Contains Nonbinding Recommendations

Reconditioning of Fish and Fishery Products by Segregation

Guidance for Industry

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U.S. Department of Health and Human Services
Food and Drug Administration
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Contains Nonbinding Recommendations

Reconditioning of Fish and Fishery Products by Segregation Guidance for Industry[1]

This guidance represents 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 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, scombrotoxin (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.

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. 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.

[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.

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), 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 (section 304(d)(1) of the FD&C Act [21 U.S.C. 334(d)(1)]). 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
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 (see section 801(a)(3) of the FD&C Act [21 U.S.C. 381(a)(3)]). 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 801of the FD&C Act; 21 CFR 1.95).

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 section 801(b) of the FD&C Act [21 U.S.C. 381(b)]). *See also* 21 CFR 1.95.[3] Approved 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
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 (see section 304(h) of the FD&C Act [21 U.S.C. 334(h)]. 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 portion(s) of the article may be inadequate without detailed descriptions of the proposed methods

[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).

and processes to bring the article into compliance with the FD&C Act and specifying the disposition of any rejected article or portion(s). 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 addressed 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 portions associated with samples we tested and found to be violative, followed by a non-statistically based sampling plan for the remaining portion(s), typically do not provide sufficient assurance that the remaining portion(s) 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.

For the segregation of fish and fishery products adulterated due to pathogens, unlawful drugs, scombrotoxin (histamine), and/or 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 portion(s)[4] of the article are adulterated, such that the proposed segregation will effectively separate and isolate the affected and violative portion(s) from the non-violative portion(s). 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 portion(s) of the article were affected by the production-based condition while other portion(s) 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 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 portion(s) 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 units[6], 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. Collectively, the goal is for the analytical test results of all of the sample units to provide sufficient information to draw inferences about the condition of the larger mass making up the segregated portion(s) 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. Each portion of the article presented to us as having been brought into compliance by the segregation, i.e., any portion(s) identified as not having been exposed to the conditions that introduced or resulted in

[4] The affected article may be made up of more than one *portion* that can be identified by various attributes. For example, there may be distinct portions of an article that are segregable by attributes such 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. Owners may suggest different attributes as a basis for separating the article into different portions.

[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."

[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).

the adulteration in the violative portion(s), should be represented in the sampling scheme for sample collection and testing. The sample units should be randomly collected representatively and proportionately from throughout the portions(s) presented to be non-violative such that, if there are multiple portions presented to be non-violative, there are more sample units that originate from the larger volume (by weight) portion(s) and fewer from the smaller volume portion(s). The randomized sampling should ensure that every sample unit within the segregated portion(s) 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(s) of the segregated article presented as non-violative, we would most likely find the reconditioning to be unsuccessful with respect to the article as a whole. 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. Further, the level of sampling and testing conducted for confirmation purposes is typically insufficient to provide statistical assurances for further segregation of the article. As a result, it is not likely that FDA 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 confirmation test results.

When 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 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 purportedly non-violative portion(s) of the affected article based on the total number of sample-sized units within the purportedly non-violative portion(s) of the affected article.

Total number of sample-sized units within the purportedly 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 Purportedly Non-Violative Portions of the Affected Article								
Pathogens or Scombrotoxin								
100[1]	190	233	263	282	296	297	300	300
Unlawful animal drugs								
95	126	135	156	170	174	175	175	175
Decomposition in scombrotoxin-forming fish and fishery products without scombrotoxic levels of histamine detected[2]								
95	126	135	141	145	150	150	150	150
Decomposition in non-scombrotoxin-forming species of fish and fishery products[2]								
90	107	110	112	114	114	115	115	115

[1] Note that when the portion sizes are quite small, the number of recommended sample units may represent a significant portion of the article (in some cases, all of the article) to ensure statistical relevance and the recommended level of confidence.

[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.

The term "sample unit" in this application refers to the smallest discrete intact component in the article or portion(s) 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. When the sample unit size is very small, multiple discrete intact components may be combined to ensure collection of an appropriate sample unit size (i.e., to treat multiple packages, fish, or fish pieces as a single sample unit even though they are discrete items). FDA's 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 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 portion(s) in the affected article. The owner of the goods should be aware that, in order to ensure statistical relevance, when the total number of sample-sized units within the purportedly non-violative portion(s) is small, there may be a need to sample and test a large volume, or all, of the product. You may wish to contact FDA if the total number of available sample units in all non-violative portion(s) of the article is less than

5,000 and you have questions about the appropriate sample size. You may also wish to contact FDA if the number of available sample units is not close to one of the of sizes in the table, or if you have other questions about situations not shown in the table. You may contact us with questions at:

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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 the entire portion(s) 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 should not be regarded as a model reconditioning proposal, in part because it lacks details pertinent to what we would look for in an actual proposal. We recommend that you 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 12,000 lbs. of decomposed seafood (non-scombrotoxin-forming species) performs an investigation and discovers processing records that reveal 2,000 lbs. of product manufactured on a particular production day was exposed to abusive time/temperature conditions that are likely to have caused 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 10,000 lbs. of 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 the 2,000 lbs. of product manufactured on the affected production date using clearly identifiable production codes on the product packaging. The remaining 10,000 lbs. of product from production 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 the 10,000 lbs. of product from the six unaffected production codes. Using the recommended sampling scheme in this guidance document for 10,000 lbs., 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 is likely to conclude that the segregation effort was unsuccessful as to all six production codes (not just the one(s) in which there is a finding of decomposition).

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 might consider segregation of the article on the basis of sampling and test results alone. Segregation of violative and non-violative portions within an article may be possible by partitioning the article into portions when you believe the adulteration can be identified and isolated in some, but not all, portions of the article. Under this approach, you would then test individual portion(s). In this approach, it may be possible to partition (i.e., establish portions within the article for the purpose of further sampling and testing) 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. In some circumstances, it might make more sense to only identify one portion of the remaining article as purportedly non-violative (i.e., not subdivide the remaining article into multiple portions). For each portion(s) you identify as purportedly non-violative, you should apply a statistically sound sampling plan to that portion(s). (More information about statistically sound sampling plans is provided below.)[7] Note that, whereas both segregation approaches discussed in this guidance 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 units[8] 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 a statistical sampling and testing approach to segregate adulterated portions of an article, we recommend using a single sampling plan of attributes, particularly a plan with a zero acceptance number,[9] to determine the number of sample units to collect and test from each portion in the article. Single sampling plans of attributes ensure a low probability of acceptance, or a high probability of rejection, for portions that contain adulterated product when implemented with appropriate statistical parameters that are protective of consumers. Just like the recommended sampling in Table 1, the recommended sampling in Table 2 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

[7] Regardless of whether you choose to sample and test a single remaining portion or multiple portions of the article, you should ensure that the sampling and testing you conduct is appropriately representative. Any violative findings from the identified portion would likely be applicable to the entire remaining portion (i.e., would likely indicate that the entire remaining portion is violative).

[8] See footnote 6 for a description of a *sample unit*.

[9] These are sampling plans that are designed to minimize the probability of overlooking nonconformities in products.

individual portion to be tested as demonstrated in the following table of examples (see Table 2, below). The sample units should be randomly collected representatively and proportionately from throughout the portions(s) to be sampled and tested. The randomized sampling should ensure that every sample unit within the segregated portion(s) is a candidate for being sampled, e.g., from every pallet, vat, carton, etc. While we generally recommend you follow the sampling plan relevant to the type of adulteration and number of sample sized units for your product that is listed in Table 2 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 Portion[1]								
Pathogens or Scombrotoxin								
100[2]	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 detected[2]								
95	155	189	225	258	290	294	298	298
Decomposition in non-scombrotoxin-forming species of fish and fishery products[3]								
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] Note that when the portion sizes are quite small, the number of recommended sample units may represent a significant portion of the article (in some cases, all of the article) to ensure statistical relevance and the recommended level of confidence.

[3] 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. When the sample unit size is very small, multiple discrete intact components may be combined to ensure collection of an appropriate sample size (i.e., to treat multiple packages, fish, or fish pieces as a single sample unit even though they are discrete items). FDA's 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 provided for a range of product volumes making up the aggregate of remaining, purportedly non-violative portions(s) in the article. The owner of the goods should be aware that, in order to ensure statistical relevance, when the total number of sample-sized units within the purportedly non-violative portion(s) is

small, there may be a need to sample and test a large volume, or all, of the product. You may wish to contact FDA if the number of available sample units is not close to one of the sizes in the table, or if you have other questions about situations not shown in the table. You may contact us with questions at:

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In this sampling approach, if one sample unit is found to be adulterated, it is an indication that the entire portion from which the sample was taken may be treated as 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. Discussion of Sampling Recommendations

The recommendations provided in Tables 1 and 2 include sample sizes based on a critical nonconformities sampling approach for hazardous, or potentially hazardous, substances, and/or for substances that adversely affect usage, as described in section 2.5.3 of the Codex Alimentarius document, General Guidelines on Sampling CAC/GL 50-2004, and in the International Organization for Standardization's documents, section 2.15 of ISO 2859-0 and section 8.2.4, ISO/TR 8550-1:2007(E). While the equation in these references guided us in developing the sampling recommendations reflected in the draft guidance, we determined that it would be appropriate to modify the equation to account more accurately for situations in which the portion(s) to be sampled may be smaller. The original published formula is $n = (N-(d/2))(1-\beta^{1/(d+1)})$ where, N is the lot size, β is the specified probability of failing to find at least one critical nonconformity $(1-\beta)$ is the selected confidence level desired, d is the maximum number of critically nonconforming items "allowed" in the lot ($d=Np$ where p is the maximum percent, expressed as a fraction, of nonconforming units specified for the portion(s)). The equation was modified to $n = (N-((d-1)/2))(1-\beta^{1/d})$ to more appropriately apply to smaller portion sizes as well as larger portion sizes. We used 95% confidence levels for detecting low prevalence (0.1% to 2.0%) of a health risk adulterant in an article and 90% confidence level for detecting low prevalence (1% to 2%) of a non-health risk adulterant.

Using this statistical sampling equation, the amount of sampling recommended can be structured commensurate with the level of concern, and risk to consumers, associated with the type of adulteration to be addressed. We take this risk-based approach to our sampling recommendations because we believe that it is appropriate to recommend more statistically rigorous sampling when the health risk to consumers is higher (and correspondingly, that it is appropriate to accept less rigorous sampling when the health risk to consumers is lower). The more severe the potential risk, the greater the need for more sampling because we want to

minimize the probability that adulteration is present in the product but not detected by sampling and testing.

A proposal to recondition an adulterated product by segregation acknowledges that an article has been adulterated. From a statistical standpoint, the number of sample units FDA typically uses for routine surveillance sampling is inadequate to provide confidence in the safety or compliance of an individual portion associated with an adulterated product. The probability of detecting adulteration is higher when the defect rate is higher, but substantially lower when the defect rate is lower. Thus, to provide assurance that adulterated product has been effectively segregated from non-adulterated product as part of reconditioning, a more rigorous sampling plan than that used in our routine surveillance sampling is advisable. It is generally recognized that, short of sampling every unit in an article, sampling and testing alone cannot absolutely ensure the absence of contamination in a portion of the article, particularly when the contaminant is present at very low levels and is not uniformly distributed throughout the article. Therefore, when adulteration is identified in one portion of an article, even if an owner of a fish or fishery product used the same sampling plan as FDA typically uses for routine surveillance sampling to sample and test the rest of the article and got all negative results, there would still be a reasonable possibility that the remaining portion of the product is adulterated.

Generally, the critical nonconformities statistical approach is associated with situations where high assurances of identifying adulteration in an article are warranted because of the level of risk. This is consistent with the types of adulteration with which FDA is typically concerned in reconditioning scenarios.

Because adulterants in seafood are not usually uniformly spread throughout a production lot, shipment or entry, we have used, and recommend using, the selected critical nonconformities approach for sampling when the owner of the goods proposes to recondition known adulterated product through segregation.

C. Proposal for Reconditioning by Segregation[10]

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-violative portions. Also, we recommend that you state how the article can be practically segregated based on the proposed parameter for segregation, e.g., by existing markings on the packaging or cartons;

[10] 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).

2. Any relevant documents and records related to the processors' HACCP plans[11];
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.), of the manner in which you propose to establish portions (if you choose to establish more than one portion of the article), 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.

[11] 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 scombrotoxin-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 scombrotoxin (histamine) formation.

- 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, ORA, 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), http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073853.htm

2. FDA's Regulatory Procedures Manual (RPM), Section 6-1-2 F, Seizures, General Guidelines for Seizures, Voluntary Reconditioning. Accessed online at http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074317.pdf

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 http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM072766.pdf

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 Compliance Program: 7304.018 Chemotherapeutics in Aquaculture Seafood (fda.gov)

6. RPM, Section 9-10-5, Import Operations and Actions, Response (Hearing) to Notice of FDA Action - Detained, Conduct of Hearing. Accessed online at http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074300.pdf

7. CAC, Codex Alimentarius Commission, "General Guidelines on Sampling CAC-GL-50," 2004, p. 28 available at: http://www.fao.org/uploads/media/Codex_2004_sampling_CAC_GL_50.pdf

8. International Organization for Standardization's documents, section 2.15 of ISO 2859-0 and section 8.2.4, ISO/TR 8550-1:2007(E).