厚生労働科学研究費補助金（食品の安全確保推進研究事業）
「新型コロナウィルス感染症対策に取組む食品事業者における
食品防御の推進のための研究」分担研究報告書（令和５年度）

海外における食品防御政策等の動向調査

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研究要旨

わが国における食品テロ対策の検討を行っていく上での基礎的資料とするため、米国 FDA「食品への意図的な混入に対する緩和戦略」規則・ガイダンスの更新状況に関する公表情報を収集・整理した。その結果、「食品への意図的な混入に対する緩和戦略」規則・ガイダンスについては、今年度中の大きな更新は見当たらなかった

また、Codex 委員会おける「食品偽装の防止及び管理に関するガイドライン」の進捗状況について調査を実施した。第 27 回食品輸出入検査・認証制度部会 CCFICS（2024 年 9 月 20 日開催予定）で議論される予定である。

A. 研究目的

令和５年度における海外での食品テロに関わる最新情報の把握を通じて、わが国における食品テロ対策の検討を行っていく上での基礎的資料とすることを目的とする。

B. 研究方法

米国 FDA（Food and Drug Administration）の公表情報や、研究班会議において収集した情報等に基づき、米国 FDA「食品への意図的な混入に対する緩和戦略」規則・ガイダンスの更新状況について確認した。

また、CODEX 委員会の食品輸出入検査・認証制度部会 CCFICS での議論されている「食品偽装の防止及び管理に関するガイドライン策定」について進捗状況を調査した。

◆倫理面への配慮

本研究において、特定の研究対象者は存在せず、倫理面への配慮は不要である。

C. 研究結果

１．米国 FDA「食品への意図的な混入に対する緩和戦略」規則・ガイダンスの更新状況

2019 年３月に公表された「食品への意図的な混入に対する緩和戦略」ガイダンス（産業界向け）（Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration）については、一昨年度「小規模な食品事業者における食品防御の推進のための研究」の分担研究「海外（主に米国）における食品防御政策の動向調査」において報告した内容から大きな更新がなされていないことを確認した。

2022 年 3 月に新たなガイダンス「Guidance for Industry: Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions　MARCH 2022 /（現行の適正製造基準及び予防的管理、外国供給者確認プログラム、意図的不純物混入、及び農産物安全規制。特定の条項に関する施行方針 産業界向けガイダンス　2022 年 3 月）」が公表された。このガイダンスでは施行裁量に関する方針が示されているが、遵守日や例外措置等について新たな変更などはなかった。事業規模によって段階的に設定されていた規則の遵守日について、2021 年 7 月 26 日に最後に設定されていた零細企業の遵守日を迎えたことにより、すべての規模の事業主体が遵守対象となり、継続運用されている状態が継続している。

「Guidance for Industry: Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions MARCH 2022 /（現行の適正製造基準及び予防的管理、外国供給者確認プログラム、意図的不純物混入、及び農産物安全規制。特定の条項に関する施行方針 産業界向けガイダンス 2022 年 3 月）」の概要は以下のとおりである。また、全文を資料 1 に示す[1]。

- 米国食品医薬品局（FDA）は、FDA 食品安全近代化法（FSMA）を実施する 5 つの規則のうち、特定の条項を施行しない意向を示すガイダンスを公表しました。5 つの規則の対象となる特定の事業体および/または活動に対して特定の規制要件を強制しないことを明らかにしている。
- 公表された施行裁量方針は、以下の 5 規則に関するものである。
  - 人間の食品の現在の適正製造慣行とハザード分析とリスクベースの予防管理
  - 動物性食品の現在の適正製造基準とハザード分析とリスクベースの予防管理
  - 人間と動物のための食品の輸入者のための外国サプライヤー検証プログラム(FSVP)
  - 人間の消費するための農産物の栽培、収穫、梱包、および保持に関する基準(PSR)
  - 意図的な異物混入から食品を保護するための緩和戦略（IA）

このうち、食品防御に関する IA 規則については、以下の施行裁量方針の記載がある（セクションⅢ.B に記載）。

- 特定の事業体に対する執行方針：2018 年 1 月の FSMA ガイダンスで、FDA は、特定の農場関連活動を行っているが、「農場」の定義の下では農場とは見なされない特定の施設に対して、執行裁量ポリシーを確立した。この新しいガイダンスでは、FDA は IA 規則に関連する執行措置を同じ施設や活動に適用するつもりはないことを明確にしている。（しかしながら、FDA は「農場」の定義を変更する可能性のある規則作成を発行しているので、これらは今後 IA の規定がこれらの事業体に適用されるかどうかに影響する。）
- 特定の状況における IA 規則の執行方針：特定の状況（たとえば、是正措置手順の実装によって対処される単一の障害がある場合など）で再分析の要件を強制しないとした。
  - IA 規則は、緩和戦略、戦略の組み合わせ、または FDP 全体が適切に実施されていない場合など、特定の状況において、食糧防衛計画(FDP)の再分析を要求している。
  - IA 規則はまた、対象となる事業体が、緩和戦略が適切に実施されていない場合に取らなければならない食品防御是正措置手順を確立し、実施することを要求している。

[1] 「Guidance for Industry: Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions MARCH 2022 /（現行の適正製造基準及び予防的管理、外国供給者確認プログラム、意図的な不純物混入、及び農産物安全規制：特定の条項に関する施行方針 産業界向けガイダンス 2022 年 3 月）」（https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-current-good-manufacturing-practice-and-preventive-controls-foreign-supplier）2024 年 1 月 31 日閲覧

重複を減らすために、FDA は、欠陥を修正し、欠陥が再び発生する可能性を減らす行動を通じて緩和戦略の不適切な実施が対処された場合には、再分析の要件については裁量をもって判断するとしている。

２．CCFICS　New Work on the development of Guidance on the prevention and　control of food fraud についての調査

2023 年 5 月に開催された食品輸出入検査・認証制度部会（CCFICS）第 26 回部会において、「食品偽装の防止及び管理に関するガイドライン」の案が報告された。概要は以下のとおりである。また、全文を資料２に示す[2]。本稿は CCFICS 電子作業部会が作業中の原案であり、未定稿である。

- 本ガイドラインは、食品偽装とその管理をターゲットとしている。
- 「2008 年の意図的な食品汚染の防止の議論に配慮すること」、「既存のテキストの重複を避けること」が明記され、既存の食品偽装に関するコーデックスのテキストのレビューを踏まえて検討されている。
- なお、CCFICS の作業範囲は、「消費者の健康を守り、公正な食品取引を確保する」、という CCFICS の権限内にすべきとしている。
- 食品偽装の定義と種類についてはまだ議論の余地があるものの、経済的利益のために意図的に行われた場合の「追加」「代替」「希釈」「偽造」「虚偽」「隠蔽」等が食品偽装の該当例として示されている。

本ガイドラインは 2024 年または 2025 年の完成を目指しており、完成までに複数回草案が提示される見込みである。改訂版の作成は電子作業部会（EWG 議長国：米国、共同議長国：英国、中国、EU、イラン）が作業を進める。CCFICS 電子作業部会の作業計画は以下のとおりである。

- 2023 年 10 月　EWG への初回草案
- 2023 年 11 月　コメント提出期限
- 2024 年 2 月初旬　ドラフト 2 を EWG に提出
- 2024 年 3 月中旬　コメント提出期限
- 2024 年 5 月　会議用文書案を EWG に提出
- 2024 年 6 月　会議用文書提出
- 2024 年 9 月　CCFICS 27

現状確認された「食品偽装の防止及び管理に関するガイドライン」についての主要な論点（2024 年 1 月時点）は以下のとおりである。[3]

- 地理的表示保護制度（GI）を含む知的財産の扱いについて
  - 「食品偽装の防止及び管理に関するガイドライン」について、地理的表示保護制度（GI）を含む知的財産に関する記載をコーデックス及び CCFICS の所掌範囲とすべきか否か、各国認識の違いから意見が分かれ、議論の余地があることが明らかになった。これについては CAC 執行部に助言を求めるとともに電子作業部会（EWG）で継続検討となった。

[2] PROPOSED DRAFT GUIDELINES ON THE PREVENTION AND CONTROL OF FOOD FRAUD（https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fwork-space.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-733-26%252FWorking%2BDocuments%252Ffc26_06e.pdf）2024 年 1 月 31 日閲覧

[3] 第 107 回コーデックス連絡協議会：農林水産省（https://www.maff.go.jp/j/syouan/kijun/codex/107.html)2024 年 1 月 31 日閲覧

- この背景にはGIの保護を拡充したい国々（EU）と、これに反対し従来通りWTOの「知的所有権の貿易関連の側面に関する協定（TRIPS）」の範囲とすべきとする国々（米国）の対立構造がある。
- 我が国はGIに関する議論はコーデックスの所掌範囲外の立場（これまで通りTRIPS等で議論すべきとの立場）。
- 仮にGIが当ガイドラインの対象となった場合にも、直ちに日本に影響はないと思われるが、日本の制度や食品貿易に影響を及ぼすガイドラインとならないよう、引き続き注視する必要がある。

・ 食品偽装の議論の進め方、対象範囲について
- 食品偽装はCCFICSだけでなく部門横断的で広範な課題であるが、議論の進め方について、まずはCCFICSで消費者の健康保護と食品の輸出入における公正な取引の保証に必要な範囲を対象として検討し、検討状況を関連他部門（CCFLやCCMAS等）に情報共有する、ということが確認された（CCGP31でも確認）。

・ 「食品偽装の防止及び管理に関するガイドライン」の今後
- ガイドライン原案をステップ2/3に戻し、CCFICS26で提出された全ての議論とコメント（角括弧内の文章を含む）を考慮し、次回CCFICS27会合（2024年9月16日～20日開催予定）までに改訂草案を作成することとなった。
- 改訂版の作成は電子作業部会（EWG議長国：米国、共同議長国：英国、中国、EU、イラン）が作業を進める。

D. 考察

2021年7月26日の最終の遵守日をもって、米国FESMAは完全に制度化され、運用されている。また、CODEX委員会では特に異物混入を伴わない食品偽装も広く食品安全の問題としてとらえ、何らかのガイドラインを作成中である。日本国内においても、こうした海外の動向を踏まえて日本の規制やガイドラインの在り方を検討する必要がある。

新型コロナウィルス感染症の拡大により、フードデリバリー業界においては事業者の多様化や市場拡大が進み、食品の無人販売所という新たな業態も生まれるなど、食品業界においては急激に構造変化が起こった。また、社会慣行にも食毒液の常設など、様々な変化が新しい生活様式として定着している。

これら急激に変化した事業者や業態、日常の変化を踏まえ、新たなルールやガイドラインの設定が求められる。

E. 結論

米国FDAの公表情報や、研究班会議において収集した情報等に基づき、米国FDA「食品への意図的な混入に対する緩和戦略」規則・ガイダンスの更新状況について整理した。

その結果、「食品への意図的な混入に対する緩和戦略」規則・ガイダンスについては、今年度中の大きな更新はなされていなかった。

また、CODEX委員会においては、2023年5月のCCFICS部会で食品偽装に関するガイダンス草案が提出された。今後、2024年9月16日～20日にオーストラリアのケアンズで開催予定のCCFICS部会で改訂版が提出される予定である。

F. 健康危険情報

なし

G. 研究発表

1．論文発表

なし

２．学会発表

なし

H. 知的財産権の出願・登録状況

１．特許取得

なし

２．実用新案登録

なし

３．その他

なし

資料１

Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions

Guidance for Industry

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2021-D-0563, listed in the notice of availability published in the *Federal Register*.

For questions regarding this document, you may contact the FSMA Technical Assistance Network online at https://www.fda.gov/food/guidanceregulation/fsma/ucm459719.htm, by mail at Food and Drug Administration; 5001 Campus Drive; Wiley Building, HFS-009; Attn: FSMA Outreach; College Park, MD, 20740, or by phone at 1-888-SAFEFOOD (1-888-723-3366).

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Center for Veterinary Medicine
Office of Regulatory Affairs

March 2022

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Contains Nonbinding Recommendations

Current Good Manufacturing Practice and Preventive Controls, Foreign Supplier Verification Programs, Intentional Adulteration, and Produce Safety Regulations: Enforcement Policy Regarding Certain Provisions

Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA, the Agency, or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The purpose of this document is to state that the Food and Drug Administration (FDA, we, or the Agency), at this time and based on our current understanding of the risks, does not intend to enforce certain regulatory requirements as they currently apply to certain entities and/or activities. The applicable requirements are established in our regulations entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" (21 CFR Part 507); "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (21 CFR Part 117); "Foreign Supplier Verification Programs for Importers of Food for Humans and Animals" (21 CFR Part 1, Subpart L (FSVP)); "Mitigation Strategies to Protect Food Against Intentional Adulteration" (21 CFR Part 121); and "Standards for Growing, Harvesting, Packing, or Holding of Produce for Human Consumption" (21 CFR Part 112).

Section II of this document describes certain enforcement discretion policies that were issued previously and are relevant to the enforcement policies discussed in sections III.B and III.C. Section III describes new or extended enforcement discretion policies. Section III.A describes our extension of FDA's enforcement discretion in certain circumstances when a receiving facility that is a contract manufacturer/processor not in compliance with certain supply-chain program requirements for food manufactured for a brand owner. Section III.B describes that we do not intend to enforce requirements of the Intentional Adulteration regulation for facilities under the preexisting farm-activity related enforcement policy. Section III.B also announces that FDA

does not intend to enforce the Intentional Adulteration regulation's requirement for reanalysis in certain circumstances—for example, when there is a single failure that is addressed through implementation of corrective action procedures. Section III.C describes that FDA does not intend to enforce the supplier approval and verification requirements in part 117, part 507, and the FSVP regulation with regard to supplier compliance with requirements that are already associated with an enforcement discretion policy.

We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). This guidance is immediately effective because FDA has determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)), on the basis that the guidance presents a less burdensome policy that remains consistent with FDA's public health mission. As with all guidance documents, the public can comment on the guidance at any time (21 CFR 10.115(g)(5)). If FDA receives comments on the guidance document, FDA will review those comments and revise the guidance document when appropriate (21 CFR 10.115(g)(3)(ii)).

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

In this guidance, pronouns such as "you" refer to entities that are covered by this guidance.

II. Background

See Table 1 for information about the rulemakings to establish five regulations as part of our implementation of the FDA Food Safety Modernization Act (FSMA; Pub. L. 111-353) and for the abbreviations that we use in this document for these regulations. You can access the listed *Federal Register* publications and other information about these regulations from our FSMA website (https://www.fda.gov/fsma) and from the Docket No. (listed in Table 1) established for each rulemaking (available at https://www.regulations.gov).

Table 1.The Regulations That Are Relevant to This Guidance Document

Title and Regulatory Citation	**Abbreviation Used in This Document**	**Docket No. and Key Publications in the *Federal Register*[1]**
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals (21 CFR part 507)	part 507	• Docket No. FDA–2011–N–0922 • Proposed rule: 78 FR 64736, October 29, 2013 • Supplemental notice of proposed rulemaking: 79 FR 58476, September 29, 2014 • Final rule: 80 FR 56170, September 17, 2015 • Final rule; extension and clarification of compliance dates for certain provisions: 81 FR 57784, August 24, 2016
Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR part 117)	part 117	• Docket No. FDA–2011–N–0920 • Proposed rule: 78 FR 3646, January 16, 2013 • Supplemental notice of proposed rulemaking: 79 FR 58524, September 29, 2014 • Final rule: 80 FR 55908, September 17, 2015 • Final rule; extension and clarification of compliance dates for certain provisions: 81 FR 57784, August 24, 2016
Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (21 CFR Part 1, Subpart L)	FSVP regulation	• Docket No. FDA–2011–N–0143 • Proposed rule: 78 FR 45730, July 29, 2013 • Supplemental notice of proposed rulemaking: 79 FR 58574, September 29, 2014 • Final rule: 80 FR 74226, November 27, 2015 • Final rule; extension and clarification of compliance dates for certain provisions: 81 FR 57784, August 24, 2016
Mitigation Strategies to Protect Food Against Intentional Adulteration (21 CFR Part 121)	IA regulation or part 121	• Docket No. FDA-2013-N-1425 • Proposed rule: 78 FR 78014, December 24, 2013 • Final rule: 81 FR 34166, May 27, 2016
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (21 CFR part 112)	Produce Safety regulation or part 112	• Docket No. FDA–2011–N–0921 • Proposed rule: 78 FR 64736, October 29, 2013 • Supplemental notice of proposed rulemaking: 79 FR 58434, September 29, 2014 • Final rule: 80 FR 74354, November 27, 2015 • Final rule; extension and clarification of compliance dates for certain provisions: 81 FR 57784, August 24, 2016

Since issuing the regulations listed in Table 1, FDA has issued three enforcement policy guidances relevant to this guidance document that recognize that industry is still in the process of coming into compliance with a requirement or that FDA is considering options to address

[1] During each rulemaking listed in Table 1, we also issued several notices extending the comment period or announcing a public meeting to discuss the proposed rule. For the complete history of *Federal Register* publications associated with each rulemaking, see the applicable final rule.

concerns raised by stakeholders.[2] Below we identify and describe several enforcement discretion policies from those guidances that are relevant to the new enforcement discretion policies discussed later in this guidance in section III. The enforcement policies identified and described in sections II.A and II.B are unchanged.

A. Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds

In a notice published in the *Federal Register* of March 28, 2019 (84 FR 11644), we announced the availability of a guidance for industry entitled "Produce Safety Rule: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds: Guidance for Industry" (the produce commodity guidance) (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-enforcement-policy-entities-growing-harvesting-packing-or-holding-hops-wine-grapes). The produce commodity guidance announced our intent not to enforce part 112 for entities growing, harvesting, packing, or holding almonds, hops, pulse crops, or wine grapes while we consider rulemaking to address the unique circumstances of these commodities.

B. Enforcement Policy for Certain Entities Subject to CGMP and Preventive Controls, Produce Safety, and/or FSVP Requirements

In a notice published in the *Federal Register* of January 5, 2018 (83 FR 598), we announced the availability of a guidance for industry entitled "Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry" (the January 2018 enforcement policy guidance) (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-policy-regarding-certain-entities-subject-current-good-manufacturing-practice-and). The January 2018 enforcement policy guidance announced our intent not to enforce certain requirements, as follows:

- Part 117 and/or part 507 as applied to specific facilities that conduct farm-related activities:
  - Facilities that would qualify as secondary activities farms except for the ownership of the facility;
  - Facilities that would qualify as farms if they did not color raw agricultural commodities (RACs);
  - Facilities that would qualify as secondary activities farms except that they pack, package, label, and/or hold processed food that consists only of RACs that have been dried/dehydrated to create a distinct commodity;
  - Farm mixed-type facilities making silage food for animals;

[2] Those guidances are: (1) "Produce Safety Rule: Enforcement Policy for Entities Growing, Harvesting, Packing, or Holding Hops, Wine Grapes, Pulse Crops, and Almonds: Guidance for Industry," (2) "Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs," and (3) "Supply-Chain Program Requirements and Co-Manufacturer Supplier Approval and Verification for Human Food and Animal Food: Guidance for Industry," all available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

- Written assurances requirements in the "customer provisions" in part 117, part 507, the Produce Safety regulation, and the FSVP regulation;
- FSVP requirements as applied to the importation of food contact substances; and
- Animal food preventive control requirements as applied to human food facilities, for certain human food by-products for use as animal food that are further manufactured/processed.

1. Specific facilities subject to part 117 and/or part 507 that conduct farm-related activities

In the January 2018 enforcement policy guidance, we stated that to provide sufficient time to pursue rulemaking related to farm-related activities and other solutions to the concerns regarding the applicability of part 117 and part 507, we intended for the enforcement policy to remain in effect until the completion of the future rulemaking related to farm-related activities. Only certain facilities that conduct farm-related activities but are subject to part 117 and/or part 507 are covered by the January 2018 enforcement policy guidance; those entities are listed in the sub-bullets (arrows) above. Until we complete the rulemaking related to farm-related activities, we intend to exercise enforcement discretion regarding: (1) the part 117 and/or part 507 preventive controls requirements for the listed entities; (2) the part 507 current good manufacturing practice (CGMP) requirements for the listed entities that are subject to the part 507 CGMPs; or the part 117 CGMP requirements with regard to non-produce RACs for the listed entities. Note that as indicated in the January 2018 enforcement policy guidance, for human food CGMPs applicable to produce RACs, we intend to enforce the requirements per our usual policies.

2. Written assurances in the "customer provisions"[3] in part 117 and related rules

In the January 2018 enforcement policy guidance, we explained that industry provided us with feedback indicating that certain distribution chains would require vastly more written assurances than FDA had anticipated. We stated that we intend to initiate a new rulemaking that takes into consideration complex supply chain relationships and resource requirements. Until the completion of such a rulemaking, we intend to exercise enforcement discretion regarding the requirements related to written assurances in part 117, part 507, the FSVP regulation section 1.507, and the Produce Safety regulation. The written assurance provisions are 21 CFR 117.136(a)(2)(ii), (3)(ii), and (4)(ii); 21 CFR 507.36(a)(2)(ii), (3)(ii), and (4)(ii); 21 CFR 1.507(a)(2)(ii), (3)(ii), and (4)(ii) (FSVP regulation); and 21 CFR 112.2(b)(3) (Produce Safety regulation).

3. Certain human food by-products for use as animal food

In the January 2018 enforcement policy guidance, we explained that we would be considering the application of part 507 preventive controls requirements to certain manufacturing/processing activities conducted on human food by-products, after separation from the human food, for use as animal food (e.g., drying/dehydrating to reduce weight, bulk, or volume of the food). While we consider that issue, we intend to exercise enforcement discretion regarding the part 507 preventive controls requirements related to human food by-products if after separation from the human food the entities are performing one of a limited number of manufacturing/processing

[3] The customer provisions of part 117, part 507, 21 CFR 1.507, and the Produce Safety regulation are listed in the January 2018 enforcement policy guidance at pp. 15-16.

activities identified in the January 2018 enforcement policy guidance.[4] This policy applies to human food facilities meeting the qualifications in 21 CFR 507.12(a)(1), including that their manufacturing/processing activities are conducted under CGMP requirements. A human food facility conducting the limited activities on human food by-products has the option to utilize either the part 117 or part 507 CGMP requirements.

III. Discussion

As discussed below, we intend to extend the duration of the enforcement policy for supply-chain program requirements for co-manufacturers (section III.A), and we anticipate continuing this policy until such time as FDA's deliberations are complete, which may occur when a related rule is finalized. In addition, we intend to exercise enforcement discretion regarding the IA regulation for certain entities and activities (section III.B), and the supplier approval and verification requirements in part 117, part 507, and the FSVP regulation with regard to supplier compliance with requirements already associated with an enforcement discretion policy (section III.C).

A. Extension of Enforcement Policy for Supply-Chain Program Requirements Applicable to Co-Manufacturers of Human Food and Animal Food

As discussed in the co-manufacturer guidance (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-supply-chain-program-requirements-and-co-manufacturer-supplier-approval-and), industry has expressed concerns that the supply-chain program requirements would require revisions to contracts between brand owners and their suppliers to allow brand owners to share certain information (e.g., audits of suppliers) with the brand owners' contract manufacturers/processors, and that establishing new contracts would take a significant period of time, impeding their ability to meet compliance dates. Therefore, FDA announced that under certain circumstances and on a temporary basis, we do not intend to take enforcement action regarding a receiving facility that is a contract manufacturer/processor, and that is not in compliance with certain supply-chain program requirements for food manufactured for the brand owner, until November 6, 2019.

In September 2019, industry submitted a request for an extension of the co-manufacturer enforcement discretion policy, contending that the supplier verification and approval challenges related to co-manufacturing cannot all be addressed by revising contracts, and suggesting that approaches utilized in other FSMA implementation contexts may be applied to find solutions to these challenges. (Refs. 1, 2). FDA has determined that it should continue to consider the additional practical challenges related to compliance with these provisions.[5]

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[4] Those activities are drying/dehydrating, evaporating, pressing, chopping and similar activities to reduce weight, bulk, or volume, and/or mixing, centrifuging, and similar activities to combine ingredients or separate components (e.g., water and solids), as long as these activities are not performed to prevent or significantly minimize animal food hazards and do not introduce animal food hazards.

[5] FDA issued a constituent update on November 6, 2019, that announced our intent to issue an extension of the enforcement discretion policy for certain supply-chain program requirements applicable to receiving facilities that are co-manufacturers, available at: FDA Continues Enforcement Discretion Policy Relevant to Certain Co-Manufacturers under FSMA | FDA.

As FDA's deliberations proceed, we do not intend to take enforcement action regarding certain supply-chain program requirements for food manufactured for the brand owner by a receiving facility that is a contract manufacturer/processor, as described in the co-manufacturer guidance and restated in this section. Specifically, we do not intend to take enforcement action regarding 21 CFR 117.410(d) and 117.415(a)(3), and 21 CFR 507.110(d) and 507.115(a)(3) in the circumstances described below for "Supplier Approval" and for "Supplier Verification." Furthermore, we do not intend to take enforcement action under the FSVP regulation regarding an importer who is relying on 21 CFR 1.502(c)(3) but whose supply-chain program is under an enforcement discretion policy regarding 21 CFR 117.410(d) and 117.415(a)(3) or 21 CFR 507.110(d) and 507.115(a)(3) in the circumstances described below for "Supplier Approval" and for "Supplier Verification." We anticipate continuing the enforcement policy until deliberations are complete, which may occur when a related rule is finalized.

For co-manufacturers under this policy that are also FSVP importers, we intend to enforce the importer identification requirements in 21 CFR 1.509 per our usual policies. Under 21 CFR 1.509(a), for each line entry of food product offered for importation into the United States, the importer must provide its name, electronic mail address, and unique facility identifier recognized as acceptable by FDA electronically when filing entry with U.S. Customs and Border Protection. For more information on the unique facility identifier, see FDA's guidance "Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-compliance-providing-acceptable-unique-facility-identifier-foreign-supplier).

Supplier Approval

As noted above, until its deliberations are complete, FDA does not intend to take enforcement action under the following circumstances: (1) a brand owner conducts supplier approval activities, (2) the co-manufacturer describes these activities in its food safety plan, and (3) the co-manufacturer conducts any necessary supplier approval activities not conducted by the brand owner. For example, FDA does not intend to take enforcement action when a brand owner (rather than the co-manufacturer) evaluates supplier performance as part of approving a supplier, the co-manufacturer's food safety plan states that the brand owner will consider supplier performance before a supplier is approved, and the co-manufacturer conducts any other necessary supplier approval activities (e.g., hazard analysis of the food). However, our usual enforcement policies apply with respect to the requirements that a co-manufacturer follow written procedures for receiving raw materials and other ingredients, and document use of the procedures (21 CFR 117.420 and 507.120).

Supplier Verification

Until its deliberations are complete, FDA also does not intend to take enforcement action under the following circumstances: (1) a brand owner determines and/or conducts supplier verification activities for its co-manufacturer, (2) the co-manufacturer describes these activities in its food safety plan, and (3) the co-manufacturer conducts any necessary supplier verification activities not conducted by the brand owner. For example, FDA does not intend to take enforcement action when an audit is determined to be the appropriate supplier verification activity but a co-

manufacturer does not independently obtain a supplier audit or review the conclusions of a supplier audit obtained and reviewed by the brand owner, the co-manufacturer's food safety plan states that the brand owner will obtain and review audits of the supplier, and the co-manufacturer conducts any other necessary supplier verification activities (e.g., sampling and testing of the raw material or other ingredient).

B. Enforcement Policy for Certain Entities and Requirements Under the Mitigation Strategies to Protect Food[6] Against Intentional Adulteration Regulation

FDA published the IA rule in the Federal Register of May 27, 2016. The IA regulation includes requirements for food defense measures against intentional adulteration and can be found in 21 CFR part 121. Specifically, the IA regulation requires covered facilities to identify significant vulnerabilities and implement mitigation strategies, including mitigation strategy management components and related activities, such as reanalysis, to establish a proactive and systematic food defense program to protect food from intentional adulteration intended to cause wide scale public health harm.

1. Enforcement policy for IA requirements for facilities covered by the January 2018 enforcement policy related to farm-related activities

The IA regulation does not apply to activities of a farm that are subject to section 419 of the FD&C Act (Standards for Produce Safety) (21 CFR 121.5(d)). Therefore, a threshold question to determine whether the IA regulation applies to an entity is whether the entity is a "farm" as that term is defined in 21 CFR 1.227 of the section 415 registration regulation.

As mentioned in section II, we previously announced our intent to exercise enforcement discretion regarding part 117 for certain facilities that would qualify as farms except for some fact or circumstance discussed in the January 2018 enforcement policy guidance (e.g., facilities that would be farms except for ownership of the facility; facilities that would be farms if they did not color RACs). As explained above, we intend to pursue rulemaking and other solutions to the farm-related activity concerns that have been raised. This rulemaking could change the applicability of the intentional adulteration requirements to some entities that conduct farm-related activities. For example, a change to the "farm" definition could change the status of an entity from a facility required to register to a farm, and consequently change its status under the IA regulation from covered to exempt.

While we pursue the rulemaking and other solutions to address concerns related to facilities that conduct farm-related activities, FDA does not intend to enforce the requirements of the IA regulation for those facilities that are under the farm-activity related enforcement policy described in the January 2018 enforcement policy guidance.

[6] The IA regulation does not apply to the manufacturing, processing, packing, or holding of food for animals other than man.

2. Enforcement policy with regard to the requirement for reanalysis in 21 CFR 121.157(b)(3)

The IA regulation requires reanalysis of the food defense plan (FDP) in certain circumstances, including whenever a mitigation strategy, a combination of mitigation strategies, or the FDP as a whole is not properly implemented (21 CFR 121.157(b)(3)). Improper implementation of mitigation strategies is also addressed by taking food defense corrective actions. Specifically, covered entities are required to establish and implement written food defense corrective actions procedures that must be taken if mitigation strategies are not properly implemented (21 CFR 121.145(a)(1)). The corrective actions procedures must describe the steps to be taken to ensure that: (1) appropriate action is taken to identify and correct a problem that has occurred with implementation of a mitigation strategy; and, (2) appropriate action is taken, when necessary, to reduce the likelihood that the problem will recur (21 CFR 121.145(a)(2)).

In light of the requirement to take corrective actions to address an implementation failure, in certain circumstances, FDA does not intend to enforce the requirement for a reanalysis of all or part of the FDP. Specifically, FDA does not intend to enforce the requirement for reanalysis in 21 CFR 121.157(b)(3) when improper implementation of a mitigation strategy or combination of mitigation strategies is addressed through implementation of corrective actions procedures that correct the problem and reduce the likelihood of recurrence.

For example, an FDP provides that a mitigation strategy for a bulk liquid storage tank is to use a lock to secure the access hatch when unattended or not in use. A monthly food defense verification review of monitoring records indicates that the mitigation strategy was not properly implemented once during the month (i.e., the hatch on the liquid storage tank was left unlocked). Corrective actions records indicate that the cause of the problem was employees working at the tank not locking the access hatch after filling the tank. Corrective actions records also indicate that the problem was corrected by relocking the lock and retraining the employees and the supervisors working at this actionable process step. FDA does not intend to enforce the requirement for reanalysis under this circumstance.

The next month, a verification review of food defense monitoring and corrective actions records shows that the lock was still not consistently being placed on the access hatch to the storage tank (i.e., the hatch on the tank was left unlocked on multiple days). Now it is clear that the corrective actions procedures are not sufficiently reducing the likelihood of recurrence. In this situation, FDA intends to apply its usual enforcement policies with respect to the requirement that the facility perform a reanalysis of the mitigation strategy. As a result, the facility might determine that a new mitigation strategy is needed (e.g., restrict access to the bulk liquid storage tank to authorized personnel).

FDA also intends to enforce, per its usual policies, the requirement in 21 CFR 121.157(b)(3) to conduct a reanalysis when the FDP as a whole is not properly implemented. For example, a facility identifies background checks as a mitigation strategy to be used in combination with other mitigation strategies for all actionable process steps within the facility. The monitoring procedure is to assess whether the checks were completed prior to assigning the employee to an actionable process step. The corrective actions procedure is to conduct the check prior to

assigning the employee to an actionable process step if the check has not yet been conducted and to reassign an employee who has been assigned to an actionable process step without a background check. A manager discovers that there are no monitoring or corrective actions records for the background checks and determines the background check program was never implemented. Further, the manager determines it is no longer feasible to implement the program. In this example, FDA intends to enforce the requirement that the entire FDP be reanalyzed per its usual policies, because the mitigation strategies at each actionable process step were determined to be adequate based on the inclusion of background checks which were not conducted. Without the implementation of background checks, the mitigation strategies may not be adequately minimizing or preventing the significant vulnerabilities at each actionable process step.

C. Enforcement Policy for Supplier Approval and Verification Requirements in Part 117, Part 507, and the FSVP Regulation

Among other things, the rulemaking to establish part 117 amended our current good manufacturing practice regulation for manufacturing, packing, or holding human food to modernize it and establish it in new part 117, primarily in subpart B, with associated requirements in subparts A and F (the human food CGMP requirements). Part 117 also includes new requirements for domestic and foreign facilities that are required to register under section 415 to establish and implement hazard analysis and risk-based preventive controls for human food (the human food preventive controls requirements). The human food preventive controls requirements are primarily in subparts C and G, with associated requirements in subparts A, D, E, and F. Specifically, subpart G of part 117 establishes requirements for a supply-chain program for those raw materials and other ingredients for which a receiving facility has identified a hazard requiring a supply-chain applied control. In certain circumstances FDA's supply-chain program provisions require a facility to conduct supplier approval and verification activities to provide assurance that raw materials and other ingredients were produced in compliance with a FSMA regulation, such as part 117 or the Produce Safety regulation.

The rulemaking to establish part 507 included new requirements for CGMPs for food for animals, primarily in subpart B, with associated requirements in subparts A and F (the animal food CGMP requirements) and requirements for hazard analysis and risk-based preventive controls for food for animals, primarily in subparts C and E, with associated requirements in subparts A, D, E, and F (the animal food preventive controls requirements). Specifically, subpart E of part 507 establishes requirements for a supply-chain program for those raw materials and other ingredients for which a receiving facility has identified a hazard requiring a supply-chain applied control. In certain circumstances FDA's supply-chain program provisions require a receiving facility to conduct supplier verification activities.

The FSVP regulation requires importers to develop, maintain, and follow an FSVP that, among other things, provides adequate assurance that foreign suppliers are producing food in compliance with processes and procedures that provide at least the same level of public health protection as those required under the Produce Safety regulation, part 117, or part 507, as

applicable, and that the food is not adulterated or misbranded with respect to allergens.[7] In certain circumstances FDA's FSVP provisions require an importer to conduct supplier approval and verification activities to provide this assurance.

As described above in sections II and III, FDA has stated it does not intend to take enforcement action regarding certain regulatory requirements under the Produce Safety regulation, part 117, and part 507. When FDA does not intend to take enforcement action regarding a provision in one of those regulations for a particular entity, we also do not intend to take enforcement action regarding the requirement for an importer or receiving facility to verify the entity's compliance with that provision. Stated differently, FDA intends for its enforcement discretion policy to extend to any requirement (under FSVP or the preventive controls supply-chain program requirements) for an importer or receiving facility to verify a supplier's compliance with a FSMA requirement which itself is associated with an enforcement discretion policy. For example, we do not intend to take enforcement action regarding the requirement for an FSVP importer of pulse crops to verify that the pulse crop grower produced the crop in compliance with the Produce Safety regulation, because FDA has stated its intent to exercise enforcement discretion regarding the requirements of the Produce Safety regulation for entities growing pulse crops.

The enforcement discretion policy for importers and receiving facilities is intended to cover the period during which the underlying enforcement discretion policy for the supplier applies. That is, when FDA intends to exercise enforcement discretion regarding a supplier's compliance with the Produce Safety regulation, part 117, or part 507, FDA also intends to exercise enforcement discretion regarding the importer's or receiving facility's obligation to verify the supplier's compliance with those provisions.

Importantly, this enforcement discretion policy does not apply to all supplier verification requirements under FSVP or the supply-chain program requirements. An FSVP importer must develop an FSVP that complies with applicable FSVP requirements, and FDA's usual enforcement policies apply for FSVP requirements that are not associated with an enforcement discretion policy. As stated above, the importer's FSVP must ensure that the foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under the Produce Safety regulation, part 117, or part 507, as applicable, and that the food meets the requirements of sections 402 (regarding adulteration) and 403(w) (if applicable, regarding misbranding of human food with respect to labeling for the presence of major food allergens) of the FD&C Act. Consequently, even though FDA does not intend to enforce the FSVP importer's obligation to verify a supplier's compliance with Produce Safety, part 117, or part 507 requirements when an enforcement discretion policy applies for the supplier's compliance with those provisions, FDA intends to enforce the requirements, per its usual policies, for an FSVP importer to develop and follow an FSVP that will ensure that the food imported from that foreign supplier is not adulterated or misbranded with respect to allergen labeling.

[7] Allergen-related requirements are not applicable to animal food. See comment/response 259 in the part 507 rule preamble, 80 FR 56170 at 56244 (Sept. 17, 2015).

IV. References

1. Request for Extension from Grocery Manufacturers Association to FDA Docket FDA-2017-D-5996.
2. Comment from Grocery Manufacturers Association to FDA Docket FDA-2017-D-5996.

資料２

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Agenda Item 6 **CX/FICS 23/26/6**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD IMPORT AND EXPORT INSPECTION AND CERTIFICATION SYSTEMS

Twenty Sixth Session

PROPOSED DRAFT GUIDELINES ON THE PREVENTION AND CONTROL OF FOOD FRAUD

(Report prepared by the Electronic Working Group[1] chaired by the United States of America and co-chaired by China, European Union, Islamic Republic of Iran, and United Kingdom)

Step 3

INTRODUCTION & BACKGROUND

1. At the 24th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS24) (2018), the European Union, as Co-Chair of the EWG on Food Integrity and Food Authenticity, introduced a discussion paper, which contained definitions of food integrity, food authenticity, food fraud and Economically Motivated Adulteration (EMA); provided an analysis of how different CCFICS texts took into account the issues around food integrity and authenticity; noted a number of areas where further work may be justified; and presented recommendations for the Committee's consideration based on inputs from the EWG.

2. CCFICS24 agreed on the important cross-cutting nature of issues relating to food integrity and food authenticity and held a wide-ranging discussion in which many delegations engaged. There was recognition that CCFICS may have a role to play in this area. CCFICS24 noted the following views:

a. The need for horizontal guidance should be carefully considered since several existing Codex texts already addressed relevant issues.

b. Any future CCFICS work in this area should be refined to avoid duplication with existing texts and well defined within the CCFICS mandate, considering the discussion held in 2008 on the prevention of intentional contamination of food.

c. Further consideration of relevant definitions may be needed and CCFICS could consider seeking advice from the Commission in that regard, including on which Codex body or bodies had the required expertise. Some delegations considered that this could be done following initial consideration by the EWG.

d. Other Codex committees were awaiting the outcome of the discussion in CCFICS on food integrity and food authenticity.

e. CCFICS could elaborate on a range of guidance, including what types of risks competent authorities should consider when designing control programmes; exchange of information and cooperation between different authorities at the national and international levels; communication with stakeholders between different authorities at the national and international levels; communication with stakeholders and the general public on food fraud incidents; and measures for targeting food fraud.

3. An EWG was established, the task of which was to conduct a comprehensive analysis of existing Codex texts within and outside of CCIFCS and to propose new work, within the mandate of CCIFCS, for consideration at CCFICS25. The EWG used a questionnaire to gather information that was used to develop the discussion paper and to frame the scope of potential new work. Furthermore, a comprehensive review of the Codex texts related to food fraud was also undertaken and it was recognized that food fraud was already covered in a variety of Codex texts. The EWG updated the discussion paper and streamlined the scope of the potential new work.

[1] Argentina, Australia, Botswana, Brazil, Canada, Chile, China, Cuba, Customs of PR China, Ecuador, El Salvador, ENAC, European Food Law, FIVS, Food Safety Consortium, FoodDrink Europe, GFSI, Hungary, ICBA, ICGA, IDF, IFU Fruit Juice, Indonesia, Iran, Japan, Kenya, Luxembourg, Malaysia, Maroc, Mexico, New Zealand, Nigeria, Norway, OIV, Panama, Peru, Republic of Korea, Singapore, Slovenia, Spain, Sweden, Switzerland, Thailand, THIE, Turkiye, United Kingdom, United States

4. At CCFICS 25, the discussion paper (CX/FICS 21/25/8) and project document were considered. The CCFICS Chairperson noted that there was strong interest in food fraud, both within Codex and beyond, and that CCFICS should seek to agree on the project document with a view to promptly starting new work on this important topic.

5. CCFICS25 noted that the scope of the work should be within the mandate of CCFICS and should address the dual mandate of Codex, protecting consumer health and ensuring fair practices in food trade. Additionally, CCFICS25 noted that the new work should not overlap with existing Codex texts and the guidance should not cause trade barriers.

TERMS OF REFERENCE

6. The Committee agreed to:

a. Start the new work and forward the project document on the development of guidance on the prevention and control of food fraud to CAC44 for approval.

b. Establish an EWG, chaired by the United States of America and co-chaired by China, EU, Iran and United Kingdom, working in English and Spanish, subject to approval of the new work, to prepare proposed draft guidance on the prevention and control of food fraud for circulation for comments and for consideration at CCFICSS26; and that:

i. The EWG may meet prior to CCFICS26 to address any outstanding issues

ii. The report of the EWG should be submitted at least three months before the next session.

c. To keep other relevant Codex Committees informed of the progress of the new work.

PARTICIPATION AND METHODOLOGY

7. Codex member and observers were invited to register (by 9 September 2021) to participate in the EWG. 35 members and 8 observers registered for the EWG.

8. A draft proposed outline and questions for the EWG were prepared by the chair and co-chairs and circulated, in English and Spanish, to the EWG in February 2022. Questions posed to the EWG included:

a. Whether feed for food producing animals should be included in the guideline

b. Whether the guideline should include test methodologies

c. Feedback on the terms included

d. Whether information related to cooperation and exchange of information between importing and exporting countries should be included.

9. The EWG provided feedback that the guideline should include feed for food producing animals. Further, the EWG provided feedback that test methodologies should not be identified as those are not within scope of CCFICS. The EWG identified additional terms for consideration for inclusion and noted that the guideline should include guidance on cooperation and information exchange between importing and exporting countries.

10. A second draft guidance based on the written comments was prepared and circulated to the EWG, in English and Spanish, in August 2022.

11. Following the final scheduling of CCFICS26 to 2023, a third draft of the guideline was circulated to the EWG in December 2022.

12. In January 2022 an invitation was issued to all Codex Members and Observers to attend a CCFICS workshop on food fraud, to be held virtually on 8 February 2023 in English and Spanish.

13. The objectives of the workshop were to:

a. find agreement on the text;

b. focus on definitions to agree on terms to be defined and their definitions.

14. 26 Codex Members and Observers, the Chairperson of CCFICS, and the Codex and Australia CCFICS secretariats participated in the workshop. The United States as chair of the EWG lead the discussion supported by the co-chairs.

15. The Chairperson and co-chairs were very appreciative of the comments received and the discussion at the workshop which they noted had greatly assisted in the preparation of the revised Draft Guidelines on the Prevention and Control of Food Fraud.

16. Based on the EWG comments received and comments received during the workshop, the final draft of the guideline is attached as Appendix 1 for consideration by CCFICS26.

SUMMARY OF DISCUSSION

17. General consensus of the EWG was reached on the Principles, Roles and Responsibilities, and Relevant Activities for Competent Authorities sections of the documents.

18. Consensus was also reached on the Annexes. While they appear in the document for purposes of discussion, consensus of the EWG was that they should be removed when the document is finalized.

19. Substantial agreement was reached on the Scope and Purpose section. One area of where lack of consensus continues is with regard to the footnote to the Scope related to exclusion of intellectual property from the scope of the document. Further discussion within the Scope section is needed on the exclusion of matters related to criminal proceedings and matters related to deliberate contamination of food in order to cause harm.

20. There continues to be comments on the Definitions and Types of Food Fraud sections. EWG members have suggested limiting the Definitions sections further, such as removing the definitions for food fraud vulnerability and authenticity. In the Types of Food Fraud section, consensus is needed on whether to include this section and, if so, which terms to include. On the final section of the draft guideline, further discussion is needed on whether to reframe the section from a focus on collaboration to cooperation.

CONCLUSIONS

21. The EWG Chair and Co-Chairs acknowledge and thank the Codex Members and Observer organizations for their ongoing and continued engagement during the development process and multiple rounds of comment on these guidelines.

22. It is the view of the EWG Chairperson and co-chairpersons that given the extensive work undertaken by the EWG, the draft has reached a stage where it is now appropriate for CCFICS to recommend progress within the step process.

RECOMMENDATIONS

23. The Committee is invited to:

a. note the extensive work undertaken to date and the level of support for completing this guideline; and

b. consider recommending advancing the proposed Draft Guidelines on the Prevention and Control of Food Fraud as contained in **Appendix 1**.

APPENDIX I

PROPOSED DRAFT GUIDELINES ON THE PREVENTION AND CONTROL OF FOOD FRAUD

(Step 3)

Section 1: Preamble / Introduction

1. The increasing complexity of food systems and global trade in food makes food supply chains more vulnerable to food fraud. Protecting the global food supply from intentional actions that undermine protection of public health and upholding fair practices in food trade are common goals for all stakeholders.

2. Food fraud incidents can present risk to public health and can result in economic loss for consumers and other stakeholders, disruption in trade, reputational damage, and unfair economic advantages.

3. Government oversight and good manufacturing practices by food business operators (FBOs) are important to protect public health, to limit the opportunity for food fraud and to maintain consumer confidence in the safety, authenticity, integrity, suitability[2], and quality of food.

4. Food fraud can be prevented or minimized using the existing controls and mitigation measures available to countries through their National Food Control Systems (NFCS) or by adopting new measures, if necessary.

5. The prevention and control of food fraud is a shared responsibility, with FBOs are responsible for producing safe and suitable food, and for presenting it in a manner so as not to deceive consumers. Thus, the FBOs should understand their supply chains and should have effective measures in place to detect, prevent, mitigate and control food fraud where appropriate.

6. Competent authorities have regulatory oversight responsibility and an important role in increasing awareness of food fraud prevention by building partnerships and collaborating with industry, academia, and other stakeholders to detect, prevent, mitigate and control food fraud.

7. While several existing Codex texts address fraudulent activities and provide tools for Members wishing to detect, prevent, mitigate, and control such activity, a need for specific guidance was identified by Codex Members. [See Annex 1 for a list of existing Codex documents addressing food fraud.]

8. Work in the area of food fraud is widespread in a range of international organizations, [some of which are noted in Annex 2]. Countries may wish to consider work from these and other organizations, as appropriate, when developing tools and strategies to detect, prevent, mitigate, and control food fraud.

Section 2: Purpose / Scope

9. The purpose is to provide guidance to competent food safety authorities, other relevant agencies, and FBOs on the detection, prevention, mitigation and control of food fraud to help protect the health of consumers, and to ensure fair practices in food trade, including feed for food producing animals. Aspects related to food fraud are already addressed through many existing Codex texts; this guidance is intended to support or supplement existing Codex texts by providing additional guidance specific to food fraud that can be considered within NFCS[3].

9bis. [It should be noted that the investigation and prosecution of food fraud offenses may be dealt with under criminal law, which is outside the scope of this guideline.]

9bis.bis [Additionally, intentional adulteration, deliberate contamination of food in order to cause harm, is outside the scope of this guideline.]

Section 3: Definitions

For the purposes of this document, the following definitions apply:

Food Fraud: Any deliberate action to deceive others in regard to the prescribed specifications or expected characteristics of food to gain an unfair economic advantage.

Food Integrity: The status of a food product in which it is not altered or modified with respect to expected characteristics, including food safety, quality, and nutrition.

Food authenticity: Conformity between the food product characteristics and the corresponding information provided through food product labelling or other information associated with food trade.

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[2] Food suitability is defined in CXC 1-1969 as "Assurance that food is acceptable for human consumption according to its intended use".
[3] [Issues of intellectual property, such as geographic indicators and related labeling restrictions which do not represent a risk to public health and are beyond the scope of Codex are not addressed within this guideline.]

Food Fraud Vulnerability: Susceptibility or exposure due to a gap or deficiency that could place consumer health or fair trade at risk and/or have a negative impact on an FBO if not addressed.

Food Fraud Vulnerability Assessment: A documented process of collection and evaluation of information on potential food fraud risk factors and their likelihood of occurring, as well as control and mitigation measures which, when combined, determine the actual food fraud vulnerability.

Section 4: Types of food fraud:

The following section provides examples, when done intentionally for economic gain, of types of food fraud, noting this list is not all inclusive.

Addition: Adding an undeclared substance to food products that would not ordinarily be present, or present in that quantity, in the food

Substitution: Replacing an ingredient, or part of a food product, of high value with an ingredient, or part of a product, of lower value.

Dilution: Adding a material, such as water, to make another ingredient present at a lower concentration than represented.

Counterfeiting: The process of making an imitation of food products.

Misrepresentation: Marketing or labelling food products as having characteristics that are not present.

Concealment: Hiding or not disclosing information on the safety, suitability, or low quality of food ingredients or food products.

Section 5: Principles

10. Prevention and control of food fraud should be based on the following principles:

Principle 1: Protection of Consumers

- Systems to address food fraud should be in place to protect the health of consumers and to maintain consumer confidence in the safety, integrity, authenticity, suitability, and quality of food.

Principle 2: Protect the Integrity of the Food Supply Chain and Legitimate FBOs

- Food fraud controls and surveillance systems should be in place to protect the integrity of the entire food supply chain, which also helps to protect legitimate FBOs.

Principle 3: Legal Foundation

- The government within each country should have in place an appropriate legal framework to address food fraud.

Principle 4: Coordination, Cooperation, and Collaboration Between Competent Authorities

- Competent authorities should operate in a coordinated, cooperative, and collaborative manner to detect, prevent, mitigate and control food fraud.

Section 6: Roles and Responsibilities

11. A relevant governmental body has the role and responsibility to, as appropriate:

a. Establish or maintain legal structures and requirements to detect, prevent, mitigate and control food fraud

b. Empower competent authorities to control, investigate and establish sanctions to deter and dissuade food fraud

12. The competent authorities have the role and responsibility to, as appropriate:

a. Establish or maintain oversight programs to detect, prevent, mitigate, and control food fraud.

b. Develop or maintain mechanisms/platforms to better detect food fraud.

c. Build partnerships and collaborations with other governments, industry, academia and other stakeholders to combat food fraud.

d. Communicate with stakeholders and other government authorities, as needed.

e. Notify any potentially impacted countries when incidents of food fraud are identified or suspected.

13. FBOs have the role and responsibility to, as appropriate:

a. Understand their supply chain and which products/ingredients/packaging in it may be susceptible to food fraud.

b. [Have measures in place to mitigate the risk that the food products and ingredients are not authentic and ensure that the nature, safety, quality, and substance are accurately represented.]

c. Represent food for sale in a manner that does not deceive or mislead consumers.

d. Inform the competent authority when they detect or suspect food fraud.

e. Take reasonable precautions to detect, prevent, mitigate, and control food fraud.

Section 7: Relevant Activities for Competent Authorities

14. Measures to detect, prevent, mitigate, and control food fraud incorporate aspects of food safety and quality, consumer protection, and ensuring fair practices in food trade, and so may be addressed within the structure of a NFCS.

15. Competent authorities may consider reviewing their NFCS and determine whether their system has an adequate [legal] [legislative] framework and appropriate policies and procedures to monitor, detect, prevent, control, and respond to food fraud incidents and strengthen fair trade. Such policies could include legal requirements, including sanctions, and responsibilities of the FBOs related to food integrity and authenticity.

16. Competent authorities may consider establishing procedures to receive and evaluate reports of food fraud and determine appropriate follow-up, consistent with the food safety risk identified and national priorities.

17. Policies, procedures, and regulatory requirements related to food fraud prevention and control should be transparent and risk-based.

18. Competent authorities should consider including risk-based planning of measures to prevent food fraud.

19. Competent authorities may consider establishing surveillance activities to detect food fraud. These activities could be conducted on a routine basis or in response to specific risk that has been identified.

20. Competent authorities may consider providing practical guidance to FBOs and other stakeholders on how to address food fraud. Such guidance could include resources and access to tools on how to develop procedures to detect, prevent, mitigate, and control food fraud.

21. Competent authorities may consider establishing appropriately secure communication channels with other governments, FBOs, academia, and other stakeholders to obtain information about situations involving food fraud and to share relevant knowledge, experience, and tools for combatting food fraud, such as food standards and analytical methods.

21 bis Competent authorities should consider developing tools to protect persons acting as “whistle-blowers” reporting such incidents.

22. If there is a potential for a food fraud incident to have an impact on food safety, the competent authority detecting the incident should immediately alert the relevant competent authority within their government if it is not the same organization.

23. Competent authorities may consider establishing communication mechanisms for timely reporting to stakeholders about incidents involving food fraud, as appropriate.

Section 8: [Cooperation] [Collaboration] and exchange of information between competent authorities

24. Competent authorities should cooperate [collaborate] and exchange information with the relevant competent authorities in situations where food fraud is suspected or identified. This exchange of information could be expanded when there is awareness that fraudulent product poses a food safety risk and has been distributed to other countries.

25. The exchange of information should be made as early as possible, recognizing that the initial information may often be incomplete and more detailed information will be provided as it becomes available. Identification of key elements, including relevant information in *CXG 19-1995* Annex, that contribute to international harmonization and collaboration on the prevention and control of food fraud are essential.

25 bis. Information exchanged should be sufficient to allow competent authorities to evaluate the food fraud incident and mitigate its impact, especially with regard to risk to consumers, without jeopardizing ongoing investigations.

26. Competent authorities may benefit from establishing appropriate information exchange routes with relevant enforcement bodies and agencies, including those responsible for dealing with criminality. In establishing such routes, competent authorities should give due consideration to information security around personal data, operationally sensitive material and also have in place systems to assure the integrity of any evidence gathered and/or shared.

Annex 1: Existing Codex Documents Addressing Food Fraud

[Note: it is proposed to remove this annex prior to finalizing the guideline]

The Committee's comprehensive review of existing Codex texts illustrates that food fraud is already covered in a variety of Codex documents.

- The Codex *Code of Ethics for International Trade in Food Concessional and Food Aid Transactions* (CXC 20-1979)
- Food fraud as it pertains to improper, inaccurate, false, or misleading labelling is addressed in:
  - *General Standard for the Labelling of Pre-packaged Foods* (CXS 1-1985)
  - *General Standard for the Labelling of Food Additives when sold as such* (CXS 107-1981).
- *Principles and Guidelines for National Food Control Systems* (CXG 82-2013)
- *Principles for Traceability / Product Tracing as a Tool Within a Food Inspection and Certification System* (CXG 60-2006)
- *Guidelines for Design, Production, Issuance and Use of Generic Official Certificates* (CXG 38-2001)
- Principles and guidelines for the exchange of information between importing and exporting countries to support the trade in food (CXG 89-2016)
- *Guidelines for the Exchange of Information between Countries on Rejections of Imported Foods* (CXG 25-1997)
- *Principles and Guidelines for the Assessment and Use of Voluntary Third-party Assurance Programmes* (CXG 93-2021)
- *Principles and Guidelines for the Exchange of Information in Food Safety Emergency Situations* (CXG 19-1995)

Annex 2: International Organizations Working in the Area of Food Fraud

[Note: it is proposed to remove this annex prior to finalizing the guideline]

- Food and Agriculture Organization of the United Nations (FAO)
- Global Food Safety Initiative (GFSI)
- Institute of Food Technologists-Global Food Traceability Center (GFTC/IFT)
- International Association for Food Protection—Food Fraud Professional Development Group (IAFP/PDG)
- International Life Sciences Institute (ILSI)
- The International Criminal Police Organization (INTERPOL)
- The United Nations Interregional Crime and Justice Research Institute (UNICRI).