BRC GLOBAL STANDARD

AGENTS AND BROKERS ISSUE 2

FSMA GUIDANCE AND PREPAREDNESS MODULE FOR AGENTS AND BROKERS

(applicable to importers of record, retailers and manufacturing sourcing)

CONTENTS

FSMA Preparedness for Agents and Brokers Module

The Brokers role and FSMA

At time of writing, the regulatory requirements for the role of agent or broker are not clear (with the exception of the importer of record). By definition, the agent or broker does not "produce or hold" product, therefor many of the regulations do not apply directly to their actions.

That being said, the role of the agent or broker is an important one, and just as a broker acts as a facilitator to the movement of product between producer source and customer, BRC has recognized the equally important role the broker has in supplier approval for those customers. Hence this module is designed to a certain degree to show where the regulations may impact the activity of the broker or agent, but primarily designed to allow the agent or broker to be a source for appropriate supplier approval information to move from the producer to customer. In the age of FSMA, it is no longer acceptable to facilitate product movement, the agent or broker must facilitate product movement and proof of compliance. Most of the requirements are laid out in such a way so that the broker uses it as part of their supplier approval, and is able to provide that supplier approval evidence to their customers. This way a broker can be closer to a "complete solution" to their customers.

Suppliers and GFSI benchmarked certifications

It is widely recognized that a GFSI benchmarked certification is a solid mechanism to assess compliance to most requirements within FSMA regulations. It is also recognized that at the time of writing, no scheme in and of itself fully meets the requirements prescriptively. Where a GFSI benchmarked scheme has an additional module to cover gaps or prescriptively identify evidence of compliance, this should be used. Where none exists, additional evidence may be required, depending on the gaps between the scheme requirements and FSMA. **To obtain information on the BRC Food Global Standard FSMA Preparedness Addendum for you suppliers, contact enquiries@BRCGlobalStandards.com**

How to use this module

This module supports agents and brokers in understanding how new regulations established under the U.S. Food Safety Modernization Act (FSMA) apply to the company's business activities. It is divided into four parts, which includes the Checklist, Appendix 1, Glossary, and References. The checklist identifies those legislative requirements across the suite of FSMA rules, which BRC recommends that—all agents

and brokers selling or trading food in the U.S. –establish and implement as a part of their food safety and quality management system for stability and transparency in supply chain operations.

The checklist addresses compliance requirements across the following FSMA rules, which have applicability to various types of agent and broker operations.

- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals
- Foreign Supplier Verification Programs for Importers of Food for Humans and Animals
- Mitigation Strategies to Protect Food Against Intentional Adulteration
- Sanitary Transportation of Human and Animal Food

The Foreign Supplier Verification Program and Sanitary Transportation rules have the greatest applicability to most agent and broker operations, thus the BRC has identified the prescriptive elements of these rules in the checklist to support agents and brokers in regulatory compliance. ***It is important to note that the BRC has established requirements of the FSVP rule, which are in addition to those required by the BRC Global Standard for Agents and Brokers, as best practice for all agents and brokers and does limit these requirements to U.S. importers as defined by the regulation***. In creating this module, the BRC aims to support agents and brokers in risk management and regulatory compliance when purchasing or trading food products sold in the U.S. regardless of whether they are sourced from a foreign or domestic (U.S. based) supplier.

Satisfying the requirements of either checklist does not guarantee compliance with U.S. legislation. Rather, compliance with the module provides clear guidance to help agents and brokers navigate the suite of FSMA rules. Examples provided throughout this module are for illustrative purposes to aid in the interpretation of BRC requirements and do not authoritatively determine the regulation or exclusion of agent and broker activities. Full regulatory compliance with FSMA legislation is the responsibility of the company.

Appendix 1 correlates some agent and broker activities with FSMA legislation to help agents and brokers determine which FSMA rules regulate their business activities. Key terms used in the following checklist are defined in the Glossary to aid in interpretation of module requirements. Additionally, a list of legislative and training references are provided to support agents and brokers in regulatory compliance.

6 Requirements of the FSMA Preparedness for Agents and Brokers Module

Clause	Checklist Item	Guidance
6.1 Preventive Controls for Human Food **Does this section apply to me?** Preventive Controls regulation is applicable to product suppliers, importers of record, and potentially to others in scope. Any facility that produces or holds product destined for the U.S. is generally required to register with the FDA as a food facility, and re-register every 2 years. For clarification, Google "registration of food facilities – FDA" or refer to guidance documents listed in the References section of the Standard. **If yes, consider the following:** Statement of Intent: The company shall assess its business operations for the need to comply with U.S. regulation 21 CFR part 117 and document compliance where required.		
6.1	The company shall comply with U.S. regulation 21 CFR part 117: *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food* where the company additionally manufactures, processes, packs, or holds food for sale in the United States and is required to register as a food facility per section 415 of the U.S. Food, Drug & Cosmetic Act (FD&C).	The company shall determine if it is required to register with the U.S. Food and Drug Administration (FDA) as a food facility according to legislative requirements set forth in FD&C, section 415. This applies to domestic (U.S. based) and foreign companies. Where a company is based outside of the U.S. territory and is required to register with FDA as a food facility due to business operations, the company must designate a U.S. representative. This process of determining the need to meet regulations is equally required for the suppliers to the broker or agent. Where a company determines it must register as a food facility with the FDA, it must then determine if its business operations are regulated by 21 CFR part 117 (Preventive Controls for Human Food rule). For example, where an agent or broker holds (or manages the holding of) food products covered under the scope of the rule in a company owned warehouse, the company is required to comply and establish a written hazard analysis, written preventive controls and written monitoring, corrective action and verification procedures. The scope of Preventive Controls for Human Food requirements are covered in the BRC Global Standard for Food Safety and accompanying FSMA Preventive Controls Preparedness Module. Additionally, certification to the BRC Global Standard for Storage and Distribution may support in achieving partial compliance with 21 CFR part 117 for storage and distribution facilities. **Regulatory Reference: 21 CFR part 117**

6.2 Preventive Controls for Animal Food

Does this section apply to me?

Preventive Controls regulation is applicable to product suppliers, importers of record, and potentially to others in scope.

Any facility that produces or holds product destined for the U.S. is generally required to register with the FDA as a food facility, and re-register every 2 years.

For clarification, Google "registration of food facilities – FDA" or refer to guidance documents listed in the References section of the Standard.

If yes, consider the following:

Statement of Intent: The company shall assess its business operations for the need to comply with U.S. regulation 21 CFR part 507 and document compliance where required.

6.2	The company shall comply with U.S. regulation 21 CFR part 507: *Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals* where the company additionally manufactures, processes, packs, or holds food for sale in the United States and is required to register as a food facility per section 415 of the U.S. Food, Drug & Cosmetic Act (FD&C).	The company shall determine if it is required to register with the U.S. Food and Drug Administration (FDA) as a food facility according to legislative requirements set forth in FD&C, section 415. This applies to domestic (U.S. based) and foreign companies. Where a company is based outside of the U.S. territory and is required to register with FDA as a food facility due to business operations, the company must designate a U.S. representative. Where a company determines it must register as a food facility with the FDA, it must then determine if its business operations are regulated by 21 CFR part 507 (Preventive Controls for Animal Food rule). For example, where an agent or broker holds pet food products covered under the scope of the rule in a company owned warehouse, the company is required to comply and establish a written hazard analysis, written preventive controls and written monitoring, corrective action and verification procedures. The scope of Preventive Controls for Animal Food requirements are primarily covered in the BRC Global Standard for Food Safety and accompanying FSMA Preventive Controls Preparedness Module. Additionally, certification to the BRC Global Standard for Storage and Distribution may support in achieving partial compliance with 21 CFR part 507 for storage and distribution facilities. **Regulatory Reference: 21 CFR part 507**

6.3 Food Defense

Does this section apply to me?

This clause is applicable to product suppliers, importers of record, and potentially to others in scope.

If yes, consider the following:

Statement of Intent: The company shall assess its business operations for the need to comply with U.S. regulation 21 CFR part 121 and document compliance where required.

6.3	The company shall comply with U.S. regulation 21 CFR part 121: *Mitigation Strategies to Protect Food*	The company shall determine if it is required to register with the U.S. Food and Drug Administration (FDA) as a food facility according to legislative requirements set forth in FD&C, section 415. This applies to domestic (U.S. based) and foreign companies. Where a company is based

	Against Intentional Adulteration where the company additionally manufactures, processes, packs, or holds food for sale in the United States and is required to register as a food facility per section 415 of the U.S. Food, Drug & Cosmetic Act (FD&C).	outside of the U.S. territory and is required to register with FDA as a food facility due to business operations, the company must designate a U.S. representative. Where a company determines it must register as a food facility with the FDA, it must then determine if its business operations are regulated by 21 CFR part 121 (Food Defense rule). For example, the company shall develop and implement a written food defense plan for holding food stored in liquid storage tanks but is excluded from this requirement for other holding activities. Additionally, the requirement to develop a food defense plan does not apply to packing and labeling activities where the container in direct contact with the food remains intact nor does it apply to food for animals. Certification to the BRC Global Standard for Food Safety or Storage and Distribution may support in achieving partial compliance with 21 CFR part 121. **Regulatory Reference: 21 CFR part 121**
6.4 Supplier Verification Program **Does this section apply to me?** This clause is applicable to all agents and brokers, importers of record, and potentially to others in scope. **If yes, consider the following:** Statement of Intent: The company shall establish a Supplier Verification Program to cover the scope of all suppliers (foreign and domestic) used to source food for sale in the U.S., which is compliant with the requirements of 21 CFR part 1 subpart L. Of particular note to brokers dealing with dietary supplements and their components: The FSVP rule has some modified requirements for agents and brokers purchasing or trading dietary supplements. This is defined in section 1.511 of the rule. It basically requires same provisions outlined in section 6.4 below but requires compliance with cGMP's as specified by 21 CFR part 111.		
6.4.1	The company shall ensure that all suppliers used to source food sold in the U.S. produce such food in compliance with sections 402, 403(w), 418, and 419 of the U.S. Food, Drug & Cosmetic Act (FD&C).	FD&C, section 402 defines adulterated food. FD&C, section 403(w) defines misbranded food. FD&C, section 418 requires that owners, operators or agents in charge of registered food facilities evaluate food hazards, apply preventive controls to ensure food is not adulterated or misbranded, and monitor the performance of applied controls. FD&C, section 419 requires farms that produce and harvest raw agricultural commodities (fruits and vegetables) to develop and implement procedures, practices and processes to minimize the risk of food hazards and ensure produce is not adulterated. Supplier compliance with U.S. legislation shall be documented through a Supplier Verification Program, written assurances and other applicable methods. **Regulatory Reference: 21 CFR part 1 subpart L (1.502)**
6.4.2	One or more Qualified Individuals shall be identified on the	Qualified Individuals are responsible for performing all activities of the Supplier Verification Program. This includes but is not limited to:

	organization chart with responsibility for activities of the company's Supplier Verification Program. Qualified Individuals with responsibility for record review must read and understand the language of the record requiring review. For importers of record, a Qualified Individual is mandatory. It is recommended that all companies dealing in the US appoint and support a Qualified Individual within the organization. Suppliers that process or hold product, must have a designated and supported Preventative Controls Qualified Individual.	• Establishing the Supplier Verification Program in compliance with the requirements of this Standard • Conducting a written hazard analysis in accordance with clause 6.4.5 • Conducting and reviewing supplier risk assessments in accordance with clauses 6.4.6 and 6.4.7 • Ensuring the use of approved or temporary suppliers in accordance with clause 6.4.8 • Establishing and conducting supplier verification activities in accordance with clause 6.4.9 – 6.4.11 • Maintaining written assurance from subsequent manufacturers regarding the control of hazards in compliance with clause 6.4.12 • Ensuring hazard labeling in accordance with clause 6.4.12 • Conducting a review of the Supplier Verification Program and updating in accordance with clause 6.4.13 • Documenting changes to the Supplier Verification Program in accordance with clause 6.4.14 • Recordkeeping activities in accordance with clause 6.4.15 **Regulatory Reference: 21 CFR part 1 subpart L (1.503a)**
6.4.3	Each designated Qualified Individual shall have completed the Food Safety Preventive Controls Alliance (FSPCA) Foreign Supplier Verification Program training course. A record documenting completion of the course must be maintained.	Qualified Individuals shall have completed the approved FDA training course for developing and implementing a Foreign Supplier Verification Program. While this training course focuses on specific regulatory requirements for importers, the BRC recommends this course for all Qualified Individuals complying with the requirements of this module as it describes how to conduct a hazard analysis, supplier risk assessment and determine appropriate supplier verification activities for the sourcing of food products compliant with U.S. legislation. Where the agent or broker processes or holds product, they will additionally need to designate a PCQI who has taken the FSPCA training for Preventive Controls and may need to take Food Defense training (e.g., if they process food or hold bulk liquid). Note: food defense training and a food defense plan would not be required if the company only holds packaged product. **Regulatory Reference: 21 CFR part 1 subpart L (1.503a)**
6.4.4	A Qualified Auditor, independent of the supplier, shall be responsible for conducting an onsite audit where this is performed as a verification activity of the company's Supplier Verification Program.	A Qualified Auditor shall be a trained and experienced food safety auditor with knowledge of the food category being evaluated, the requirements of this Standard and applicable U.S. food legislation. Where an onsite audit is an established verification activity for a supplier, the Qualified Auditor shall conduct the assessment on behalf of the company. Examples of qualified auditors may be registered auditors with GFSI benchmarked schemes, government inspectors or appropriately trained and experienced second-party auditors.

		While not mandatory—but strongly recommended based on current interpretations of FSMA regulation—company managed auditors should receive the Qualified Individual training noted in clause 6.4.3 in addition to qualifications in audit technique and category risk assessment. **Regulatory Reference: 21 CFR part 1 subpart L (1.503b)**
6.4.5	Conduct a written hazard analysis for **each food type** purchased or traded by the company, which is sold in the U.S., to identify known or reasonably foreseeable hazards associated with the food or facility. This includes: • Naturally occurring hazards • Economic adulterants which affect food safety • Environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step • Radiological hazards • Unintentional adulterants which affect food safety	A Qualified Individual is responsible for conducting a written hazard analysis, which identifies and evaluates all known or reasonably foreseeable hazards for each food type purchased or traded by the company where that food is offered for sale in the U.S. Similar to Codex Alimentarius HACCP methodology, the hazard analysis must include an assessment of the severity of illness or injury and likelihood of occurrence if the hazard were to occur in the absence of CCP's and/or preventive controls. The hazard analysis must consider known or reasonably foreseeable hazards in all • Materials (or material groups) • Process steps • Production environment • Supply and distribution chain activities • Intended and reasonably foreseeable use • Other related activities A company's existing hazard analysis—developed in compliance with section 2 of this Standard—should be reevaluated in consideration of the provisions of this module requirement for regulatory compliance. For example, a company may need to integrate or cross-reference material risk assessments, supplier risk assessments and/or security risk assessments into the hazard analysis. The company may utilize a supplier's hazard analysis provided that it was conducted by a Qualified Individual as defined in clauses 6.4.2 and 6.4.3 of this Standard. The company is responsible for reviewing and assessing the supplier's hazard analysis for integration into its own. Examples of naturally occurring hazards include heavy metals or mycotoxins. Unintentionally introduced hazards may refer to pathogen cross-contamination or allergen cross-contact. Intentionally introduced hazards for economic gain include economically motivated adulterants (EMA's) such as melamine or other harmful substitution ingredients (e.g., industrial oil, wood pulp, etc.). Radiological hazards must be identified and evaluated where there is a known prevalence in the raw material or ingredient due to sourcing from a susceptible region or where materials or the food product has the potential to be contaminated (e.g., from water sources in susceptible areas) Additionally, the hazard analysis must evaluate environmental pathogens where a ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step to eliminate or significantly minimize the pathogen. Examples of environmental pathogens include *Salmonella* spp. (typically found in dry processing environments) and *Listeria monocytogenes* (common in wet

		processing environments) although these pathogens are generally ubiquitous in food handling and processing environments. **Regulatory Reference: 21 CFR part 1 subpart L (1.504)**
6.4.6	Conduct and document a supplier risk assessment, which evaluates a supplier's performance and risk posed by the food. Supplier approval criteria as required by clause 4.1.1 and supplier verification activities as required by clause 6.4.10 of this Standard shall be based on the supplier risk assessment required by this clause.	A Qualified Individual is responsible for conducting a written supplier risk assessment in compliance with clause 4.1.1 of this Standard, which shall additionally include an evaluation of • Hazards requiring a control • Entity administering the control • Supplier's food safety procedures and practices • Supplier performance based on food safety history • FDA regulatory compliance • Storage and transportation practices The company may utilize an established risk assessment for a given supplier to conduct the supplier risk assessment required by this clause provided that it was conducted by an entity other than the foreign supplier (i.e., no self-evaluation) and performed by a Qualified Individual as defined in clauses 6.4.2 and 6.4.3 of this Standard. The company is responsible for reviewing and assessing the established risk assessment for integration into its own supplier risk assessment. The supplier risk assessment shall serve as the basis for determining supplier approval and appropriate supplier verification activities (including frequency) as required by the applicable requirements of this Standard. **Regulatory Reference: 21 CFR part 1 subpart L (1.505a)**
6.4.7	Review the supplier risk assessment when new information about risk assessment criteria raises additional concerns as to the safety or legality of the food or, at a minimum, every 3 years if new information does not trigger a review. Document each review of the supplier risk assessment.	A Qualified Individual is responsible for reevaluating the supplier risk assessment when new information raises additional concerns about one or more suppliers and the food produced. For example, the supplier risk assessment shall be reevaluated where a new hazard requiring a control emerges for a food purchased or traded by the company. Alternatively, it shall be reevaluated where the supplier has received an FDA warning letter, import alert or other food safety compliance action from another country's food safety agency. Additionally, it may need to be reevaluated where an onsite verification audit reveals changes to a food safety procedure or practice resulting in audit non-conformities. Where new information changes a supplier's risk ranking, this shall prompt the company to reconsider the supplier's approval status and whether verification activities and frequency need to be changed. At a minimum, the supplier risk assessment shall be reevaluated every 3 years where new information does not trigger an earlier review. **Regulatory Reference: 21 CFR part 1 subpart L (1.505c)**
6.4.8	The company shall purchase or trade food from an approved supplier according to the supplier approval procedure established for compliance	The supplier approval procedure shall describe the process and responsibility for approving suppliers and ensuring that the company only purchases from approved suppliers. The procedure shall additionally describe the process and responsibility for using unapproved suppliers by exception on a temporary basis, which

	with clauses 4.1.1 and 4.1.6 of this Standard. Where a temporary situation requires the use of an unapproved supplier, the approval procedure shall document the process and conditions for this exception, which shall include adequate verification before trading, purchasing or importing. Use of the supplier approval procedure shall be documented.	shall include the requirement for conducting supplier verification activities before purchasing or trading. Use of the supplier approval procedure shall be recorded by a Qualified Individual. **Regulatory Reference: 21 CFR part 1 subpart L (1.506a)**
6.4.9	Establish and implement a written procedure(s), which describes the process for ensuring supplier verification activities are conducted to provide assurance that hazards are significantly minimized or prevented.	The supplier verification procedure shall describe the process and responsibility for ensuring that the following activities are conducted for all suppliers: • Use of approved suppliers based on the outcome of a supplier risk assessment • Determination of supplier verification activities, which provide assurance that hazards are significantly minimized or prevented • Determination of verification activities and frequency based on the outcome of a supplier risk assessment • Implementation of verification activities before purchasing or trading • Implementation of verification activities at the determined frequency following initial use of supplier • Recordkeeping requirements for all supplier verification activities Documented processes for supplier verification activities required by clauses 4.1.2, 4.1.5, 4.4.1, and 4.5.1 of this Standard should be reevaluated in consideration of the provisions of this module requirement for regulatory compliance. For example, a company may need to integrate or cross-reference its procedures for ongoing review of supplier performance, verification of buying specs through product sampling and testing, and other verification activities which are conducted to ensure the legality of products in the country of sale. **Regulatory Reference: 21 CFR part 1 subpart L (1.506b-c)**
6.4.10	Determine and document appropriate verification activities for **each supplier** before trading, purchasing or importing and periodically thereafter. Verification activities must include one or more of the following commensurate with the level of risk determined in the supplier risk assessment:	A Qualified Individual is responsible for determining and documenting verification activities for each supplier based on risk. Initial and ongoing supplier approval activities established for compliance with clause 4.1.2 of this Standard may be identified as supplier verification activities where all conditions of clause 6.4.11 are met. An example of this would be certification of the supplier to a GFSI benchmarked scheme, which includes assessment of regulatory compliance with applicable FDA regulation (e.g., Preventive Controls or Produce Safety rules). Additionally, ongoing review criteria established in clause 4.1.5, product sampling and testing established in clause 4.4.1, and/or activities which verify the legality of products established in clause 4.5.1 may be used as

	• Onsite audit by a Qualified Auditor • Product sampling and testing • Review of supplier's food safety records • Other appropriate activities, which verify that hazards are controlled and are based on the supplier's performance and risks associated with the food For serious hazards, an annual onsite audit is required. Serious hazard typically includes ready-to-eat products, as well as any product or commodity that has been linked to a health incident in the U.S. in the past.	verification activities where all conditions of clause 6.4.11 are met. An example of this would be lot or batch specific testing for a hazard controlled by the supplier (e.g., *Salmonella*) according to a statistically valid sampling plan for detection of the hazard where present. Other verification activities more appropriate to ensure hazards are effectively controlled by the supplier or less frequent audits may be applied where documented justification is provided. **Regulatory Reference: 21 CFR part 1 subpart L (1.506d)**
6.4.11	Conduct verification activities initially and periodically thereafter according to the following criteria. (1) Onsite audits shall be performed by a Qualified Auditor and include assessment of the food safety plan and compliance with FDA regulation where applicable. (2) Product sampling and testing shall identify the lot or batch, number of samples, method of analysis, results, and laboratory conducting the test. (3) Record review shall pertain to relevant records of the supplier's food safety system with documented conclusions. (4) Verification activities may not be performed by the supplier with the	Supplier verification shall be conducted by a Qualified Individual according to the activity and frequency determined in 6.4.10. Verification activity results—whether conducted by the company or another entity—shall be promptly reviewed and assessed by a Qualified Individual. Where results do not provide assurance as to the safety of the food, corrective action shall be applied in accordance with clauses 3.9.1 and 6.4.13 of this Standard. Qualified Individuals conducting or reviewing verification activities shall be free of financial conflict of interest. For onsite audits, a record of the audit report to include date, auditing firm, Qualified Auditor, results, non-conformity and associated corrective action shall be maintained by the company. FDA inspection results—or regulatory inspection by a country whose food safety system is recognized as equivalent by FDA—may suffice for an annual audit. Product sampling and testing shall meet the requirements of section 4.4 of this Standard in addition to ensuring documentation (e.g., Certificates of Analysis) conforms to the requirements of this clause. Where a hazard is detected through product testing, corrective action shall be linked to the out-of-specification result. Each review of a supplier's food safety records shall be documented and identify the date, records reviewed, outcome, and applicable corrective actions. Where other verification activities are utilized, records of the activity shall be maintained. **Regulatory Reference: 21 CFR part 1 subpart L (1.506e)**

	exception of sampling and testing. (5) Qualified Individuals shall conduct or review verification activities.	
6.4.12	Where a known or reasonably foreseeable hazard is not controlled by the supplier, the company shall have annual written assurance from a subsequent manufacturer that they (or a downstream party) are responsible for controlling a hazard in compliance with Preventive Controls or other applicable legislation. Where the hazard is subsequently controlled, product documents used for sale, trade or importation, shall identify the food as "not processed to control [identified hazard]".	This clause requires the hazard analysis to look "forward" into the supply chain, document and communication hazards past to customers. One example would be buying and selling unpasteurized tree nuts. The hazard of pathogens is identified, but if not controlled (via some form of pathogen reduction such as pasteurization) the customer's responsibility for managing the risk must be identified. Where the company purchases or trades product from a supplier that does not control an identified hazard because it is controlled downstream in the supply chain by a manufacturer, the company shall acquire written assurance from its customer that they (or a subsequent entity) take responsibility for applying appropriate controls prevent or minimize the hazard in compliance with applicable FDA regulation. Written assurance provided by the company shall include the following elements and be reissued annually. • Effective date • Description of the assurance including a description of procedures for preventing or minimizing the hazard • Printed names and signatures of authorized individuals In addition to documenting written assurance for the control of hazards, the company shall ensure that product documents (e.g., purchase orders, contracts, bill of lading, shipping manifest, etc.) clearly identify the product as "not processed to control [identified hazard]". **Regulatory Reference: 21 CFR part 1 subpart L (1.507)**
6.4.13	The corrective action procedure shall include review of the Supplier Verification Program and modification where necessary when a system non-conformity identifies that a supplier does not produce food in compliance with the requirements of this module.	The corrective action procedure established in compliance with clause 3.9.1 of this Standard shall additionally include the requirement for the company to review its Supplier Verification Program where a non-conformity is the result of a failure by the supplier to produce food in compliance with sections 402, 403(w), 418, and 419 of the U.S. Food, Drug & Cosmetic Act (FD&C). Review of the Supplier Verification Program as a part of the corrective action process shall be performed by a Qualified Individual and documented. Modification to the Supplier Verification Program shall be considered to prevent recurrence of the non-conformity and may include additional or more frequent verification activities or alternatively, supplier disapproval. The corrective action process shall consider the company's obligations under U.S. law relating to product recalls, which shall be performed in accordance with section 3.11 of this Standard. **Regulatory Reference: 21 CFR part 1 subpart L (1.508)**

6.4.14	The Supplier Verification Program shall be signed and dated upon initial completion and following any changes.	A Qualified Individual is responsible for signing and dating the Supplier Verification Program upon completing and following any changes. **Regulatory Reference: 21 CFR part 1 subpart L (1.510)**
6.4.15	The company shall keep all records related to the Supplier Verification Program as original or electronic records for a minimum of 2 years. Offsite records shall be retrievable within 24 hours. English translations shall be provided upon request. Records relating to the company's processes and procedures (e.g., approval procedure or verification activities) shall be retained for 2 years after discontinued use.	This recordkeeping requirement expands clause 3.3.2 of this Standard for all documents, procedures and records related to the Supplier Verification Program. This shall include but is not limited to: • Hazard analysis • Supplier approval procedure • Supplier risk assessment • Supplier verification procedure • Supplier contracts • Records of onsite audits (including the review of audit reports) • Records of sampling and testing (including the review of COA's or laboratory reports) • Records pertaining to the review of a supplier's food safety records • Records of other supplier verification activities • Records pertaining to the review and modification of the Supplier Verification Program • Corrective action procedure and records • Written assurance of hazard control • Training records for Qualified Individuals Electronic records are defined as onsite. **Regulatory Reference: 21 CFR part 1 subpart L (1.510)**
6.5 Sanitary Transportation **Does this section apply to me?** This section applies to suppliers and agents or brokers who arrange transportation or receive product. **If yes, consider the following:** Statement of Intent: The company shall ensure sanitary transportation practices for food transported by motor or rail vehicle within the U.S., which are compliant with the requirements of 21 CFR part 1 subpart O.		
6.5.1	The company shall ensure that contracts with U.S. shippers, receivers, loaders, and carriers specify their responsibility for compliance with FSMA's Sanitary Transportation rule. Where the company acts as the shipper or receiver, it shall ensure compliance with the rule. Responsibilities shall ensure transportation operations are conducted in a manner to prevent	Agents and brokers who arrange for the transportation of food in the U.S. are defined as "shippers" in the Sanitary Transportation rule. Agents and brokers who receive food at any point in the U.S. after ground transportation—even where they are not the final recipient—are defined as "receiver" in the Sanitary Transportation rule. Examples of conditions and controls to prevent food from becoming unsafe include: segregation, isolation, packaging, hand washing, and temperature control. The type of food must be considered when establishing transport conditions and controls. Where controls fail and food may be rendered unsafe, the shipper, receiver, loader, or carrier shall not sell or distribute food. They are responsible for communicating the failure to other parties to ensure food is not sold unless a Qualified Individual determines that the control deviation did not render the food unsafe.

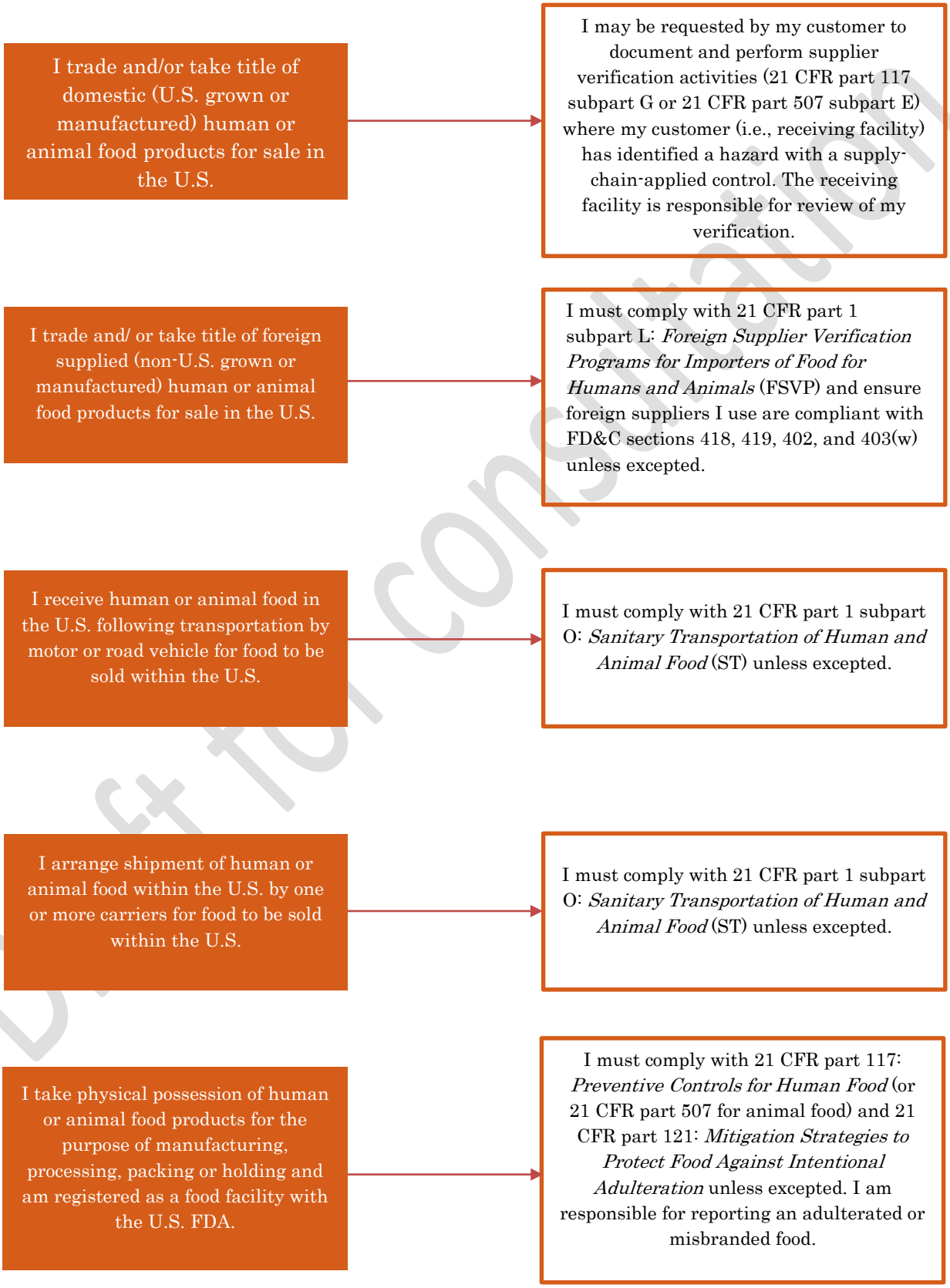
	food from becoming unsafe during transport (i.e., apply controls) and that responsibility for compliance with the regulation is assigned to competent supervisory personnel.	**Regulatory Reference: 21 CFR part 1 subpart O (1.908a)**
6.5.2	Where the company arranges transportation, it shall document sanitary design requirements and cleaning procedures of vehicles appropriate for the type of food to be transported. These requirements shall be communicated to the loader and carrier. Where the company does not arrange transportation, the above provision shall be documented in the shipping service contract to ensure the shipper documents sanitary specifications of vehicles for the loader and carrier, which are appropriate for the type of food.	The shipper shall specify in writing and communicate to the U.S. carrier or loader, sanitary specifications for ensuring vehicles and equipment are in an appropriate sanitary condition for the transport of food. This shall include sanitary design requirements and cleaning practices, which are appropriate for the type of food. Examples of sanitary specifications may include: • Specifying the temperature and any requirements for a pre-cooling phase where temperature controlled product is shipped • Procedures for ensuring that the previous load does not cross-contaminate food where bulk food is transported • Procedures for cleaning, sanitizing and inspecting vehicles • Segregation methods to prevent cross-contamination or cross-contact **Regulatory Reference: 21 CFR part 1 subpart O (1.908b)**
6.5.3	Contracts with loaders shall specify that the loader is responsible for following sanitary specifications provided by shipper.	Contracts with U.S. loaders shall provide agreement between the company and its service provider that loaders shall follow written sanitary specifications from the shipper regardless of whether the shipper is the company or another entity. This shall supplement the requirements of clause 4.2.3 of this Standard. **Regulatory Reference: 21 CFR part 1 subpart O (1.908c)**
6.5.4	Where the company receives temperature controlled product immediately following transportation, it shall conduct an assessment to determine whether the food was subject to temperature abuse.	Where the company receives temperature controlled product, they are responsible for assessing and recording whether the food was subject to temperature abuse. The assessment may include: • Measuring product temperature upon unloading • Documenting the refrigeration unit's temperature setting • Measuring ambient temperature of the container or refrigeration unit holding product • Evaluating product for physical and quality indicators of temperature abuse (e.g., warm product, off-odors, etc.)

		Where the company's customer or another entity receives the product, they bear responsibility for assessing and documenting temperature abuse. This clause applies even where the company is not the final recipient. **Regulatory Reference: 21 CFR part 1 subpart O (1.908d)**
6.5.5	Contracts with carriers shall specify that the carrier is responsible for the following sanitary activities where agreed to in writing with shipper. • Sanitary condition of vehicles and transportation equipment • Following shipper's sanitary specifications • Recording compliance with operating temperature where critical to food safety	Where formally agreed upon with shipper, the U.S. carrier is responsible for the following sanitary activities. • Ensuring vehicles and activities meet shipper's sanitary specifications • Documenting compliance with specified operating temperature where temperature controlled product is shipped (e.g., data loggers or recording the temperature during loading and unloading) • Pre-cooling of the refrigeration unit where specified by the shipper • Identifying previous cargo of bulk transport to shipper upon request • Disclosing the most recent cleaning of the vehicle to shipper upon request • Establish and implement cleaning, sanitizing and inspection procedures for ensuring vehicles and transportation equipment are maintained in sanitary conditions **Regulatory Reference: 21 CFR part 1 subpart O (1.908e)**
6.5.6	Contracts with carriers shall specify that the carrier implements a training program for all personnel engaged in transportation activities, which covers • Awareness of potential food safety problems that may occur during food transportation • Basic sanitary transportation practices to address those potential problems • Responsibilities of the carrier	The company shall document assurance that U.S. carriers implement adequate training programs required by the Sanitary Transportation rule in carrier contracts. Training requirements defined in the Sanitary Transportation rule include the following where the U.S. carrier is responsible for the sanitary conditions of transportation operations. • Provide adequate training to all personnel engaged in transportation regarding the awareness of potential food safety problems that may occur during food transportation, basic sanitary transportation practices to address those potential problems, and the responsibilities of the carrier. • Provide training upon hire and periodically thereafter. • Maintain training records, which include: the date of the training, the type of training, and the person(s) trained. **Regulatory Reference: 21 CFR part 1 subpart O (1.910)**
6.5.7	The company shall keep all records related to U.S. transportation operations and transportation service contracts as original or electronic records for a minimum of 12 months beyond termination of the activity or contract. Offsite	Shippers shall retain records that they provide to carriers documenting transportation specifications and operating temperatures as well as carrier agreements for 12 months beyond termination of the agreement with the carrier. Carriers shall retain records of implemented procedures for 12 months beyond expiration of transportation agreements and records of training for 12 months beyond when the individual no longer performs the activity.

	records shall be retrievable within 24 hours.	Any person providing services for compliance with the Sanitary Transportation rule shall maintain records of activities and agreements for 12 months beyond termination of the transportation agreement. Electronic records are defined as onsite. **Regulatory Reference: 21 CFR part 1 subpart O (1.912)**

Appendix 1

Correlation of some agent and broker activities with FSMA legislation



Glossary

Carrier

A person or entity that physically moves food by rail or motor vehicle in commerce within the United States. The term carrier does not include any person who transports food while operating as a parcel delivery service.

Entity

A legal business.

Environmental Pathogen

A pathogen of the manufacturing, processing, packing, or holding environment, which can contaminate food and cause foodborne illness if consumed. An example of an environmental pathogen common in wet environments is *Listeria monocytogenes*. An example of an environmental pathogen common in dry environments is *Salmonella*.

Food Defense

Activities, which protect food from intentional adulteration.

Foreign Supplier

A supplier that produces, processes, or manufactures food, which is exported to the United States.

Hazard requiring a control

A *known or reasonably foreseeable hazard* (see definition) requiring one or more controls to prevent, significantly minimize or eliminate the hazard in the food as determined by a hazard analysis.

Holding

All activities related to the storage of food. Examples of holding activities include the following provided that the activity does not process or transform the product: storage, drying, blending, fumigation, and handling unexposed product. Holding facilities may include (but are not limited to) bulk silos, cold storage facilities, grain elevators, liquid tanks, shipping containers, and warehouses.

Known or Reasonably Foreseeable Hazard

A biological, chemical (including radiological) or physical hazard associated with a food or the process/ facility of production.

Loader

A person or entity that loads food onto a motor or rail vehicle during transportation operations.

Mitigation Strategy

A risk-based measure determined from a vulnerability assessment, which is applied at a point in the supply chain or at a process step to prevent or minimize a threat intending to cause wide scale public health harm.

Qualified Auditor

An individual independent of the supplier who has appropriate education, technical expertise and experience in auditing principles and food safety management systems to assess food suppliers for compliance with the requirements of this Standard and regulatory compliance under the U.S. Food, Drug and Cosmetic Act. Qualified auditors may be registered auditors with GFSI benchmarked schemes,

government inspectors or appropriately trained and experienced second-party auditors provided they meet all expectations of this definition.

Qualified Individual

An individual who is responsible for conducting and/ or overseeing all activities of an agent or broker's food safety plan, foreign supplier verification program or other compliance program required by legislation under the FSMA. The individual must have received appropriate education, training, and experience to conduct such activities, which includes completion of the applicable FSMA training program (e.g., FSPCA Preventive Controls or FSVP training courses).

Receiver

A person or entity who receives food at a point in the United States after transportation, whether or not they represent the final point of receipt for the food.

Shipper

A person or entity (e.g., the manufacturer or a freight broker) who arranges for the transportation of food in the United States by a carrier or multiple carriers sequentially.

Transportation Operations

All activities associated with transporting food, which may affect the sanitary condition of the food. This includes but is not limited to cleaning, inspection, maintenance, loading and unloading, and operation of vehicles and transportation equipment. Transportation operations do not include activities associated with the transportation of food completely enclosed by a container except for food requiring temperature control for safety, compressed food gases, food contact substances, human food byproducts transported for use as animal food without further processing, or live food animals except molluscan shellfish.

Vulnerability Assessment

An evaluation of vulnerabilities within the supply chain or food production process, which can be exploited to intentionally contaminate a product and cause wide spread public health harm. The assessment must include an evaluation of the degree of physical access to product, the ability of an attacker to successfully contaminate product and the severity and magnitude of harm in the event of successful contamination.

FSMA References

Legislation

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

Foreign Supplier Verification Programs for Importers of Food for Humans and Animals

Mitigation Strategies to Protect Food Against Intentional Adulteration

Sanitary Transportation of Human and Animal Food

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Guidance

Food Facility Registration User Guide: Step-by-Step Instructions

Questions and Answers Regarding Food Facility Registration (Seventh Edition): Guidance for Industry

FSMA Rules & Guidance for Industry (a list of all FSMA related guidance documents)

Training

Food Safety Preventive Controls Alliance (FSPCA) Foreign Supplier Verification Program Training

Food Safety Preventive Controls Alliance (FSPCA) Intentional Adulteration Training

Food Safety Preventive Controls Alliance (FSPCA) Preventive Controls for Human Food Training

Food Safety Preventive Controls Alliance (FSPCA) Preventive Controls for Animal Food Training

Produce Safety Alliance (PSA) Training