47-2001).

The provisions in this document should be applied as appropriate, with consideration of the diversity of ingredients, processes, and control measures of the products and various degrees of risk involved in managing allergenic ingredients/foods.

2.3 Definitions[LK5]

For the purpose of this Code, the following expressions have the meaning stated:

Allergen means a usually harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction. In the case of foods, it is a protein which is found in food capable of triggering a response in individuals sensitised to it.

Allergen Profile means the food allergens present (or the absence of any allergens) in a consumed/sold unit of food.

Coeliac disease is a serious illness where the body's immune system attacks its own tissues when you eat gluten. This causes damage to the lining of the gut and means the body can't properly absorb nutrients from food. Coeliac disease is not an allergy or food intolerance.

Competent Authorities means the official government agency having jurisdiction.[HT6]

Cross-contact occurs when a residue or other trace amount of an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food. Cross-contact may result from customary methods of growing and harvesting crops, as well as from the use of shared storage, transportation, or production equipment.

Food business operator (FBO) means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control[HT7].

Food service and retail:
EWG feedback - Potential definitions could be[HT8]:
[businesses, institutions, and companies responsible for any meal prepared outside the home. This industry includes restaurants, school and hospital cafeterias, catering operations, and many other formats.]

or
[A restaurant, canteen, club, public house, school, hospital or similar establishment (including a vehicle or a fixed or mobile stall) where, in the course of a business, food is prepared for delivery to the ultimate consumer and is ready for consumption without further preparation.]

or
[Any establishment (including a vehicle or a fixed or mobile stall), such as restaurants, canteens, schools, hospitals and catering enterprises in which, in the course of a business, food is prepared to be ready for consumption by the final consumer.]

Good Hygienic Practices (GHPs) means

Hazard Analysis and Critical Control Points *(HACCP)* A system that identifies, evaluates and controls hazards that are significant for food safety[HT9].
~~provides a systematic way of identifying food safety hazards and making sure that they are being controlled.~~

Rework ("Rework", "Work in process", "Semi-finished goods", or "Intermediate product" might all be used in a global context.) means clean, unadulterated food that has been removed from processing for reasons other than insanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food

Visibly clean 'Clean' means free from soil, food residue, dirt, grease or other objectionable matter[HT10] ~~dirt, marking, or soiling~~. Visibly clean surfaces look, smell and feel clean. Dirt and soil can be organic, for example, fat, blood; or inorganic, for example rust, limescale.

SECTION III – PRIMARY PRODUCTION[LK11][福島12]

PRINCIPLE:

Where required, primary production should be managed in a way that reduces the likelihood of introducing an allergen which may adversely affect the allergen profile of food at later stages of the food chain.

This section is focused on primary production of cultivated commodities identified as food allergens (allergenic commodities), for example soybeans.

3.1 Environmental hygiene

Where appropriate, growers should know the history of the specific growing area, i.e., what has been grown in that area previously, to assess the potential for allergen cross-contact during primary production. For example, the potential for an allergen from a prior crop (e.g., soybeans) to be harvested with a subsequent crop that is different (e.g., corn) may need to be managed. This may require, where possible and practical, ploughing under previous

crops or destroying or removing old seed heads and stalks of plants prior to planting the new crop. Allowing sufficient time between planting different crops in specific production areas may also help prevent growth of previous crop survivors.

The use of field separation practices could also be considered to minimize the risk of co-mingling of grains at harvest. Where feasible, growers should be aware of the crops planted in the neighbouring fields and consider signposting where crops will be planted to help ensure crop segregation and reduce the risk of cross contact.

3.2 Hygienic production of food sources[LK13]

During growing, ensure that maintenance machinery (e.g. used for weeding) does not contain other plant material which could result in allergen cross-contact. Prior to harvest ensure that equipment used for harvesting of crops is clear of visible plant debris and signs of previous crops/ food material.

3.3 Handling, storage and transport

Freshly harvested commodities should be cleaned using various methods such as sifting via size, aeration and mechanical cleaning, to remove foreign allergenic matter where feasible and consistent with Codex standards. To minimise the risk of allergen cross contact, storage facilities that hold different commodities should be visually inspected and thoroughly cleaned . When handling multiple commodities such as grains/pulses/seeds ensure that physical segregation is in place to minimise the potential for cross-contact. Having a clear "allergen map" of the storage facility will show where allergenic crops enter and are stored so the potential for cross-contact is managed. [LK14]

Where bagging of the commodity is required, bags should be clean, dry and stacked. Bags that have been used for an allergenic commodity should not be reused for a different commodity. Where grains or pulses are bagged and stored together, store allergens on the bottom shelves so that spillages can be easily managed from the perspective of preventing contamination of non-allergenic commodities.

Transportation of food stuff should be carried out using a clean transport vehicle that is dry and free of the previous load to minimize the potential for allergen cross-contact. As necessary, transport containers should be cleaned before use. At unloading, transport containers containing allergenic commodities should be emptied of all cargo and cleaned as appropriate to minimize the potential for allergen cross-contact of the next load. For more detail on transportation refer to Section 8.

3.4 Cleaning, maintenance and personnel hygiene at primary production

Refer to the *General Principles for Food Hygiene*.

In addition, ensure that the area where commodities are dried is clean and physical barriers are in place to prevent spillage and cross contact. Materials or containers used to lay, hang or bag commodities should be cleaned to remove foreign matter and allergenic contaminants. For example, avoid the re-use of jute / canvas bags for non-allergenic commodities if they have already been used for allergenic commodities. Ensure storage areas and storage materials designated for allergenic commodities are clearly labelled or colour coded to prevent unintentional mix of commodities.

SECTION IV – ESTABLISHMENT: DESIGN AND FACILITIES

PRINCIPLE:

Establishment design should minimise the potential for cross-contact with allergens with respect to delimitation and isolation of areas, location of equipment, process flow, personnel movement and ventilation systems.

4.1 Location

4.1.1 Establishments

FBOs producing food at more than one site should consider whether it is feasible to consolidate production, processing and storage of products containing allergens at one location. Although this will not be a common strategy, particularly for small businesses, it could be used to manage cross-contact. If this is not possible, the production could be separated in time (see 5.2.1.) and the establishment may be designed to have a linear flow in the production.

4.1.2 Equipment

EWG – please provide feedback on which paragraph you prefer a or b below

a. [Where feasible, manufacturers should consider the use of dedicated processing lines for processing foods with and without a particular allergen (e.g., separate lines for dark chocolate and milk chocolate; separate lines for milk or soy-based beverages and other beverages that do not contain these allergens). This may be the best way to prevent cross-contact for some foods that are not cleaned with water to minimise microbial hazards or are viscous or sticky and thus difficult to remove from equipment during cleaning, particularly if some parts of the equipment are inaccessible. If dedication of equipment is not feasible, then other effective allergen management controls and production scheduling matrices should be used.]

Alternate text for paragraph above[HT15]
b. [Food manufacturing facilities commonly handle multiple allergens, frequently on the same equipment. Ideally these facilities would be designed to use processing lines dedicated to food with specific allergen profiles and where feasible, manufacturers should consider the use of dedicated lines, however, this is not feasible in most cases. An analysis of the process, including the equipment design, should be conducted to determine the risk to the allergic consumer and whether dedicated processing lines, equipment redesign, or other control measures are needed to ensure appropriate consumer protection.]

If separate production lines are used for foods with different allergen profiles (e.g., for foods that do not contain a particular allergen and for foods that do), manufacturers should provide sufficient separation to minimize the potential for cross-contact from one line to another based on the food, the process, and the likelihood of cross-contact. Manufacturers should eliminate cross-over points or provide a means to contain, or shield food (e.g., closed pipes, enclosed or covered conveyors) to prevent food spilling from one line to another.

Retail and food service operators should, where feasible, use equipment dedicated to foods with a particular allergen (e.g., use a separate slicer for cheese, which contains milk, and for meats that do not contain milk).

4.2 Premises and rooms

Where feasible, manufacturers, as well as retail and food service operators, should provide a dedicated production area within the establishment for the preparation of foods that do not contain allergens, or provide dedicated production areas for foods with different allergen profiles. For example, an establishment that handles different types of tree nuts could dedicate separate rooms or other areas for handling each type of nut. One that handles different types of protein powders such as soy protein and whey powder could dedicate separate areas for handling these powders. Where applicable, the rooms should be appropriately designed such that effective cleaning could be administered to reduce cross-contact.

Manufacturers should consider providing barriers (e.g., walls, partitions, curtains) when necessary to prevent allergen cross-contact when foods with different allergen profiles are processed at the same time.
[When necessary, manufacturers should consider designing premises and rooms to ensure appropriate allergen dust removal or hood systems to mitigate the risk of airborne allergen contamination throughout the processing area, especially when powdered allergens such as wheat flour, dried milk powder, soy protein, etc. are used[HT16].] [LK17]Store allergens separately and separate them from non-allergenic ingredients.

4.3 Equipment

4.3.1 Manufacturing

Equipment, tools, utensils and containers (other than single-use containers and packaging) contacting foods that contain allergens should be designed and constructed to ensure that allergens can be removed during cleaning. To minimise the potential for allergen cross-contact, ideally they should not contain areas where allergens, especially particulate allergens (e.g., peanuts, tree nuts), could get caught in crevices such that they are not removed by the cleaning procedures applied. Welds should be smooth, seals and hoses should not contain cracks, and “dead ends” or other areas where pockets of foods containing allergens can accumulate should be eliminated.

4.3.2 Retail and Food Service

Retail and food service operators should use equipment, tools, utensils and containers (other than single-use containers and packaging) that have been designed and constructed to ensure that allergens can be removed during cleaning.

4.4 Facilities

FBOs, including retail and foodservice[HT18] should place hand wash basins in appropriate areas to prevent allergen cross-contact via personnel. Having convenient hand wash basins will encourage employees to wash hands with soap and water between handling foods that have different allergen profiles. FBOs should also consider facilities to enable change of protective clothing, especially when moving from particular areas within the manufacturing facility.

SECTION V – CONTROL OF OPERATION

PRINCIPLE:

The unintentional presence of allergens in food is minimised by taking preventative measures at appropriate stages in the operation.

5.1 Control of food hazards

FBOs should control allergens by minimising the potential for allergen cross-contact, by ensuring that labels identifying the allergens present in foods are correct, and that retail and food service establishments are able to communicate the allergens present in the foods they prepare. Controls should be risk-based. Information helpful in assessing risk include;

- allergens present in the facility;
- the nature of the allergen (i.e., whether the food itself is an allergen, or the allergen is a component in an ingredient);
- whether the allergen is a particle, powder, liquid or paste; and
- the processing steps where the allergen is used.

It is important that FBOs educate and train staff to have awareness of food allergens and their health impact in order to ensure staff implement the necessary allergen controls.

5.1.1 Manufacturing

Manufacturers should:

- identify any steps in their operations that pose a risk of allergen cross-contact, assess the level of risk at those steps and identify the ones that are critical;
- implement effective [control[HT19]] [management] [LK20]procedures to minimise allergen cross-contact at those steps;
- identify steps in the operation that are critical to ensuring allergens are properly labelled;
- monitor [control] [management] procedures to ensure their continuing effectiveness; and
- review allergen [control] [management] procedures periodically, particularly when the operations change.
- ensure suppliers are familiar with food allergen specifications; and
- ensure staff are aware of and follow allergen [control] [management] procedures.

5.1.2 Retail and Food Service

Retail and food service operators should:

- identify any steps in their operations that pose a risk of allergen cross-contact;
- implement effective procedures to minimise allergen cross-contact at those steps;
- monitor [control] [management] procedures to ensure their continuing effectiveness;
- review allergen [control] [management] procedures periodically, particularly when the operations change
- ensure suppliers are familiar with food allergen specifications;
- ensure staff are aware of and follow allergen [control] [management] procedures; and
- manage menus, including in-store and on websites, if they contain allergen information to assure content is current and matches product.

5.2 Key aspects of hygiene control systems

5.2.1 Manufacturing

5.2.1.1 Minimising cross-contact during processing

Allergen cross-contact can result from a number of factors in processing foods, some of which pose a greater potential for cross-contact than others. The control measures implemented to minimise cross-contact should be based on risk. In some instances, it may not be possible to prevent cross-contact, despite the implementation of preventative measures and good hygienic practices. However, it may be possible to minimize cross-contact to an extent that the amount of allergen present due to cross-contact is below a threshold that would cause an adverse reaction in an allergenic consumer. Information on population threshold dose responses is becoming available. The data show that some allergen dose exposures, as well as the presence of certain allergen-derived ingredients, may not cause allergic reactions in most food allergic individuals. This information will be important in the development of allergen [control] ~~[management]~~ programs to appropriately manage the risk to allergic consumers.[HT21]

If the same production area is used for foods with different allergen profiles, manufacturers should, where feasible, implement production scheduling to separate by time the manufacture of products with different food allergen profiles, e.g., process foods that do not contain allergens before foods with allergens. For instance, production schedules could be established in some cases whereby products that do not contain allergens are handled at the beginning of the schedule and different products containing the same food allergen profile could be run sequentially before products with different allergen profiles to reduce the potential for allergen cross-contact (e.g., all frozen desserts containing only milk are run before those containing both milk and egg). Where possible, allergenic ingredients should be added as late in the production process as possible, or as far downstream as possible in the processing line (e.g., closest to the filling and packaging equipment), to minimise the amount of equipment in the production area that comes in contact with the allergen. This will help minimise potential allergen cross-contact.

Manufacturers should develop traffic flow of allergen-containing ingredients, packaging supplies and employees during the manufacture of foods to minimize the potential for allergen cross-contact. This should include consideration for managing the movement for transient people such as managers, quality assurance personnel, inspectors, engineers, and visitors.

"Allergen mapping" (a floor map[HT22] ~~flow diagram~~ that identifies where allergens are stored, handled and prepared on site, overlaid with the processes involved) can be useful in identifying areas where controls should be applied to minimise allergen cross-contact. Where feasible, employees working on processing lines that contain an allergen should be restricted from working on lines that do not contain that allergen. Manufacturers should

consider a system to clearly identify employees working on lines manufacturing foods containing different allergen profiles, e.g., different coloured uniform or hair net.

Containers and tools used to hold or transfer foods that contain allergens should, where possible, be dedicated to holding a specific allergen and be marked, tagged, or color-coded to identify the allergen. Where such dedication is not possible, effective cleaning procedures should be in place to clean containers before use for a food with a different allergen profile.

Manufacturers should provide shielding, permanent and/or temporary partitions, covers, and catch pans to protect exposed unpackaged product from allergen cross-contact. Dry ingredients should be physically contained by covering specific equipment, such as conveying equipment, hoppers, storage silos, shakers, and size graders. Where feasible, manufacturers should dedicate utensils and tools for processing lines with different food allergen profiles; these utensils and tools should be distinguishable (e.g., through marking, tagging or color-coding) to minimize the potential for allergen cross-contact.

Manufacturers should not use ingredients for which the allergen profile is unknown, and should never guess or assume that an allergen is not present. Allergen-containing ingredients should, if feasible and necessary to minimise the potential for cross-contact, be opened and weighed in designated areas before being transferred in covered or closed containers to the processing line. Dry ingredients that are, or contain, a food allergen should be added in a manner that minimizes the potential for unintentional dispersion by dust. For example, the formation and dispersion of allergen dust can be minimized by adding liquid ingredients to mixers at the same time as powders, using dust collection systems (e.g., local exhaust, ventilation systems and/or vacuum systems), controlling surrounding dust sources, and/or covering equipment.

The use of dry allergens with a propensity for dust formation should, where feasible, be scheduled at the end of a production/processing day to allow sufficient time for the air handling system to evacuate any residual allergenic dust from the establishment environment overnight[HT23].[LK24]

Manufacturers should evaluate the potential for cross-contact due to using cooking media, such as water or oil. Frying oil may need to be filtered to remove allergen-containing particulate material if it is likely that such particles could end up in a food with a different allergen profile.

Spills that contain food allergens should be cleaned up immediately avoiding further dispersion (e.g., care not to generate aerosols with high pressure washers)..

5.2.1.2 Rework and Work-in-Process

Rework and Work-in-Process (WIP) that contains allergens should be stored in sturdy containers with secure covers in designated, clearly marked areas. The rework or WIP should be appropriately labelled and properly inventoried and accounted for during storage and when used, to minimise the potential for incorporation into the wrong product. Manufacturers should implement a policy for rework to be added back to same finished product whenever feasible. Alternatively, rework can be added to another product with the same food allergen profile.

5.2.1.3 Application of Product Labels

Manufacturers should implement procedures to ensure that product labels are accurate (see 5.3 Incoming Material Requirements) and verify that the correct product labels are used on the production line when packaging/labelling products. This could involve manual checks and/or automated checks

such as bar code recognition to ensure the correct packaging is used. Labels and labelled containers should be stored in a way that minimises the potential to pull incorrect labels or containers during production.. All labels and labelled containers should be removed at the end of the production run and returned to their designated storage area. Manufacturers should implement procedures to segregate and re-label food products that have been labelled incorrectly. If it is not possible to re-label such food they should have a procedure to destroy the food.

5.2.1.4 Monitoring and verification

Regular internal audits of production systems should be conducted to verify that the product formulation matches the records of allergenic ingredient use, that the final product matches the ingredients specified on the label, that allergen cross-contact controls are properly implemented and that operatives are appropriately trained.

Manufacturers should use allergen-specific testing procedures where necessary and feasible to identify sanitation failures or possible allergen cross-contact. The test used should be appropriate for the targeted allergen, e.g., casein test should not be used when whey is the allergen of concern. The test should be validated to work with the matrix/food of concern.

Manufacturers should ~~monitor suppliers to~~[福島25] ensure that multi-component ingredients (e.g., sauces, spice mixes) have not changed and verify that advisory statements are only applied in instances where the manufacturer cannot reasonably prevent allergen cross-contact.

5.2.1.5 Product development and change

When developing new products, or changing formulations or ingredient suppliers, manufacturers should, where feasible, avoid introducing a new allergen into the establishment or a processing line and consider whether it is feasible to use a non-allergenic ingredient to provide the same functionality as an allergenic ingredient. Where the introduction of a new allergen into the establishment or a processing line is unavoidable e.g. during factory trials or consumer testing, care should be given to avoid cross-contact with existing products. Procedures for preventing cross-contact, as well as relevant HACCP documents, operating procedures and associated staff training, may need to be reviewed and revised to address a new product or formulation with a different allergen profile, especially when a new allergen to the company is involved. Product labels should be developed and verified to match the formulation before the new product or changed formulation is produced, and product and label specifications that are no longer used should be destroyed or archived in a manner that prevents accidental use.

5.2.2 Retail and Food Service

Equipment that has been used for allergen-containing foods should be marked, tagged, or color-coded to identify the allergen. Where this is not practical, equipment should be cleaned between use for foods with different allergen profiles.

Food that contains allergens should also be stored separate from food that does not contain allergens.

5.2.2.1 Minimising cross-contact during preparation

Retail, and food service operators and staff (e.g., cooks and front of house staff that interact with customers) should know the allergenic ingredients contained in their products and inform the allergic consumers on these ingredients when necessary. They should also know the risks of allergen cross-contact from the processes followed in the preparation of food items. Cross contact during preparation primarily occurs in the following ways:

- Food to food, e.g., by foods touching or one food dripping onto another food.
- Food to hand to food, e.g., handling by cooking staff, front service staff or using hands in multiple containers of ingredients containing different allergen profiles without washing in between such as adding toppings to pizzas, assembling sandwiches etc.
- Food to equipment/utensils/surface to food, e.g., sharing of utensils, for example, using a whisk to stir a milk-based sauce and then using the same whisk to stir eggs, without thoroughly washing and drying the whisk between procedures, or using the same cutting board, griddle/frying pan, or other surface to prepare fish and shellfish.
- Food to cooking media, e.g., shared fryers for cooking food.

Preparation processes should be designed to prevent allergen cross-contact during food preparation, e.g., separate equipment and utensils that are used for foods with different allergen profiles, dedicate utensils/equipment for allergen-containing products, or clean equipment, utensils and preparation surfaces thoroughly between uses for foods with different allergen profiles.

Containers and tools used to hold or transfer foods that contain allergens should, where possible, be dedicated to holding a specific allergen and be marked, tagged, or color-coded to identify the allergen. Where such dedication is not possible, effective cleaning procedures should be in place to clean containers before use for a food with a different allergen profile.

Food preparation staff should only use ingredients listed in the recipe, and not replace one ingredient with another unless the ingredient is known not to contain an allergen. Operators should not use foods for which the allergen profile is unknown, and should never guess or assume that an allergen is not present. Retail and food service operators should consider whether it is feasible and necessary to dedicate cooking media, such as water or oil, to foods with specific allergen profiles to prevent allergen cross-contact, for example, not using oil to fry both fish and potatoes, if fish particles could end up in the potatoes. Frying oil may need to be filtered to remove allergen-containing particulate material if it is likely that such particles could end up in food with a different allergen profile.

Foods displayed for consumer purchase should be protected from cross-contact during display, e.g., by wrapping or by separation that could include plastic barriers. Designated serving utensils should be provided to handle foods with different allergen profiles, where feasible, and should only be used for that food, or the utensils should be cleaned between uses for foods with different allergen profiles.

Personnel handling product at display and consumer purchase, as well as servers in restaurants and other food service operations, should be knowledgeable about the allergens in products; alternatively, the personnel should know how to obtain the information about the allergens in products rapidly - especially when the food does not contain labelling that identifies the allergens.

5.2.2.2 Rework

Rework and Work-in-Process (WIP) should be stored in sturdy containers with secure covers in designated, clearly marked areas. The rework or WIP should be appropriately labelled to minimise the potential for incorporation into the wrong product. Food handlers should implement a policy for rework to be added back to the same finished product) whenever feasible. Alternatively, rework can be added into another product with the same food allergen profile.

5.2.2.3 Application of Product Labels

In retail and food service operations that package and label foods sold directly to consumers, the label or allergen information is usually generated and provided on site, and often at the point of purchase. Retail and food service operators should implement procedures to ensure that product labels are accurate and the correct product labels/information are provided when packaging/labelling products. They should implement procedures to segregate and then destroy or re-label food products that have been labelled incorrectly.

5.2.2.4 Monitoring and verification

Supervisors of food production in retail and food service operations should periodically verify that employees are following the procedures established to minimise the potential for allergen cross-contact and inform the consumer about allergens in foods, including applying the appropriate label to packaged foods and providing the relevant information with respect to unpackaged foods. Regular review of ingredients and recipes to ensure accuracy of allergen information should also be undertaken.

5.2.2.5 Product development and change

When introducing a new product or recipe with a different allergen profile, procedures for preventing cross-contact will need to be reviewed and possibly revised. Employees that handle these foods, in particular those who have direct interaction with customers should be made aware of the changes in a timely manner.

5.3 Incoming material requirements

5.3.1 Manufacturing

The source of an allergen unintentionally present in a finished product may be an ingredient obtained directly from a supplier or an ingredient manufactured by a third-party supplier. Manufacturers should establish specifications for their suppliers that address allergen controls as appropriate to the supplier and the use of the ingredient by the manufacturer.

Suppliers should have good allergen management practices to minimise the risk of cross-contact between foods with different allergen profiles. Suppliers should also ensure that all food allergens, including allergens in ingredients they use to manufacture another product, are listed in product information or on the label of the finished product (e.g., milk in a spice blend ingredient used in a food).

Manufacturers should have programs in place to assess the allergen control programs of suppliers when necessary, e.g., a supplier questionnaire/survey and/or an audit to assess the allergen profile of foods produced at the supplier's site and the supplier's allergen management plan, including cross contact controls and cleaning schedules. A specification sheet, certificate of analysis, vendor guarantee with each lot can also be useful in addressing a supplier's control of food allergens. Manufacturers should have procedures/policies in place for suppliers to notify the manufacturer of any changes in the supplier's operation as necessary [maff26] that could impact the allergen profile of the ingredient from the supplier (e.g., a change in formulation affecting the allergen profile [maff27] or the introduction of a new allergen into the supplier's establishment, particularly if that allergen will be used on the same line as the ingredient provided to the manufacturer). Manufacturers should have a procedure/policy for ensuring that any change in supplier is accompanied by a review of the product being manufactured with respect to that supplier's allergen control program.

Incoming foods that are, or that contain, allergens should be labelled to identify the allergens that are present using common terms (e.g., 'milk' when casein is an ingredient). Manufacturers should review labels on, and documents accompanying, shipments of ingredients (including minor ingredients such as spice blends and flavours) to confirm that the ingredient contains only the expected food allergen(s). Particular attention should be paid to multi-component pre-mixed ingredient packages. Manufacturers should have policies in place to address ingredients that include advisory statements on the label.

Manufacturers should inspect ingredients, especially allergen-containing ingredients, upon receipt to ensure that the containers are intact and that the contents have not leaked or spread. If containers have leaks, tears, or other defects, manufacturers should inspect nearby containers for evidence of allergen cross-contact. Manufacturers should reject (or properly dispose of) ingredients when a container is not intact or there is evidence of allergen cross-contact, or handle damaged containers in a manner that minimises the potential for allergen cross-contact (e.g., place a damaged container inside another container, or move the contents of the damaged container to a different container).

Manufacturers should clearly identify allergen-containing ingredients and processing aids using a system that adequately distinguishes between ingredients with different food allergen profiles (e.g., tags or colour coding of cases/pallets/bags) to alert personnel that these materials are subject to special precautions and handling procedures throughout the establishment.

Secure, closable containers should be used to store allergen-containing ingredients and processing aids. Manufacturers should segregate allergen-containing ingredients based on allergen type and from ingredients that do not contain allergens – e.g., in a dedicated storage room or area of the establishment, or in separate bays or areas of a storage room. When this is not feasible, ingredients that contain allergens should be stored below those that do not contain allergens to prevent allergen cross-contact in the event of a spill or leak.

5.3.2 Retail and Food Service

Retail and food service operators should purchase ingredients for which the allergen profile is known, e.g., packaged foods that list all ingredients. For example, if a bag of dried porcini mushroom and herb risotto mix does not list all the contents, then the product should not be used.

Retail and food service operators should inspect ingredients, especially allergen-containing ingredients, upon receipt to ensure that the containers are intact and that the contents have not leaked or spread. If containers have leaks, tears, or other defects, operators should inspect nearby containers for evidence of allergen cross-contact. Retail and food service operators should reject (or properly dispose of) ingredients when a container is not intact or there is evidence of allergen cross-contact, or handle damaged containers in a manner that minimises the potential for allergen cross-contact (e.g., place a damaged container inside another container, or move the contents of the damaged container to a different container).

The labels of incoming packaged ingredients used in the preparation of foods should be reviewed for allergens to ensure knowledge about the allergens present in the final prepared food. Retail and food service operators should store allergen-containing ingredients in a manner to minimise the potential for allergen cross-contact.

5.4 Packaging

FBOs should have procedures in place to review and approve all proposed product labels of all foods to ensure they are accurate with respect to allergens. There should be a procedure

for destroying old packaging and labels (and to maintain electronic document control of old labels) when recipes/formulations have been changed to avoid allergen label errors.

5.5 Water

Water that has come in to contact with a food that is or that contains an allergen (e.g., water used for cooking or washing) should not be recirculated for use on a food that does not contain that allergen if such use could result in allergen cross-contact that could present a risk to allergic consumers.

Re-use of CIP rinse water from washing equipment containing an allergen should be avoided if this could result in allergen cross-contact that could present a risk to allergic consumers.

5.6 Management and supervision

Food Business Operator managers and supervisors need to have enough knowledge of allergen control principles and practices to be able to judge potential risks and determine the need for new or revised procedures to prevent allergen cross-contact or the need to take corrective action when allergen control procedures are not properly implemented.

5.7 Documentation and records

5.7.1 Manufacturing

Records could include those for:

- suppliers' allergen management (e.g., questionnaire, survey and/or an audit to assess the allergen profile of foods produced at the supplier's site and the supplier's allergen management plan, including cross contact controls and cleaning schedules),
- procedures for handling and storage of allergens,
- label review,
- label application,
- proper allergenic ingredient storage,
- scheduling,
- batching,
- rework,
- cleaning,
- validation data,
- verification activities (including any analytical test results for allergens), and
- training.

5.7.2 Retail and Food Service

Records could include those for

- allergenic ingredients associated with each menu item,
- cleaning, and
- training.

5.8 Recall procedures

Refer to the *General Principles of Food Hygiene*. 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) to enable the withdrawal of products where necessary. Procedures and processes should be in place that

facilitate a one step back and one step forward traceability review in the case of a food allergen incident.

5.8.1 Consumer complaints[LK28][HT29]

FBOs should have procedures in place for collecting and triaging information and complaints about undeclared allergens in foods.

The complaint particulars should be evaluated and a decision made as to what action to take. The decision on action will consider the potential risk identified along with the timeliness, motivation and plausibility of the complaint. FBOs may need to contact their relevant Competent Authority for assistance in determining the most appropriate course of action.

The prime objective of an investigation into undeclared allergens in a food is to ensure that public health and safety is protected and the incident will not re-occur. The action plan depends on the outcome of the investigation. Action should always be taken in a timely manner to ensure further incidents do not occur, and public health and safety is protected.

SECTION VI – ESTABLISHMENT: MAINTENANCE AND SANITATION

PRINCIPLE:

The effective control of food allergens is facilitated by establishing effective maintenance and cleaning programs that minimise the potential for allergen cross-contact.

6.1 Maintenance and cleaning

6.1.1 Manufacturing

Inspect and remove any hand tools and utensils if they are damaged and not easily cleanable. Where feasible, label or colour code maintenance tools to correspond with specific allergens.

Equipment and preparation areas should be adequately cleaned between manufacturing foods with different allergen profiles to minimise the potential for allergen cross contact. Cleaning procedures to remove allergen residues depend on the nature of the food residue, the food contact surface, the nature of the cleaning (e.g., dry cleaning or wet cleaning) and the equipment, tools and materials used for cleaning. Equipment may need to be disassembled to adequately remove allergen residues where feasible, however some equipment cannot be disassembled. This should be taken into account in the allergen management program.

When wet cleaning, low pressure water hoses should be used instead of high pressure water hoses for removing food residues from wet processing areas, since high pressure water hoses could spread and aerosolize food allergen residues during cleaning. When removing dry food residue from difficult-to-clean areas, scrapers, brushes and vacuum cleaners (that are fit for purpose) should be used, rather than compressed air, since compressed air can disperse food allergen residues from one area to another[LK30]. If vacuums cannot remove such residues and it is not practical to disassemble equipment for cleaning food residue, manufacturers should take precautions to contain food residues that are removed by the compressed air. Cleaning should include the ductwork in ventilation systems where necessary to minimize allergen cross-contact.

Bins, totes, and containers used for ingredients that are, or contain, a food allergen should be cleaned as soon as possible after being emptied to avoid being a source of cross-contact. Such items should remain labelled as containing an allergen until cleaning is complete.

Where feasible, cleaning equipment, tools, cloths, sponges, and cleaning solutions should be designated for foods with specific allergen profiles and used in a manner that does not result in cross-contact. For example, freshly prepared cleaning solutions should be used rather than reusing cleaning solutions that have been used for foods with different allergen profiles to prevent recontamination of surfaces with allergenic food residues.

6.1.2 Retail and Food Service

Equipment, utensils, containers and preparation areas should be adequately cleaned (at a minimum visually clean) immediately after the preparation storage and dispensing of allergen-containing foods to prevent allergen cross-contact.

6.2 Cleaning programmes

6.2.1 Manufacturing

Manufacturers should develop cleaning procedures designed to remove food allergens. These procedures should specify the equipment, utensil, or area of the establishment to be cleaned using the procedures; the tools and cleaning materials to be used; the sequence of steps to be followed, any disassembly required; the monitoring activities, and any actions to be taken if the procedures have not been followed or if food residues have not been adequately removed.

If a manufacturer uses Clean in Place (CIP) systems to clean pipe work, equipment and machinery, there should be verification that the CIP system is effectively removing allergens (e.g., testing rinse samples or swabs).

Because introducing water into some facilities and equipment can result in microbial problems, some production procedures includes a “push-through” technique in which the subsequent product, an inert ingredient (such as sugar or salt), or an allergen-containing ingredient (such as flour) that will be an ingredient in the subsequent product is pushed through the system to remove food residue. Test kits should be used to evaluate “push-through” material, or the first product through the line, to demonstrate that a food allergen from a previous production run has been removed by this process.

Manufacturers should develop allergen clean up procedures for the manufacturing line in the event of spills of allergen-containing ingredients.

Manufacturers should maintain cleaning records, including any test results, and review them to verify that cleaning procedures have been conducted and adequately remove allergens.

6.2.2 Retail and Food Service

Retail and food service operators should develop allergen clean up procedures for the food service preparation, storage and presentation areas and in the event of spills involving allergen-containing foods.

6.3 Pest control systems

Refer to the *General Principles of Food Hygiene*. In addition, pest control system should not use allergens (e.g., peanut butter, cheese) as bait in traps. It is important for FBOs to make pest control service providers aware of their allergenic concerns.

6.4 Waste management

FBOs should place waste materials that contain food allergens in covered bins, totes, or containers that are identified as holding waste and handled in a manner to minimise the potential for allergen cross-contact.

6.5 Monitoring effectiveness

Cleaning procedures should be validated, where feasible, to demonstrate that if the procedures are followed, allergens are effectively removed. Equipment should be inspected after each cleaning to determine whether it is visibly clean; this is particularly useful with particulate allergens.

Manufacturers should periodically conduct tests (e.g., rapid ATP (adenosine triphosphate) or protein swabs or test kits) to detect food residues that remain after cleaning as verification that the cleaning procedures have been appropriately implemented and are effective. Where feasible, these tests should include using an allergen-specific test kit (if one is available for the food allergen(s) of interest in the food matrix). FBOs should know the detection level of the test used.

SECTION VII – ESTABLISHMENT: PERSONAL HYGIENE

PRINCIPLE:

Personal hygiene practices should manage the potential for food handlers to contribute to allergen cross-contact.

FBOs should consider the potential for cross contact of products with allergenic materials via food handlers. For example, food handlers may become a vector for cross contact if food allergens on their skin or clothing are transferred directly to foods. In addition to allergens from foods, this could include allergens that may be present in some hand creams (e.g., nuts such as almonds). FBOs should encourage employees to wash hands between handling foods that have different allergen profiles. Allergens present as dry products (powders) are more likely to be transferred than non-volatile liquids containing allergens.

7.1 Manufacturing

Where necessary, [福島31] ~~f~~Food handlers should wear dedicated clothing in areas where specific allergens are handled and there is a high risk of allergen cross-contact. The wearing of this clothing should be restricted to those areas. It may be appropriate to visually identify which personnel work on processing lines with different allergen profiles (e.g. different coloured clothing such as smocks or hair nets).

Personnel should not be permitted to bring food or drink into areas where product, ingredients or primary packaging is exposed as these foods may contain allergens and result in allergen cross-contact.

7.2 Retail and Food Service

In retail and food service operations consider, where feasible, assigning one individual to prepare an allergenic food (e.g., deveining prawns/shrimp). Where that is not feasible, ensure that the operator's hands, equipment and preparation surfaces are thoroughly cleaned before handling another food.

SECTION VIII – TRANSPORTATION

PRINCIPLE:

Food allergen profiles should be managed during transportation so that allergen cross-contact is prevented.

8.2 General

FBOs should only distribute foods that have appropriate allergen labelling and/or be able to provide appropriate documentation (e.g., unpacked foods for catering purposes) for recipients to determine the allergen status of the food.

Foods that are being distributed should be adequately contained or packaged to protect against allergen cross-contact.

8.2 Requirements

Foods should be arranged for transport in such a way that unpackaged products with incompatible allergen profiles are transported separately. If this is not possible, consider other means of segregating the foods, such as inserting a pallet cover (i.e. big plastic bag used to cover the entire pallet) to reduce the risk of allergen cross contact, stacking non-allergenic food on top of allergenic food, or packaging the food using poly bags super sacks, or bags with plastic overwrap. Procedures should minimise unnecessary movement of materials.

The food transportation unit, should be suitably designed and constructed to facilitate inspection and cleaning, see "*Code of Hygienic Practice for the transport of food in bulk and semi-packed food, CAC/RCP 47-2001*."

The haulier/transporter should demonstrate a clear understanding of the food goods they carry and ensure staff can identify and understand potential allergen cross-contamination situations.

8.3 Use and maintenance

Vehicles such as bulk tankers used to transport liquids (raw milk, dairy mixes, liquid egg, oil, water) must be adequately cleaned between loads to prevent allergen cross contact. In some instances dedicated bulk tankers may be best e.g., for dry powders such as wheat flour.

Food transportation units* [1](includes relevant accessories, connections) and load carrying areas, should be inspected and, if necessary, cleaned to remove any residue of the previous load, to the extent possible, before re-loading. The method of cleaning adopted must be appropriate to the type of commodity and type of allergen to be loaded in the unit.

Carts and trolleys used to transport food within a retail or food service establishment must be kept clean between uses; e.g., a meal of cheese omelette and toast spilled onto a cart and not properly cleaned between uses could contaminate a subsequent meal, utensils or cups transported to another customer that has allergies to egg, milk or wheat.

For commercial scale haulage, a record should be made when a vehicle has been inspected even if cleaning is not needed. If feasible, designated vehicles should be used for transporting allergenic ingredients e.g., raw tree nuts.

Spillages of foods containing allergens that occur during transportation should be cleaned up as soon as possible to ensure that there is no subsequent allergen cross-contact. If any incident occurs during loading, transportation or unloading which could result in allergen contamination, the circumstances should be reported to the owner of the goods or their customer for their consideration and for them to advise if specific measures are needed.

SECTION IX – CONSUMER AWARENESS AND PRODUCT INFORMATION

PRINCIPLE:

Consumers should have access to adequate and correct information on the allergenic nature of a food. This should ensure those with allergies can avoid allergenic foods and ingredients.

9.1 Lot identification

Refer to the *General Principles for Food Hygiene* (CAC/RCP 1-1969).
The *General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985) applies.

9.2 Product information

Refer to the *General Principles for Food Hygiene* (CAC/RCP 1-1969).

9.2.1 Manufacturing

All food products and ingredients should be accompanied by or bear adequate information to ensure other food manufacturing or processors and consumers can be informed whether the food is, or contains, an allergenic ingredient.

Manufacturers should have procedures in place to ensure that food is labelled appropriately, as per section 9.3.

[1] Code of Hygienic Practice for the transport of food in bulk and semi-packed food, CAC/RCP 47-2001

*Food transportation unit refers to food transport vehicles or contact receptacles (such as boxes, containers, bins, bulk tanks) in vehicles, aircraft, trailers and ships and other transport receptacles in which food is transported.

9.2.3 Retail and food service

All food products and ingredients should be accompanied by or bear adequate information to ensure customers can be informed whether a food is, or contains (or may contain) an allergenic ingredient.

Restaurants should ensure that customers can be informed whether a food is, or contains (or may contain) ~~an~~ allergenic ingredients[maff32] ~~any allergen information~~ on the menu (~~, both~~e.g. in store and online) and/or by face-to-face communication with staffs[maff33]~~,~~ ~~is current~~.

~~Front of house e~~E[福島34]mployees that serve food to customers should be knowledgeable about the allergens in menu items and preparation practices of the business that may result in cross-contact. They should also ask customers about any food allergies. Where the ~~food business operator~~FBOs[福島35] cannot ensure that a food does not contain an allergen, this should be clearly communicated to the customer.

Self-serve areas where consumers handle unpackaged food products may pose a particular risk for cross-contact. Provision of information on the risk of cross-contact should be considered in these instances (e.g., allergen alert signage). Dedicated equipment for handling allergenic food should not be used for non-allergenic food.

9.3 Labelling

Refer to the *General Principles for Food Hygiene* (CAC/RCP 1-1969).
The *General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985) applies.

The *General Standard for the Labelling of Pre-packaged Foods* lists the foods and ingredients known to cause hypersensitivity that should always be declared on the label.

When allergen cross-contact for a specific food cannot be prevented using GHPs, occurs sporadically, and is detected at levels that, based on an assessment of risk, could result in adverse health consequences to allergic consumers, “advisory” statements (e.g., “may contain…”) should be used to inform FBOs and consumers on the risk that the products might contain an allergen other than those that are listed as ingredients. The use of “advisory” statements should, however, be restricted to those situations in which cross-contact cannot be controlled, e.g. processing equipment cannot be accessed for cleaning or that cannot be cleaned with water such that allergens are not adequately removed.

9.4 Consumer education

Refer to the *General Principles for Food Hygiene* (CAC/RCP 1-1969).

SECTION X – TRAINING

PRINCIPLE:

Personnel engaged in food operations should have sufficient training in food allergen management to ensure measures to minimise allergen cross-contact are implemented.

10.1 Awareness and responsibilities

All personnel involved in the production, manufacturer, preparation, distribution, retail, [福島36]and service of foods should understand the food safety implications of the presence of

undeclared food allergens and their role in allergen management. This includes temporary staff.

10.2 Training programmes

All staff in a food business should receive food allergen training as appropriate to their job responsibilities, so they can contribute to the measures needed to minimise the risk of allergen cross-contact and labelling errors. All appropriate personnel should be encouraged to take immediate action, if any risk of cross-contact is suspected.

Training programs should include, as appropriate to the person's duties:

- General allergen awareness including the nature and possible health consequences of their unintended or undeclared presence in products from a consumer perspective;
- Awareness of the allergen cross-contact risks identified at each stage of the food supply chain, and the preventive measures and documentation procedures applicable in the food business;
- Good hygiene practices, for example, clothing, hand washing, and hand contact with foods to prevent allergen cross-contact;
- Hygienic design of facilities and equipment in preventing allergen cross-contact and minimizing allergen transfer[福島37]~~relation to allergens~~;
- Cleaning of premises, equipment and tools and its importance in preventing allergen cross-contact;
- Handling of rework materials to prevent unintended allergens from being incorporated into a food;
- Waste management, for example how waste should be handled to prevent allergen cross-contact;
- Situations where potential allergen cross contact can occur between products, production lines or equipment, and prevention measures;
- Procedures for managing people traffic patterns around the site to minimize allergen transfer from one area to another, for example people changing production line or site, movement to the canteen/break room and of visitors;
- Equipment movement around the site, for example, maintenance tools, carts, food trays, etc to minimize allergen transfer from one area to another;
- Labelling and the awareness of allergen presence in raw materials, semi-finished goods and finished products; and
- Sources of allergen information, e.g. supplier specifications, supplier audit records.

10.3 Instruction and supervision

Refer to the *General Principles for Food Hygiene* (CAC/RCP 1-1969).

10.4 Refresher training

Refer to the *General Principles for Food Hygiene* (CAC/RCP 1-1969).