

Contains Nonbinding Recommendations

Draft — Not for Implementation

Reconditioning of Fish and Fishery Products by Segregation: Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://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 listed in the notice of availability that publishes in the *Federal Register*.

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**

September 2019

Table of Contents

I. Introduction	1
II. Background	2
III. Discussion	3
A. RECONDITIONING BY SEGREGATION	3
1. <i>Segregation Based on a Production-Related Rationale Identifying the Cause of the Adulteration and Its Restriction to Only a Portion of the Article, Along with Confirmation Sampling and Testing</i>	<i>4</i>
2. <i>Segregation Based on Sampling and Testing Results Alone</i>	<i>8</i>
B. PROPOSAL FOR RECONDITIONING BY SEGREGATION	10
IV. References	12

Reconditioning of Fish and Fishery Products by Segregation: Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration's (FDA or we) on this topic.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

I. Introduction

This guidance is intended to clarify steps that owners of fish and fishery products, or their representatives, can take to segregate non-violative products from products adulterated with pathogens, unlawful animal drugs, scombrototoxin (histamine), and decomposition, to demonstrate compliance with the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Specifically, this document provides guidance for reconditioning by:

1. segregation based on a production-related rationale, supported by production records identifying the cause of the adulteration and its restriction to only a portion of the article,² along with sampling and testing to confirm that the segregation was successful; or
2. segregation based on the results of statistically significant sampling and testing. Here the sampling and testing forms the basis for the segregation.

This guidance does not supersede Compliance Policy Guide Sec. 160.700, Reconditioning of Foods Adulterated Under 402(a)(4) (Ref. 1). Nor does this guidance apply in situations where reconditioning is proposed by means other than segregation, such as by cooking or conversion to animal feed. Also, segregation alone may not be a reliable or acceptable means of reconditioning adulterated fish and fishery products that are adulterated under section 402(a)(4) of the FD&C Act.

¹ This guidance has been prepared by the Office of Food Safety/Divisions of Seafood Safety and Seafood Science and Technology in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

² As used in this guidance, the term *article* refers to the quantity of food deemed by us to be adulterated.

Contains Nonbinding Recommendations

Draft — Not for Implementation

Our guidance documents, including this guidance, 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 agency guidance documents means that something is suggested or recommended, but not required. Throughout this guidance the terms "you" and "your" refer to persons or establishments that are owners of fish and fishery products, or their representatives, interested in bringing adulterated products into compliance with the FD&C Act by means of segregating non-violative product from adulterated product.

II. Background

Anyone introducing, delivering, or receiving fish and fishery products in interstate commerce is ultimately responsible for ensuring that the food is safe and complies with all applicable laws and regulations.

Domestic fish and fishery products

Although voluntary destruction of violative goods before seizure is encouraged (see Ref. 2, RPM Section 6-1-2 F, Seizures, General Guidelines), section 304(d)(1) of the FD&C Act [21 U.S.C. 334(d)(1)] provides that a court may order a seized and condemned article of food (the group of products or lot(s)) to be delivered to the owner to be brought into compliance with the FD&C Act instead of destruction. The order may be made only after entry of a decree of condemnation, payment of the condemnation proceedings cost by the claimant, and execution of a good and sufficient bond by the claimant. The court may by order, direct the article to be brought into compliance, referred to as "reconditioning," under the supervision of an FDA employee, and the claimant must pay the expenses for such supervision.

Imported fish and fishery products

Under section 801(a)(3) of the FD&C Act [21 U.S.C. 381(a)(3)], an article of food imported or offered for import into the U.S. is subject to refusal of admission if it appears to be adulterated. However, the owner or consignee may introduce testimony including evidence in support of an application for authorization to perform an action to bring the article into compliance with the FD&C Act (see section 801 of the FD&C Act; 21 CFR 1.95).

As provided under section 801(b) of the FD&C Act [21 U.S.C. 381(b)], FDA may authorize action to bring an article detained under section 801(a)(3) into compliance upon the timely submission of an application for authorization to recondition. *See also* 21 CFR 1.95.³ Approved

³ Proposals for reconditioning products offered for import should be submitted on Form FDA 766 (Ref. 3, Form FDA 766) or another appropriately completed notice (such as a letter). In addition, a good and sufficient bond must be executed ("CBP redeliver bond") by the owner or consignee (see section 801(b) of the FD&C Act).

Contains Nonbinding Recommendations

Draft — Not for Implementation

reconditioning operations are to be carried out under the supervision of an FDA officer or a U.S. Customs and Border Protection officer (21 CFR 1.96(a)(3)).

Administratively detained fish and fishery products

Under section 304(h) of the FD&C Act [21 U.S.C. 334(h)], we may order the detention of any article of food if an officer or qualified employee has reason to believe, during inspection, examination, or investigation, that the article of food is adulterated or misbranded. We intend to consider reconditioning proposals for administratively detained fish and fishery products on a case-by-case basis.

Authorization to recondition

The courts may direct, or we may authorize, reconditioning of adulterated product by segregation as a means to bring an article into compliance with the FD&C Act. Applications stating to simply "segregate," "sort," "sample," "test," "convert," "reject," or "destroy" the article or portions of the article may be inadequate without detailed descriptions of the proposed methods and processes to bring the article into compliance with the FD&C Act and specifying the disposition of any rejected article or portions. All proposed reconditioning methods should be approved by us before their implementation, and all products should be held intact until release is authorized. Following the reconditioning effort, we may collect and test audit samples at our discretion.

Our approval of a reconditioning action as described in this guidance does not transfer responsibility for the safety or compliance of the products to anyone other than the owner. Moreover, the submission and/or authorization of a proposed reconditioning action to address one type of adulteration will not necessarily ensure that all adulteration or misbranding associated with the article will be captured or that the proposal will serve as an acceptable reconditioning for any other type of adulteration or misbranding of the article needing to be resolved. The owner remains responsible for the safety and compliance of the products.

III. Discussion

A. Reconditioning by Segregation

Proposals for reconditioning by segregation should provide sufficient evidence that violative product can be reliably separated from non-violative product. Proposals to separate out or destroy only those lots associated with samples we tested and found to be violative, followed by a non-statistically based sampling plan for the remaining lot(s), typically do not provide sufficient assurance that the remaining portions are in compliance. This approach is unlikely to give assurance that the action will successfully bring the article into compliance, and we do not recommend it as an appropriate reconditioning action.

Contains Nonbinding Recommendations

Draft — Not for Implementation

For the segregation of fish and fishery products adulterated due to pathogens (if applicable), unlawful drugs, scombrototoxin (histamine), and decomposition, we recommend one of the following approaches: 1) an investigation by or on behalf of the owner of the article that, based on a production-related rationale, supported by production records, identifies the cause of the adulteration and its restriction to only a portion of the article, and offers a segregation strategy based on that root cause, followed by relatively modest sampling and testing to confirm that the segregation was successful in isolating and removing the adulterated portion(s); or 2) when the root cause has not been identified, sampling and testing in a sufficiently robust manner to provide statistical assurance that the adulterant is not present in other portions of the article.

1. Segregation Based on a Production-Related Rationale Identifying the Cause of the Adulteration and Its Restriction to Only a Portion of the Article, Along with Confirmation Sampling and Testing

Production-related documents and records could identify occurrences or deviations as the root cause of an adulteration and may form the basis of a meaningful segregation. You may provide production-based information specific to the article or its manufacture to support a science-based assertion that only the identified portions⁴ of the article are adulterated, such that the proposed segregation will effectively separate and isolate the affected and violative portion from the non-violative portion. The segregation is followed by sampling and testing to confirm that the segregation was successful. In this approach, meaningful segregation is the action bringing the article into compliance, not the sampling and testing.

Rationale

You should provide applicable production records supporting the claim that only the specified portions of the article were affected by the production-based condition while other portions were not exposed to the same conditions that caused the adulteration. The assertion should not be simply a hypothetical consideration that the adulteration might be restricted to only a portion of the article by some possible mechanism that could have potentially taken place.

If the cause of the adulteration is related to information in one or more processors'⁵ Hazard Analysis Critical Control Point (HACCP) plan(s) in effect at the time the product was manufactured, you should include the HACCP plan(s) in the reconditioning submission. In

⁴ The affected article may be made up of more than one *portion* that can be identified by such attributes as production code, market form, aquaculture pond, or combinations of such attributes. As used in this guidance, the owner may present evidence that not all portions of the article are adulterated, but rather that only one or more portions of the article are adulterated and can be effectively separated out or segregated.

⁵ Under 21 CFR 123.3(l), a processor is “any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. A [processor] includes any person engaged in the production of foods that are to be used in market or consumer tests.”

Contains Nonbinding Recommendations

Draft — Not for Implementation

addition, you should include relevant records, such as those related to monitoring, corrective action, verification, and sanitation, to assist our review.

Confirmation Sampling

In conjunction with the segregation, your proposal should provide protocols and criteria for sampling and testing to be performed on the portions of the article segregated as non-violative to confirm that the reconditioning, i.e., the segregation, appears to have been successful.

The sampling plan (e.g., number of sample units⁶, sample unit size, and accept/reject criteria) should be sufficiently rigorous to ensure that the article, which has already been found to be violative, has been successfully brought into compliance by the segregation action. Each portion of the article presented to us as having been brought into compliance by the segregation, i.e., portions identified as not having been exposed to the conditions that introduced or resulted in the adulteration in the violative portions, should be represented in the sampling scheme for sample collection and testing. The sample units should be randomly collected representatively and proportionately from throughout all portions of the article presented to be non-violative such that there are more sample units that originate from the larger volume (by weight) portions and fewer from the smaller volume portions. The randomized sampling should ensure that every sample unit within the segregated portions presented to be non-violative is a candidate for being sampled, e.g., from every pallet, vat, carton, etc.

If adulteration is found in any confirmation sample unit from any portion of the segregated article presented as non-violative, we would most likely find the reconditioning to be unsuccessful. Such a finding would indicate that the rationale for the segregation was flawed and that the adulteration was not successfully segregated based on the partitioning parameter used to support the segregation action. The level of sampling and testing conducted for this confirmation is typically insufficient to provide statistical assurances to reliably accomplish further segregation of the article, i.e., separate portions that test positive for the adulteration as violative from portions that test negative for the adulteration as non-violative, based solely on the confirmation test results.

Provided a valid production-related rationale, supported by production records, identifying the cause of the adulteration is established to form the basis of a meaningful segregation, we

⁶ A *sample unit* is a small quantity of material randomly selected from a larger quantity of material (a portion in this application) intended to provide information on a given characteristic of the material (the presence, absence, or concentration of an adulterant in this application). Collectively, the analytical test results of all of the sample units provide sufficient information to draw inferences about the condition of the larger mass making up the segregated portions that the applicant maintains to be non-violative as a whole and, consequently, in this application, draw an inference about the overall effectiveness of the segregation.

Contains Nonbinding Recommendations

Draft — Not for Implementation

recommend that the following confirmation sampling and testing approach be included in an application to recondition an article (see Table 1, below). The recommended confirmation sampling is based on the risk to health that the adulteration generally represents to consumers, with more sampling and testing recommended when the risk is expected to be greater. While we generally recommend you follow the sampling plan in the Table below, 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 and we will consider whether your plan is appropriate:

Table 1: Total number of sample units recommended to collect from the non-violative portions of the affected article based on the total number of sample-sized units within the non-violative portions of the affected article.

Total number of sample-sized units within the non-violative portions of the affected article

100	200	300	500	1,000	5,000	10,000	50,000	100,000
-----	-----	-----	-----	-------	-------	--------	--------	---------

Total Number of Sample Units to Collect and Test from the Non-Violative Portions of the Affected Article¹

Pathogens or Scombrototoxin

100	190	233	263	282	296	297	300	300
-----	-----	-----	-----	-----	-----	-----	-----	-----

Unlawful animal drugs

95	126	135	156	170	174	175	175	175
----	-----	-----	-----	-----	-----	-----	-----	-----

Decomposition in scombrototoxin-forming fish and fishery products without scombrototoxic levels of histamine detected²

95	126	135	141	145	150	150	150	150
----	-----	-----	-----	-----	-----	-----	-----	-----

Decomposition in non-scombrototoxin-forming species of fish and fishery products²

90	107	110	112	114	114	115	115	115
----	-----	-----	-----	-----	-----	-----	-----	-----

¹Sampling stratified proportionately across lines/codes and inference made to all portions of the affected article that the applicant maintains are non-violative.

²When 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 ppm or greater are considered scombrototoxic for this application.

The term “sample unit” in this application refers to the smallest discrete intact component in the article or portions of the article to be sampled and tested. For example, for packaged products, a sample unit is the smallest discrete package. For bulk fish and fishery products, each fish or fish piece (e.g., loin, fillet, or steak) may be a sample unit. Multiple packages, fish, or fish pieces may be applicable when the sample unit size is very small. FDA’s Import Seafood Products Compliance Program, Attachment A, Sampling Schedule (Ref. 4) and

Contains Nonbinding Recommendations

Draft — Not for Implementation

Chemotherapeutics in Aquaculture Seafood Compliance Program for unlawful animal drug sampling (Ref. 5) may be helpful in determining the appropriate sample unit size for each product type and adulterant combination.

The number of sample units recommended in Table 1 are provided for a range of product volumes making up the aggregate of non-violative portions in the affected article. If the total number of available sample units in all non-violative portions of the article is less than 5,000 and is not close to one of the of sizes in the table, or if you have questions about situations not shown in the table, you can contact us with questions at:

Office of Compliance
Division of Enforcement
Center for Food Safety and Applied Nutrition
5001 Campus Dr., College Park, MD 20740
Phone: 240-402-1750
Email: CFSANenforcement@fda.hhs.gov

Assurance that this reconditioning approach is adequate rests on both the validity of the rationale supporting the segregation and the fact that the confirmation sampling and analysis is adequately inclusive and representative of every portion of the article that the applicant maintains is non-violative.

Example of Segregation Based on a Production-Related Rationale Identifying the Cause of the Adulteration:

Note: The following example is provided for illustrative purposes only; it is not a model reconditioning proposal and lacks details pertinent to what we would look for in an actual proposal. Please refer to the body of this guidance, and references cited herein, in developing a reconditioning approach and proposal specific to your situation.

The owner of a detained import shipment of decomposed seafood (non-scombrotoxin-forming species) performs an investigation and discovers processing records that reveal product manufactured on a particular production day was exposed to abusive time/temperature conditions that could lead to decomposition of the product. The production day corresponds to the production code of the sample analyzed and found adulterated by FDA. However, the records show that product from six other days' production included in the detained import shipment (or seized domestic article) were not exposed to the abusive conditions. Submitting the processing records for all seven days as support, the owner prepares an application proposing to recondition the article by segregating and destroying product manufactured on the affected production date using clearly identifiable production codes on the product packaging. Product from production

Contains Nonbinding Recommendations

Draft — Not for Implementation

dates believed to be unaffected by the abusive conditions will thus be segregated from violative product.

As confirmation of the success of the segregation, the owner intends to sample and test product from the six unaffected production codes. Using the recommended sampling scheme in this guidance document, 115 sample units are to be randomly collected across product from the six codes that are believed non-violative, proportionately, based on the percentage of weight that each code contributes to the whole of the product comprising the six codes. If there is a finding of decomposition in any sample unit from any of the six production codes, FDA may conclude that the segregation effort was unsuccessful.

2. Segregation Based on Sampling and Testing Results Alone

When the root cause for the adulteration in an article has not or cannot be identified, you may consider segregation of the article on the basis of sampling and test results alone. Segregation of violative and non-violative portions within an article is possible by testing individual portions. In this approach, partitioning the article into portions may be proposed when it may be possible that the adulteration could be identified and isolated in some, but not all, portions of the article. Partitioning could be based on product or production distinctions such as production date or manufacturing code, market form, raw material supplier, or some other attribute that could potentially be linked to the adulteration that was found. The portion(s) from which the original finding of adulteration was detected should be segregated as violative and should not be included in further sampling or testing. Note that, whereas both segregation approaches involve use of sampling and testing, this second approach is solely based on sampling and testing (by contrast, the first segregation approach involves a production-related rationale followed by sampling and testing). The owner of the goods should be aware that, from a statistical standpoint, the number of sample units⁷ to be collected and tested from each of the remaining portions to assure that they are not adulterated may be substantial and, particularly in the case of smaller volume portions, all or most of the product might need to be sampled to ensure statistical relevance.

If you choose this statistical sampling and testing approach to segregate adulterated portions of an article, we recommend using a single sampling plan of attributes, particularly plans with a zero acceptance number, to determine the number of sample units to collect and test from each portion in the article. These sampling plans ensure a low probability of acceptance, or a

⁷ See footnote 6 for a description of a *sample unit*. However, in footnote 6, associated with the rationale-related confirmation sampling strategy, the compilation of confirmation sample units collected from the article will be used to make an inference about the article and the effectiveness of the applied rationale-based segregation as a whole. In contrast, in this application, associated with segregation on the basis of sampling and test results alone, the compilation of sample units collected from each individual portion from within the article will be used to make an inference about the respective portion only.

Contains Nonbinding Recommendations

Draft — Not for Implementation

high probability of rejection, for portions that contain adulterated product when implemented with appropriate statistical parameters that are protective of consumers. Here again, the recommended sampling is based on the risk to health that the adulteration generally presents to consumers, with more sampling and testing warranted when the risk is expected to be greater. The number of sample units that should be collected and tested depends on the number of sample units making up each individual portion to be tested as demonstrated in the following table of examples (see Table 2, below). While we generally recommend you follow the sampling plan in the Table below, 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 and we will consider whether your plan is appropriate:

Table 2: Total number of sample units recommended to collect from individual portions of the affected article to be tested based on the total number of sample-sized units within the individual portions.

Number of sample-sized units within the portion to be tested

100	200	300	500	1,000	5,000	10,000	50,000	100,000
-----	-----	-----	-----	-------	-------	--------	--------	---------

Number of Sample Units to Collect and Test from the Portion¹

Pathogens or Scombrotoxin

100	200	300	500	950	2,253	2,588	2,907	2,950
-----	-----	-----	-----	-----	-------	-------	-------	-------

Unlawful animal drugs

100	200	285	388	527	695	721	742	745
-----	-----	-----	-----	-----	-----	-----	-----	-----

Decomposition in scombrotoxin-forming fish and fishery products without scombrotoxic levels of histamine detected²

95	155	189	225	258	290	294	298	298
----	-----	-----	-----	-----	-----	-----	-----	-----

Decomposition in non-scombrotoxin-forming species of fish and fishery products²

90	137	161	184	205	224	227	229	229
----	-----	-----	-----	-----	-----	-----	-----	-----

¹ Sampling should be representative across lines/codes within the portion as may be appropriate, and the inference is made to the portion tested as a whole.

² 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 ppm or greater are considered scombrotoxic for this application.

Here again, the term “sample unit” in this application refers to the smallest discrete intact component in the article or portions of the article to be sampled and tested. For example, for packaged products, a sample unit is the smallest discrete package. For bulk fish and fishery products, each fish or fish piece (e.g., loin, fillet, or steak) may be a sample unit. Multiple packages, fish, or fish pieces may be applicable when the sample unit size is very small. FDA’s

Contains Nonbinding Recommendations

Draft — Not for Implementation

Import Seafood Products Compliance Program, Attachment A, Sampling Schedule (Ref. 4) and Chemotherapeutics in Aquaculture Seafood Compliance Program for unlawful animal drug sampling (Ref. 5) may be helpful in determining the sample unit size for each product type and type of adulteration.

The number of sample units recommended in Table 2 are for illustration purposes to help you decide if you want to pursue this reconditioning approach. If you have questions about situations not shown in the table, you may contact us at:

Office of Compliance
Division of Enforcement
Center for Food Safety and Applied Nutrition
5001 Campus Dr., College Park, MD 20740
Phone: 240-402-1750
Email: CFSANenforcement@fda.hhs.gov

In this sampling approach, if one sample unit is found to be adulterated, it is an indication that the portion may be adulterated. Especially in the scenarios involving larger numbers of recommended samples (where the safety risk is generally higher), generating sufficient assurances of the safety of the product by end-product testing may become impractical, particularly if the test is destructive.

B. Proposal for Reconditioning by Segregation⁸

We recommend you include the following information in a proposal to recondition adulterated fish or fishery products by segregation:

For segregation based on a production-related rationale identifying the cause of the adulteration and its restriction to only a portion of the article, along with confirmation sampling and testing:

1. An explanation supported by processing and/or manufacturing records demonstrating the conditions under which one or more portions of the article became adulterated while other portions did not, and how segregation will isolate and separate the adulterated portions from the non-adulterated portions. Also, we recommend that you state how

⁸ For imported product, you should consider the validity of the FDA charge(s); if you conclude that the charges are valid, you can submit a proposal for reconditioning the violative article (Ref. 6, RPM, Section 9-10-5, Import Operations and Actions, Response (Hearing) to Notice of FDA Action - Detained, Conduct of Hearing).

Contains Nonbinding Recommendations

Draft — Not for Implementation

the article can be practically segregated based on the proposed parameter for segregation, e.g., by existing markings on the packaging or cartons;

2. Any relevant documents and records related to the processors' HACCP plans⁹;
3. A detailed description of the article to be reconditioned (e.g., product names, lot or portion sizes (invoices or inventory documents are helpful), production codes, etc.) and of the samples to be collected from each portion. The sample description should include the number of sample units from each portion, the composition of each sample unit (e.g., the size and number of pieces in each sample unit), and assurance that the sample units will be collected in a manner that will be representative of the entire portion and will be held and transported in an appropriate manner;
4. Identification of the entity (individual(s) and affiliation) conducting the sampling, and assurance that the sample collection will be appropriately executed and documented;
5. Identification and accreditation, if any, of the laboratory that will analyze the samples;
6. A detailed description of the test method(s) and procedures to be used to analyze the sample(s);
7. Documentation of the analysts' qualifications;
8. A clear explanation of the accept/reject criteria to be applied to the analytical findings;
9. The time and place where such sampling and testing operations will be carried out and the approximate time for their completion (21 CFR 1.95(b));
10. Assurance that we will be provided all original and complete sample collection reports and analytical data and reports regardless of the findings; and
11. A clear description of the intended disposition and handling of rejected portions of the article, including the original violative portion. Examples of dispositions for rejected portions include: destruction (specify mode and logistics of performing destruction); reprocessing in a manner that eliminates the violative nature of the product (a separate application for authorization to recondition should be submitted for these portions); or diversion to an appropriate non-food use.

For segregation based on sampling and testing results alone:

See items 2 through 11 above.

- For questions related to an enforcement action or related to the process of submitting a proposal to recondition a violative article, contact the compliance officer handling the seizure of your goods or, if the article is an import, the compliance officer listed on the FDA Notice of Action.

⁹ The HACCP plans and related records may be relevant to determine if the manufacturers had appropriate controls over any of the product produced within the article to prevent the adulteration. For submissions related to decomposition in scombrototoxin-forming fish or fishery products, the HACCP plans and records may also be relevant to determining whether the entire article is adulterated, given the potential association with time and temperature abuse and scombrototoxin (histamine) formation.

Contains Nonbinding Recommendations

Draft — Not for Implementation

- For questions on policy or sample collection recommendations, contact the Office of Compliance, Division of Enforcement, CFSAN, at 240-402-1750.
- For questions or issues concerning preparation of samples for analysis or analytical methodology, contact the Office of Regulatory Science, ORA, at 301-796-6600.
- For questions or issues involving import operations, contact the Division of Import Operations at 301-796-0356.

IV. References

The following references are on display at the Dockets Management Staff, 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 addresses, but websites are subject to change over time.

1. Compliance Policy Guide Sec. 160.700, Reconditioning of Foods Adulterated Under 402(a)(4), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-160700-reconditioning-foods-adulterated-under-402a4>
2. FDA's Regulatory Procedures Manual (RPM), Section 6-1-2 F, Seizures, General Guidelines for Seizures, Voluntary Reconditioning. Accessed online at <https://www.fda.gov/media/71837/download>
3. Form FDA 766, Application for Authorization to Relabel or to Perform Other Action of the Federal Food, Drug, and Cosmetic Act and Other Related Acts (electronically fillable form). Accessed online at <https://www.fda.gov/media/71537/download>
4. FDA Compliance Program CP 7303.844, Import Seafood Products Compliance Program, Attachment A, Sampling Schedule. Accessed online at <https://www.fda.gov/media/78911/download>
5. FDA Compliance Program CP 7304.018, Chemotherapeutics in Aquaculture Seafood Compliance Program, Part III. 1. C. Sample Collections. Accessed online at <https://www.fda.gov/media/71452/download>
6. RPM, Section 9-10-5, Import Operations and Actions, Response (Hearing) to Notice of FDA Action - Detained, Conduct of Hearing. Accessed online at <https://www.fda.gov/media/71776/download>