1.0 Purpose

The purpose of the UL R Food Safety Modernization Act (FSMA) Certification Program is to assess the extent to which an organization conforms to the applicable regulations and/or standards regarding the human and animal food products being farmed, harvested, produced, manufactured, packaged, stored, imported and transported.

2.0 Scope

Certification is open to all interested organizations. The purpose of the Certification process is to assess the extent of the organization's conformance with the applicable regulations and/or standards regarding food products.

- 21 CFR Part 117 cGMP, Hazard Analysis Risk Based Preventative Controls for Human Food (Rev. 9/2014)
- 21 CFR Part 507 cGMP, Hazard Analysis Risk Based Preventative Controls for Animal Food (Rev. 9/2015)
- 21 CFR Part 112 the Standards for the Growing, Harvesting, Packaging and Holding of Produce for Human Consumption (Rev. 11/2015)
- 21 CFR Part 1 –Subpart O Sanitary Transportation of Human and Animal Food Final Rule (Rev. 4/2016)
- 21 CFR Part 1 – Subpart L Foreign Supplier Verification Program (Rev. 11/2015)
- Final Rule: Mitigation Strategies to Protect Food Against Intentional Adulteration (Rev. 5/2016)

All organizations that utilize UL Registrar LLC's (UL R) assessment and certification services are guided by these procedures and are required to comply with all of the relevant provisions contained herein, including implementing appropriate changes when they are communicated by UL Registrar LLC.

The organization shall make all necessary arrangements for UL Registrar LLC personnel to conduct the FSMA assessment [1]with respect to examining documentation, access to all areas, records, investigation of complaints, participating observers and personnel (including subcontractors) associated with the scope of the initial FSMA Certification including a Consultative and Regulatory Audits. FSMA Certification Audits are conducted annually.

3.0 Program Participation

(New Applicants/Current Clients)

Application for Certification

[1] 21 CFR 1 Sub-part M 1.600 - Assessment means: (ii) With respect to a third-party certification body, an evaluation by a recognized accreditation body (or, in the case of direct accreditation, FDA) of the competency and capacity of a third-party certification body under the applicable requirements of this subpart for the defined scope of accreditation. An assessment of the competency and capacity of the third-party certification body involves evaluating the competency and capacity of the operations of the third-party certification body that are relevant to decisions on accreditation and, if accredited, an evaluation of its performance and the validity of its audit results and certification decisions under the applicable requirements of this subpart.

Organizations to undergo assessment for the first time must provide UL Registrar LLC pre-audit information on the Audit Request Profile Sheet supplied by UL R to include but not limited to the following:

- FDA Registration Number
- The size and location of the facility to undergo audit,
- The number of employees at the organization;
- All requested audit scope(s) under audit,
- And a list of all products farmed, harvested, produced, animal raised, manufactured, packaged, stored, transported/ imported which may be provided for consumption by human and animal.

UL R will utilize a site audit duration matrix or other time matrix to determine the minimum number of days for the audit as described within this scheme.

Upon receipt of the Audit Request Profile Sheet, a Contract/Proposal (Agreement) will be forwarded to the applicant. This document will be used as a contractual agreement between UL Registrar LLC and the organization to carry out certification services.

Copies of the Agreement will be provided to the manufacturer for the purpose of signing. One copy will be submitted to UL Registrar LLC and one copy will be retained by the organization. To the extent that there is any inconsistency between this "Procedure for Certification" document and the final contractual agreement (proposal), the terms of this procedure shall control.

The Agreement shall remain in effect for three years and shall automatically renew for subsequent three year terms until such time that UL Registrar informs the organization or the organization informs UL Registrar LLC in writing of their intention to cease participation in the FSMA Certification Program with thirty calendar (30) days prior written notice to the other party.

Cancellation of the Agreement causes the Certificate of Conformity to be immediately withdrawn and reported to the FDA as required in 21 CFR Part 1[2]. The Certificate of Conformity is the property of UL Registrar LLC and must be surrendered without delay upon request to do so. All Certification Marks provided for use by the organization shall be surrendered as well and all advertising bearing the marks removed immediately from use and/or public domain.

Upon submission of a signed contractual agreement (contract), the organization will be contacted by UL Registrar LLC scheduling personnel. At such time, the organization will be requested and required to provide a 30 day operating schedule (production schedule), for the purpose of scheduling the assessment at the earliest possible date. All assessments are unannounced[3].

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[2]21 CFR 1 Sub-part M 1.656 (d**) -** Immediate notification to FDA of withdrawal or suspension of a food or facility certification. An accredited third party certification body must notify FDA electronically, in English, immediately upon withdrawing or suspending any food or facility certification of an eligible entity and the basis for such action.

[3] 21 CFR 1 Sub-part M 1.600 - Food safety audit means a regulatory audit or a consultative audit that is conducted to determine compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and for consultative audits, also includes conformance with industry standards and practices. An eligible entity must declare that an audit is to be conducted as

Audit Scope
Unless otherwise specified and agreed to between UL R and the organization, the audit scope applies to one site/one supplier and includes the organizational structure, responsibilities, procedures, processes, and resources for implementing food safety and quality management systems in meeting specified food safety and management system objectives and regulatory requirements.
Multi-site organizations are assessed independently based on the design of operation management as describe below:

- Elements of an organization's food safety and quality system that may be within the audit scope are dependent upon the technical scope selected and agreed to with the applicant organization as follows:
- All applicable management and food safety systems will be audited according to the FSMA FDA Regulations per the applicant organization's agreement.
- Sufficient objective audit evidence should be available to demonstrate the operational aspects and overall effectiveness of the Code of Federal Regulations food safety and management systems.
- The resources committed to the audit must be sufficient to meet its intended scope and depth.

The Assessment Tool/Report utilized by UL R is guided by the regulatory status of the human and / or animal food farmed, produced, manufactured, packaged, stored, important and/or transported and included in scope of assessment as agreed to by the applicant:

- Any FDA Regulated Human Food will be assessed by Part 117 cGMP, Hazard Analysis Risk Based Preventative Controls for Human Food
- Any FDA regulated Animal Food will be assessed with the requirements listed in the Part 507 cGMP, Hazard Analysis Risk Based Preventative Controls for Animal Food.
- Any FDA regulated Produce Food process will be assessed with the requirements listed in Part 112 the Standards for the Growing, Harvesting, Packaging and Holding of Produce for Human Consumption
- Any FDA regulated Part 1 –Subpart O Sanitary Transportation of Human and Animal Food Final Rule
- Any FDA Regulated Part 1 – Subpart L Foreign Supplier Verification Program
- Any FDA Regulated Mitigation Strategies to Protect Food Against Intentional Adulteration

4.0 FSMA Pre-Certification On Site Assessment (Consultative Audit - for internal use only)
At the option of the organization, a pre-assessment (consultative audit[4]) can be conducted by UL Registrar LLC prior to the Initial FSMA Certification audit. This pre-assessment will be charged on a per diem basis at the prevailing daily rate. The pre-assessment is an activity that is used to measure the applicant's readiness for a full and formal (regulatory) audit.

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are regulatory audit or consultative audit at the time of audit planning and the audit will be conducted on an unannounced basis under this subpart.

[4] 21 CFR 1 Sub-part M 1.600 Consultative audit means an audit of an eligible entity: (i) To determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and industry standards and practices; (ii) The results of which are for internal purposes only; and (iii) That is conducted in preparation for a regulatory audit; only the results of a regulatory audit may form the basis for issuance of a food or facility certification under this subpart.

An Audit Summary Report will be left on-site with the organization at the conclusion of the assessment, but a formal "pre-assessment report" will NOT be issued to the organization. Consultative Audit Summary Reports shall not be provided to any other organization, as it is for internal use only (mandated by 21 CFR Part 1 Subpart M 1.600)

NOTE: The consultative audit (pre-assessment) is an activity of an eligible entity to determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and industry standards and practices. The results of which are for internal purposes only and that is conducted in preparation for a regulatory audit. Only the results of a regulatory audit may form the basis for issuance of a food or facility certification.

NOTE: Audit observations[5] and other data and information from the examination, including information on corrective actions, are documented and are used to support the findings contained in the audit report and maintained, as required by 21 CFR 1 Subpart M.

Regardless of whether the pre-assessment reveals significant omissions or deviations, UL R will notify the organization, in order to allow them time to make necessary corrections and implement those changes prior to the On-site, Initial Certification Assessment (Regulatory Audit) described in this procedure.

5.0 FSMA Initial Certification Assessment (Regulatory Audit) Process

The purpose of the Initial certification assessment (Regulatory Audit[6]) process is to determine that the organization has implemented acceptable food safety and quality systems in accordance with defined audit standards, as described herein. The initial certification assessment occurs in 2 stages: an off-site records review prior to an on-site examination, and the unannounced, on-site assessment. In order to ensure a successful outcome to the assessment, the Organization shall:

- Have effectively implemented food safety and quality management systems that meet the cGMP requirements for the technical scope(s) applied for. The formal assessment shall take place at the client's location.
- Have completed one complete round of internal audits
- Have appointed a "management or designated representative" who is responsible to oversee the safety of auditors while onsite and provide access to all documentation needed to seek an acceptable level of compliance and conformance to FSMA Certification Program requirements
- Have arranged to see that the assessment team has access to all parts of the organization's farm and/or facility, subcontractor's farm and/ or facilities, relevant documentation, and personnel for which the scope of assessment is being sought;
- Have performed monitoring, verification, measuring, and reviewing against key performance objectives, targets and preventive controls;
- Comply with applicable laws and statutes;
- Maintain operational control over processes;

[5] 21 CFR 1 Sub-part M 1651((4) Audit observations and other data and information from the examination, including information on corrective actions, must be documented and must be used to support the findings contained in the audit report required by §1.652 and maintained as a record under §1.658.

[6] 21 CFR 1 Sub-part M 1.600 (i) To determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations; and (ii) The results of which are used in determining eligibility for certification under section 801(q) or under section 806 of the FD&C Act.

- Maintain statistically valid sampling practices and procedures as required by industry standard and/or regulatory requirements sufficient to ensure acceptance and release
- of final products;
- Maintain policies with proper management responsibility and approval;
- Have defined links between various parts of the management system including: food safety policy, management policy, performance objectives, targets and preventive controls, applicable legal requirements, responsibility and competence of qualified personnel, operations, procedures, performance data, internal audit findings, and conclusions;
- Ensure that a minimum of up to three commercial batches for all products included in the requested scope have been produced and fully released;
- Ensure that the product(s) and/or a representative product(s) included within the requested scope of certification will be in operation at the time of audit. Failure to ensure that the product(s) and/or a representative product(s) included within the requested scope of certification are in production at the time of audit will result in an aborted audit at the client's expense.

Prior to commencing the formal (regulatory audit) assessment, the audit team will meet with the organization's management to conduct an opening meeting. An agenda will be provided in the opening meeting. The opening meeting is the first stage of the audit process.

The Opening Meeting
The opening meeting ensures that:

- The organization's personnel have a clear understanding of the certification assessment process and agenda;
- The organization's personnel are clear on the scope of the activity for which application has been made;
- All parties involved in the process are clear with regards to the primary contact person;
- There are no points of misunderstanding with respect to any areas of a sensitive nature and confidentiality is carefully maintained regarding proprietary aspects of the organization's operations;
- Management personnel are clear and committed regarding the purpose of the assessment;
- Classification of Nonconformities (Critical, Major and Minor) is understood by the organizations management to ensure all parties are clear regarding how the audit results will be reported and recorded;
- The organization has an understanding of the UL R Inquiry, Complaints, Disputes and Appeals Process Complaints and Appeals Process.

Upon completion of the opening meeting, a brief walk-through of the organization's physical premises will take place in order to orient the auditor of the location. Followed by an in-depth appraisal of each food safety and quality system component. This assessment will be conducted by the auditor in order to determine the adequacy of the organization's implementation of the specific regulatory requirement(s) pertinent to the organization's scope of certification.

As product standards specify cGMP conformance in regulated industries, UL Registrar LLC will verify that manufacturers are in conformance with the applicable manufacturing regulations. The

audit will be conducted based on the audit standards that are appropriate to the products being produced.

Dual Regulations under One Manufacturing Roof
In cases where the organizations with two or more types of regulated products, governed by two or more different FDA regulations, both standards will be utilized to carry-out the audit unless the certificate holder or audit client has specifically requested on their Application for Certification that UL R carry out one regulatory audit covering one FSMA scope.

If this is the case, the requested FSMA Scope will be specifically governed and carried out according to the auditee's request. In this case, UL R's audit activities, Certificate of Conformity and FSMA Audit Report will only cover the requested scope and corresponding products; unless the audit is conducted covering all Standards.

The organization will accept the risk of a re-audit if the FDA does not accept the requested single scope. UL R urges dual regulated organizations to have their audit cover all Standards allowing for the broadest scope of Certification coverage.

Note: Per 21 CFR Part 1[7], the FDA has the right to visit or conduct their own Food Safety Audit/Inspection whether or not the auditee is certified.

Aborting the Audit
An audit that has already been started may be aborted when, for example:

- The safety of the auditor is in question;
- The organization refuses to cooperate during the audit process;
- The organization requests that the audit be stopped;
- The auditor immediately determines that the organization's food safety and quality systems within the Audit Scope of this procedure are significantly non-conforming with the applicable standard(s) and/or regulations.
- The audit may be aborted if due to possible health risk or death to human or animal. I is highly recommended the facility productions cease and remain un-operational until clearance from the FDA. According to regulation UL R has to report the possible health risk to the FDA.[8]

Failure to ensure that the product(s) and/or a representative product(s) included within the requested scope of certification are in production at the time of audit will result in an aborted audit at the client's expense.

[7] 21 CFR 1 Subpart M 1.680 - FDA may, at any time, conduct an onsite audit of an eligible entity that has received food or facility certification from an accredited third-party certification body under this subpart. Where FDA determines necessary or appropriate, the unannounced audit may be conducted with or without the accredited third-party certification body or the recognized accreditation body (where applicable) present. An FDA audit conducted under this section will be conducted on an unannounced basis and may be preceded by a request for a 30-day operating schedule.

[8] 21 CFR 1 Subpart M 1.680 (c) - (c) Notification to FDA of a serious risk to public health. An accredited third-party certification body must immediately notify FDA electronically, in English, if during a regulatory or consultative audit, any of its audit agents or the accredited third-party certification body itself discovers a condition that could cause or contribute to a serious risk to the public health, providing the following information: (1) The name, physical address, and unique facility identifier, if designated by FDA, of the eligible entity subject to the audit, and, where applicable, the registration number under subpart H of this part; (2) The name, physical address, and unique facility identifier, if designated by FDA, of the facility where the condition was discovered (if different from that of the eligible entity) and, where applicable, the registration number assigned to the facility under subpart H of this part; and (3) The condition for which notification is submitted.

The audit must be re-scheduled at the earliest possible date the organization's operational schedule allows, when the organization has corrected or resolved the reason for stopping the audit.

The Closing Meeting
Pre Closing Meeting Activities After completion of the audit and prior to the closing meeting, the auditor will meet privately with the company's designated representative and will clearly identify deficient areas or non-conformances regarding the overall food safety and quality systems, which will require an organization to develop an appropriate corrective action plan (CAPA). CAPAs will be signed by the designated company representative and copies left on site by the auditor.

A formal closing meeting will be held on the final day of the assessment for the purpose of:

- Presenting a summary of the auditor's activities to management personnel present;
- Presenting the findings of the audit regarding matters of non-conformance (if applicable);
- Ensuring that the organization understands the classification of Nonconformities (Critical, Major and Minor) and to ensure all parties are clear regarding how the audit results will be reported and recorded;
- Listening to and acknowledging the organization's understanding of any non-conformance(s) which may be presented (if applicable);
- Communicating that any CAPA document must be signed by the management's representative and the auditor for each nonconformity noted;
- Presenting the auditor's recommendation concerning the issuance of a Certificate of Conformity;
- Answering any questions concerning the auditor's findings and recommendation to be made to the Certification Review Committee;
- Requesting that the organization provide any written comments or observations to UL Registrar LLC for consideration on improving the Certification process;
- Explaining that the ultimate decision with respect to Certification lies with UL R's Certification Committee;
- Explaining UL R post audit process and reporting, including notification to the FDA;
- Explaining that the FDA, as a regulatory governmental agency, has the right to refuse any certification given by any certification body, conduct an unannounced assessment and issue warning letters at any time before, during or after the audit. [9]

The Audit Summary and Audit Conclusions
An Audit Summary Report will be left on-site with the organization at the conclusion of the assessment.

The final Regulatory audit report will be provided to the Certification Committee without delay for processing.

[9] 21 CFR 1 Subpart M 1.653 - (3) FDA may refuse to accept any certification for purposes of section 801(q) or 806 of the FD&C Act, if FDA determines, that such food or facility certification is not valid or reliable because, for example: (i) The certification is offered in support of the admissibility of a food that was not within the scope of the certification; (ii) The certification was issued by an accredited third-party certification body acting outside the scope of its accreditation under this subpart; or (iii) The certification was issued without reliable demonstration that the requirements of paragraph (a) of this section were met.

Reports are required to be released by UL Registrar LLC to the organization, FDA[10], and ANSI[11] and any additional parties, as otherwise agreed to in advance between the audit client and UL R.

The Certification Committee will review all audit records along with other appropriate documentation and issue a final audit report, Certificate of Conformance and ANSI Accreditation Marks and when applicable, the UL R Certification Marks to the organization within a reasonable period of time after the decision to grant initial or continued certification. The organization shall not use any audit records or any part thereof in a misleading manner.

Assessment Results
All audit types will be assessed utilizing the methodology of the six system approach. The six systems evaluated will be the Quality System as a whole, plus the interaction with the Farm/Facilities and Equipment System, Production System, Material /Vendor/ Supply Chain System, Packaging System, and the Laboratory or Inspection System. Within each Assessment Tool/Narrative Checklist Report, each system contains the list of requirements intended to demonstrate effective control of the system and also, in cases deemed necessary to ensure consistency, guidance for the auditor on inspectional techniques and sampling to be used.

Within each system, the element of risk will be evaluated based on the UL Registrar LLC Process Evaluation Assessment of Risk, or PEAR.

The UL Risk Assessment is defined as a systematic process of organizing information to support a risk decision (Risk Priority Number (RPN) and Level of Risk Determination) to be made during the audit process.

UL's proprietary PEAR model uses a combination of risk based criteria generated from a detailed analysis matrix. The risk matrix takes into account the probability of nonconformance occurring and the likelihood and severity of risk to consumers and other stakeholders.

The PEAR and the FSMA Audit Tool take into account many factors, such as:

- FDA 483s
- FDA Warning Letters
- FDA Current “Hot Spots”
- Previous UL OTC CAPAs
- Recalls
- UL Technical Knowledge
- Personal Industry Experience
- Stakeholder Concerns

These criteria were selected in order to establish a Risk Priority Number (RPN) for each specific CFR Clause or Paragraph specific to the audit and/or Standard under assessment. A

[10] 21 CFR 1 Subpart M 1.623 (a) - (a) Reporting results of assessments of accredited third-party certification body performance. A recognized accreditation body must submit to FDA electronically, in English, a report of the results of any assessment conducted under §1.621, no later than 45 days after completing such assessment. The report must include an up-to-date list of any audit agents used by the accredited third-party certification body to conduct food safety audits under this subpart.
[11] 21 CFR 1 Subpart M 1.620 (b) - A recognized accreditation body must require a third-party certification body, as a condition of accreditation under this subpart, to comply with the reports and notification requirements of §§1.652 and 1.656 and to agree to submit to FDA, electronically and in English, any food or facility certifications it issues for purposes of sections 801(q) or 806 of the FD&C Act.

mathematical equation is used to generate a Final Risk Priority Number (FRPN) at the conclusion of the assessment.

The audit team will provide a risk level or quantitative output to the audit based on those requirements that can be verified as implemented and effective by the organization. Where conformance can be demonstrated and verified by the auditor, the Assessment Tool/Narrative Checklist Report will be scored with a “yes” and the organization will receive full credit for the value of the requirement listed. Where conformance to the requirement cannot be demonstrated, the organization will lose full credit for the stated requirement.

Nonconformities (CAPA) defined
The following nonconformance classifications shall be used during the audit as well as being documented in the audit reports:

Critical (CAPA) Nonconformity
A systemic failure of any system, procedure or process or failure to comply with required regulations that would have significant risk or cause harm to the user. Any deficiencies observed during the assessment that present a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death to humans and animals, will be classified as a critical nonconformity.

A critical nonconformity would preclude FSMA Certification until the nonconformity is corrected and verified effective upon completion of a follow-up audit of the facility. FSMA certification will be withheld or not granted until a written CAPA plan and root cause analysis is submitted and is accepted by UL Registrar LLC within 30 calendar days of issuance of the CAPA

An on-site re-audit shall be conducted to assure conformance to the requirements and for verification of effective action within 90 calendar days of the date the auditor accepted the CA Plan. Once the CAPA is closed and deemed effective, the certification (certificates and UL R and ANSI Accreditation Marks) will be issued.

For clients that underwent their Initial Certification/Recertification assessment and failed to demonstrate effective Corrective Action for a critical nonconformance shall be denied certification and the next audit activity will be an Initial Certification assessment.

Note: UL R is required to immediately notify the FDA of a serious risk to public health.

Major (CAPA) Nonconformity
A systemic failure of any system, procedure or process or failure to comply with required regulations that would have significant impact on the quality, strength, identity or purity of the product or the lack of a system, process or procedure required by regulations.

A major nonconformity would preclude FSMA Certification until the nonconformity is corrected and verified effective upon completion of a follow-up audit of the facility. FSMA Certification will be withheld or not granted until a written CAPA plan and root cause analysis is submitted and is accepted by UL Registrar LLC within 30 calendar days of issuance of the CAPA.

An on-site re-audit should be conducted to assure conformance to the requirements and for verification of effective action within 90 calendar days of the date the auditor accepted the CA Plan. Once the CAPA is closed and deemed effective, the certification (certificates and UL R Marks) will be issued.

Once the CAPA is closed, the certification will be granted. Failure to demonstrate effective corrective action for a major nonconformance shall result in suspension for the existing certificate until such time that effective corrective action has been demonstrated.

For clients that underwent their Initial Certification/Recertification assessment and failed to demonstrate effective Corrective Action for a major Nonconformance shall be denied certification and the next audit activity will be an Initial Certification assessment.

Minor (CAPA) Nonconformity
Failure to adhere to an approved policy, procedure, instruction or process or failure to comply with required regulations where:

- There is insufficient evidence to be classified as a major;
- There is little potential for significant health risk to the consumer;
- The quality, strength, identity, purity of the product has not been compromised.

A Minor Nonconformity requires a written Corrective Action plan and a cause analysis with a response to be submitted within 30 calendar days or as agreed to between the auditor and the auditee.

The minor nonconformity, corrective action plan and cause analysis must be accepted by UL Registrar LLC prior to awarding of the certification. A follow-up audit would be required if the factory grade falls within the Medium Risk or High Risk levels. The verification of effectiveness of CA taken will be followed up during the next annual audit activity. If the CA was verified as ineffective at the next annual audit activity, the nonconformance shall be documented as a new CAPA, and considered for elevation to a major nonconformance.

Additional Nonconformity Information
CAPA Plans submitted and not approved[12] will be resubmitted to the organization for follow-up and resubmission back to UL R with a 5 calendar day response time from the date of rejection by the auditor. In no case shall the time for responding with a CA Plan and a cause analysis exceed 45 calendar days. If factory does not respond or provide acceptable plans within 45 calendar days, certification will not be granted and/or existing certificates will be suspended.

The verification of effectiveness of CA taken will normally be followed up during the next recertification audit activity. If during the next annual audit activity the corrective action taken is found to be “not effective”, a new CAPA shall be issued and may be elevated to a major nonconformity as deemed necessary by the auditor and/or the Review Committee.

Once CAPA plans and root cause analysis[13] are approved, changes that are made by the organization to approved CA plans must be re-submitted to UL Registrar LLC.

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[12] 21 CFR 1 Subpart M 1.653 (a)(2) - If, as a result of an observation during a regulatory audit, an eligible entity must implement a corrective action plan to address a deficiency, an accredited third-party certification body may not issue a food or facility certification to such entity until after the accredited third-party certification body verifies that eligible entity has implemented the corrective action plan through methods that reliably verify the corrective action was taken and as a result the identified deficiency is unlikely to recur, except onsite verification is required for corrective actions required to address deficiencies that are the subject of a notification under §1.656(c).

[13] 21 CFR 1 Subpart M 1.653 (a)(3) - An accredited third-party certification body must consider each observation and the data and other information from a regulatory audit and other activities conducted under §1.651 to determine whether the entity was in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations at the time of the audit

When nonconformities/deficiencies are identified during the course of the assessment, additional deductions from the score shall be applied to render a final score. Nonconformities will be identified as either Critical, Major or Minor depending on the type of production and severity of the deficiency noted.

The UL Registrar LLC FSMA Risk Scoring Criteria

FINAL RISK PRIORITY NUMBER	RISK LEVEL
100 to 96	Reasonable Risk
95.99 to 89.99	Limited Risk
89.98 to 80.99	Average Risk
80.98 to 71.99	Medium Risk
71.98 and below	High Risk

Each audited facility will fall into one of the above risk levels and will receive an overall Risk Priority Number.

The risk levels can be defined as:

- Reasonable Risk: With all audit activities, there is assumed risk, but no current threats identified.
- Limited Risk: A minor departure from GMP/FSP (Food Safety Plan) Requirements.
- Average Risk: A minor departure from GMP/FSP/SOP Requirements, and objective evidence gathered during the audit that may conclude limited/no health risk to the consumer.
- Medium Risk: A Deviation from GMP/ FSP (i.e. departure from Regulations and Requirements) or for which a 483 may be issued by FDA and would conclude some health risk to the consumer.
- High Risk: Potential risk of harm/death to the user/warning letter may be issued by the FDA.

Additionally, the Final Risk Priority Number (FRPN) correlates to the level of risk deemed at the audited organization. Though this FRPN will look like a numerical score, it will simply express the level of risk based on a mathematical calculation associated with the level of risk noted on the PEAR. The audit tool and final report will not contain an overall numerical score. This enhanced tool is strictly risk-based, therefore the outcome of the audit is also strictly risk-based.

and whether the eligible entity, given its food safety system and practices, would be likely to remain in compliance for the duration of any certification issued under this subpart.

Requirements will be weighted based on the risk severity and probability of occurrence. Corrective Actions will be defined as Critical, Major and Minor. Any Critical or Major CAPAs will require a follow-up assessment, as will falling within the Medium and High Risk Levels

Audit Standards Defined
The standards for the FSMA audits for all products shall be the prevailing regulations as published in the Code of Federal Regulations, the Federal Register, FD&C Act and the Food Safety Modernization Act, and this FSMA Certification Program document with respect to all food for human and animal consumption.

In addition, any farm, producer, harvester or manufacturer (contracting work to another organization) and organization animal/ human food FSMA Regulations specific requirements may be included by specific reference, i.e., annual product reviews include but not limited to the food safety plan, supplier verification, etc.

If an organizations has more than one product that is regulated by the FDA under different audit scopes, the requirements specified in the paragraph entitled Dual Regulations under One Manufacturing Roof shall apply.

6.0 Contract Organizations

Contract Organization who conduct business on behalf of another entity whom are subject to the FSMA Regulations, must also have a consultative audit and/or annual regulatory audits. Regulatory Audit Certificates will be issued under the contractor's name to assure traceability of the supply chain, food safety and FDA Federal Regulations. Entities using contractors must conduct an assessment according to the scope to ensure the supply chain is not compromised, adulterated or misbranded. Upon this successful assessment the entities utilizing contractors may obtain a certificate under its brand.

7.0 The FSMA Certification Review

The purpose of the UL Registrar LLC Certification Review [14] is to review the auditor's audit summary report, notes, any checklist/audit report, audit schedule, CAPA's and recommendation for certification concerning the issuance of the UL Registrar LLC Certificate of Conformance. It is the responsibility of the Certification Committee to grant, issue, suspend, withdraw or withhold issuance of the certificate.

If the Certification is granted[15], UL Registrar LLC will:

- Notify the organization that a Certification Certificate has been granted for a period of one year. Provided Continued conformity with these procedures for certification;
- Provide the organization with a Certificate of Conformance;
- Authorize the organization to reference UL Registrar LLC certification in its advertising, subject to the provisions stated for their use in paragraph 13.0.

[14] 21 CFR 1 Subpart M 1.651 (c)(4)- Audit observations and other data and information from the examination, including information on corrective actions, must be documented and must be used to support the findings contained in the audit report required by §1.652 and maintained as a record under §1.658.
[15] 21 CFR 1 Subpart M 1.653 (a)(5) - (4) Audit observations and other data and information from the examination, including information on corrective actions, must be documented and must be used to support the findings contained in the audit report required by §1.652 and maintained as a record under §1.658.

- If the Certification Review Committee denies the granting of a certificate, the organization shall be notified in writing for the reasons for not awarding certification. All outstanding fees shall be paid at that time.

8.0 Recertification Audits

The FSMA Certification Program is an ongoing program with three year contract[16] to conduct audits annually, throughout the term of the contract with yearly certificates being issued upon completion of a successful yearly audit. The first year a Regulatory (Initial FSMA Certification) audits is conducted for any organization. Following the second and third year a Recertification (Regulatory) audits is conducted to obtain annual certification.[17] In the fourth year, a new contractual agreement will be generated and approved by the organization to continue in the FSMA Certification Program.

At least 90 days prior to the expiration date of the certificate, a recertification audit shall be conducted. The recertification audit will be the same duration as the initial (Regulatory) certification audit unless there has been a significant change in the number of employees, size of the location or number of items provided to the market.

The one year cycle of certification/ recertification assessments will continue until the organization chooses to end their participation in the program.

9.0 Modifications or Revisions to the Certificate of Conformity

The Certificate of Conformity is only valid at the location(s) that appear(s) on the certificate. Changes in ownership, physical location, key personnel, and/or changes in facilities must be provided in writing to UL Registrar LLC who will determine whether the changes impact the existing Certification. When there is a change in geographical location, or addition of a technical scope or product family, the Scope Extension form will be completed and returned to UL Registrar LLC. UL Registrar LLC will determine if a special audit is required in order to maintain the validity of the certificate.

After all audit fees have been paid, a revised Certificate of Conformity will be issued to the organization.

10.0 Complaints & Recalls

Regardless of the regulatory status of the products being produced, each organization must maintain records of all product complaints received from purchasers or other interested parties, including corrective measures taken to preclude those problems from recurring in the future. These records should be maintained in a separate file in order to be reviewed and evaluated as part of the effectiveness of the organization's quality system.

In the event of a warning letter, recall or market withdrawal of product that is covered and described on the certificate's scope of certification, UL Registrar LLC shall be notified via email to ULWarningsRecalls@ul.com without undue delay. Upon receipt of such notice, UL Registrar LLC performs a review of the recall or warning letter, including additional information from the

[16] 21 CFR 1 Subpart M 1.651 (b) - *Authority to audit.* In arranging a food safety audit with an eligible entity under this subpart, an accredited third party certification body must ensure it has authority, whether contractual or otherwise.

[17] 21 CFR 1 Subpart M 1.653 (b) - *Issuance of a food or facility certification and submission to FDA.* (1) Any food or facility certification issued under this subpart must be submitted to FDA electronically and in English. The accredited third-party certification body may issue a food or facility certification under this subpart for a term of up to 12 months.

firm, if necessary. A decision will be rendered regarding whether or not a special audit will be required and if a new certificate needs to be issued based on the recalled product or market withdrawal.

In any event, all recalls/withdrawals will be reviewed as part of the next FSMA audit. If analysis of a complaint or significant recall or if any other information indicates that the certified organization no longer conforms with these Procedures for Certification,

UL Registrar LLC's certification review committee reserves the right to suspend or withdraw Certification, as well as monitoring activities such as conducting an on-site assessment to verify whether or not the organization remains in compliance with the FSMA Certification Program and applicable regulations.

11.0 Withdrawing, Maintaining, Limiting, Extending & Suspending a Certification

An organization may at any time, may terminate its participation in the FSMA Certification Program with UL Registrar LLC. If an organization wishes to terminate its involvement with the FSMA Certification Program, the organization shall cease to make reference to involvement with the UL Registrar LLC FSMA Certification Program. It is the understanding of the organization that if they cease the FMSA Certification Program, they will likely be subjected to multiple audits from other organizations or the FDA.

UL Registrar LLC may, at its discretion[18], withdraw or suspend the Certification of an organization for cause such as violating the terms of Certification listed in this document or failure to notify UL Registrar LLC of any significant changes that may affect the food safety and quality of the products supplied to consumers, human and animal.

UL Registrar LLC also has the right to suspend or withdraw Certification and remove the organization's name from the certified companies list for failure to complete the next activity by the applicable anniversary date of the audit cycle. Upon suspension, withdrawal, or termination of certification, the client discontinues its use of all advertising matter that contains any reference thereto, returns the certificate, and takes any other required measure as requested by UL Registrar LLC.

UL Registrar LLC maintains an impartial and nondiscriminatory disputes and appeals program to evaluate the consideration of disputes and appeals against any and all decisions. (See Section 14.0)

UL Registrar LLC may terminate its certified organization for its use in accordance with this document.

The organization may refer to involvement with the UL Registrar LLC FSMA Certification Program and publish their Certification status and use the UL Certificate in any professional,

[18] 21 CFR 1 Subpart M 1.654 - If an accredited third-party certification body has reason to believe that an eligible entity to which it issued a food or facility certification may no longer be in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations, the accredited third-party certification body must conduct any monitoring (including an onsite audit) of such eligible entity necessary to determine whether the entity is in compliance with such requirements. The accredited third-party certification body must immediately notify FDA, under §1.656(d), if it withdraws or suspends a food or facility certification because it determines that the entity is no longer in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations. The accredited third-party certification body must maintain records of such monitoring under §1.658.

technical, trade or other business publication. Claims regarding certification must be consistent with the scope of certification.

Such references must not imply product be disclosed to any third party with the exception of the FDA and the accreditation body ANSI unless in response to legal process or the organization has requested such disclosure in writing, in which case UL Registrar LLC will notify the organization prior to disclosing the information.

Upon request UL Registrar LLC will send duplicate copies of a confidentiality agreement to the organization. One signed copy of the agreement should be signed and returned.

Certification program at any time provided that all qualified companies are notified at least six (6) months in advance.

UL R will immediate notify[19] the FDA electronically of withdrawal or suspension of a food or facility certification. Immediately upon withdrawing or suspending any food or facility certification of an eligible entity and the basis for such action.

After notifying FDA, UL R must immediately notify the eligible entity of such condition to ANSI [20]that granted its accreditation. Where feasible and reliable, the UL R may contemporaneously notify ANSI and/or the eligible entity when notifying FDA.

12.0 Certification Criteria Changes

As requirements change, UL Registrar LLC may revise this document and any checklists accordingly at any time.

When substantive changes are made to the Certification process, UL Registrar LLC will notify those organizations of the change(s) and if necessary, of the effective date, allowing the organization time to implement the change(s).

Proposed changes may be provided for review to all certified organizations. UL R may allow for a 30 calendar day review and comment period. Comments and/or feedback received within the 30 calendar days will either be communicated or handled directly with the petitioner or organization prior to implementation of such changes.

13.0 Use of Certificate of Conformity, Use of Certification Marks and Reference to FSMA Program Participation

The Certificate of Conformity and Certification Marks are the property of ANSI and UL Registrar LLC and is on loan to the organization. The client shall not use its certification in such a manner as to bring UL Registrar into disrepute and shall not make any statements regarding its certification that UL Registrar may consider misleading or unauthorized. Prior approval is

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[19] 21 CFR 1 Subpart M 1.656 (d) - *Immediate notification to FDA of withdrawal or suspension of a food or facility certification.* An accredited third party certification body must notify FDA electronically, in English, immediately upon withdrawing or suspending any food or facility certification of an eligible entity and the basis for such action.

[20] 21 CFR 1 Subpart M 1.656 (e) - *Notification to its recognized accreditation body or an eligible entity.* (1) After notifying FDA under paragraph (c) of this section, an accredited third-party certification body must immediately notify the eligible entity of such condition and must immediately thereafter notify the recognized accreditation body that granted its accreditation, except for third party certification bodies directly accredited by FDA. Where feasible and reliable, the accredited third-party certification body may contemporaneously notify its recognized accreditation body and/or the eligible entity when notifying FDA.

required by completing and signing the UL Registrar LLC Agreement for use of the FSMA Certificate and Certification Marks, which outlines correct use of the certificate and marks.

14.0 Inquiries, Complaints, Disputes, and Appeals

The Inquiries, Complaints, Disputes, and Appeals Committee will review all disputes and appeals from an applicant, certified organization or individual. The audit report/ CAPA, written testimony and any additional documents provided by the applicant will be reviewed prior to any decision being rendered.

The Certificate Holder may request a copy of the UL R Inquiries, Complaints, Disputes and Appeals process by written request to ULRegistrarQAReportRelease@UL.com.

15.0 Confidentiality

UL Registrar LLC maintains a high level of confidentiality at all levels of its organization concerning information obtained in the course of its business. No information will prior to the audit.

Reports must be released by UL Registrar LLC to the organization, FDA, ANSI and specified by the audit client and/or auditee or as otherwise agreed to in advance between the audit client and UL R.[21]

16.0 Accreditation

The certification services offered in this Procedure will be conducted in conformance with the ISO/IEC17065 Standard, UL R is pending accreditation[22] by the American National Standards Institute (ANSI) for the FSMA Certification Program. UL R is required by accreditation bodies to share information for the purpose of demonstrating conformance to the standards for which UL R is accredited. Such records may include audit results and UL Registrar's certification processes and procedures. If the certification client does not wish to allow their records to be shown to the accreditation body, notification must be provided to UL R in writing. UL Registrar holds confidentiality agreements with all accreditation bodies.

For more information, please contact ULRInfo@ul.com.

[21]FDA 21 CFR 1 Subpart M 1.652 (a) Consultative audits. An accredited third-party certification body must prepare a report of a consultative audit not later than 45 days after completing such audit and must provide a copy of such report to the eligible entity and must maintain such report under §1.658, subject to FDA access in accordance with the requirements of section 414 of the FD&C Act.
FDA 21 CFR 1 Subpart M 1.656 (a) Reporting results of regulatory audits. An accredited third-party certification body must submit a regulatory audit report, as described in §1.652(b), electronically, in English, to FDA and to the recognized accreditation body that granted its accreditation (where applicable), no later than 45 days after completing such audit.

[22] 21 CFR 1 Subpart M 1.600 - Accredited third-party certification body means a third-party certification body that a recognized accreditation body (or, in the case of direct accreditation, FDA) has determined meets the applicable requirements of this subpart and is accredited to conduct food safety audits and to issue food or facility certifications to eligible entities. An accredited third party certification body has the same meaning as accredited third-party auditor as defined in section 808(a)(4) of the FD&C Act.

Appendix – Procedure certification terms and definitions

(a) The *FD&C Act* means the Federal Food, Drug, and Cosmetic Act.

(b) Except as otherwise defined in paragraph (c) of this section, the definitions of terms in section 201 of the FD&C Act apply when the terms are used in this subpart.

(c) In addition, for the purposes of this subpart:

Accreditation means a determination by a recognized accreditation body (or, in the case of direct accreditation, by FDA) that a third-party certification body meets the applicable requirements of this subpart.

Accreditation body means an authority that performs accreditation of third-party certification bodies.

Accredited third-party certification body means a third-party certification body that a recognized accreditation body (or, in the case of direct accreditation, FDA) has determined meets the applicable requirements of this subpart and is accredited to conduct food safety audits and to issue food or facility certifications to eligible entities. An accredited third party certification body has the same meaning as accredited third-party auditor as defined in section 808(a)(4) of the FD&C Act.

Assessment means:

(i) With respect to an accreditation body, an evaluation by FDA of the competency and capacity of the accreditation body under the applicable requirements of this subpart for the defined scope of recognition. An assessment of the competency and capacity of the accreditation body involves evaluating the competency and capacity of the operations of the accreditation body that are relevant to decisions on recognition and, if recognized, an evaluation of its performance and the validity of its accreditation decisions under the applicable requirements of this subpart.

(ii) With respect to a third-party certification body, an evaluation by a recognized accreditation body (or, in the case of direct accreditation, FDA) of the competency and capacity of a third-party certification body under the applicable requirements of this subpart for the defined scope of accreditation. An assessment of the competency and capacity of the third-party certification body involves evaluating the competency and capacity of the operations of the third-party certification body that are relevant to decisions on accreditation and, if accredited, an evaluation of its performance and the validity of its audit results and certification decisions under the applicable requirements of this subpart.

Audit means the systematic and functionally independent examination of an eligible entity under this subpart by an accredited third-party certification body or by FDA. An audit conducted under this subpart is not considered an inspection under section 704 of the FD&C Act.

Audit agent means an individual who is an employee or other agent of an accredited third-party certification body who, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited third-party certification body. An audit agent includes a contractor of the accredited third-party certification body but excludes subcontractors or other agents under outsourcing arrangements for conducting food safety audits without direct control by the accredited third-party certification body.

Consultative audit means an audit of an eligible entity:

(i) To determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and industry standards and practices;

(ii) The results of which are for internal purposes only; and

(iii) That is conducted in preparation for a regulatory audit; only the results of a regulatory audit may form the basis for issuance of a food or facility certification under this subpart.

Direct accreditation means accreditation of a third-party certification body by FDA.

Eligible entity means a foreign entity in the import supply chain of food for consumption in the United States that chooses to be subject to a food safety audit under this subpart conducted by an accredited third-party certification body.

Eligible entities include foreign facilities required to be registered under subpart H of this part.

Facility means any structure, or structures of an eligible entity under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, holds, grows, harvests, or raises animals for food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership. The private residence of an individual is not a facility. Non-bottled water drinking water collection and distribution establishments and their structures are not facilities. Facilities for the purposes of this subpart are not limited to facilities required to be registered under subpart H of this part.

Facility certification means an attestation, issued for purposes of section 801(q) or 806 of the FD&C Act by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish whether a facility complies with the applicable food safety requirements of the FD&C Act and FDA regulations.

Food has the meaning given in section 201(f) of the FD&C Act, except that food does not include pesticides (as defined in 7 U.S.C. 136(u)).

Food certification means an attestation, issued for purposes of section 801(q) of the FD&C Act by an accredited third-party certification body, after conducting a regulatory audit and any other activities necessary to establish whether a food of an eligible entity complies with the applicable food safety requirements of the FD&C Act and FDA regulations.

eCFR — Code of Federal Regulations

http://www.ecfr.gov/cgi-bin/text-idx?SID=4d0e560ac34ad637273d2c140d29367b&mc=true&node=pt21.1.1&rgn=div5#sp21.1.1.c

Food safety audit means a regulatory audit or a consultative audit that is conducted to determine compliance with the applicable food safety requirements of the FD&C Act, FDA regulations, and for consultative audits, also includes conformance with industry standards and practices. An eligible entity must declare that an audit is to be conducted as a regulatory audit or consultative audit at the time of audit planning and the audit will be conducted on an unannounced basis under this subpart.

Foreign cooperative means an autonomous association of persons, identified as members, who are united through a jointly owned enterprise to aggregate food from member growers or processors that is intended for export to the United States.

Recognized accreditation body means an accreditation body that FDA has determined meets the applicable requirements of this subpart and is authorized to accredit third-party certification bodies under this subpart.

Regulatory audit means an audit of an eligible entity:

(i) To determine whether such entity is in compliance with the applicable food safety requirements of the FD&C Act and FDA regulations; and (ii) The results of which are used in determining eligibility for certification under section 801(q) or under section 806 of the FD&C Act.

Relinquishment means:

(i) With respect to an accreditation body, a decision to cede voluntarily its authority to accredit third-party certification bodies as a recognized accreditation body prior to expiration of its recognition under this subpart; and

(ii) With respect to a third-party certification body, a decision to cede voluntarily its authority to conduct food safety audits and to issue food and facility certifications to eligible entities as an accredited third-party certification body prior to expiration of its accreditation under this subpart.

Self-assessment means an evaluation conducted by a recognized accreditation body or by an accredited third-party certification body of its competency and capacity under the applicable requirements of this subpart for the defined scope of recognition or accreditation. For recognized accreditation bodies this involves evaluating the competency and capacity of the entire operations of the accreditation body and the validity of its accreditation decisions under the applicable requirements of this subpart. For accredited third-party certification bodies this involves evaluating the competency and capacity of the entire operations of the third-party certification body and the validity of its audit results under the applicable requirements of this subpart.

Third-party certification body has the same meaning as third-party auditor as that term is defined in section 808(a)(3) of the FD&C Act and means a foreign government, agency of a foreign government, foreign cooperative, or any other third party that is eligible to be considered for accreditation to conduct food safety audits and to certify that's eligible entities meet the applicable food safety requirements of the FD&C Act and FDA regulations. A third-party certification body may be a single individual or an organization. Once accredited, a third-party certification body may use audit agents to conduct food safety audits.