Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination (DWPE) and Removal of a Foreign Manufacturer's Goods from DWPE: Guidance for Industry

Draft Guidance

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For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Safety/Division of Seafood Safety, at 240-402-2300.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition

February 2024

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Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination (DWPE) and Removal of a Foreign Manufacturer's Goods from DWPE: Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or we) on this topic.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 listed on the title page.

I. Introduction

This guidance is intended to provide recommendations for collecting a representative sample for testing when fish and fishery products[2] are subject to detention without physical examination (DWPE) due to the appearance of adulteration caused by pathogens, unlawful animal drugs, scombrotoxin (histamine), and/or decomposition.[3] This guidance is also intended to help foreign manufacturers and other processors of fish and fishery products subject to DWPE under an import alert (IA) to introduce evidence to FDA to support a request to have products removed from DWPE. This guidance does not apply to seafood-related import alerts when sampling and testing is not relevant to securing release of individual shipments or removal from DWPE.

[1] This guidance has been prepared by the Office of Food Safety/Divisions of Seafood Safety and Seafood Science and Technology in consultation with the Office of Compliance and the Office of Regulations and Policy, all in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

[2] Effective March 1, 2016, the United States Department of Agriculture's Food Safety Inspection Service assumed responsibility for the regulation of domestic and imported Siluriformes fish, and fish products. Siluriformes include fish commonly known as "catfish," "tra," "swai", and "basa." This guidance is not applicable to these fish.

[3] The recommendations regarding sampling and testing may also be relevant when fish and fishery products are subject to other types of enforcement action, such as seizure and/or administrative detention. However, because of the volume of questions FDA receives regarding sampling and testing when seafood products are subject to DWPE, the guidance focuses on shipments subject to DWPE.

In this guidance, we address the following issues regarding seafood products subject to DWPE due to pathogens, unlawful animal drugs, scombrotoxin (histamine), and/or decomposition:

- Recommendations for the number of sample units (e.g., "subsample" as used by FDA) to be collected and tested from an article of fish and fishery products subject to DWPE to ensure statistical confidence and a representative sample;
- A description of a "sample unit" and other characteristics of an article to help identify the amount of product and product groups or portions within the affected article to be sampled;
- References for analytical methods that may be used to analyze the samples collected;
- Recommendations for evidence to include in a submission requesting FDA to release an article detained under DWPE;
- Recommendations for types of production-related evidence that may be useful for FDA to assess the efforts instituted by the processor(s) to prevent adulteration; and
- Recommendations for the types of evidence that may be useful when requesting removal of a fish and fishery product or manufacturer from DWPE.

If you have questions about whether the guidance is relevant to your situation, you may contact CFSAN, Office of Food Safety, Division of Seafood Safety at 240-402-2300.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Background

Under section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(a)(3)), an article[4] of food imported or offered for import into the United States is subject to refusal of admission if it appears "from the examination of such samples or otherwise" to be adulterated.

FDA issues import alerts to inform its field staff about products that appear to be in violation of FDA's laws and regulations and thus may be detained without physical examination. We may subject future shipments of fish or fishery products to DWPE when there is information that causes future shipments of a product or products to appear violative within the meaning of section 801(a) of the FD&C Act. Such information may exist based on the violative history of a product, manufacturer, shipper, grower, importer, geographic area, or country.[5]

To carry out the provisions of section 801(a) of the FD&C Act when we detain an article that appears violative, we provide notice to the owner or consignee (referred to as the "owner" or

[4] As used in this guidance, the term *article* refers to the quantity of food within a shipment offered for entry that is subject to DWPE.

[5] For more information about import alerts, see https://www.fda.gov/industry/actions-enforcement/import-alerts.

"you") of the nature of the violation and the right to present testimony regarding the admissibility of the article (21 CFR 1.94). In other words, you can submit evidence to demonstrate the admissibility of the article that is subject to DWPE. Frequently, owners or consignees submit analytical test results based on samples taken from the article subject to DWPE. FDA then determines if the testimony (analytical package, information, or other evidence) is sufficient. If the evidence is adequate to overcome the appearance of the violation(s), FDA will allow the article to proceed for entry into the United States. If the evidence is not adequate to remove the appearance of the violation(s), the entry will be refused admission into the United States.

In addition, interested parties may request that their products be removed from DWPE. FDA decisions to remove a product, manufacturer, or other entity from DWPE are based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and we have confidence that future shipments of the product to the United States will be in compliance with the FD&C Act. FDA may consider analytical results from consecutive tests as part of evidence to support removal from DWPE.

When food testing is used as evidence in these scenarios (i.e., in support of admission of an article or to support removal from an import alert for consecutive testing), the food testing is covered by the Laboratory Accreditation for Analyses of Foods (LAAF) Rule (21 CFR 1.1107(a)(4) and (5)). [6] The LAAF Rule includes certain specific requirements for food testing and analytical results that must be submitted to FDA. This guidance provides recommendations to help owners, consignees, and other interested parties collect representative samples for food testing used to secure the release of fish and fishery products when FDA has identified the appearance of adulteration linked to a pathogen, unlawful animal drug, scombrotoxin (histamine), and/or decomposition and the appearance of these adulterants serve as the basis for DWPE. This guidance also provides recommendations to help foreign manufacturers and other processors of fish and fishery products subject to DWPE under an import alert introduce evidence to FDA to support a request to have products removed from DWPE.

[6] Under the LAAF Rule, owners and consignees are required to use a LAAF-accredited laboratory for food testing in certain circumstances, including to support admission of an imported food detained at the border because it is or appears to be in violation of the FD&C Act and to support removal from an import alert through successful consecutive testing. The LAAF Rule includes certain requirements for sampling, analysis of samples, methods of analysis, and the notifications, results, reports, and studies that LAAF-accredited laboratories must submit to FDA (see 21 CFR 1.1149, 1.1150, 1.1151, 1.1152, and 1.1153). FDA is taking a stepwise approach to implementation of the LAAF program based on laboratory capacity. When there is sufficient LAAF-accredited laboratory capacity for the food testing covered by the final rule, we will publish one or more documents in the *Federal Register* giving owners and consignees 6 months' notice that they will be required to use a LAAF-accredited laboratory for such food testing. For more information, see FDA's LAAF Rule website, available at https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-laboratory-accreditation-analyses-foods-laaf. At the time of publication of this draft guidance, owners and consignees are not yet required to ensure that food testing is conducted in accordance with the LAAF rule due to current insufficient laboratory capacity. However, that will change if FDA publishes an applicable document in the *Federal Register* giving owners and consignees notice about the requirement to use a LAAF-accredited laboratory.

III. Discussion

A. Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Articles Subject to DWPE

When a product is subject to DWPE due to the appearance of adulteration linked to a pathogen, unlawful animal drug, scombrotoxin (histamine), and/or decomposition, we recommend that you develop a statistically robust representative sample consisting of sample units collected proportionately from the affected article in order to support the admissibility of the product. The term "sample unit" refers to the smallest discrete intact component in the article or portions of the article (e.g., whole fish, fish fillet, shrimp, can, tub, bag, etc.). Appendix A provides sampling schedule recommendations for the number of sample units to collect and test.[7] Appendix B provides the minimum amount of product recommended for collection to represent each sample unit. The recommended sampling schedules consist of three groupings based on the risk to health that the adulteration generally represents to consumers, with more sampling and testing warranted when the risk is expected to be greater. While we generally recommend you follow the sampling schedules in Appendix A, we recognize that there may be circumstances where another sampling plan could be justified. If you believe that another sampling plan is justified, you may propose such a plan to us before collecting the sample, and we will consider whether your plan is appropriate.

In addition to the total number of sample units collected being statistically robust based on the total weight of the article, the adequacy of the evidence depends on ensuring that the sampling is representative of every portion of the affected article. If the sampling is not representative and statistically robust, there will generally be insufficient evidence supporting the admissibility of the article. To ensure that the sampling is representative across different product portions, we recommend using commercial documentation, such as invoices, packing lists, and manufacturer's or shipper's lists of production codes, to identify discrete 'portions' making up the article.

The owner or consignee of an article subject to DWPE may identify discrete "portions" making up the article on the basis of:

1. Line - Product within the article that can be grouped by attributes or characteristics, such as uniform type (e.g., species), size (e.g., size of product portions/pieces, count, package weight), and market form (e.g., head on/off, tail on/off, peeled, deveined, butterflied, cooked, raw, skin on/off, filleted, headed and gutted, breaded, ingredient formulation/treatments), that often appears as a single line item in the shipment manifest, invoice, or packing list. When sampling based on a product line, the individual collecting the sample ("sampler") should ensure cross-representation of production codes (see "2" below) within each line; or

[7] For more information about the basis for FDA's recommendations in Appendix A, see Derivation of Sampling Recommendations Related to Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery Products Subject to Detention Without Physical Examination (DWPE) and Removal of a Foreign Manufacturer's Goods from DWPE: Guidance for Industry (Ref. 1).

2. Production Code - Product within the article associated with the same history of exposures, e.g., product originating from a specific farm, harvest area, or harvester and processed and packed under uniform conditions in a specific period of time (e.g., day or shift) at a specific packing facility and production line, or the same sequence of facilities and lines, culminating in coding the packed product with the same manufacturer's production code. Coding is frequently specific to product attributes or lines such as those described in "1" above, but if the coding is a production date code only, then the sampler should ensure cross-representation of product attributes or lines within each production code-based sample.

Owners may propose different attributes as a basis for separating the article into different portions. Documents such as invoices, packing lists, and manufacturer's or shipper's listing of production codes and photographs may be helpful to demonstrate that the proposed sample is representative.

When the article subject to DWPE consists of two or more discrete portions, the recommended number of sample units should be collected proportionately from each portion making up the article (i.e., the percentage of sample units from each portion should correlate to the volume (net weight) of product that the specific portion represents in the article). For example, a 40,000-pound article of tilapia fillets subject to DWPE due to the appearance of unlawful animal drugs should result in a total sample size of 150 units per the recommended sampling Table in Appendix A. A portion of the 40,000-pound article consisting of 6,360 pounds of product should result in the collection of 24 of the 150 units collected from that 6,360-pound portion, i.e., 6,360 ÷ 40,000 = 0.159 (or 15.9%) and 0.159 x 150 units rounds off to 24 (see Line 001/003 in the illustration below).

> **Example:** *An importer has an article of frozen tilapia fillets subject to DWPE due to the appearance of unlawful animal drug residues. The article consists of seven line items delineated by the size or weight of the fillets. A suggested sampling scheme is as follows:*

Line	Line Description	Net Wt. (lbs)	Number of Sample Units to Collect & Test
001/001	Tilapia fillets, 6-8 oz	16,800	63
001/002	Tilapia fillets, 4-6 oz	8,580	32
001/003	Tilapia fillets, 8-10 oz	6,360	24
001/004	Tilapia fillets, 10-12 oz	4,150	16
001/005	Tilapia fillets, 12-14 oz	2,810	10
001/006	Tilapia fillets, < 4 oz	980	4
001/007	Tilapia fillets, > 14 oz	320	1
	Total	40,000	150

In this example, the 150 sample units recommended in the sampling Table in Appendix A for unlawful animal drugs are collected proportionately by the volume of product in the lines. In addition, consistent with the recommendations above for sampling by lines, assurances should be made that a cross representation of production codes are included within the group of sample units collected from each line as may be applicable to that line.

To the extent possible within the sampling scheme, sample units should be collected randomly to give the broadest representation of each portion (i.e., one subsample per carton/tote/container randomly selected from the portion to be sampled). Random sampling within each portion means that every unit of fish or fishery product within the portion sampled should have an equal chance to be selected. For example, any package, from any carton, from any layer on any pallet within the portion, has an equal chance to be selected. The selection of sample units should not be restricted to only some pallets or some layers on the pallets that are conveniently accessible. It may be appropriate to add additional sample units to those randomly selected if some important attribute of the portion was completely missed in the random draw (e.g., a particular prominent production code may have been missed when sampling was stratified based on line item).

If the adulterant associated with the import alert is detected in any sample unit analyzed from any portion or portions of the article, FDA may determine that the appearance of the violation remains for all portions of the detailed article.[8] The overall sample size and the number of sample units collected from each portion, when applying the recommended sampling strategy in this document, are generally not adequate to provide sufficient statistical assurances to signal that the adulteration is restricted to the specific portion or portions of the article in which a positive sample unit(s) was identified, such that a reliable segregation of the article could be performed, portion-by-portion, on the basis of these limited sampling and analytical results. As a result, it is unlikely that we would consider it reasonable to separate (and treat as violative) only the portion(s) of the article that test positive for the adulteration, based solely on the test results.[9]

As part of the review of your request for release of an article subject to DWPE, we may request additional documentation to ensure that the products in the shipment do not appear adulterated. For example, we may request such additional information if our review of the national entry data for your products(s) shows there has been a history of mixed analytical results, such as successive shipments alternately having positive and negative results such that the results for a new shipment may not convincingly demonstrate lack of adulteration.

When submitting analytical results of food testing as evidence in this scenario, the LAAF Rule requires owners or consignees to use a LAAF-accredited laboratory (see 21 CFR 1.1107(a)). The LAAF rule describes the oversight standards that apply to sampling and the documentation that a LAAF-accredited laboratory must submit to FDA with test results (see 21 CFR 1.1149 and 21 CFR 1.1152(c)). Generally, this documentation includes submission of the sampler's

[8] Violative concentrations of some contaminants in a sample unit or appropriate composite analytical unit, as established in FDA regulations and guidance, may be applicable, e.g., florfenicol residue greater than 1.0 ppm.
[9] If the owner or consignee presents evidence to FDA that the adulteration does not apply to all portions of the detained article, FDA will consider such evidence.

applicable qualifications, a written sampling plan used to conduct the sampling, and a written sample collection report for each sample collected (see 21 CFR 1.1149(a)). The written sampling plan must identify the sampler and sampling firm and must list the factors that will be controlled to ensure the sampling does not impact the validity of the subsequent analytical testing, including controlling for the representational nature of the sample (see 21 CFR 1.1149(a)(2)).[10,11] The LAAF Rule provides detailed information about what information must be submitted to FDA with analytical results (see 21 CFR 1.1152).

B. Recommended Analytical Methods

For fish and fishery products subject to DWPE, the general methods found in the Analytical section of FDA's Compliance Programs, relevant to the specific adulteration identified in the import alert, may be used.

For unlawful animal drug residues, see Chemotherapeutics in Aquaculture Seafood Compliance Program, CP 7304.018, https://www.fda.gov/media/71452/download or see Drug or Chemical Residues Methods https://www.fda.gov/food/science-research-food/laboratory-methods-food.

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[10] As stated in a previous footnote, FDA is taking a stepwise approach to implementation of the LAAF program based on laboratory capacity. When there is sufficient LAAF-accredited laboratory capacity for the food testing covered by the final rule, we will publish one or more documents in the *Federal Register* giving owners and consignees 6 months' notice that they will be required to use a LAAF-accredited laboratory for such food testing. At the time of publication of this draft guidance, food owners and consignees are not yet required to ensure that testing is conducted in accordance with the LAAF rule due to current insufficient laboratory capacity. However, that will change if FDA publishes an applicable document in the *Federal Register* giving owners and consignees notice about the requirement to use an LAAF-accredited laboratory.

[11] For shipments that, (1) are not the subject of a *Federal Register* notice indicating that owners or consignees will be required to use an LAAF-accredited laboratory for food testing, but for which (2) sampling and analytical results are included in the evidence submitted in a request to secure release, we recommend that you provide FDA with a comprehensive submission that includes:

1. A detailed description of the detained article, and any pertinent attributes of the portion or portions within the article that may have been selectively sampled, including the identity, size (e.g., volume by weight, and number of pallets, cartons, vats, bags, etc.), composition, and configuration. Documents such as invoices, packing lists, and manufacturer's or shipper's listing of production codes and photographs are helpful.
2. A detailed sample description of how the number of sample units collected was calculated including the total number of sample-sized units in the article, the smallest discrete component, the number of sample units collected from each portion of the article, the composition of each sample unit (e.g., the amount of product and number of pieces in each sample unit), the production code of each sample unit, a description and/or diagram of the locations (e.g., pallets, layers on pallets, cartons within layers) within the article or portions from where each sample unit was collected, the sampling method used (i.e., the manner or technique by which each sample unit is collected), and the sample preparation and shipping procedures used.
3. The identity and qualifications of the entity and individual(s) conducting the sampling.
4. Identification and accreditation, if any, of the laboratory and individual(s) that performs the specified analysis of the samples.
5. Documentation of the analysts' qualifications (see Ref. 2, Sec. 4.1, Private Laboratory Guidance, Information About Private Laboratories, Private Laboratory Analysts).
6. A detailed description of the test method(s) and procedures used to analyze all of the sample units. You may utilize the general methods found in the Analytical section of FDA's Compliance Programs, relevant to the specific adulteration at issue.
7. All original and complete sample collection reports and analytical data and reports regardless of the findings.

For adulteration associated with pathogens, scombrotoxin (histamine), and decomposition in fish and fishery products, see the Seafood Processor, Products, and Importer Inspection Program, CP 7303.842, or as indicated elsewhere within that compliance program, https://www.fda.gov/media/71302/download.

Alternatively, other methods that involve appropriate validation/verification procedures for the specific adulteration and sample matrix under consideration may be used. If such alternatives are used, we recommend that you provide information that supports the use of the methods.

Compositing of sample units to the extent indicated in the specific methods is acceptable.

C. Recommended Evidence for Requests for Removal from DWPE Under an Import Alert

Foreign manufacturers or other interested parties may request to be removed from DWPE.[12] They should provide information to FDA to adequately demonstrate that the conditions that gave rise to the appearance of the violation have been resolved. For example, it may be appropriate to provide evidence of a root cause analysis, relevant corrections to the manufacturing process, and/or other controls that have been implemented to address the violation, and hazard analysis critical control point (HACCP) documents, in addition to testing results for consecutive non-violative shipments. The Guidance section of the import alert may contain additional information for requesting removal from DWPE.

For general guidance on removal from DWPE, including recommendations for the number of consecutive non-violative shipments that FDA may request, refer to FDA's Regulatory Procedures Manual (RPM), Chapter 9, Sections 9-8-15 and 9-8-16 (Ref. 2). RPM Chapter 9 includes recommendations about the number of consecutive non-violative shipments (typically five (5) or twelve (12)) that may help demonstrate that the conditions that gave rise to the appearance of the violation have been resolved.[13] The testing submitted to FDA should be from a statistically robust number of samples based on the size of the article and representative of the affected article. We recommend the sampling and testing protocols outlined in section III.A. of this guidance. At the same time, we recognize that there may be circumstances where another sampling plan could be justified. If you wish to use other levels of sampling and testing, you may submit them to us, and we will consider whether such requests are appropriate.

To facilitate and expedite a review of a request for removal of fish and fishery products from DWPE, we recommend that the manufacturer or other party submit information to allow us to adequately assess whether the conditions that gave rise to the appearance of the violation have been resolved. The purpose of this is so that we can have confidence that future shipments of the

[12] For some import alerts, being removed from DWPE may mean being removed from a "Red List." For other import alerts, being removed from DWPE may mean being added to a "Green List." For more information about import alerts, see FDA's "Import Alerts" website, available at http://www.fda.gov/industry/actions-enforcement/import-alerts#typelist.

[13] For more information about the recommended numbers of shipments that may be appropriate in different circumstances, see RPM Chapter 9.

product will not appear violative. Such documentation (which should be provided in English to facilitate review) may include the following:

1. Documentation of a root cause analysis. The root cause analysis should consider all potential sources of adulteration and explain the basis for their elimination to demonstrate how the root cause was ultimately identified as the likely source of the adulteration. If the likely source of the adulteration cannot be identified, then the root cause analysis should thoroughly investigate and evaluate all potential sources, implemented controls, and problems.

2. Documentation of corrective actions taken to address the likely or potential sources and routes of contamination identified in the root cause analysis. The corrective actions should provide details on the controls implemented to prevent future adulteration based on the root cause analysis.

3. Documentation pertinent to current processing of the fish or fishery product(s), including:

    a. Where applicable, a copy of the most current HACCP plan in effect by each processor involved with the processing of the product(s) for which removal from DWPE is requested.

    b. Where applicable, HACCP monitoring records reflecting control and monitoring of the pertinent critical control point(s) and sanitation monitoring records. We recommend providing records that cover five (5) production days to help demonstrate that the conditions that gave rise to the appearance of the violation have been resolved. This may include records from:

        i. The foreign manufacturer requesting removal from DWPE, and

        ii. Each of the manufacturer's suppliers or intermediary processors.

4. Documentation of food testing analytical results[14] (see 21 CFR part 1, subpart R; see FDA's Regulatory Procedures Manual, Chapter 9, Sections 9-8-15 and 9-8-16 (Ref. 2) for information about the number of consecutive non-violative shipments that FDA may expect).

The specific information that should be provided will depend on the nature of the violation at issue, the relevant history for the firm/product, the information in the relevant import alert, the nature of the growing, harvesting, or processing conditions, and other relevant information.

[14] As discussed in footnote 6, once there is sufficient LAAF-accredited laboratory capacity, owners and consignees will be required to use a LAAF-accredited laboratory to conduct food testing in this scenario. At the time of publication of this draft guidance, food owners and consignees are not yet required to ensure that testing is conducted in accordance with the LAAF rule due to current insufficient laboratory capacity. However, that will change if FDA publishes an applicable document in the *Federal Register* giving owners and consignees notice about the requirement to use an LAAF-accredited laboratory.

Note: In some cases, manufacturers or other parties will have previously submitted information to FDA to secure release of individual shipments. In some cases, that same information (for example, processing records) may also be relevant to the firm's request to be removed from DWPE. There is no need to submit the same information to FDA more than once. To avoid duplication, the firm's request for removal from DWPE may include references to the previously submitted information.

A request for removal of a manufacturer's product(s) from DWPE, along with information supporting the request, should be forwarded to FDA at the address provided in the import alert.

IV. Conclusion

This guidance provides recommendations for collecting a representative sample and testing when fish and fishery products are subject to DWPE due to the appearance of adulteration caused by pathogens, unlawful animal drugs, scombrotoxin (histamine), and/or decomposition. The guidance provides recommendations for requests for removal from DWPE. Importers of fish and fishery products remain subject to the statutory prohibition against the introduction or delivery for introduction into interstate commerce of adulterated food (section 301(a) of the FD&C Act (21 U.S.C. 331(a))). Nothing in this guidance prevents owners of seafood products from conducting sampling for purposes unrelated to this guidance (i.e., unrelated to demonstrating admissibility of an article of seafood or requesting removal from DWPE). If you have questions about evidence to submit, you may contact the appropriate office listed in this guidance to ask questions specific to the article offered for entry.

Following the receipt and review of the sample collection reports, laboratory results, and any associated corrective and preventive action documentation requested by, or submitted to, FDA, we may collect and analyze audit samples before making a final decision on the admissibility of any article.

- For questions related to a detention or regarding the process of submitting evidence of admissibility, contact the compliance officer listed on your FDA Notice of Action.
- For questions on policy or sample collection recommendations, contact the Office of Compliance, Division of Enforcement, CFSAN, at 240-402-1750 or CFSANEnforcement@fda.hhs.gov.
- For questions or issues concerning preparation of samples for analysis or analytical methodology, contact the Office of Regulatory Science, Office of Regulatory Affairs (ORA), at oraorsprivatelabimportalerts@fda.hhs.gov.
- For questions related to the LAAF Rule, contact FDALAAFInquiry@fda.hhs.gov.
- For general questions or issues involving import operations, including requests for removal from DWPE, contact the Division of Import Operations at 301-796-0356 or FDAImportsInquiry@fda.hhs.gov.

V. References

The following references are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov. FDA has verified the website address, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. FDA, Derivation of Sampling Recommendations Related to Recommendations for Collecting Representative Samples for Food Testing Used as Evidence for Release of Certain Fish and Fishery products Subject to Detention Without Physical Examination (DWPE) and Removal of a Foreign Manufacturer's Goods from DWPE: Guidance for Industry.
2. FDA's Regulatory Procedures Manual, Chapter 9, Section 9-8-15, Removal From Detention Without Physical Examination, and Section 9-8-16, Removal of Products Manufacturers/Countries Except Fresh Produce. Accessed online at https://www.fda.gov/media/71776/download.

VI. Appendices

Appendix A – Sampling Schedule Recommendations

Appendix B – Amount of Product Recommended Per Sample Unit

Appendix A – Sampling Schedule Recommendations

Table 1 provides recommended numbers of sample units to collect and test when an article of fish or fishery product is subject to DWPE due to the appearance of adulteration by pathogens, unlawful animal drugs, scombrotoxin (histamine), and/or decomposition, and the sampling and testing results are submitted to demonstrate admissibility. The number of sample units to be collected may be adjusted based on the total size (by weight) of the article. However, as can be seen in Table 1 below, to ensure statistical relevance, the number of sample units to be collected becomes impractical for articles that are small in total amount (by weight) because the number of sample units to be collected eventually equals the amount of product in the article.

The recommendations in the main body of this guidance document are applicable to collecting a proportionate number of sample units to represent all portions of the article (e.g., lines or codes) such that inferences of test results can apply to the entire article, as opposed to portions of the article.[15]

Our sampling recommendations are as follows:

Table 1: Total number of sample units to collect and test from the affected article based on the number of sample-sized units within the affected article.

Number of sample-sized units within the affected article (see *Note* below) >>	**50**	**100**	**200**	**350**	**500**	**1,000**	**5,000**	**10,000**	**50,000**	**100,000**
Pathogens, Unlawful Animal Drugs, or Scombrotoxin	50	95	126	137	141	145	150	150	150	150
Decomposition in Scombrotoxin-forming Fishery Products without Scombrotoxic Levels of Histamine Detected*	48	78	105	109	110	116	119	120	120	120
Decomposition in Non-Scombrotoxin-forming Species of Fishery Products*	45	69	74	87	87	87	90	90	90	90

* When chemical indices of decomposition are applicable, e.g., histamine or indole, all sample units should be tested by sensory and chemical analyses. Histamine levels at 200 parts per million (ppm) or greater are considered scombrotoxic for this application.

Note: To determine the "Number of sample-sized units within the affected article," Appendix B provides the amount (by weight) of product recommended for collection to represent each sample unit. Depending on the type of product and its packaging, the recommended sample unit

[15] This guidance does not apply when owners or other representatives seek to segregate non-violative products from products that they acknowledge are adulterated. FDA's recommendations for sampling and testing in that situation can be found at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-reconditioning-fish-and-fishery-products-segregation.

amount (by weight) in Appendix B may be collected by withdrawing the smallest discrete intact component (e.g., whole fish, fish fillet, shrimp, can, tub, bag, etc.) in the article. For packaged products, it may be the smallest discrete intact package in the article (e.g., can, tub, bag, etc.). For bulk products, it may be a single fish or fish piece (e.g., loin, fillet, or steak). When the packages, fish, or fish pieces are very small, we recommend that you collect multiple packages, fish, or fish pieces to meet the recommended sample unit amount (by weight) in Appendix B. For other products, the smallest discrete intact component collected may be a larger amount (by weight) than the sample size unit amount (by weight) from which the recommended sample unit amount in Appendix B can later be drawn by the laboratory and tested. However, the smallest discrete intact component should not be used for more than one sample unit. To determine the recommended number of sample-sized units within the affected article, divide the amount (by weight) of the article by the recommended collection amount (by weight) for each sample unit (see Appendix B), adjusting for the product type and packaging as shown in Examples 1-3 below.

Example 1: When the exact amount for the sample unit is collected, the total amount (by weight) of product in the article is divided by the sample unit amount (by weight) recommended in Appendix B. This scenario applies when the recommended sample unit amount (by weight) equals the smallest discrete component (by weight) which can be single or multiple small fish or fishery product from a bulk container or single or multiple small packages.

- Sample calculation example 1: The recommended sample unit amount (by weight) in Appendix B is 8 oz. (0.5 lbs.) and the smallest discrete intact component is an 8 oz. package. The article consists of 35,000 pounds of product. The total number of "sample-sized units" in the article to be applied in the Table is 70,000 units (35,000 lbs. ÷ 0.5 lbs. = 70,000 sample-size units).

or

Example 2: When the smallest discrete intact component of the article is a larger amount (by weight) than the recommended sample unit amount (by weight), the total amount (by weight) of product in the article is divided by the smallest discrete intact component amount (by weight). This scenario applies when the recommended sample unit amount (by weight) is less than the smallest discrete component (by weight) which can be a fish or fishery product from a bulk container or a package.

- Sample calculation example 2: The recommended sample unit amount (by weight) in Appendix B is 8 oz. (0.5 lbs.). The article consists of 1 lb. packaged units that are destroyed once opened, thus, a 1 lb. package is the smallest discrete intact component that will be collected to represent a sample unit. The article consists of 35,000 pounds of product. The total number of "sample-sized units" in the article is 35,000 units (35,000 lbs. ÷ 1 lbs. = 35,000 sample-size units).

or

Example 3: When the article consists of a mix consisting of two or more discrete portions, the total amount (by weight) of product in the article is divided proportionately by the smallest discrete intact component amount (by weight) for each portion. This scenario applies when the smallest discrete intact component in the article is not uniform (e.g., consists of 1 lb. and 2 lbs. packages, etc.), which can be a fish or fishery product from a bulk container, packaged, or both.

- Sample calculation example 3: The recommended sample unit amount (by weight) in Appendix B is 8 oz. (0.5 lbs.). The article consists of different sized (smallest discrete intact) packaged units that are destroyed once opened. The total number of "sample-size units" should be the sum of the "sample-size units" calculated proportionately based on the total weight of the product for each package size. The article consists of 35,000 lbs. of product for which 20,000 lbs. are packaged in 1 lb. sealed bags and 15,000 lbs. are packaged in 2 lbs. sealed bags. The total number of "sample-size units" in the article is 27,500 units ((20,000 lbs. ÷ 1 lb.) + (15,000 lbs. ÷ 2 lbs.) = 27,500 sample-size units).

Our sampling recommendations are based on achieving the following levels of confidence for detecting the different types of adulteration, as follows:[16]

- For pathogens, unlawful animal drugs, and scombrotoxin – 95% confidence that contamination is present in no more than approximately 2.0% of the units in the article;
- For decomposition in scombrotoxin-forming fish and fishery products – 95% confidence that contamination is present in no more than approximately 2.5% of the units in the article; and
- For decomposition in non-scombrotoxin-forming fish and fishery products – 90% confidence that contamination is present in no more than approximately 2.5% of the units in the article.[17]

The table reflects our general recommendations. You may propose alternative sampling plans and explain the basis for such alternatives.

The table reflects sampling recommendations only, and the levels of confidence we recommend for detecting the different types of adulteration should not be misinterpreted to signify acceptable levels of the identified adulterants in the food.

[16] The recommendations are derived from a critical nonconformities statistical application.

[17] FDA may consider the article adulterated when the contamination is detected in any sample unit within the recommended sample number.

Appendix B – Amount of Product Recommended Per Sample Unit

The recommended amount (by weight) of product to be collected for each sample unit as applicable to the relevant adulteration that forms the basis of the article being subject to DWPE is provided in the table below:

Application	Recommended Amount (by Weight) of Product to be Collected for Each Sample Unit
Pathogens	
Salmonella or *Listeria monocytogenes*	114 grams (4 oz.)
Other Pathogens	227 grams (8 oz.)
Unlawful Animal Drugs	
Unless Otherwise Noted	454 grams (1 lb.)
Shrimp	
▪ Fresh, Frozen,	454 grams (1 lb.)
▪ Whole, In-Shell, Breaded	680 grams (1.5 lbs.)
Crab or Crawfish	
▪ Processed	454 grams (1 lb.)
▪ Whole, In-Shell, Cut Pieces	680 grams (1.5 lbs.)
Frog Legs	680 grams (1.5 lbs.)
Finfish	454 grams (1 lb.)
Scombrotoxin (Histamine)	
Unless Otherwise Noted	250 grams (can be obtained from the 1 lb. decomposition sample unit in most instances)
Cans or Retorted Pouches/Cups	142 grams (5 oz.) or 1 can/cup/pouch if > 5 oz.
Decomposition	
Unless Otherwise Noted	454 grams (1 lb.)
Cans or Retorted Pouches/Cups	
▪ Scombrotoxin-Forming Fishery Products	142 grams (5 oz.) or 1 can/cup/pouch if > 5 oz.
▪ Non-Scombrotoxin-Forming Fishery Products	1 can/cup/pouch regardless of weight