Partnership for Food Protection
Laboratory Science Workgroup

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Human & Animal Food Regulatory Compliance Review Checklist

Human & Animal Food
Regulatory Compliance Review Checklist

Introduction

This checklist is designed to assist a human and animal food organization in preparing a data package intended for review by a compliance officer for possible regulatory action. In addition, this checklist is structured to aid compliance officers in the review of data packages. Familiarity with the elements of this checklist will assist regulatory inspection and laboratory groups in planning their sample collections and analyses to assure they can provide essential regulatory information.

This checklist provides guidance on establishing and maintaining evidentiary integrity of laboratory test results to assure that the identity and authenticity of evidence associated with a human or animal food sample will be admissible in a legal proceeding. As regulatory findings may result in regulatory actions leading to destruction of product, loss of revenue and/or monetary fines, it is important that the processes used by the program throughout sampling and analysis to preserve evidentiary integrity are documented for each sample. For an agency to take regulatory action to remove possibly hazardous human or animal food from commerce, test results must be representative of and traceable to a decision unit.

The sample in all its forms [sampled decision unit, primary sample, laboratory sample, analytical sample, test portion, test result(s)] must be properly collected, processed, and stored in a way to ensure its identity and authenticity. Without this framework, the data packet may be vulnerable to loss of merit as evidence. The integrity of physical evidence from sampled decision unit to test result is built on ability to link the test results to the decision unit, sampling/subsampling procedures that control error, and processes to maintain analyte integrity. Chain of custody documents the chain of sample possession to facilitate trace back. Proper sampling procedures ensure sample representivity by controlling error during sample mass reduction efforts (primary sample collection, sample splitting, selection of test portion) from the laboratory sample down to the test portion. Also, the field and laboratory personnel must implement processes to ensure analyte integrity (non-mass reduction efforts such as particle size reduction (e.g., comminution by grinding, chopping, blending, etc.) or proper storage conditions (e.g., proper packaging and shipping, protection from light or maintaining in a frozen state)

A data package should contain information that satisfies these questions:

1) Can the test results be traced to the test portion, to the analytical sample, the laboratory sample, the primary sample, and to the sampled decision unit?
2) Was the test portion representative of the sampled decision unit? Was the analyte present in the same proportion in the test portion as in the sampled decision unit? If so, then sample representivity was maintained in all sample mass reduction efforts in the field and laboratory.
3) Were processes in place to ensure the analyte did not change (e.g., degrade, concentrate, evaporate, mutate, adsorb) during collection, packaging, shipping, handling or storage.
4) Is the testing recognized as appropriate by other scientists and performed using validated and/or official methods?

The reader is directed to *GOODSamples* and *GOOD Test Portions* (available without cost from www.aafco.org) for additional information on evidentiary integrity.

The laboratory may need to coordinate the submission of a data package with other departments or agencies to provide all the necessary information for regulatory action. A data package may include data documenting inspection findings, reasons for sample collection, sample collection processes, compliance history, and laboratory analyses. A data package may be linked to previous findings, even in other jurisdictions. Laboratory testing may be the final step in the identification of a non-compliant product.

This checklist assumes that the laboratory is either accredited to ISO/IEC 17025 or has a similar quality management system in place. For discussions of quality systems for regulatory laboratories, also refer to *The Partnership for Food Protection Human and Animal Food Testing Laboratories Best Practices Manual* and *Best Practices for Submission of Actionable Human and Animal Feed Testing Data Generated in State and Local Laboratories*.

General Instructions for Completing This Checklist: The Regulatory Compliance Review Checklist may be used to provide information about an individual sample or group of samples that are closely related. If there are multiple samples, it may be necessary to use multiple forms and submit them together. The checklist coversheet is intended to provide an index to the detailed data package to assure that all necessary information is included and easily located. In many cases, the information on the form will be a reference to the relevant documents in the data package. It may also be a reference to a regulatory organization's internal procedures that are not included in the package unless requested. It is not necessary to provide information that is not relevant. The boxes above can expand as needed to provide additional space as needed.

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Coversheet

Package contains data and relevant details on the pages indicated.

Date of Submission:

1. Submitting Organization

ISO/IEC 17025 accredited to method performed?
Yes ☐ No ☐ Other quality system:

Page(s):

2. Sample #'s

Page(s):

3. Primary Sample, Laboratory Sample and Decision Unit Description

Page(s):

4. Evidentiary Integrity Intact? Yes or No ☐ ☐

Page(s):

5. Net Quantity of Contents

Page(s):

_____% of the amount declared on the label

6. Description of Labeling

Page(s):

6a. Label attached? Yes ☐ No ☐

7. Analytical Findings

Page(s):

Analyte: _____

7a.

_____ _____
Amount **Unit**

7b.

_____ _____
Allowable Limit **Unit**

8. Analysis Status

Page(s):

☐ Preliminary or Screening
☐ Confirmed
☐ Other

9. Regulatory Status

Page(s):

☐ Compliant
☐ Non-compliant
  ☐ Adulterated
  ☐ Misbranded
☐ Other

10. Relevant Regulations / Legal Authority

Page(s):

☐ Import
☐ Domestic
☐ Domestic Import
☐ Other

Violation(s):

11. Compliance Status

Page(s):

☐ No action taken
☐ Warning issued
☐ Stop Sale / Cease Harvest issued
☐ Recall issued
☐ Seizure / destruction
☐ Import Alert
☐ Relabeling
☐ Other:

12. Related Sampling Events

Page(s):

Yes or No
☐ ☐
If yes, describe:

13. List Attachments

Page(s):

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Checklist

Ensures organization provides requested information or reference(s) to related document(s).
A compliance package may include data from multiple primary samples that are closely related.

	Date of Submission: Date paperwork is sent for review.
	1. Submitting Organization: • Name and mailing address of the organization submitting the data. • Name and physical location of laboratory (laboratories) conducting the testing. This should be the facility where the laboratory sample was received, stored, and tested; location of any remaining sample material could be obtained or returned. • Contact information (name, title, address, email, phone #) for a person with knowledge of the data and authority to provide the compliance officer with answers to questions and any additional information as needed.
	2. Sample Number(s): Provide any numbers necessary to assure evidentiary integrity and chain of custody. Include all unique sample number(s). Identify the decision unit(s), primary sample(s), laboratory sample(s), analytical sample(s), and test portion(s) number(s) where relevant throughout the data package. Other numbers that could be associated with sample(s) could include: inspection number, sample numbers of any replicates or reserve samples, method analysis number, or instrumental sequence number. • Provide a legend or key of the identification numbers for the samples. • Primary Sample identification number: A unique number, assigned to the sample at the time of collection.
	3. Decision Unit, Primary Sample and Laboratory Sample Descriptions: Much of this information may come from the sample collection form. It is important to identify how the sample was collected in order to make defensible decisions about the material sampled. Sample Quality Criteria (SQC): Describe analyte of interest, action limit, how inference was made, the decision unit, the scale of decision making (single lot, import shipment, all products from that supplier, etc.), and the needed confidence to support defensible decisions. (See *GOODSamples* and *GOOD Test Portions*, www.aafco.org/publications). Provide regulatory purpose/reason for collection (routine surveillance, compliance follow-up, routine non-regulatory monitoring, consumer complaint, etc.), Sampled decision unit: • Describe the food/feed product, commodity type, or other material sampled to which an inference is made. • Size of sampled decision unit (weight or volume, including units) Specify the total amount of product the sample represents. Indicate the total amount of product that the sampling statistically represents and not the total amount of product present

at the facility. How large is the unit from which a sample was collected? Was it selected from a single box or refrigerator case or was it selected from several randomly selected cases of warehouse product or at multiple locations from a crop field? Do not report numbers of cases barrels or boxes unless also specifying the weight or volume in each package. If a growing crop was sampled, indicate the total acres represented. (e.g. 40,000 6 oz. bottles; 4 acres; 3,000 lbs.)

- Provide pictures of sampled decision unit

Primary Sample:

Describe the material selected from the sampled decision unit. In order to be representative, it is important to collect multiple increments from the decision unit.

- Specify the number and size of increments collected during sampling (e.g. 6 x 12 oz. cans, 12 x 1 lb. increments, 10 cucumbers)
- Detailed visual description of the primary sample. (e.g., commodity, color, shape, texture, and other general appearance)
- Physical state of primary sample when initially collected including cooking/temperature status (raw, fresh, frozen, canned, cooked, dried, ready to eat, etc.) when distributed/stored/sold/consumed, if known
- Sampling Protocol or Sampling Plan to obtain Primary Sample: A detailed procedure describing how a representative sample is taken from the decision unit.
- Describe any deviations from sampling protocol
- Describe sampling site location and way primary sample was collected
  Provide the sample collector's description of how the primary sample was collected. If possible, provide a copy of a sample collection report.
- Name and title of persons collecting the samples
- Name and title of person(s) who were present when the primary sample was sealed
- Applicable qualifications, authorizations, credentials or training of sample collector(s)
- Method of transportation (or explain that samples were delivered by state inspector and handed off directly to a laboratory employee)
- Custody of primary sample to the testing location including carrier, date, time of shipment
- Include original, copies and/or photos of custody seals.

Laboratory sample

- Product Name. A common name used to describe the food (e.g. fresh tomato, applesauce, egg product, canned dog food)
- Number of laboratory sample increments (e.g., six apples or four 2 oz. portions)
- Total (gross) size of laboratory sample (mass, weight, volume, etc.)
- Number of replicate (or reserve) laboratory samples submitted
- Controls, standards, or any other items contained in the shipment
- Physical condition of the laboratory sample upon receipt (fresh, frozen, intact, thawed, rotten, etc.)
- Physical controls (e.g., temperature and any apparent abnormalities; if thawing was necessary, describe thawing conditions; temperature of sample if an appropriate temperature measurement method is in place or note if received sample frozen)
- Temperature control to verify temperature of laboratory sample upon receipt.
- Non-selection processes (husked, shelled, blended, etc.)
- Describe any deviations from laboratory sample receiving procedures or related concerns.

	• Pictures of the primary sample as received by the laboratory
	4. Evidentiary Integrity Evidentiary Integrity is the "Identity and authenticity of the evidence (test results)." It is evidence that samples have been properly collected, processed, and stored in a manner to ensure that test results)s) can be traced to the decision unit and are a true representation of the decision unit. Evidentiary integrity is demonstrated by documentation of trace-back (e.g. chain of custody forms); proper sampling procedures to ensure representivity (e.g. sample correctness); and processes to ensure analyte integrity is maintained. Product Integrity: Describe how the analytical result(s) can be traced to the decision unit. This information is provided to verify the authenticity and traceability of the test results. Much of this information may be included on the sample collection form. . • If obtained from a patient's home: o How was the product handled after purchase? o How was the product prepared for consumption? o How was the product stored following preparation? o How was leftover product stored following consumption? o Was the leftover product (collected for analysis) subjected to any temperature abuse prior to collection? o Who handled the product in the home? • Temperature of product at the time of collection. • Describe any sample preservation techniques employed (e.g., pH adjustment, addition of preservative, refrigeration, freezing, protection from light) prior to shipping to the laboratory • Food Product Packaging: Describe the materials used to hold the primary sample. (e.g., aseptic bag, cardboard box, Ziploc bag in Styrofoam cooler and condition of the packaging at the time of collection and upon receipt at the laboratory.) • Amount of product remaining available for use or for sale • Picture(s) of product. • Detailed description of the containers (e.g., coolers, boxes) used to transport the sample or specimen • Observe and record if original packaging had already been opened prior to sample collection. Trace-back and trace-forward information Provide copies of any invoices, receipts (including date and time if purchased from retail outlet), shipping manifests or other documents tracing the product to a previous owner or shipments to customers. • Address and Contact information for the o Collection Site o Owner o Grower o Manufacturer / Producer o Distributor o Importer

- Exporter
- Customer
- Other

- Firm identification code: *Some organizations such as the USDA FSIS have code numbers for food establishments. USDA FSIS Meat and Poultry Inspection Directory: https://www.fsis.usda.gov/wps/portal/fsis/topics/inspection/mpi-directory*
- Location where consumer sample/evidence was collected (e.g., restaurant freezer, patient's home kitchen)
- Details of consumer purchase (if applicable): *dates, name and address of purchase location, how much was purchased*
- Receipts (document indicating payment for the product sampled or document showing receipt of product without payment) and/or shopper's loyalty card number if available for product traceability
- Sampled firm's product identification numbers, order, invoice, receipt and distribution documents
- Country of Origin
- Product in other locations
- If known, document any other locations having the same product. If known, include the amount. These may include order forms or shipping manifests provided by the owner of the product.
- Shipping documents
- Import entry documents
- Pictures of product during collection and/or sampling
- If no packaging information is available at sample collection, make a note of this.
- Ingredient list
- Manufacturer / distributor name, contact information
- Product lot(s), import entry number(s), shipment number, production code, or other product codes. Many organizations, including the FDA, have databases of food and animal products with unique codes. Include any relevant codes and the respective agency issuing the codes.
  For example: Product: Canned Tomato Soup (Concentrated), Product Code: 38BEE27)
- FDA product codes: https://www.fda.gov/ForIndustry/ImportProgram/Resources/ucm462993.htm
- USDA FSIS Product descriptions: https://www.fsis.usda.gov/wps/wcm/connect/abbf595d-7fc7-4170-b7be-37f812882388/Product-Categorization.pdf?MOD=AJPERES
- Sell by, use by, best by or expiration date
- USDA Establishment number
- Brand names
- Any other identification numbers or marks on packaging, product, decision unit, or primary sample
- Unique sample identifier such as Federal or State sample identification or barcode. Take pictures or make copies of these labels, if possible.

<u>Chain of Custody – record every time custody is relinquished</u>

- Collection date (and time, if applicable)
- Laboratory receipt date
- Received from/by
- Condition of custody (e.g., seals intact)
- Condition of product (e.g., sample integrity maintained)
- Secured storage information (e.g., from receipt through testing, how any remaining sample material is stored if retained after testing, and disposal)
- Sample storage conditions at the laboratory
- Custody transfers to and from storage including date, time and person.
- Replicate and reserve laboratory sample storage information. (if applicable)

	• Disposition, including date and method and by whom. (e.g., shipment to another laboratory, long-term storage, or destruction) • Photo of laboratory sample seal before and after it is broken • Record of who broke the seal and when Analyte Integrity • Steps taken to preserve analyte(s) • Any signs of degradation • Possible metabolites or degradation products • Any signs of contamination
	5. Net Quantity of Contents: The Net Quantity of Contents (Net Quantity) is the statement on the human or animal food label that provides of the amount of food in the container or package. It must be expressed in weight, volumetric measure or numeric count. Indicate if Net Contents was "Not Applicable" or "Not Determined" • Number of packages or units examined. • Declared quantity of contents per package declared on package label • Amount of actual contents of package quantified by laboratory testing after opening (if applicable) • % of the declared contents (Calculation of the measured quantity of package contents divided by amount declared on label times 100) (if applicable)
	6. Description of Labeling Human Food: FDA regulated foods should comply with food packaging label regulations in 21 CFR 101, including statement of identity (name of food), manufacturer or other responsible party, ingredients, net quantity, nutrition facts and, if applicable % juice, allergens, nutrient content and health or other claims. Country of origin labeling requirements are described in 19 CFR 134. Also consult the FDA Food Labeling Guide, https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm2006828.htm. USDA FSIS regulated products should comply with labelling requirements in https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/labeling Animal Food: Pet food labeling is regulated at two levels. The federal regulations, enforced by the United States Food and Drug Administration (FDA), establish standards applicable for all animal feeds: proper identification of product, net quantity statement, manufacturer's name and address, listing of ingredients and nutritional adequacy. Some states also enforce their own labeling regulations. Many states have adopted the model pet food regulations established by the Association of American Feed Control Officials **(**https://petfood.aafco.org/). These regulations are more specific in nature, covering aspects of labeling such as the product name, nutritional adequacy statement, feeding directions, and calorie statements. Many state regulations require a pet food "guaranteed analysis" which states the minimum percentages of crude protein and crude fat, and the maximum percentages of crude fiber**,** moisture and other nutrients.

	The FDA Center for Veterinary Medicine (CVM) manages the FDA's medicated feed and pet food programs including labeling for medicated feeds. Blue Bird labels are submitted by medicated feed manufacturers for approval and include recommended product labels. The AAFCO Feed Labeling Committee reviews labeling requirements and maintains Feed Labeling Guides (https://www.aafco.org/Publications) . Medicated feed labeling should include information for veterinarians and animal owners including product name, manufacturer or responsible party, indications for use, guaranteed analysis statement, ingredient statement, dosage form, route of administration, recommended dosage and net quantity of contents. Nutritional guarantees are also commonly included on commercial feeds. Food Product Labels: • Description of the product label on sample containers • Number of original labels submitted • Number of copies of labels submitted • Pictures of labels Labeling Non-Compliance: • Description of any non-compliance (e.g. Is the food product name inaccurate or misleading? Is required information not present? Did analyses indicate that information displayed on the label is incorrect? Are nutritional guarantees inaccurate or absent?) • Specific non-compliance (e.g. a specific required component absent, a specific component that is not in compliance with regulations, a specific allergen that is present or the quantitative amount of an ingredient or additive that is not consistent with the label…)
	7. Analytical Findings 7. Analyte: Provide the name of analyte detected. 7a. Amount/unit: Provide the concentration of analyte found and ISO units 7b. Applicable limit/unit: Provide any relevant regulatory limit or guidance limit and ISO units. **Analytical findings may be provided in a table or report.** Provide a reference to the report. As these reports may be complex and contain both compliant and non-compliant information, it may be useful to add the most relevant non-compliance information on the cover page. There are times when multiple samples or follow-up data in a regulatory case are compliant. In these cases, it may be just as relevant to provide compliant data for review. For additional information, refer to *Human and Animal Food Testing Laboratories Best Practices Manual*, Chapters 6 & 7, https://www.pfp-ifss.org/ifss-resources/. Provide all relevant findings. While it is common practice to only report a final result to a customer, it is important to provide all relevant analytical data including preliminary, confirmatory, averaged and/or replicate data findings for compliance reviews, and they should be clearly identified. Analytical Samples and Test Portions • If the laboratory does not test the laboratory sample in its entirety, then describe or refer to laboratory procedures for sample preparation that are used to obtain analytical sample(s) and test portion(s). Laboratory sampling records should describe all nonselection and selection processes. Refer to *GOOD Test Portions*. • Report mass, volume, concentration, etc. of aliquots used to create analytical samples and test

portions

- Include identification numbers of analytical samples and test portions
- Include Total Sampling Error (TSE): *Estimate of error from all nonselection and selection processes.*
- Include Global Estimation Error (GEE): *Estimate of the total error in the entire process from primary sampling through testing. (Includes total sampling error (TSE) and total analytical error/uncertainty.*

Test Results

- Kits: If a test kit is used, provide copy of kit inserts.
- Method Validation: Provide test method validation documentation or matrix extension validation [both external and internal where appropriate in a similar matrix], if performed. Note if the method used by the laboratory has been validated for use by a recognized independent body (such as AOAC, AFNOR, or ISO 17025) or is considered a reference method by FDA or USDA FSIS. Any modifications of the method must be shown.
- Method Verification: Provide test method verification conducted in the laboratory.
- Control Results: Clearly indicate and describe controls used during sample testing (positive, negative, blanks, etc.). Indicate when the controls were run (i.e., at the same time as the test?).
- Designate if the method is for screening method, confirmation, or both.
- When testing for foodborne pathogens, provide assurance that the result is not due to cross-contamination with the laboratory's control culture.
- Worksheets: Provide copies of all analysis worksheets for sample along with final results in data packet.
- If DNA typing is performed, provide actual worksheets and output for WGS analysis (local and national database), If performed by another laboratory, provide contact information for the laboratory conducting DNA typing.
    - Were WGS data uploaded to PulseNet and/or NCBI? Provide the NCBI number or any other identifier for the isolate.
    - Were any matches found?
- 7. Analytes: *Provide name of the analyte(s) tested. Be sure to document any calculations which include the total of parent and metabolites or convert the analyte found to a different compound such as the measurement of a metabolite that is converted to the mass of the parent compound. Note inclusion of metabolites or corrections to active ingredient. Provide the name of the chemical, biological or radiological analyte found. This may be a contaminant, residue, ingredient or labeling finding. There may be multiple findings. This information may be provided by reference to a final report. Provide all findings relevant to the compliance case.*
- 7a. Amount and Units: *Each analyte should be associated with the amount found and measurement units if relevant (e.g. ethyl parathion 1.8 mg/kg). Qualitative data may be reported as "positive", "negative" or approximated.*
- 7b. Allowable Limit and Units: Reporting limit, specification limit, action limit, label guarantee, detect or non-detect, defect: If applicable, provide the quantitative or qualitative detection limit for the method.
- Limit of quantitation (LOQ): *If applicable, provide the method quantitation limit. This may or may not be the same as the "Reporting Limit."*
- Limit of detection (LOD): *If applicable, provide the method limit of detection. For some applications, the limit of detection is no longer relevant and not reported.*
- Measurement Uncertainty (MU): *For most quantitative regulatory results, it is important to provide the measurement uncertainty (also called total analytical error). It may not be as applicable for pass/fail and qualitative results.*
- Calculations: *Provide all calculations made that are not included in the calibrations and quantitation's provided by the automated data station results. Include calculation or proof that instrument made the correct calculations: (e.g., a screenshot of the instrument showing that isotope calculation includes all necessary isotopes. The instrument output should be clear, or additional documentation can be provided).*
- Analyst: *Provide the name and title of all persons involved in the testing. This information should be provided on the respective individual reports, usually with analyst signature and date. At least one analyst should be identified as*

responsible for the reporting of the final analytical results usually including reviewer's signature and date. Also, have available laboratory minimum standards for analyst training, competence to perform specific analyses.

Testing Instrumentation & Equipment

- Type: *Provide the manufacturer, name, model number and any special features of the instrumentation. (e.g. Thermo Fisher Scientific Q Exactive Plus Orbitrap Liquid Chromatographic Mass Spectrometer in negative ion mode)*
- Identification number: *Provide a unique number used by the laboratory to identify the specific instrument used to generate the testing. In some cases, multiple instruments may have been used.*
- Calibration: *Make available results of relevant instrument calibrations.*
- Performance Verifications: *Provide instrument performance verifications conducted as part of the testing.*
- Instrumental Results: *Instrumental results are usually provided by referencing data station reports with the following information. These reports should include as much detail as practical in order to aid in the review, such as chromatograms and mass spectra.*
- Sequence: *Provide a report showing the sequence of analytical samples, analytical standards, quality control samples and reference materials tested in each batch. The information on the sequence should be sufficient to trace the testing to the method used, the instrument, the analyst, the time and date of testing and all reference standards and quality control used for the testing.*
- Instrumental method: *Provide a copy of the instrumental method(s)*
- Calibrations and/or analytical standards at beginning and end of sequence: *Provide detailed information about any analytical standards or reference materials used to conduct the testing in a manner that will enable the reviewer to trace them to their origins and certification. In some cases, the reviewer may request Certificates of Analysis and descriptions of the preparation and verification of for any working standards used in testing.*
- Blanks and any findings or interferences: *Provide data showing results of relevant instrument, reagent and matrix blanks.*
- Spikes and spike recoveries: *Provide data showing results of spike testing.*
- Reference materials: *Provide data showing results of reference material testing.*
- Laboratory sample test results and replicates, if included in testing: *Provide copies of instrumental data results in a much detail as necessary to demonstrate the validity of the results.*

Quality Control (QC):

Information such as quality control charts and results of on-going proficiency or inter-laboratory tests as well as on-going QC should be provided if relevant. Some of the data requested may have already been provided. Sections may be combined by adding an evaluation of the QC results to the instrumental data reports. This is often automated and provided with the data station output. A QC evaluation provides the reviewer with the analyst's interpretation of the data.

- Quality control blanks: *Material that is as free of analyte as possible and that is analyzed in test method to provide internal validation of each batch and determine if the process is in control; provide evaluation and explanation of any unexpected results from their use in quality control.*
- Instrument Blanks: *Provide evaluation of blanks and explanation of any interference from instrumental background in the analysis.*
- Blanks from Laboratory Sampling Processes: *May include swabs of equipment and containers used); provide evaluation of blanks and explanation of any unexpected results from sampling processes.*
- Reagent Blanks: *Provide evaluation of blanks and explanations of interference from reagents used in the analysis.*
- Matrix Blanks: *Provide evaluation of blanks and explanations of interference from the sample/commodity matrix in the analysis.*
- Replicates: *If a sample was tested multiple times, provide data for all testing results including copies of calculations such as averaging replicates.*
- Laboratory Sample Replicates: *Provide evaluation of replicated laboratory*

samples

- Analytical Sample Replicates: *Provide evaluation of replicated analytical samples*
- Test Portion Replicates: *Provide evaluation of replicated test portions.*
- Spikes: *Provide an evaluation of spike results showing the true spike amount compared to the test findings and the % recovery. If applicable, provide a quality control chart showing acceptable performance and explanations of any deviations from expected performance.*
- Estimate of Systematic Error (Accuracy): *Control of systematic error may be demonstrated with incorporation of blanks, spike recovery results, as well as method validation data and laboratory sampling validation data.*
- Estimate of Random Error (Precision): *Random error may be monitored with incorporation of replicates, quality control charts and/or method validation data. Precision may also be demonstrated with repeat analyses of the test sample.*
- Reproducibility: *Quality control charts may demonstrate reproducibility over time, especially if they represent testing conducted by multiple analysts and/or multiple instruments.*
- Analytical Standards: *Provide the origin and certificate of analysis as well as documentation of the preparation and concentrations for any analytical reference standards.*
- Identity and lot numbers/expiration dates for sterile supplies used.
- Identity and lot numbers/expiration dates for media used.
- Identity and lot numbers/expiration dates for reagents used.
- Quality control standard information
- Quality control organism identification information *(e.g. ATCC#, genus and species)*
- Results of controls *(e.g., outcome of media control, blank, spikes)*
- Linearity: *Provide an evaluation of the analytical standard linearity of the testing.*
- Reference Materials: *Provide the testing vs the expected results for any reference materials tested.*
- On-going verifications: *Provide findings and evaluations of any other verifications of the testing performance.*
- Proficiency testing: *Provide findings and evaluations of any relevant and recent proficiency testing conducted.*
- Analyst's notes on the testing

<u>Laboratory results report:</u>

Provide evidence of current accreditation or participation in other quality management program. Indicate if sampling and/or testing is included in the scope of accreditation. Indicate any testing conducted that is not within the scope of accreditation. Also, indicate how long the laboratory has been accredited

- Title
- Laboratory name and address
- Location where the laboratory activities were performed
- Unique test report identification, identifying all components as part of a complete report, including page number, total number of pages, and a clear indication of the report's end
- Customer name and contact information
- Date of sampling
- Laboratory sample receipt date
- Test item description, condition, and unambiguous identification
- Test date(s)
- Test results and units of measurement
- Identification of the method used
- Describe any deviations (such as modifications, additions, or exclusions from testing procedures or related concerns

	• Date when report issued • Sampling plan or procedure reference, if relevant; if laboratory did not do the sampling, state that results apply to the sample as received • Primary sample collection date (and time, if necessary for analysis) • Primary sample collection location and condition • Identification of person(s) completing and authorizing the test report and clear indication when the results are from external providers (test report format should accommodate each type of test performed and minimize the possibility of misunderstanding or misuse) • Estimation of error associated with test results. • State that results relate only to items tested and/or sampled • Discussion of any anomalies observed in the analysis of the sample that is subject of the report, and an estimation of the impact of said anomalies on reliability of the reported result. • State that report is not be reproduced except in full without approval of the laboratory • Clearly identify any customer-provided data included on the laboratory test report and state that data supplied by a customer can affect the validity of results
	8. Analysis Status Some analyses are screening in nature and provide only a preliminary or qualitative test result. Subsequent data may provide quantitation and/or confirmation (e.g. mass spectrometry, confirmed viable bacterial species, subtyping, or DNA analyses)
	9. Regulatory Status • Does this laboratory sample meet the regulatory requirements? If the laboratory sample is in violation of any of the laws or regulations, it is non-compliant (sometimes referred to as violative) for that particular requirement. • If Net Contents or Labeling are non-compliant, indicate "non-compliant" and provide further information in #5 or #6. • If the sample does not meet regulatory requirements, to whom, when and how was the relevant federal agency notified? • Other status may include findings which do not meet guidelines or other suggested limits.
	10. Relevant Regulations / Legal Authority Include any information that the compliance reviewer will need to link the product to the relevant regulation. • Identify the federal, state or local laws, statutes, rules or any other regulation governing the enforcement of the analyte(s) and food(s) relevant to this case. • Specify the specific violation(s) relevant to this case. (e.g. "exceeds the regulatory limit of ____" or "is prohibited from use in _____".) These limits may also be stated in # 7. • Additional information could include: imported, country of origin, entry number, or domestic status.
	11. Compliance Status Indicate any regulatory actions taken by the submitting organization in response to a non-compliant finding. Provide copies of any final reports, stop sale, cease harvest, recall issued, seizure, destruction, import alert, warning letters, notices of violation or other status assigned by the submitting organization.
	12. Related Sampling Events

	Compliance actions frequently involve multiple resampling events, findings by other state or federal agencies, or other related sampling events with the same or similar non-compliance findings. These may or may not be included in the submitted data package but may be relevant to the compliance review. Be sure to provide enough information that the reviewer may be able to find and/or cross-reference the data if needed. Compliant sampling events of the same products may also be relevant.
	13. <u>List of Attachments</u> Provide a list of attachments and page numbers, in the order they appear in the package. Use the check list numbering system and terminology wherever possible (e.g. 7. Method Validation). Besides laboratory reports, some additional attachments might include pictures, trace back information from food handling firms and method validation reports. Every data package is different. It may not be relevant to provide all the information described in the checklist. The *List of Attachments* will make it easier for a reviewer to determine if all the needed information was submitted.