Sections in This Document

1. Objective

The objective of this section is to establish a uniform, systematic, and effective approach to ensuring that private laboratories performing analyses on FDA-regulated, commodities submit scientifically sound data. The FDA Food Safety Modernization Act (FSMA) final rule on Laboratory Accreditation for Analyses of Foods (LAAF) establishes an accreditation program for the analyses of foods in certain circumstances. The LAAF program is currently in the implementation phase; once implemented this document will be updated to include LAAF program requirements.

2. Introduction

Importers are responsible for ensuring that the articles they import comply with all provisions of the Federal Food, Drug and Cosmetic Act. In some instances, products may be detained as soon as they are offered for entry into the United States. This procedure, detention without physical examination (DWPE), is based on history or other information indicating that the product may be out of compliance with federal laws and regulations. Products or shippers that have met the criteria for DWPE are identified on Import Alerts, which disseminate information to FDA personnel about problems and violative trends. (Import Alerts (fda.gov)

FDA has the obligation of evaluating the analytical data submitted by private laboratories to determine whether import entries comply with the Act and can be released into commerce. It is essential, that the data provided is technically valid, has been obtained using sound methods of sampling and analysis, and has recognized quality assurance measures applied.

While this document is written in reference to private laboratories, the owner or consignee is ultimately responsible for compliance with applicable laws and regulations. If a private laboratory does not provide acceptable evidence and documentation to support the credibility of the analysis, the owner/consignee bears the responsibility and consequences of the inadequacy.

Although FDA has legal authority over regulated imported products, it does not have such direct authority over the private laboratories. (Note: This applies to private laboratories that analyze imported products. Laboratories that test domestic products may be subject to different regulations. For example, private laboratories used by pharmaceutical firms are to register as manufacturers with the agency and are subject to GMPs. Such laboratories are not addressed in this guidance.) The agency can make decisions on a lot-by-lot basis regarding the entries submitted for importation. The acceptability of the work performed by the private laboratory is an important element in this decision.

It should be noted that because circumstances vary among division offices and laboratories, there is no single set of procedures that can be prescribed for the entire field. For example, divisions that are physically near their servicing laboratory can more easily call on them to perform such services as on-site assessment visits than divisions that are not. For this reason, this document recommends suggested procedures that divisions and field laboratories may adapt to their needs.

The use a of LAAF-accredited laboratory is required in certain food testing circumstances. FDA has determined that sufficient LAAF-accredited laboratory capacity has been reached for two import testing circumstances related to specific analytes as listed on the LAAF Dashboard: in support of admission of an article of food under section 801(a) of the FD&C Act (21 CFR 1.1107(a)(4)); and to support removal from an import alert through successful consecutive testing (21 CFR 1.1107(a)(5)). See Federal Register Notice https://www.federalregister.gov/documents/2021/12/03/2021-25716/laboratory-accreditation-for-analyses-of-foods .

Although the LAAF program is being implemented for these specific import testing circumstances, sufficient laboratory capacity has not been reached for all analytical testing areas related to imported food. “The LAAF-Compliance Dates” table FDA Dashboards - Laboratory Accreditation for Analyses of Foods Program lists the specific analytes for which food testing must be conducted by a LAAF-accredited laboratory, the compliance date, and additional references, where applicable, such as pertinent import alerts. Imported food testing for analytes or analyte groups not listed in this table do not require the use of a LAAF-accredited laboratory at this time.

3. Sampling

A. Sampling for analysis is to represent the lot. If, in the judgment of the reviewing office, the method of collection does not result in a representative sample, the analytical package should be rejected. Sampling should be performed in conformance with FDA-recommended sampling procedures and Compliance Programs.

Investigations Operations Manual | FDA

Manual of Compliance Policy Guides | FDA

B. To maintain chain of custody, the sampler must properly collect, identify, and maintain samples from the time they are collected until they are delivered to the private laboratory. The sampler should:

1. Verify the location and identity of the lot to be sampled.

2. Collect samples following FDA sampling guidelines or other equivalent, established guidelines.
3. Ensure the integrity of the sample (avoid contamination with use of aseptic technique, maintain storage temperature, and utilize additional measures as needed to ensure the integrity of the sample);
4. Identify the containers from which samples are collected with the FDA sample number and/or the U.S. Customs Service entry number.
5. Prepare and ship the sample using precaution to prevent contamination and maintain sample integrity; and
6. Complete a collection report for each sample collected which includes sample collection methods, sample preparation techniques, lot size and identification number, sample size, identity of the sample collector, statement from the collector of any observations about the lot, containers, etc., and description of chain of custody of the sample.

C. If the method of collection does not result in a representative sample, the analytical package is considered unacceptable.

See Attachment A for an example collection report.

4. Information about the Private Laboratories

A. For the sake of efficiency and historical perspective, the field components that deal with private laboratories should retain databases or files on each one from which it receives analytical packages. Examples of useful information for these files are described in the following list.

1. The name, address, and telephone number of the laboratory and the name and title of key officers or contacts.
2. Information on the background, experience, and training of the analysts. (See below for additional guidance.)
3. Types of analyses performed by the private laboratory on regulated commodities. Such a list indicates the scope of the laboratory's work.
4. Equipment used for conducting the analyses. This aids in determining whether laboratory equipment is present to perform the routine methods.
5. Information on the laboratory's internal quality assurance program. This information is useful in evaluating the validity of analytical data generated by the laboratory, although it in no way lessens the need for

the QA data for the analysis being performed to be submitted as part of the analytical package.

6. Reports of FDA's prior contacts with the private laboratory, including previously reviewed packages, reports of on-site assessment visits, correspondence, and summaries of telephone conversations and meetings.

B. If the reviewing office cannot obtain the information it needs to perform the review of the scientific analytical data generated by the private laboratory, either directly from the laboratory or through the importer/ broker, the analytical packages received from the laboratory will be considered incomplete. Without credible information, there is no way of assuring the scientific integrity of the data being submitted.

4.1. Private Laboratory Analysts

A. Information on the background, training, and experience of the analysts bears further discussion. Just as a laboratory is to have the appropriate equipment to do the work, so too it is essential to have properly trained or experienced staff.

B. Often, the analyst's curriculum vita (CV) is attached to the package. If it is not, and the reviewing FDA component doesn't have a prior record in lab file, then the laboratory should be contacted and asked to provide it.

Attachment B is a suggested format for the Analyst CV or Training/Background. It may be shared with the private laboratory.

C. The CV for each person who participated in the analysis must be submitted or be available on file as needed by each reviewing division or laboratory. It is not sufficient to have only the laboratory director's CV, unless he or she was the only one performing the work. A private laboratory director or supervisor may sign a package; however, the analyst signatures must also be included.

D. On occasion, a private laboratory will contract it's work out to a second laboratory. The package should be shown as being done by the laboratory that performed the analysis, not the laboratory that contracted it out. If the paperwork does not make it clear that this was done, the contracting laboratory should be contacted and asked to submit a CV for that analyst if one was not provided.

E. The CV provides documentation of the analyst's ability to perform the analysis performed. The CV should provide evidence of training and

experience directly related to the analysis performed by the analyst in question. For example, documentation of an analyst's ability in pesticide analysis is not sufficient for a subsequent submission of a sensory analysis.

F. Once the CV is received, it is reviewed for adequacy. While there are no requirements for the background of the private laboratory analyst, there should be evidence that they have the education, training, or experience to perform the work. Often, the analysts do not have a college degree and may have received their training on the job. This would not in itself disqualify them from being able to perform the analysis. There should, however, be documentation that they have had preparation for each kind of analysis they submit.

G. If, as recommended, FDA personnel review the analytical packages, it is further suggested that the CVs be reviewed by a laboratory supervisor, manager, or senior analyst. The CV should be retained for filing. If the CV is not sufficient, this information should be communicated with the private laboratory and explain what additional information is needed. If the laboratory does not provide the information, then the package should be evaluated as unacceptable.

4.2. Review of Analytical Packages

A. The analytical package consists of the collection report, the private laboratory worksheet, and the laboratory report form (see Attachment C for example of a report). Since the worksheet is the most important part of the package, a thorough technical review of the work performed is needed. Qualified FDA personnel who work in the area of analysis under review are best suited to perform this review. They are most familiar with current methods, acceptable practices, and quality controls that are needed. Therefore, it is strongly recommended that whenever possible, these packages be sent to the laboratory for review.

B. A review should begin with the Import Alert. This will provide the reason for detention. The analysis performed should correspond to the problem area identified in the Import Alert. For example, if the reason for the Import Alert is the possible presence of a particular pathogen or pesticide, then an analysis for the detection of that analyte is to be performed.

C. Once the analysis has been established, the reviewer should look at the collection report and determine whether the sample size, type, and method of collection were consistent with resolving the problem. Next, the

availability of a CV for the analysts should be ascertained, as described in the section above.

D. In some senses, then, the private laboratories are doing agency work. They are analyzing regulated commodities, and they are to do so with the same care and control with which FDA does its work. This should be kept in mind when reviewing the packages. While the worksheet format used by the private laboratory may differ from FDA practices, all the essential elements that are needed for FDA analyses are to be documented in the package. It would be inconveniently lengthy to itemize each of the elements for all types of analysis, but in general, this is the standard that the packages are to meet.

E. The following documentation should be provided for each analytical package submitted to FDA, as applicable. This information helps establish that valid analytical techniques and quality assurance practices were used.

1. Identity of the analysts, signatures, and dates on which the work was performed.
2. Statement from the Lab Director stating if the product has been previously analyzed.
3. Statement from the Importer stating that the results submitted include all the analytical work for that sample. See example statements below:

4. LABORATORY DIRECTOR'S STATEMENT: Review of records indicate that the product and lot referred to in this report have____ have not____ been subject to prior analysis by this laboratory. If the lot has been subject to prior analysis by this laboratory, copies of the final results are hereto attached. The prior analysis was conducted on the following date(s) and covered by the following laboratory report numbers(s):

5. IMPORTER'S STATEMENT: The analytical results submitted with this report include all analytical work related to this sample performed by this laboratory and all other laboratories which may have conducted the analyses.

6.

7. Analytical methods used, method verifications, references, and any modifications, in-house validations of the methods.
8. Signed worksheets containing instrument calibration data, readings and conditions, calculations, quality controls applied, blanks, fortified samples, sample weights and measurements, dilutions, matrix clean-up procedures, and any other analytical data.

9. Calculations presented in a logical manner. Reference to chromatograms and spectra are made in a clear order.
10. Source and purity of reference standards, storage conditions, and procedure for preparation.
11. Analytical documentation such as chromatograms, charts, graphs, observations, and photographs of thin layer chromatographic plates.
12. A copy of the label from the immediate container and any additional labeling needed to evaluate the product.

F. Attachment D is a private laboratory package review guide that may be used as an aid in evaluating the analytical worksheets.

G. *Unacceptable versus Violative Results*. The purpose of performing the package reviews is to evaluate whether packages are clear, complete, and accurate records of the analytical work that was performed. This review is primarily performed on packages with non-actionable results. It should be noted, however, that the evaluation of the acceptability of a package is separate from its actionable or non-actionable status. A violative package may be acceptable, and a non-actionable package may be unacceptable. The validity of a non-actionable package is important because it could result in the release and distribution of harmful product that otherwise would have been detected if the correct method was used or the proper laboratory controls followed.

H. *Packages with unacceptable results*. The following description of packages that may be unacceptable is meant as guidance only. The list is neither all-inclusive nor exclusive. For example, there may be something that makes a package unacceptable although it is not on the list. The reviewer's judgment, in consultation with his or her supervisor is extremely important in this process.

Many of the items that are not on the list were left off because they can and should be worked out by calling the private laboratory to discuss them. An example of this is uncertainty about the identity of the sample. If there is disagreement between the collection records and the analytical worksheet, this is resolved with the private laboratory before going further. There are occasions when the private laboratory is contacted because the packages are missing essential information, such as legible reports or chromatograms.

1. Incorrect results for the particular type of sample or unusual results. An example of this is questionable biochemical reactions obtained during microbiological testing.
2. Incorrect amount of sample used for analysis. For example, a method calls for 100g of sample and the private laboratory uses 500g without adjusting the initial extraction volume or the other dilutions. Methods are tested and validated at particular levels and exceeding those levels may invalidate the results.
3. Incorrect number of subsamples analyzed. The number of subsamples examined is not consistent or does not follow guidelines. For example, a method may call for the examination of 15 subsamples for Salmonella and the private laboratory only tested 10.
4. Failure to determine values for each part of surgical forceps. Both sides of forceps should be tested because there may be a difference (per CDRH).
5. Omission of significant analytical data. For example, biochemical reactions are missing, such as the recording of TSI and LIA reactions for Salmonella. Records of use of controls are absent.
6. Omission of quality assurance numbers. For example, omission of several microbiological quality assurance numbers, or a single omission of a quality assurance number for an important component (such as manufacturer's lot number and expiration date for a microbiological test kit).
7. Method modifications without indication of validation.

I. When a package is found to be unacceptable, the compliance officer is responsible for communicating the findings to the importer and private laboratory. They may ask the ORA laboratory for assistance in discussing technical issues.

J. *Packages that are acceptable with comments*. A package may be acceptable but may contain flaws or weaknesses. For instance, the workflow may be difficult to follow, or the worksheets may have numerous cross-outs. Sometimes, the reviewer has suggestions that may make future packages stronger or clearer. In these cases, the reviewer should evaluate the package as being acceptable with comments. These comments are typically communicated to the laboratory via email by the Compliance Officer or Program Coordinator. If a phone call or meeting is held with the

laboratory, the reviewer may be asked to participate. A memo of the telephone conversation should be written to document the discussion and be given to the compliance officer as well as copied to the file.

K. *Packages with violative results*. In general, violative packages should not be sent to the laboratory for review since the importer is not asking the agency's permission to admit the entry (at least, not prior to reconditioning). This, however, is subject to local practice in the divisions.

L. *Packages with borderline results*. If a package is reviewed that has borderline results (for example, if 1 ppm of methyl mercury in swordfish is violative, and the analytical package reports 0.9 ppm methyl mercury) note this in the review of the package. This does not make the package unacceptable but is simply information for the compliance officer.

M. *Analyses on multiple sub-portions of one entry*. Some entries have separate analyses performed on smaller sub-portions of the entry. These sub-portions may correspond to Customs or FDA line numbers, date codes or sizes, for example. This is often true for seafood samples. It may also occur under other circumstances, for example, when ethylene oxide sterilization and subsequent analysis is performed on separate portions of a spice entry. At other times, the reverse situation occurs, that is, one analysis is submitted for several sub-portions. In such cases, each analysis submitted should be evaluated.

N. *Packages from foreign laboratories*. These are reviewed using the same criteria as for domestic private laboratories. When a Memorandum of Understanding (MOU) exists, packages should be in accord with the MOU. If the division office has information (such as audit sample results) that the products are violative, the entry in question should be detained, despite certification, and the Office of Import Operations (OIO) and Office of Chief Scientist (OCS) for device or drug products or the HFP/OLOAS/ORTS (Human Foods Program/Office of Laboratory Operations and Applied Science/Office of Regulatory Testing and Surveillance for food products, should be notified. OIO and OCS/ORTS will work with the International Affairs staff and the relevant SME offices to resolve the problem.

O. *Timeliness*. Since an entry cannot be released until the private laboratory analysis has been reviewed, the agency is under the same obligation to complete its review in a timely manner as it is for the products it analyzes. The laboratories should track receipt of analytical packages and the dates the results are sent out. It is suggested that laboratories complete these

reviews and report back to the compliance officer within two working days, five working days for device or drug products, of receipt of the analytical packages. Packages documenting analysis of fresh, perishable products should be completed within one day. The need for additional information, an analyst's CV for example, "re-sets" the clock to the date of receipt of the information. PLAPS including data such as validation and/or verification data require additional review time.

P. *Reporting the results*. FDA laboratories typically report their results to home divisions. In this case, however, there are as many as three possibilities for what may be called the home division. The private laboratory may be located in one division, the importer in a second, and the entry may be made in a third. For the purposes of this document, the division where the entry is being made is considered to be the home division. This is the primary location to which results should be reported. The home division compliance officer is responsible for informing the importer and private lab.

5. Audit Samples

At times, audit samples are collected, preferably from the same container as the original sample collected by the importer, sampling service, or private laboratory. They are tested by an FDA laboratory to verify the analytical results that purport the product to comply with the FD&C Act. The package reviewer may request collection of an audit sample. Because resources are limited, not every request will necessarily result in a collection. The factors below are suggested criteria for the recommendation for collection of audit samples. Collection should be made when substantial and significant incidences are observed in the following analytical areas.

5.1. Private Laboratory Observations

A. If analytical problems are found during an assessment visit of a private laboratory made by any division. Samples should be related to the types of analytical problems observed.

B. If this is the first submission of a private laboratory or analyst for a particular type of analysis.

C. In general, our goal is to collect audit samples for 10% of the work performed by a private laboratory, to be increased if findings warrant. This includes both samples collected due to factors on this list and random samples.

5.2. Analytical Packages

A. For analytical packages that are unacceptable upon initial review. However, no audit sample should be collected until corrections have been made so that the package is found to be acceptable. For example, if a package is incomplete, no audit samples should be collected until the missing information has been supplied and reviewed.

B. For types of analyses and commodities for which reports with errors, technical problems, or missing data have been submitted during the past year.

C. For reports with abnormal or unexpected results or data—such as reports indicating no growth of microorganisms or negative filth or decomposition results. These can be in a product, shipper, or country combination that often has these elements, or exceptionally "clean" chromatograms for products that usually exhibit product peaks.

D. For multiple borderline analytical results of a given type, or other potentially suspect findings associated with borderline results. For example:

1. 0.9 ppm methyl mercury in swordfish.
2. 11.5% chromium in surgical instruments.
3. 1 of 18 cans of tuna for decomposition.
4. 3 of 18 subsamples of shrimp for decomposition.
5. large numbers of class 2 shrimp.
6. excessive filth in one subsample but none in other subsamples.
7. pesticide residues close to the tolerance levels; or
8. aflatoxin close to the tolerance levels.

5.3. Detention without Physical Examination (DWPE)/MOU's

A. It is recommended that at least one audit sample should be collected and analyzed before removing a product, shipper, or country off DWPE.

B. As called for by MOUs or compliance programs and assignments.

5.4. Sampling

A. When there are past findings of erroneous, incomplete, or suspect sampling procedures by the private laboratory, importer, or third-party sampler.

B. For samples collected by the importer rather than by the private laboratory or an independent sampler.

5.5. Evaluation of Audit Sample Result

If the FDA laboratory finds an audit sample violative for an entry that the private laboratory had previously found in compliance, it can not necessarily be concluded that the discrepancy is due to a problem on the part of the private laboratory. Possibly the analyte was not homogeneously distributed, or the sampling was not done correctly (for which the private laboratory would not be responsible unless it had performed the sample collection). Each case is evaluated individually. If it cannot be determined where the problem lies, then additional audit samples or an on-site assessment visit may be warranted.

6. On-site Assessment Visits

A. At times, the agency visits the laboratory to ascertain that it has the capability or capacity to perform the analyses. Often, these visits are precipitated by an accumulation of elements that may call the laboratory's capabilities into question. Differences from FDA's results on audit samples, repeated borderline or questionable results, or multiple unacceptable packages are typical examples. Alternatively, visits may be made simply for the laboratory or division to become familiar with the private laboratories in their vicinity.

B. The on-site visit provides the opportunity to observe that equipment, reagents, and standards needed to conduct the proposed analyses are present and in good order; to review the adequacy of the laboratory's quality assurance and record-keeping programs; and to observe the techniques and practices of the analysts. Site visits should ideally occur when the analyses at issue can be observed. These information-gathering activities round out the picture of the laboratory's capabilities.

C. On-site assessment visits are not inspections. They differ in many significant ways. They are voluntary; the laboratory may decline to participate. Neither a Notice of Inspection (Form FDA 482) nor Inspectional Observations (Form FDA 483) is presented. The date of the visit is by appointment. If the visit is being made in connection with a particular package, it should be scheduled in advance with the private laboratory through the importer or broker whose entry is under review.

D. A team of inspectional and laboratory personnel may conduct the assessment visits, or they may be conducted by experienced FDA

laboratory personnel alone. In the latter case, the laboratory personnel should discuss the visit with the home division staff prior to the visit. Ideally, analysts familiar with each of the analytical areas to be observed should participate.

E. If the private laboratory is located outside the region of the reviewing component, an FDA laboratory or division closer to the laboratory may be asked to conduct the visit or, if the distance does not pose too great a barrier, analysts from the reviewing laboratory may conduct the on-site assessment. In the latter situation, the home district of the private laboratory should be notified and consulted prior to the visit.

F. In all cases, inspectors and analysts who conduct on-site assessment visits should be fully briefed with any information about the laboratory prior to the visit. Afterwards, they should prepare a memorandum describing the visit. The memo should be sent to the home division of the private laboratory. The private laboratory or the importer or broker may request a copy under the Freedom of Information Act.

7. Consultations

Private laboratories often request FDA guidance and advice. The most frequently asked questions are about the methods to be used. FDA should be helpful in providing this information, although it is ultimately the responsibility of the importer and the private laboratory to provide FDA with the documentation and assurance needed. As long as information from standard sources is provided, such as a referral to the AOAC Official Methods of Analysis, it need not be documented by the FDA employee. If the advice is to an alternate source, or involves other issues, then it should be documented in a memo of the conversation. A copy of the memo should be given to the compliance officer and a copy kept with the file on the private laboratory.

8. Meetings

Meetings may be held between the private laboratory and the FDA laboratory and/or the home division. Sometimes, these are held at the request of the private laboratory. More commonly, they are held when FDA feels that they are needed to facilitate the resolution of unresolved problems involving the private laboratory. If there is a particular entry involved, the importer or broker should be notified and invited to such discussions. The FDA laboratory and division staff should provide the firms with clear explanations as to why the analytical results are not acceptable and with the criteria that is to be met for acceptance. The increase in understanding that frequently results, and the ensuing discussion can often be helpful in resolving outstanding problems. At each of these

meetings, a secretary (from FDA) should be designated. The secretary is responsible for preparing notes of the meeting, which should be provided to the home division and copied to the file.

9. Continuing Problems

If indications are that the private laboratory has not made the requested corrections, the agency may continue to find the analytical packages unsatisfactory on an entry-by-entry basis. OCS/ORTS should be notified of such on-going situations.

10. Time Reporting

Operating employees should report the time spent reviewing private laboratory packages in the Compliance Management System (CMS). All other private laboratory related activities should be recorded in FACTS (Field Accomplishments and Compliance Tracking System).

11. Requests for Referrals

Persons in need of the services of a private laboratory often call the agency asking for referrals. FDA does not make such recommendations, but callers may be referred to organizations of private laboratories such as the American Council of Independent Labs (ACIL) at 1629 K. St., NW, Suite 4000, Washington, D.C. 20006-1633 (202-887-5872 or www.acil.org); or ASTM at 1916 Race St., Philadelphia, PA 19103-1187 (www.astm.org). If a LAAF accredited laboratory is needed, they may refer to the LAAF dashboard FDA Dashboards - Laboratory Accreditation for Analyses of Foods Program.

12. LAAF Program

The FDA Food Safety Modernization Act (FSMA) final rule on Laboratory Accreditation for Analyses of Foods (LAAF) establishes a laboratory accreditation program for the testing of food in certain circumstances. Under the LAAF program, FDA recognizes accreditation bodies (ABs) that accredit laboratories to the standards established in the final rule (referred to as LAAF-accredited laboratories). For more information about the LAAF program see FSMA Final Rule on Laboratory Accreditation for Analyses of Foods (LAAF) | FDA .

13. Document History

Revision #	Status* (D, I, R)	Date	Author Name and Title	Approving Official Name and Title
1.2	R	06/22/05	LMEB	LMEB
1.3	R	11/10/05	LMEB	LMEB
1.4	R	01/30/13	LMEB	LMEB
02	R	08/13/2019	LMEB	LMEB
03	R	SEE QMIS	LMEB	LMEB
04	R	SEE QMIS	LEMB	LMEB

* - D: Draft, I: Initial, R: Revision

14. Change History

Revision #	Change
1.2	Table of Contents – added Document History Section 7.4 – removed paragraph on *Referree Samples.* Attachment 2 – boxes replaced with _
1.3	Section 7.3.1 – first sentence in third paragraph revised.
1.4	Header – Division of Field Science changed to Office of Regulatory Science 7.3.2 *Packages from foreign laboratories* – Divisions changed to appropriate Offices
02	The document was reformatted.
03	• Changed title • Added information pertaining to upcoming implementation of FSMA final rule on Laboratory Accreditation for Analysis of Foods (LAAF). • Replaced mention of “Districts” to “Division” due to recent organization sunsetting of Districts. • Clarified reviewers as “Qualified FDA Personnel” vs. “Laboratory analysts.” • Added inclusion of method verifications to documentation that should be submitted. • Added “private laboratory” in addition to importer for compliance officer communications sent. • Changed notification of on-going problems from DFS to ORS. • Added inclusion of FACTS for time reporting. • Document transferred and reformatted to ORA Template-000054 ORS Document Template.
04	• Updated with information about the Laboratory Accreditation for Analyses of Food Program (LAAF • Removed references to ORA, replaced with relevant offices. • Added information about Lab Director and Import statements. • Added a review timeframe for device and drug packages. • Added information about additional review time for validations and verifications

15. Attachments

List of Attachments

Attachment A - Example of Collection Report

Brokers' reference no._____
Port of entry _____ Truck license no._____
Importer or broker of record
(Name, address, phone) _____
_____
Grower_____ Shipper _____
Address_____ Address _____

Description of product_____
Description of container_____
Brand name_____
Labeled size_____ Product code_____
Invoiced quantity_____ Actual quantity_____
Copy of invoice attached? Y/N Package label attached? Y/N
Carton label attached? Y/N Bulk label attached? Y/N

Warehouse/freezer lot no._____
Address where sampled_____
_____
_____
_____

Method of collection_____
No. of cartons/drums opened_____
No. of packages/portions from each_____
Weight/volume of portions collected_____
Identified by collector on each portion as_____
Method of sealing_____
Observations or comments about the lot, container(s) or anything else relative to the integrity of the sample collected (*required)*: _____
_____
_____
Description of the chain of custody of the sample_____
_____
_____

Date of collection _____ Signature_____
Collector's name _____
Collector's employer _____
Supervising federal representative (if any) _____
Date _____ Agency _____

Signature _____

FDA agent notified of intent of sample collection_____

Date_____ Time_____

Attachment B - Example of Analyst Background and Training Record

Laboratory Name _____

Analyst's Name _____ Title _____

Years employed in present position _____ Total years as an analyst _____

Highest education received (institution, degree [if any], dates, major subject)

_____

Certifications, Technical licenses (Granting body, date, brief description of entitlement)

_____

Type of Analysis Employee is Qualified to Perform (Check all that apply, but document each separately)

_Macroscopic/Microscopic Filth _Sensory Decomposition _Chemical Decomposition _Metals _Colors _Additives _Pesticides _Aflatoxin _Drug Analysis _Condom Testing _Microbiological - Pathogenic and non-pathogenic organisms _Other

Provide information about training, with dates, that qualifies the employee to perform the analysis referred to above. (Use back of form if more space is needed.)

Provide information about work experience, with dates, that qualifies the employee to perform the analysis referred to above. (Use back of form if more space is needed.)

Laboratory Director _____ Date _____

Signature _____

Attachment C - Example of Analytical Report

Description of product received _____
Brokers' reference no. _____
FDA sample no. _____ Laboratory sample no. _____
Date received _____ Seal intact? Y / N
Condition of sample: _____frozen _____refrigerated _____ambient
Sample description (size, no. of portions) _____
_____
Container code if present _____
Portions identified by collector as _____
Portions agree with description? Y/N
Date analysis begins _____Date analysis completed _____
Method used (reference(s) and any modifications) _____
Analyst(s) _____
Number of sub samples _____ Amount analyzed per sub _____
Total amount analyzed _____ Sample composited? Y / N
How composited

Note: Clearly indicate on each analytical worksheet who did what part of the analysis, with signature(s) and dates(s). Equipment used: Identify equipment and parameters used to weigh and process samples, analyze extracts, etc.

LABORATORY DIRECTOR'S STATEMENT: Review of records indicate that the product and lot referred to in this report have____ have not____ been subject to prior analysis by this laboratory. If the lot has been subject to prior analysis by this laboratory, copies of the final results are hereto attached. The prior analysis was conducted on the following date(s) and covered by the following laboratory report numbers(s):

_____

Signed _____ Date _____

IMPORTER'S STATEMENT: The analytical results submitted with this report include all analytical work related to this sample performed by this laboratory and all other laboratories which may have conducted the analyses.

Signed _____ Date _____

Notice: The knowing and willful making of any false, fictitious or fraudulent statements or representations in any manner within the jurisdiction of any department or agency of the United States is a matter subject to the provisions of Title 18 of the U.S. Code, Section 1001

Attachment D - Private Laboratory Package Review Guide

1. SAMPLING

a. Lot is described.
b. Sample is collected randomly.
c. Sample is collected from sufficient number of cartons (proper distribution).
d. Proper size sample is collected.
e. Sufficient number of subs are collected.
f. Collection is documented/collector is identified.

2. SAMPLE DATA

a. Sample number on worksheet relates to final report.
b. Sample is accurately described and relates to invoice (e.g. dimensions for ceramic ware, size of fish, shrimp, etc.).
c. Contents of each sub composited (or portion taken, if whole sub).
d. The correct portion of composite is taken and weight is shown.
e. Where individual subs are analyzed, the correct number of subs examined.
f. Sample is correctly prepared.
g. Sample is correctly stored e.g. temperature.
h. Label is submitted if present on the product.

3. ANALYTICAL METHOD

a. The correct method is used and cited. Non-official methods are validated. Current versions of official methods are used.
b. Each step of the method is followed.
c. Deviations from official method are explained and validated.
d. Use of special reagents and equipment is described.
e. All equipment is identified to be traceable to its QA records.
f. No unresolved analytical problems are evident.
g. All analytical attempts are included, and discarded results are explained.
h. Recovery and blank data are acceptable.
i. Calculations are clear, accurate, and easy to follow.
j. All raw data, including chromatograms and spectra and reproductions of TLC plates, are submitted, as well as printouts of reader instruments, e.g. Vidas.
k. Laboratory conclusions are supported by analytical results.
l. All analysts sign worksheet and ‘who did what’ is clearly indicated. ‘When’ can also be determined as called for by the method (e.g. for microbiological analysis).

4. STANDARD DATA

a. Source of standard is cited.
b. Preparation dates *and* preparer of primary and working standards are cited.
c. Weights, dilutions, and concentrations of standard materials are documented.
d. Standard curve has the correct number of points; sample results are within the limits of the standard

curve.
e. Standard curve submitted unless regression analyses used to calculate sample results.
f. Standard and/or blank injections bracket sample injection, as needed.

5. INSTRUMENT PARAMETERS

The following parameters are documented:
a. Name & model of instrument, accessories used
b. Parameters for operation of instrument
c. Wavelength used
d. Lamp power settings
e. Type of flame used
f. Column type, ID., and length used
g. Gas/Liquid phases med
h. Flow rates
i. Detector and mode used
j. Temperature settings
k. Attenuation
l. Chart speed

6. CONDOMS/GLOVES

a. Sample is of a single type and brand.
b. Proper sample size is collected and examined according to method and is of scheduled number to be examined (lots, glove size, use).
c. Label is reviewed.

7. MICROBIOLOGICAL ANALYSIS

a. Batches of media are identified with QA numbers.
b. Positive and negative controls traceable to reference cultures are run concurrently with sample analysis and carried through until the sample is completed. Controls are within range for a valid assay.
c. Refrigerators, freezers, and water baths are identified on the worksheet.
d. Biochemical reactions/patterns are obtained in the analysis.
e. Expired media, reagents or test kits are not used in the analysis.
f. FDA guidelines followed on such items as number of colonies to pick.
g. Each step of the method is followed, with media, incubation temperatures, amounts transferred, etc. being documented.

To be confirmed during on-site assessment visits:
a. Media used in microbiological analysis undergoes QA checks for pH, sterility, and growth promotion.
b. Batches of media have expiration dates.
c. Batches of media are traceable to autoclaves and autoclave runs.
d. Autoclave processing cycles are validated with biological indicators.
e. Refrigerator, freezer, and water bath temperatures are monitored daily.
f. Laboratory grade water, free from traces of dissolved metal, bactericidal, and inhibitory compounds is used to prepare media, reagents, and dilution blanks.

8. PERSONNEL

Analyst CVs are on file or are submitted with worksheet packages. CVs should include analyst's training or experience or both in the areas covered by the analysis.