PREAMBLE DISCUSSION

F. Role of Supplier Approval and Verification Programs in a Food Safety System

A food can become contaminated through the use of contaminated raw materials or ingredients. In the past several years, thousands of food products have been recalled as a result of contamination of raw materials or ingredients with pathogens such as Salmonella and E. coli O157:H7. The ingredients included peanut-derived ingredients (Refs. recall refs from peanut guidance), pistachio-derived ingredients (Refs. recall refs from pistachio ingredient guidance), instant nonfat dried milk, whey protein, fruit stabilizers (Ref. 2 Plainview pieces on website and fda.gov press announcement) and hydrolyzed vegetable protein (Ref. “For Consumers; The HVP Recall”).

The incident involving Salmonella in hydrolyzed vegetable protein illustrates the impact one supplier can have on the food industry (Ref. FDA RFR First Annual Report). A receiving facility (manufacturer) detected Salmonella in verification testing of finished product. In determining the source of the contamination, the manufacturer detected Salmonella in samples of a hydrolyzed vegetable protein ingredient and reported the finding through FDA’s RFR. After FDA determined that the incident was a reportable food, FDA requested that the supplier notify the immediate subsequent recipients of the reported hydrolyzed vegetable protein ingredient. Over one thousand reportable food reports were submitted to FDA from numerous companies concerning the potentially contaminated hydrolyzed vegetable protein or products made with the hydrolyzed vegetable protein. The hydrolyzed vegetable protein recall involved at least eleven different commodity categories and 177 products, showing the magnitude of this contamination event originating from one supplier (Ref. FDA RFR First Annual Report).

FDA recently reviewed CGMP-related food recall information from 2008-2009 to assess potential root causes for the contamination events. We determined that 36.9 percent of the 960 Class I and Class II recalls were directly linked to lack of supplier controls (Ref. Summary of Food Recalls, 2008 – 2009 July 7, 2011 memo). The recent large recalls of foods containing contaminated or potentially contaminated ingredients have focused attention on supplier approval and verification programs intended to help a manufacturer/processor prevent the introduction of a contaminated raw material or other ingredient into another product (Ref. PCA Peanut recall, HVP recall, Plainview Milk recall). The application of preventive approaches by the entire supply chain (including ingredient vendors, brokers and other suppliers and, ultimately, the manufacturer of a food product) is recognized as essential to effective food safety management (Ref. GMA Supply Chain Handbook 2008).

The development of a supplier approval and verification program is part of a preventive approach. Because many facilities acting as suppliers procure their raw materials and ingredients from other suppliers, there is often a chain of suppliers before a raw material or other ingredient reaches the manufacturer/processor. To ensure safe food and minimize the
potential for contaminated food to reach the consumer, each supplier in the chain must implement preventive controls appropriate to the food and operation for hazards reasonably likely to occur in the raw material or other ingredient. A facility receiving raw materials or ingredients from a supplier must ensure that the supplier (or a supplier to the supplier) has implemented preventive controls to significantly minimize or prevent hazards that the receiving facility has identified as reasonably likely to occur in that raw material or other ingredient unless the receiving facility will itself control the identified hazard.

A supplier approval and verification program is a means of ensuring that raw materials and ingredients are procured from those suppliers that can meet company specifications and have appropriate programs in place, including those related to the safety of the raw materials and ingredients. A supplier approval program can ensure a methodical approach to identifying such suppliers. A supplier verification program is essential to provide initial and ongoing assurance that suppliers are complying with practices to achieve adequate control of hazards in raw materials or ingredients.

Supplier approval and verification is widely accepted in the domestic and international food safety community. The NACMCF HACCP guidelines describe Supplier Control as one of the common prerequisite programs for the safe production of food products and recommend that each facility should ensure that its suppliers have in place effective GMP and food safety programs (Ref. NACMCF 1998). The American Spice Trade Association advocates that spice manufacturers establish robust supplier prerequisite programs to evaluate and approve suppliers (Ref. ASTA Spice Guidance 2011). The Grocery Manufacturers Association’s (GMA’s) Food Supply Chain Handbook, developed for ingredient suppliers to the food industry, recommends that all suppliers in the food chain consider approval programs for their own suppliers; such supplier approval programs consist of a collection of appropriate programs, specifications, policies, and procedures (Ref. GMA Supply Chain Handbook 2008). GMA recommends a number of verification activities that suppliers can take in its Food Supply Chain Handbook, including self-auditing, third-party auditing and product testing. GMA’s handbook also references verification activities that a supplier’s customers might take, including second-party audits (done by an employee of the customer) or third-party (independent) audits (conducted by persons who do not work for either the supplier or the customer). Codex specifies that no raw material or ingredient should be accepted by an establishment if it is known to contain parasites, undesirable microorganisms, pesticides, veterinary drugs or toxic, decomposed or extraneous substances which would not be reduced to an acceptable level by normal sorting and/or processing (Ref. Codex GPFH CAC/ RCP 1-1969, Rev 4-2003). Codex also specifies that, where appropriate, specifications for raw materials should be identified and applied and that, where necessary, laboratory tests should be made to establish fitness for use (Ref. Codex CAC/ RCP 1-1969, Rev 4-2003).

One of the key supplier verification activities is auditing a supplier to ensure the supplier is complying with applicable food safety requirements, such as the requirements of part 110. Audit activities may include a range of activities, such as on-site examinations of establishments, review of records, review of quality assurance systems, and examination or laboratory testing of product samples (Ref. FDA Guidance Voluntary Third-Party Certification Programs for Foods and Feeds, 2009).
An increasing number of establishments that sell foods to the public, such as retailers and food service providers, are independently requiring, as a condition of doing business, that their suppliers, both foreign and domestic, become certified as meeting safety (as well as other) standards. In addition, domestic and foreign suppliers (such as producers, co-manufacturers, or re-packers) are increasingly looking to third-party certification programs to assist them in meeting U.S. regulatory requirements (Ref. FDA Guidance for Industry – Voluntary Third-Party Certification Programs for Foods and Feeds). There are many established third-party certification programs designed for various reasons that are currently being used by industry. Many third party audit schemes used to assess the industry’s food safety management systems incorporate requirements for manufacturers and processors to establish supplier approval programs.

The GFSI was established in 2000 to drive continuous improvement in food safety management systems to ensure confidence in the delivery of safe food to consumers worldwide. Their objectives include reducing risk by delivering equivalence and convergence between effective food safety management systems and managing cost in the global food system by eliminating redundancy and improving operational efficiency (Ref. GFSI guidance document V 6.1). GFSI has developed a guidance document as a tool that fulfills the GFSI objectives of determining equivalency between food safety management systems (Ref. GFSI guidance document). The document is not a food safety standard, but rather specifies a process by which food safety schemes may gain recognition, the requirements to be put in place for a food safety scheme seeking recognition by GFSI, and the key elements for production of safe food or feed, or for service provision (e.g., contract sanitation services or food transportation) in relation to food safety (Ref. GFSI guidance document). This benchmark document has provisions relevant to supplier approval and verification programs. For example, it specifies that a food safety standard must require that the organization control purchasing processes to ensure that all externally sourced materials and services that have an effect on food safety conform to requirements. It also specifies that a food safety standard must require that the organization establish, implement, and maintain procedures for the evaluation, approval and continued monitoring of suppliers that have an effect on food safety. Thus, all current GFSI-recognized schemes require supplier controls to ensure that the raw materials and ingredients that have an impact on food safety conform to specified requirements. The GFSI guidance document also requires audit scheme owners to have a clearly defined and documented audit frequency program, which must ensure a minimum audit frequency of one audit per year of an organization’s facility (Ref. GFSI Guidance Document 6th ed. Aug 2011).

Because GFSI is a document that outlines elements of a food safety management system for benchmarking a variety of standards, it does not have details about how facilities should comply with the elements. This type of information is found in the food safety schemes that are the basis for certification programs. For example, the Safe Quality Food (SQF) 2000 Code, a HACCP-based supplier assurance code for the food industry, specifies that raw materials and services that impact on finished product safety be supplied by an Approved Supplier. SQF 2000 specifies that the responsibility and methods for selecting, evaluating, approving and monitoring an Approved Supplier be documented and implemented, and that a register of Approved Suppliers and records of inspections and audits of Approved Suppliers be maintained. SQF 2000 requires that the Approved Supplier Program contain, among other items, agreed specifications; methods for granting Approved Supplier status;
methods and frequency of monitoring Approved Suppliers; and details of certificates of analysis if required.

According to SQF, the monitoring of Approved Suppliers is to be based on the prior good performance of a supplier and the risk level of the raw materials supplied. The monitoring and assessment of Approved Suppliers can include:
• The inspection of raw materials received;
• The provision of certificates of analysis;
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• The inspection of raw materials received;
• The provision of certificates of analysis;
• Third party certification of an Approved Supplier; or
• The completion of 2nd party supplier audits.

Supplier approval and verification program: Proposed § 110.152 would require that the owner, operator, or agent in charge of a receiving facility establish and implement a supplier approval and verification program for those raw materials and ingredients for which the receiving facility has identified a hazard that is reasonably likely to occur and for which the receiving facility does not have a preventive control to significantly minimize or prevent the hazard. The program must include:
• A written list of approved suppliers;
• A written determination of which designated food safety regulation(s), if any, the supplier is subject to;
• Verification activities, including, as appropriate, audits and other activities such as periodic sampling and testing.

H. Proposed § 110.152--Supplier Approval and Verification Program
1. Requirements of Section 418 of the FD&C Act
Section 418(c) of the FD&C Act specifies, in relevant part, that “[t]he owner, operator, or agent in charge of a facility shall identify and implement preventive controls, including at critical control points, if any, to provide assurances” that:
• “(1) hazards identified in the hazard analysis conducted under [section 418(b)(1) of the FD&C Act] will be significantly minimized or prevented;” and
• “(3) the food manufactured, processed, packed, or held by such facility will not be adulterated under [section 402 of the FD&C Act] or misbranded under [section 403(w) of the FD&C Act].”

Section 418(g) of the FD&C Act specifies that “[t]he owner, operator, or agent in charge of a facility shall maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented under [section 418(c) of the FD&C Act], instances of nonconformance material to food safety, the results of testing and other appropriate means of verification under [section 418(f)(4) of the FD&C Act], instances when corrective actions were implemented, and the efficacy of preventive controls and corrective actions.”
418(o)(3) of the FD&C Act defines preventive controls and, as discussed in section X.C.4 of this document, proposed § 110.3 would include the statutory definition in part 110. Under section 418(o)(3)(G) of the FD&C Act, the procedures, practices, and processes described in the definition of preventive controls may include “supplier verification activities that relate to the safety of food.”

2. Proposed § 110.152(a)--Requirement for a Supplier Approval and Verification Program
   a. Proposed § 110.152(a)(1)--Requirement for establishing and implementing a supplier approval and verification program. Proposed § 110.152(a)(1) would require that, except as provided by proposed § 110.152(a)(6), the owner, operator, or agent in charge of a receiving facility establish and implement a supplier approval and verification program for those raw materials and ingredients for which the receiving facility has identified a hazard that is reasonably likely to occur. Under proposed § 110.3, a receiving facility would mean, for an article of food, a facility that is subject to part 110, subpart C and that manufactures/processes a raw material or ingredient that it receives from a supplier. A receiving facility will generally use multiple raw materials and ingredients in the manufacturing/processing of a food. Limiting the program to raw materials and ingredients for which the receiving facility has identified a hazard that is reasonably likely to occur would, as with other preventive controls established in proposed § 110.135, be a risk-based approach that would be consistent with sections 418(c)(1) and (3) of the FD&C Act. The proposed requirement would not apply to raw materials or ingredients for which no hazard has been identified as reasonably likely to occur. For example, a receiving facility manufacturing RTE salads that is obtaining salt and pepper from a supplier would likely determine there are no hazards reasonably likely to occur in salt, but would identify Salmonella as a hazard in the pepper. The need for a supplier approval and verification program for the pepper would depend on how the pepper will be used by the receiving facility. Under proposed § 110.152(a)(6), discussed below within this section XII.H, a supplier approval and verification program would not be required for raw materials and ingredients for which the preventive controls at the receiving facility are adequate to significantly minimize or prevent the hazards. Rather, we are proposing to require such a program only when the receiving facility relies on controls applied earlier in the supply chain for hazards that are reasonably likely to occur in the raw material or ingredient. Thus, the receiving facility would develop a supplier approval and verification program for the pepper if it is to be used to season the salad without a treatment applied by the receiving facility that would adequately reduce Salmonella but not if the only use for the pepper is in the preparation of a cooked ingredient for the RTE salads.

Currently, receiving facilities use a variety of means to approve suppliers. For example, the receiving facility may conduct a “pre-assessment” questionnaire or survey to gather information about the supplier’s operation and then conduct a pre-approval site visit to assess programs and process capability before conducting an onsite audit verification activity. Some receiving facilities use raw material or ingredient testing to assess compliance with specifications for the raw material or ingredient. FDA is proposing to require an initial onsite audit (as well as periodic onsite audits) where the supplier is controlling the hazard reasonably likely to occur in the raw material or ingredient and is subject to one or more designated foods safety regulations, as proposed in § 110.152(b)(1).
Under proposed § 110.3, a supplier would mean, for an article of food, the establishment that manufactures/processes the food, raises the animal, or harvests the food (other than a farm that harvests a raw agricultural commodity that is a fruit or vegetable) that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature. Specifying that the food would be provided to a receiving facility without further manufacturing/processing, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature, would focus the attention of the receiving facility on a supplier whose activities have the greatest potential to affect any hazards that may be present in the food, either by introducing hazards through its manufacturing/processing activities (e.g., if the supplier provides an RTE food that has the potential to be contaminated with an environmental pathogen) or by conducting activities to significantly minimize hazards (e.g., if a supplier pasteurizes milk that it provides to a facility that makes cheese).

Identifying establishments that manufacture/process food, raise an animal, or harvest food would address all types of establishments that could be suppliers of raw materials or ingredients. Some of these establishments may be facilities that are required to register under section 415 of the FD&C Act. However, a supplier could also be an establishment that is not required to register under section 415 of the FD&C Act (e.g., a farm that provides wheat to be used in the production of flour). As discussed within this section XII.H, some of the proposed requirements for a supplier approval and verification program would depend on whether the supplier is subject to a designated food safety regulation as would be defined in proposed § 110.3.

At present, a farm that harvests a RAC that is a fruit or vegetable is not included within the definition of “supplier,” which would have the effect of excluding these foods from the scope of the supplier approval and verification requirement. Section 419 of the FD&C Act requires that FDA conduct rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are RACs for which FDA has determined that such standards minimize the risk of serious adverse health consequences or death. We intend to propose appropriate changes to this regulation to include these foods concurrent with the issuance of the proposed produce safety regulations.

Although raw agricultural commodities that are fruits or vegetables would be temporarily excluded from the supplier verification requirements under our proposed approach, we strongly encourage receiving facilities who conduct onsite audits of farms that harvest raw agricultural commodities, or perform other activities to ensure the safety of these products, to continue these practices as part of their efforts to ensure the safety of the foods they manufacture/process.

The NACMCF HACCP guidelines describe supplier controls as one of the common prerequisite programs for the safe production of food products and recommend that each facility assure that its suppliers have in place effective CGMP and food safety programs (Ref. NACMCF 1998). Likewise, Codex addresses the safety of ingredients in the General Principles of Food Hygiene and recommends that, where appropriate, specifications for raw materials be identified and applied and laboratory tests be conducted to establish fitness for
use. Federal HACCP regulations for seafood, juice, and meat and poultry do not include explicit requirements for supplier controls.

Proposed § 110.152(a)(1) is consistent with recommendations from industry trade associations. For example, as discussed in section II.F of this document, the American Spice Trade Association recommends that spice manufacturers establish robust supplier prerequisite programs to evaluate and approve suppliers (Ref. ASTA Spice Guidance 2011). GMA recommends that all suppliers through the food chain consider approval programs for their own suppliers (Ref. GMA Supply Chain Handbook 2008). One of the requirements for GFSI recognition of food safety schemes relates to controls on purchasing and suppliers (Ref. GFSI Guidance Document, 6th Edition).

b. Proposed § 110.152(a)(2)--Required assurance. Proposed § 110.152(a)(2) would require that the supplier approval and verification program provide adequate assurances that the hazards identified as reasonably likely to occur by the receiving facility are significantly minimized or prevented. Proposed § 110.152(a)(2) would implement section 418(c) of the FD&C Act and is consistent with domestic and international approaches for the application of preventive approaches by the entire supply chain (Refs. NACMCF HACCP guidelines, Codex GPFH, GMA Supply Chain Handbook 2008, and GFSI guidance document V 6.1).

c. Proposed § 110.152(a)(3)--Required elements of a supplier approval and verification program. Proposed 110.152(a)(3)(i) would require that the supplier approval and verification program include a written list of approved suppliers. A written list of approved suppliers is essential to ensuring that raw materials and ingredients are purchased from appropriate suppliers. The list also would be essential in determining that appropriate verification activities in accordance with proposed § 110.152(b) and (c) are being conducted for each approved supplier. Thus, the list is needed for consistent implementation of the supplier approval and verification program by personnel who order raw materials and ingredients, personnel who receive raw materials and ingredients, and personnel who conduct supplier verification activities, as well as for training such personnel. It also is essential to a facility’s food safety personnel, any auditors, and to government inspectors. The list would be used during reanalysis, audits, and inspections to verify adherence to the supplier approval and verification program.

Proposed § 110.152(a)(3)(ii) would require that the supplier approval and verification program include for each raw material and ingredient, a written determination of which designated food safety regulation or regulations, if any, the supplier is subject to with respect to the raw material or ingredient. Under proposed § 110.3, a designated food safety regulation would mean a regulation contained in subpart B (Current Good Manufacturing Practice) or subpart C (Hazard Analysis and Risk-Based Preventive Controls) of part 110, part 106 (Infant Formula Quality Control Procedures), part 107 (Infant Formula), , part 110 (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements), part 113 (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers), part 114 (Acidified Foods), part 118 (Production, Storage, and Transportation of Shell Eggs), part 120 (Hazard Analysis and Critical Control Point Systems), part 123 (Fish and Fishery Products), or part 129 (Processing and Bottling of Bottled Drinking Water).
Each of these regulations contains preventive controls, CGMPs, or related requirements that are intended, at least in part, to require the use of processes and procedures that will help a supplier to significantly minimize or prevent the occurrence of biological, chemical, physical, and radiological hazards in food it manufactures/processes, raises or harvests.

Determining which, if any, food safety regulation is applicable will help the receiving facility in approving suppliers by clearly identifying food safety regulations that apply to a specific raw material or ingredient. Such information is essential for conducting appropriate supplier verification activities, because under proposed § 110. 152(e)(2) an audit of a supplier facility must assure compliance with the provisions of the relevant designated food safety regulation or regulations that are relevant to the hazards that are reasonably likely to occur and for which the receiving facility is expecting control by the supplier facility.

As discussed in section II.H.3.a of this document, we are proposing to exclude from the definition of “supplier” farms that harvest a raw agricultural commodity that is a fruit or vegetable, which would have the effect of excluding these foods from the scope of the supplier verification requirements. We intend to propose appropriate changes to this regulation to include these foods concurrent with the issuance of the proposed produce safety regulations.

Proposed § 110.152(a)(3)(ii) also would require that, if the owner, operator, or agent in charge of a receiving facility determines that a supplier is not subject to part 110, subpart C because the supplier is a qualified facility, then the owner, operator, or agent in charge of the receiving facility must obtain written assurance that the supplier meets the conditions for exemption as a qualified facility under proposed § 110.2(a) and that FDA has not withdrawn such exemption under Subpart E. As discussed in section X.B.1 of this document, proposed § 110.2(a) would implement an exemption for a facility that meets the conditions for a “qualified facility” as that term is described in section 418(l)(1) of the FD&C Act. A receiving facility would audit against the requirements of subparts B and C (as would be required by proposed § 110.152(b)) if the supplier is subject to both subparts, but only against subpart B if the supplier facility was exempt from subpart C. Thus, to determine the appropriate verification activities for a specific supplier, a receiving facility must know whether the facility meets the conditions for an exemption under proposed § 110.2(a). Under section 418(l)(3) of the FD&C Act and proposed subpart E, FDA may withdraw an exemption provided under proposed § 110.2(a). Thus, to determine the appropriate verification activities for a specific supplier, a receiving facility also must know whether an exemption under proposed § 110.2(a) has been withdrawn.

Proposed § 110.152(a)(3)(iii) would require that the supplier approval and verification program include verification activities as would be required by proposed § 110.152(b) and (c). (See the discussion of proposed § 110.152(b) and (c) later in this section XII.H.)

Proposed § 110.152(a)(3)(iii) would make clear that the verification activities in proposed § 110.152(b) and (c) are part of the supplier approval and verification program but would not otherwise establish specific requirements.

d. Proposed § 110.152(a)(4)—Supplier verification activities when there is more than one type of hazard associated with a raw material or ingredient. Proposed § 110.152(a)(4) would provide that when supplier verification activities are required under §§ 110.152(b) or (c) for more than one type of hazard, the owner, operator, or agent in charge of a receiving
facility conduct the verification activity or activities appropriate for each of those hazards. Proposed § 110.152(a)(4) would establish that, in some situations, a single verification activity will be appropriate for multiple hazards. For example, if a receiving facility that uses peanuts as an ingredient in its products obtains roasted peanuts from a supplier that roasts peanuts and tree nuts, and the receiving facility has identified Salmonella and undeclared tree nuts as hazards reasonably likely to occur in the peanuts, a single verification activity such as an audit of the supplier would be appropriate to assess whether the supplier is significantly minimizing or preventing both hazards. Proposed § 110.152(a)(4) would also establish that in other situations, multiple hazards will require more than one verification activity to provide adequate assurances that each hazard is significantly minimized or prevented. For example, if a receiving facility has identified pesticides and aflatoxin as hazards reasonably likely to occur in corn meal it is receiving from a supplier, and the supplier tests for aflatoxin but not pesticides, the receiving facility could obtain the aflatoxin testing results from the supplier but would conduct its own testing for pesticides as a verification activity.

e. Proposed § 110.152(a)(5)--Supplier verification activities when more than one verification activity is needed for a hazard. Proposed § 110.152(a)(5) would establish that, for some hazards, in some situations, under §§ 110.152(b) or (c) it will be necessary to conduct more than one verification activity and/or to increase the frequency of one or more verification activities to provide adequate assurances that the hazard is significantly minimized or prevented.

For example, if a receiving facility is obtaining shredded cheese from a supplier for use in an RTE salad and has identified L. monocytogenes as a hazard reasonably likely to occur because the supplier has had a problem with L. monocytogenes in the past (but has corrected the cause of the problem), the receiving facility would use both auditing and periodic testing (to verify both that pasteurization is adequately reducing L. monocytogenes and that the supplier is preventing contamination from the environment) as verification activities. Because the supplier has had problems with L. monocytogenes, the receiving facility could also determine that audit frequency for this supplier should be increased until it obtains adequate assurances that the hazard is significantly minimized or prevented.

A receiving facility also might find it necessary to conduct more than one verification activity when using a new supplier, until the verification activities provide sufficient assurance that the hazard is significantly minimized or prevented. For example, a receiving facility might determine through an initial audit that a new supplier of cheese has appropriate programs to control L. monocytogenes contamination from the environment; however, until the receiving facility gains experience with the supplier, the receiving facility would also test the cheese to verify control of L. monocytogenes. The frequency of testing would likely be higher initially (e.g., monthly) and then reduced (e.g., quarterly) until the receiving facility builds confidence in the supplier. Subsequently, after a history is established of the supplier significantly minimizing or preventing the hazard, the receiving facility may reduce the testing further, or even eliminate it and rely entirely on auditing.

As another example, Salmonella and L. monocytogenes in RTE raw materials or ingredients that will not be treated further to significantly minimize the hazard pose a greater risk than if they were present in raw materials or ingredients that are used in a food that is not RTE. Thus, the frequency of verification activities would be increased for RTE raw materials or
ingredients that will not be treated further to significantly minimize the hazard. Because of the risk presented by Salmonella and L. monocytogenes in RTE raw materials or ingredients that will not be treated further to significantly minimize the hazard, the receiving facility would also likely conduct multiple verification activities such as audits and periodic testing for the hazard in the raw material or ingredient.

f. Proposed § 110.152(a)(6)--Exception to the requirement to establish and implement a supplier approval and verification program. Proposed § 110.152(a)(6) would provide that the owner, operator, or agent in charge of a receiving facility is not required to establish and implement a supplier approval and verification program for raw materials and ingredients for which the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the hazards the receiving facility has identified as reasonably likely to occur. If the receiving facility’s own preventive controls can ensure that the hazard is adequately controlled, there would be no need to establish additional controls on the hazard through a supplier approval and verification program. For example, a receiving facility that uses peanuts as an ingredient in its products and has identified Salmonella as a hazard reasonably likely to occur in the peanuts would not be required to establish a supplier approval and verification program with respect to the hazard Salmonella in peanuts if the receiving facility itself treats the peanuts using a process validated to adequately reduce Salmonella.

For some types of hazards, it is unlikely that a receiving facility would have established and implemented preventive controls that would significantly minimize or prevent those types of hazards at its own establishment and would instead need to rely on controls earlier in the supply chain. For example, it is unlikely that a facility could establish preventive controls (other than supplier controls) for chemical hazards (such as pesticides, mycotoxins and drug residues) or radiological hazards (such as iodine-131). In other cases, a receiving facility may have established and implemented preventive controls for use at its own establishment, but these preventive controls may not be adequate to control a hazard originating from the supplier. For example, a receiving facility’s allergen controls cannot address an undeclared allergen introduced by the supplier through cross-contact.

We request comment on our proposed risk-based approach that receiving facilities would not need a supplier approval and verification program when ingredients will be subjected to preventive controls at the receiving facility that significantly minimize or prevent the hazard.

3. Proposed § 110.152(b)--Requirement for Supplier Verification Activities for Hazards to be Controlled at the Supplier’s Establishment, if the Food is Subject to One or More Designated Food Safety Regulations.

Proposed § 110.152(b) would require that the owner, operator, or agent in charge of a receiving facility conduct initial and periodic verification activities for hazards to be controlled at the supplier’s establishment, if the raw material or ingredient is subject to one or more designated food safety regulations with regard to the raw material or ingredient. Examples of preventive controls that could be applied at the supplier to control a hazard reasonably likely to occur in an ingredient include process controls (such as roasting nuts); food allergen controls (such as controls on labeling ingredients for allergens); and sanitation controls (such as cleaning procedures designed to prevent L. monocytogenes from establishing a harborage in food processing equipment used to prepare RTE ingredients.
that support its growth). As discussed immediately below, proposed § 110.152(b)(1) and (2) would require that, when the supplier is controlling the hazard and is subject to one or more designated food safety regulations, the verification activities must include onsite audits. FDA tentatively concludes that in these circumstances an onsite audit always is necessary to provide adequate assurance that the hazard is significantly minimized or prevented by the supplier. Other verification activities may be needed, but none are sufficient in the absence of an audit. Through an audit conducted onsite, the auditor can observe physical conditions, interview employees, and review records to verify that controls to address the identified hazard are being implemented consistently and, if there is a written plan for controlling the hazard, that the controls are being implemented according to that plan. We tentatively conclude that it is appropriate to require an audit as a verification activity only when there is one or more designated food safety regulations that apply because in the absence of such a regulation there may not be clearly defined processes, procedures, or standards against which the supplier’s actions to control the hazards can be evaluated in an onsite audit.

We also tentatively conclude that for some hazards, it will be necessary to conduct more than one verification activity to provide adequate assurances that the hazard is significantly minimized or prevented, as provided in proposed in § 110.152(a)(5). Such could be the case, for example, when there have been compliance problems with control of the identified hazard or when using a new supplier for which the receiving facility has little information to provide assurance the hazard is significantly minimized or prevented. When a facility determines that more than one verification activity is needed, the facility has flexibility to determine what additional verification activities are appropriate as long as they provide the necessary assurance that the hazard is significantly minimized or prevented. We request comment on this approach.

a. Proposed § 110.152(b)(1) –Requirement for initial onsite audit. Proposed § 110.152(b)(1) would require that the owner, operator, or agent in charge of a receiving facility conduct, or obtain documentation of, an onsite audit of the supplier before using the raw material or ingredient from the supplier. An initial onsite audit is often used by the receiving facility as part of establishing supplier approval status. An onsite audit of the supplier must assure compliance with the provisions of the relevant designated food safety regulation or regulations that are relevant to the hazards that are reasonably likely to occur that the receiving facility is expecting the supplier to control. An initial onsite audit would be conducted before a receiving facility uses the raw material or ingredient from the supplier for the first time; proposed § 110.152(b)(1) would not require the owner, operator, or agent in charge of a receiving facility to conduct an audit before using a raw material or ingredient each time that raw material or ingredient is received. The initial onsite audit can be conducted by an employee of the receiving facility or the receiving facility can obtain documentation of an audit that has been conducted at the supplier by a third party auditor.

For example, before a receiving facility obtains roasted peanuts, for which the receiving facility has identified Salmonella as a hazard, from a supplier that roasts nuts and is subject to subparts B and C of part 110, the receiving facility would audit the supplier’s facility (or obtain an audit performed by a third party) to determine whether the roasting process used by the supplier is adequate to significantly minimize Salmonella in peanuts. Because the supplier of roasted peanuts would be subject to subparts B and C of part 110, the audit would include a review of the supplier’s food safety plan and ensure compliance with the provisions of subparts B and C relative to control of the Salmonella hazard.
For example, the auditor would review whether the roasting process for the nuts had been validated to significantly minimize Salmonella in peanuts and would review whether the implementation of the roasting procedures was in accordance with the food safety plan, e.g., by observations in the plant and by review of records. If the supplier is not subject to subpart C of part 110 (e.g., because the supplier meets the definition of a qualified facility) the auditor would consider the requirements of subpart B in assessing whether the supplier is adequately controlling the hazard, e.g., process controls in proposed § 110.80(b). In this case, the auditor would review the roasting process for the nuts to determine if it will significantly minimize Salmonella in peanuts and the roasting procedures being implemented by the facility; the auditor would also review any relevant records the supplier can provide. The results of the audit would then be used by the receiving facility in determining the status of the supplier (e.g., approved, conditionally or provisionally approved, not approved) and, if the supplier is approved, the audit results could be a factor in determining appropriate verification activities (e.g., whether activities other than an annual audit, in accordance with proposed § 110.152(b)(2)(i), are needed) to provide adequate assurances that the hazard is significantly minimized or prevented, in accordance with proposed § 110.152(a)(4).

b. Proposed § 110.152(b)(2)--Requirement for periodic onsite audits. Proposed § 110.152(b)(2)(i) would require that when a hazard that is reasonably likely to occur with a raw material or ingredient is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the owner, operator, or agent in charge of the receiving facility must conduct or obtain documentation of an onsite audit of the supplier at least annually, unless more frequent onsite audits are necessary to adequately verify control of the hazard. The annual audit would include consideration of the standards and requirements of the applicable designated food safety regulations to which the supplier is subject in assessing whether the supplier is adequately controlling the hazard. Hazards for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals are those which for which a recall of a violative product posing such a hazard is designated as “Class 1” under 21 CFR 7.3(m)(1). Examples of such hazards that, in some circumstances, have resulted in serious adverse health consequences or death to humans or animals include pathogens or their toxins in RTE food and undeclared food allergens. For example, if Salmonella, a hazard that can cause serious adverse health consequences or death to humans or animals, is identified as a hazard reasonably likely to occur in peanuts, and the supplier applies a process control, e.g., oil roasting, then an annual audit would be conducted to ensure that the supplier’s roasting process is adequate to significantly minimize Salmonella, that the roasting process is being conducted in accordance with the supplier’s food safety plan (which is required by subpart C), and that the supplier is in compliance with the provisions in subparts B and C of part 110 (the applicable designated food safety regulations) relevant to control of the hazard.

As another example, undeclared milk in dark chocolate can cause serious adverse health consequences or death to humans. The supplier providing dark and milk chocolate to a receiving facility would be audited annually to ensure that the supplier is preventing cross-contact and appropriately labeling products to prevent undeclared allergens from being present in the raw materials or ingredients provided to the receiving facility.
We tentatively conclude that conducting onsite audits at least annually is necessary for hazards for which there is a reasonably possibility that exposure will result in serious adverse health consequence or death of humans or animals to provide adequate assurance that the hazards identified in the raw material or ingredient are significantly minimized or prevented by the supplier. The annual audit frequency is a minimum frequency. If more frequent onsite audits are necessary to adequately verify control of the hazard, the receiving facility would be required to conduct or obtain documentation of audits more frequently. The frequency of the audit would be increased based on risk, including the supplier’s performance or changes to the supplier’s processes or facility. For example, if the receiving facility were to become aware of the supplier’s raw materials or ingredients being the source of a hazard, the receiving facility could decide to conduct an audit more frequently than annually, and/or the receiving facility could implement additional verification activities as discussed in section XII.H.3.e. If the supplier were to change the process used to control the hazard, e.g., a change in the roasting time or temperature applied to sesame seeds (which can impact the lethality for the identified hazard of Salmonella), the receiving facility would likely decide to conduct an audit (or require documentation that an audit has been conducted) to provide assurance that the roasting parameters adequately reduce the hazard. If the supplier were to modify the facility producing the raw material or ingredient in a way that could impact the safety of the raw material or ingredient, the receiving facility could decide to conduct or obtain documentation of an audit. For example, construction in a facility has been known to increase the risk of contamination of RTE foods with L. monocytogenes (Ref. Tompkin et al. 1999); a facility receiving an RTE raw material or ingredient for use in manufacturing without a further kill step could decide to conduct or obtain documentation of an audit during the time of construction to assess whether the supplier has adequate controls to prevent contamination during the construction period.

The requirement for annual onsite audits is consistent with GFSI’s recommendation for a minimum frequency of one audit per year (Ref. GFSI Guidance Document, 6th Edition). The GFSI guidance also indicates that the frequency of audits may be influenced by a number of factors such as previous audit history, concerns about compliance with an audit scheme’s standard, and changes in product technology (Ref. GFSI 6th Edition Guidance). We request comment on the proposed annual onsite audit frequency as well as comment on what criteria, if any, should be specified for determining whether more frequent audits are necessary. We are aware that there are circumstances in which suppliers are audited multiple times each year due to multiple customer requests (in addition to, in some cases, the company’s internal audit). It is not our intent to increase the number of audits of each supplier; rather, we anticipate there will be consolidation of audits and that a supplier will be able to use the results of one audit as documentation for multiple receiving facilities. We request comment on this approach.

Proposed § 110.152(b)(2)(ii) would require that when a hazard that is reasonably likely to occur with a raw material or ingredient is not one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the owner, operator, or agent in charge of the receiving facility must conduct or obtain documentation of an onsite audit of the supplier at least every 2 years, unless more frequent onsite audits are necessary to adequately verify control of the hazard. Examples of hazards that historically have not resulted in serious adverse health consequences or death to humans or animals generally include mycotoxins, drug residues, and hard or sharp foreign objects. We therefore tentatively conclude that a less frequent
auditing schedule (every other year instead of annually) is adequate for such hazards, which are less severe than those subject to more frequent auditing. This necessary audit frequency, however, would be increased, for example based on poor supplier performance, or additional verification activities would be implemented as discussed in section XII.H.3.e if necessary to provide adequate assurances that the hazard is significantly minimized or prevented.

We request comment on the proposed frequency of onsite audits when a hazard that is reasonably likely to occur with a raw material or ingredient is not one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals.

4. Proposed § 110.152(c)—Supplier Verification Activities for Other Hazards.

a. Proposed § 110.152(c)—General requirements. Proposed § 110.152(c) would require that, for a hazard that would not be subject to proposed § 110.152(b), the owner, operator, or agent in charge of a receiving facility conduct one or more of the verification activities listed in proposed § 110.152(c)(1) through (5), as appropriate for the hazard, before using the raw material or ingredient and periodically thereafter. Such hazards include hazards to be controlled at the supplier’s establishment and the supplier is not subject to one or more designated food safety regulations with respect to the raw material or ingredient. The frequency of verification activities must be based on the risk associated with the hazard.

Proposed § 110.152(c) sets forth the supplier verification requirements for hazards not specified in proposed § 110.152(b) (proposed § 110.152(b) applies to hazards controlled at the supplier’s establishment for which the raw material or ingredient is subject to a designated food safety regulation). These hazards would include hazards to be controlled at the supplier’s establishment when the raw material or ingredient in which the hazard occurs is not subject to a designated food safety regulation. In some cases, a hazard that is controlled by a supplier during manufacturing/processing, raising or harvesting is present in a raw material or ingredient, but the supplier is not subject to a designated food safety regulation. For example, a farm that produces corn is not subject to a designated food safety regulation. As stated in section XII.H.4 of this document, because the supplier is not subject to a designated food safety regulation, we tentatively conclude that it is not appropriate to mandate onsite auditing for such a hazard because there may not be clearly defined processes, procedures, or standards against which the supplier’s actions to control the hazards can be evaluated in an onsite audit.

Also included in the hazards subject to § 110.152(c) are hazards for which a supplier, upon receipt of a raw material or ingredient from another entity, takes steps to verify that the hazards have been adequately controlled before the supplier processes the received raw material or ingredient. For example, a receiving facility might identify Salmonella as a hazard reasonably likely to occur in a seasoning mix made by blending milk powder and spices. The supplier of the seasoning mix might not apply a control for Salmonella in its blending operation but instead might conduct verification to ensure that the suppliers of milk powder and spices have used proper controls. Another example is when a supplier conducts testing to verify that its raw material or ingredient supplier has applied a procedure that removes a hazard posed by the potential presence of a pesticide residue in the raw material. We tentatively conclude that, for such hazards, a supplier may not be able to apply a process control during the manufacturing/processing of a raw material or ingredient to
adequately reduce the hazard. Because of this, the supplier must rely on testing the incoming raw material or ingredient or on conducting some other activity to verify that the hazard is appropriately controlled by its supplier.

To address hazards not subject to proposed § 110.152(b), proposed § 110.152(c) would require that the receiving facility conduct one or more of the verification activities specified in proposed § 110.152(c)(1) through (4), appropriate for the hazard, before using the raw material or ingredient and periodically thereafter. As set forth in proposed § 110.152(c)(1) through (4), the supplier verification activities that receiving facilities may choose to conduct, if they are appropriate for the hazard, are as follows:

- Periodic onsite audits (proposed § 110.152(c)(1));
- Periodic or lot-by-lot sampling and testing of the raw material or ingredient (proposed § 110.152(c)(2));
- Periodic review of the supplier’s food safety records (proposed § 110.152(c)(3)); and
- Other appropriate supplier control verification measures (proposed § 110.152(c)(4)).

These verification procedures, and examples of types of foods/hazards for which they may be appropriate, are discussed below in sections XII.H.5.(b) - (e).

Proposed § 110.152(c) would require that the frequency of verification activities be based on the risk associated with the raw material or ingredient. For example, a receiving facility might obtain ground black pepper from a new supplier that receives peppercorns from a facility that steam-treats the peppercorns to significantly minimize the hazard of Salmonella. Because the ground pepper supplier does not control the hazard of Salmonella in the raw material at the supplier’s own establishment, the supplier would not be subject to the mandatory audits required by proposed § 110.152(b). The receiving facility might initially ask its new supplier of ground black pepper to provide lot-by-lot certificates of analysis (COAs) for Salmonella in accordance with a designated sample size and method. (A certificate of analysis is a document that states the results of tests performed on food, as is commonly used in the food industry.) The receiving facility might determine that lot-by-lot COAs are necessary based on the following factors: the lack of a performance history for the new supplier; the seriousness of the hazard (Salmonella is a hazard that can cause serious adverse health consequences or death to humans or animals); and the supplier’s reliance on testing each lot of incoming steam-treated, black peppercorns for Salmonella to verify its raw material supplier’s preventive controls for steam treatment rather than applying a preventive control for Salmonella in its grinding facility. Until a performance baseline is established with the supplier, the receiving facility might even conduct its own periodic sampling and testing, in addition to reviewing the COAs from the supplier. Once the supplier has established a history of no Salmonella in the ground black pepper, the receiving facility might decide that it is appropriate to have the supplier provide COAs at some lesser frequency, such as every tenth delivery. The receiving facility also might reduce the frequency of its own verification testing. The receiving facility also would conduct an annual audit of the supplier providing the ground black pepper to ensure the supplier is adequately controlling the hazard of Salmonella contamination from the environment. The audit also could be used to verify the supplier’s verification testing results for incoming steam-treated, black peppercorns for Salmonella.
b. Proposed § 110.152(c)(1) -- Periodic onsite audits. Proposed § 110.152(c)(1) would provide, as a verification option when appropriate, for periodic onsite audits that the owner, operator, or agent in charge of the receiving facility conducts, or for which the owner, operator, or agent in charge of the receiving facility obtains documentation.

Under proposed § 110.152(c)(1) a receiving facility could determine that it is appropriate to conduct or obtain documentation of an onsite audit to verify control of a hazard subject to § 110.152(c). Using the example provided above involving a seasoning mix, the receiving facility might choose to conduct an audit or use a third-party auditor to conduct an audit of the supplier’s operations to verify that the supplier conducts appropriate verification activities for incoming lots of powdered milk and spices to verify that controls for Salmonella are adequate. In this example, the suppliers of powdered milk and spices are also suppliers, and the supplier of the seasoning mix is a receiving facility with respect to the powdered milk and spices. The verification activity performed with respect to the powdered milk and spices would depend on whether the suppliers of these raw materials or ingredients are controlling the hazard of Salmonella at their facilities or whether control measures are applied farther back in the supply chain. If the suppliers of the powdered milk and spices are treating them to reduce Salmonella, then the supplier of the seasoning mix (as a receiving facility) would conduct an audit to verify the hazard of Salmonella has been significantly minimized or reduced, review the supplier’s food safety plan and determine the suppliers are operating in compliance with the provisions relevant to the control of the hazard in any designated food safety regulations to which the facilities are subject (e.g., subpart B and C of part 110). The receiving facility for the seasoning mix may decide that an audit of the supplier is appropriate to observe the physical blending operation to assure no hazards are introduced during blending. The auditor would review the procedures used by the seasoning mix supplier to ensure that control of Salmonella in the powdered milk and spices is adequate, including a review of the audits the supplier conducts, or for which documentation has been obtained, on the suppliers of the powdered milk and spices. If the supplier of the seasoning mix conducts additional verification measures such as testing the powdered milk or spices for Salmonella, the auditor would review the results of such testing.

The audit frequency for verifying controls applied to address hazards that cause serious adverse health consequences, e.g. Salmonella, would generally be greater than for a hazard that does not, e.g. a mycotoxin. Supplier performance could be another factor that influences audit frequency. After the initial onsite audit, the frequency of the periodic audit for a hazard such a mycotoxins may be annual until a history is developed with the supplier, at which point a re-evaluation of the supplier could be conducted to determine whether the annual audit could be replaced by one of the other verification activities proposed in this section.

As discussed in section XII.H.7.b below, checking the written control plan of a supplier, if any, is required under proposed § 110.152(e)(2) when an onsite audit is conducted.

c. Proposed § 110.152(c)(2) -- Periodic or lot-by-lot sampling and testing by or on behalf of the receiving facility. Proposed § 110.152(c)(2) would provide, as a verification option when appropriate, for periodic or lot-by-lot sampling and testing of the raw material or ingredient from the supplier that the owner, operator, or agent in charge of the receiving facility conducts, or has conducted, for the hazard. Under proposed § 110.152(c)(2), a receiving facility might determine that it is appropriate to conduct periodic or lot-by-lot sampling and
testing of a raw material or ingredient before the receiving facility uses it. For example, the receiving facility of the above-described seasoning mix might choose to conduct its own periodic Salmonella testing or use a contracted lab to test samples of seasoning mix, perhaps on a monthly basis. This monthly testing could be conducted until a good history is established for the seasoning mix supplier, after which time the receiving facility could determine it would be appropriate to test less frequently, such as quarterly.

Alternatively, a receiving facility could choose to obtain documentation (such as a COA) of lot-by-lot or periodic testing of the raw material or ingredient that is conducted before the raw material or ingredient is used. This supplier verification method is consistent with the recommendation in GMA's Food Supply Chain Handbook that customers ask suppliers to provide COAs documenting that major analytical parameters for the specific foods, or lots, contained in a specific shipment have been met (Ref. GMA’s Food Supply Chain Handbook, 2008).

Although requirements for a COA or other documentation of testing will depend on factors such as the raw material or ingredient involved, information included in a COA might include the following: a description of the food; the name of the supplier; lot number(s) for products in the shipment; the date of production; whether the testing was done in-house or by an outside lab; the date the food was shipped; results of chemical, physical, and/or microbiological analyses; methods of analysis; descriptions of sampling plans used to generate results contained in the COA; and the signature of analysis or person issuing the certificate (Ref. GMA's Food Supply Chain Handbook, 2008).

As with the other verification activities, proposed § 110.152(c)(2) would require that the frequency of testing of raw materials and ingredients be based on the risk associated with the hazard in the food. An example of risk-based sampling was provided in XII.H.5. for a receiving facility and ground black pepper. FDA requests comment on whether we should specify particular situations or product types for which raw material or ingredient testing would be required as a supplier verification activity, and whether the frequency of testing should be specified.

d. Proposed § 110.152(c)(3) – Periodic review by the receiving facility of the supplier’s food safety records. Proposed § 110.152(c)(3) would provide, as a verification option when appropriate, for periodic review by the owner, operator, or agent in charge of the receiving facility of the supplier’s food safety records (e.g., records of audits of their supplier for the hazard). Under proposed § 110.152(c)(3), a receiving facility could determine that it is appropriate to periodically review a supplier’s food safety records for the raw material or ingredient provided. Food safety records are records documenting that the food safety procedures that have been established to control hazards reasonably likely to occur are being followed and are adequately controlling such hazards. Such records might include, for example, records of a supplier’s audit of its supplier’s hazard control activities.

Record review would be an appropriate verification activity when, for example, the supplier of a spice mix containing steam-treated black pepper performs onsite audits of its supplier that is steam-treating the black pepper to verify that the identified hazard of Salmonella is being controlled. The supplier of the spice mix containing steam-treated black pepper could provide the receiving facility with copies of the reports of these audits. The supplier of the spice mix might conduct additional verification activities such as periodic testing of the
steam-treated black pepper; the receiving facility of the spice mix could also review these food safety records.

Record review would be an appropriate verification activity, for example, if the hazard identified by the receiving facility in the raw material or ingredient is a mycotoxin, such as in corn meal or flour. The receiving facility would verify that the supplier, e.g. the miller, has verified that mycotoxin has been controlled by the miller’s supplier by testing the incoming grain for mycotoxins. The receiving facility would conduct a review of the grain mycotoxin testing records at the supplier.

e. Proposed § 110.152(c)(4)--Other appropriate supplier control verification measures.

Proposed § 110.152(c)(4) would provide, as a verification option, for other appropriate supplier control verification measures based on the risk associated with the hazard. Under proposed § 110.152(c)(4), a receiving facility could choose to follow any other supplier verification measure that it has established as being appropriate, based on the risk associated with the raw material or ingredient, for verifying that a supplier is adequately controlling (or verifying control of) the hazard, as long as the measure is adequate to verify whether a supplier is adequately controlling a hazard. We are aware that receiving facilities currently uses onsite audits, product testing, and record review as verification activities for raw materials and ingredients. We request comment on other supplier verification measures that may be appropriate.

As discussed in section XII.H.7.b below, checking the food safety plan of a supplier, if any, is required under proposed § 110.152(e)(2) when an onsite audit is conducted for a raw material or ingredient that is subject to a designated food safety regulation. We have not included this as an activity in proposed § 110.152(c) that could be used by itself for supplier verification, and we tentatively conclude that it would not be appropriate as a stand-alone activity under § 110.152(c). We are concerned that checking a supplier’s food safety plan, without auditing the supplier’s facility or performing some other verification step, would not provide adequate assurances that a supplier is controlling hazards. We request comment on whether we should permit the use of a verification approach solely involving checking the food safety plan of a supplier and, if so, under what circumstances this verification activity would be appropriate.

5. Proposed § 110.152(d)--Requirement for Records

Proposed § 110.152(d) would require that all supplier verification activities conducted in accordance with this section must be documented in records. The required records would be subject to the requirements of subpart F, as discussed in section XV. Proposed § 110.152(d) would implement section 418(g) of the FD&C Act and is consistent with the NACMCF HACCP guidelines, the Codex HACCP Annex, and Federal HACCP regulations for seafood, juice, and meat and poultry. The NACMCF HACCP guidelines recommend that the records maintained for the HACCP system include records that are generated during the operation of the plan (Ref. NACMCF 1998). The Codex HACCP Annex recommends that documentation and record keeping should be sufficient to assist the business to verify that the HACCP controls are in place and being maintained (Ref. Codex 2003). Federal HACCP regulations for seafood, juice and meat and poultry require that recordkeeping document the HACCP plan and its implementation (§ 123.9, § 120.12, and 9 CFR 417.5).
Documentation of supplier verification activities could include audit reports, reports for the raw material or ingredient testing conducted by the receiving facility, supplier COAs, and supplier food safety records. Audit reports could address the audit criteria used, identification of the auditor, the audit observations and findings, and the audit rating, e.g., numerical score, pass/fail. The receiving facility’s raw material or ingredient testing reports could address the description of the raw material or ingredient tested, production information, e.g. lot number, the laboratory used, method used, sample size, and the test results compared to specification to be met. The supplier COA could address the description of the raw material or ingredient tested, production information, e.g. lot number, the laboratory used, method used, sample size, and the test results compared to specification to be met. The supplier’s testing records could address the supplier’s testing of incoming components and/or testing of outgoing raw material or ingredients including corrective actions if test performed did not meet supplier’s acceptance criteria.

The receiving facility’s food safety personnel need verification documentation, e.g., audit or testing results, as applicable, to determine the acceptability of the supplier’s raw materials or ingredients before use. Having such documentation provides a history of supplier performance so risk-based decisions can be made, e.g. a change in verification frequency. The documentation is also essential to personnel who order raw materials and ingredients.

6. Proposed § 110.152(e) -- Requirements that apply to onsite audits
   a. Proposed § 110.152(e)(1) -- Requirements for persons who conduct the onsite audit.

   Proposed § 110.152(e)(1) would require that an onsite audit be performed by a qualified individual with the technical expertise obtained by a combination of training and experience appropriate to perform the auditing function. This approach is consistent with the NACMCF HACCP guidelines that acknowledge it is important that individuals doing verification have appropriate technical expertise to perform this function (Ref. NACMCF 1998). The person conducting the audit may be an employee of the receiving facility (second party auditing) or a qualified third party auditing firm. If third party auditing firms are used, GMA recommends requesting an auditor experienced with the food commodity item the supplier produces (Ref. GMA Food Supply Chain Handbook). GMA also recommends that an auditor’s competency include education/experience; advanced HACCP training; and a minimum amount of auditing expertise (Ref. GMA Food Supply Chain Handbook). GFSI specifies that an auditor’s qualifications include minimum full-time work experience in food or an associated industry; formal training in auditing techniques, initial training for each product category in which the auditor will be expected to be working; audit experience; and continuous professional development (Ref. GFSI Guidance Document 6th Edition).

   FDA tentatively concludes that a person performing onsite audits as proposed in § 110.152(b) and 110.152(c) would have training and experience similar to existing industry standards. Proposed § 110.155(b) would require that a qualified individual have successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by the FDA, or be otherwise qualified through job experience to develop and apply a food safety system. We recognize that a person qualified to develop and apply a food safety system may not have the training and experience to conduct facility audits. However, we tentatively conclude that a person conducting an onsite audit must have, in addition to auditing skills, the training and experience to develop and apply a food safety system for the food being produced at the facility being audited. Thus, we are proposing to
require in proposed § 110.152(e)(1) that the onsite audit be performed by a qualified individual (as defined in § 110.3) with training and/or experience in the development and application of risk-based preventive controls and the technical expertise required to perform audits. We request comment on FDA’s approach on auditor qualifications and whether it is appropriate to require auditors to meet the qualified individual training requirements proposed in § 110.155.

b. Proposed § 110.152(e)(2)--Requirement for content of an onsite audit. Proposed § 110.152(e)(2) would require that if the raw material or ingredient at the supplier is subject to one or more designated food safety regulations, to provide adequate assurance that the hazard is significantly minimized or prevented, an onsite audit must consider such regulations and include a review of the supplier’s written plan, if any, including its implementation, for the hazard being audited. Proposed § 110.152(e)(2) sets forth the basic requirements for an onsite audit when the audit concerns a food that is subject to a designated food safety regulation. We tentatively conclude it is appropriate that an onsite audit of the supplier of a food should include an evaluation of the supplier’s level of compliance with the particular regulations to which the supplier is subject as they relate to the control of hazards being audited. Thus, an onsite audit conducted by either the receiving facility or a third-party auditor would assess, in the context of the standards and requirements of the applicable designated food safety regulations, whether the measures the supplier has applied are effectively controlling the hazards identified by the receiving facility as reasonably likely to occur. Because the designated food safety regulations vary in scope and detail, the parameters and key components of an onsite audit conducted under § 110.152(b)(1), (b)(2) or (c)(1) would necessarily vary depending on what regulations applied to the supplier.

We also tentatively conclude that review of the supplier’s written plan, if any, and the supplier’s implementation of such plan, would be an important part of an effective onsite audit. For example, if the supplier is required by section 418 of the FD&C Act to have a food safety plan, the onsite audit would focus on the plan and assess the implementation of the preventive controls applied by the supplier to address the hazards that the receiving facility has identified as reasonably likely to occur. Preventive controls might include process controls, food allergen controls, sanitation controls, and other controls for biological, chemical, physical, or radiological hazards identified as reasonably likely to occur. For suppliers that are not required to have a food safety plan under section 418 of the FD&C Act but are required to have one under another designated food safety regulation, the onsite audit should include a review of the supplier’s written plan, and the supplier’s implementation of the plan, to assure that hazards identified by the receiving facility are effectively controlled.

We request comment on these proposed requirements, as well as on whether any other requirements regarding the scope and content of onsite audits are appropriate.

7. Proposed § 110.152(f)--Independence of persons conducting an onsite audit

Proposed § 110.152(f) would require that a person who conducts an onsite audit as set forth in § 110.152(b) or § 110.152 (c) not have a financial interest in the supplier and payment not be related to the results of the activity. Proposed § 110.152(f) would provide
that this does not prohibit the owner, operator, or agent in charge of the receiving facility from conducting the audit.

Proposed § 110.152(f) addresses the issue of financial conflicts of interests that might arise in the performance of audits by a person conducting the audit. We recognize the possibility that a conflict of interest might arise when there is a financial relationship between a person that is conducting an audit and the supplier whose procedures the person is reviewing. For example, the owner of an auditing firm might own substantial shares of stock in a supplier that has requested an audit by the firm. On the other hand, § 110.152(b)(1), (b)(2) and (c)(1) permit the receiving facility itself to conduct onsite audits of suppliers and other verification activities under these regulations. We tentatively conclude there is no conflict of interest when a person employed by a receiving facility conducts an audit of a supplier, even when the supplier is an entity under the same corporate ownership as the receiving company. In addition to the person who conducts an onsite audit not having a financial interest in the supplier, we would require in proposed § 110.152(f) that payment for the audit not be based on the outcome of the audit, e.g., that there is a higher payment for the audit when the supplier is substantially in compliance with the provisions against which the supplier is being audited.

We request comment on whether this prohibition reflects the appropriate approach to concerns about conflicts of interest in the performance of audits and, if not, what changes would be appropriate. We also request comment on whether and, if so, how, the regulation should specify what constitutes a financial interest.

8. Proposed § 110.152(g)—Supplier non-conformance

Proposed § 110.152(g) would require that, if the owner operator, or agent in charge of a receiving facility determines through auditing, verification testing, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as reasonably likely to occur, the receiving facility must take prompt action, which may include discontinuing use of the supplier, to ensure the hazards associated with the raw material or ingredient have been significantly minimized or prevented.

Proposed § 110.152(g) would require a receiving facility to take appropriate action, e.g., corrective actions, if it determines that one of its suppliers is not controlling hazards that the receiving facility has identified as reasonably likely to occur. Such a determination may come from auditing, verification testing, or other means. Regardless of how a receiving facility obtains the information that forms the basis of the determination that its supplier did not control the hazards in the raw material or ingredient, the receiving facility must take action in response to this noncompliance. The appropriate corrective actions by the receiving facility will depend on the circumstances, but could include discontinuing use of the supplier until the cause or causes of the supplier’s non-conformance have been adequately addressed. Because the actions to be taken will depend on the specific root cause of the noncompliance, FDA is not proposing the actions to be taken other than to provide that one option is to discontinue use of the supplier. FDA tentatively concludes that because the lack of control of the hazard by the supplier can result in a hazard in the food manufactured/processed at the receiving facility, discontinuing use of the supplier until the supplier can adequately control the hazard is appropriate. FDA requests comment on the requirement to address supplier non-conformance.
DISCUSSION OF DEFINITIONS

FDA is proposing to define the term “designated food safety regulation” to mean a regulation contained in part 106 (Infant Formula Quality Control Procedures), part 107 (Infant Formula), subpart B (Current Good Manufacturing Practice) or subpart C (Hazard Analysis And Risk-Based Preventive Controls) of part 110, part 111 (Current Good Manufacturing Practice In Manufacturing, Packaging, Labeling, Or Holding Operations For Dietary Supplements), part 113 (Thermally Processed Low-Acid Foods Packaged In Hermetically Sealed Containers), part 114 (Acidified Foods), part 118 (Production, Storage, And Transportation Of Shell Eggs), part 120 (Hazard Analysis and Critical Control Point Systems), part 123 (Fish And Fishery Products), or part 129 (Processing And Bottling Of Bottled Drinking Water). We are proposing to define “designated food safety regulation” as a concise term to be used to reference multiple regulations in the proposed provisions for a supplier approval and verification program (proposed § 110.152). We explain the basis for including the named regulations within the term “designated food safety regulation” in section XII.H of this document (i.e., in the discussion of the applicable provision of proposed § 110.152).

…

FDA is proposing to define the term “hazard that is reasonably likely to occur, in the context of supplier controls” to mean a hazard for which a prudent owner, operator, or agent in charge of a receiving facility would establish controls or verify that the supplier has controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being received in the absence of those controls. We are proposing to distinguish the term “hazard that is reasonably likely to occur” in the context of supplier controls to make clear that, in some cases, a receiving facility may verify that a supplier has controls for a hazard rather than establish controls at the receiving facility. For example, the owner, operator, or agent in charge of a receiving facility that manufactures cheese may rely on the supplier of milk to pasteurize the milk as a control on biological hazards rather than pasteurize the milk at the receiving facility. We also are proposing to distinguish the term “hazard that is reasonably likely to occur” in the context of supplier controls to emphasize that, in the proposed supplier approval and verification program (see discussion of proposed § 110.152 in section XII.H of this document), the focus would be in the context of whether the hazard would be in the food as it is received by the receiving facility.

FDA is proposing to define the term “receiving facility” to mean, for an article of food, a facility that is subject to subpart C of part 110 and that manufactures/processes a raw material or ingredient that it receives from a supplier. We are proposing to define “receiving facility” as a concise term to be used in the proposed provisions for a supplier approval and verification program (proposed § 110.152). Some receiving facilities obtain food from suppliers who are part of the same corporate structure and who may, along with the receiving facility, be subject to a single, integrated, company-wide approach to food safety in which hazards are controlled and verified by a common supply chain management system. We request comment on whether receiving facilities should not be required to
conduct supplier verification when receiving food from entities under the same corporate ownership and, if so, the specific justifications and conditions under which supplier verification should not be required.

FDA is proposing to define the term “supplier” to mean, for an article of food, the establishment that manufactures/processes the food, raises the animal, or harvests the food (other than a farm that harvests a raw agricultural commodity that is a fruit or vegetable) that is provided to a receiving facility without further manufacturing/processing, except for further manufacturing/processing by another establishment that consists solely of the addition of labeling or similar activity of a de minimis nature. We are proposing to define the term “supplier” to make the meaning of the term clear in the proposed requirements for a supplier approval and verification program (proposed § 110.152). We are proposing to specify that the supplier could be an “establishment” rather than a “facility” because a supplier may be an entity that is not required to register under section 415 of the act and, thus, would not be a “facility” as that term would be defined for the purpose of this rule. We are proposing to identify establishments that manufacture/process food, raise an animal, or harvest food to address types of establishments that could be suppliers of ingredients under proposed § 110.152. Under the proposed definition of “supplier,” we would not consider a facility that packs or holds the food without any type of manufacturing/processing to be a supplier.

CODIFIED LANGUAGE

§ 110.3 Definitions.

Designated food safety regulation means a regulation contained in part 106 of this chapter (Infant Formula Quality Control Procedures), part 107 of this chapter (Infant Formula), subpart B of this part (Current Good Manufacturing Practice) or subpart C of this part (Hazard Analysis and Risk-Based Preventive Controls) of part 110, part 111 of this chapter (Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements), part 113 of this chapter (Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers), part 114 of this chapter (Acidified Foods), part 118 of this chapter (Production, Storage, and Transportation Of Shell Eggs), part 120 of this chapter (Hazard Analysis and Critical Control Point Systems), part 123 of this chapter (Fish and Fishery Products), or part 129 of this chapter (Processing and Bottling of Bottled Drinking Water).

Hazard reasonably likely to occur, in the context of supplier controls, means a hazard for which a prudent owner, operator, or agent in charge of a receiving facility would establish controls or verify that the supplier has controls because experience, illness data, scientific reports, or other information provides a basis to conclude that there is a reasonable possibility that the hazard will occur in the type of food being received in the absence of those controls.

Receiving facility means, for an article of food, a facility that is subject to subpart C of this part and that manufactures/processes a raw material or ingredient that it receives from a supplier.
Supplier means, for an article of food, the establishment that manufactures/processes the food, raises the animal, or harvests the food (other than a farm that harvests a raw agricultural commodity that is a fruit or vegetable) that is provided to a receiving facility without further manufacturing/processing by another establishment, except for further manufacturing/processing that consists solely of the addition of labeling or similar activity of a de minimis nature.

§ 110.126 Requirement for a food safety plan.

… (b) Contents of a Food Safety Plan. The food safety plan must include:

… (7) The written list of approved suppliers and the written determination of which designated food safety regulation or regulations, if any, the supplier is subject to with respect to the raw material or ingredient as required by § 110.152(a)(3)(i) and (ii).

§ 110.135 Preventive controls for hazards that are reasonably likely to occur.

… (d) Preventive controls must include, as appropriate:

… (5) Supplier program. Supplier approval and verification program as required by § 110.152.

… (e)(1) Except as provided by paragraph (e)(2) of this section, the preventive controls required under this section are subject to:
   (i) Monitoring as required by § 110.140;
   (ii) Corrective actions as required by § 110.145; and
   (iii) Verification as required by § 110.150.

(2) The recall plan established in § 110.137, and the supplier approval and verification program established in § 110.152, are not subject to the requirements of paragraph (e)(1) of this section.

§ 110.150 Verification.

(a) Validation. Except as provided by paragraph (a)(3) of this section, the owner, operator, or agent in charge of a facility must validate that the preventive controls identified and implemented in accordance with § 110.135 to control the hazards identified in the hazard analysis as reasonably likely to occur are adequate to do so. The validation of the preventive controls:

…

(3) Need not address:

…

(iv) The supplier approval and verification program in § 110.152.

…

(d) Implementation and effectiveness. The owner, operator, or agent in charge must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards that are reasonably likely to occur, by
conducting activities that. This must include the following activities, as appropriate to the facility and the food:

… (5) Review of the following records within the specified timeframes, by a qualified individual, to ensure that the records are complete, the activities reflected in the records occurred in accordance with the food safety plan, the preventive controls are effective, and appropriate decisions were made about corrective actions:

…
(ii) Records of consumer, customer, or other complaints, calibration, finished product testing, environmental monitoring, and supplier verification activities within a reasonable time after the records are made.

§ 110.152 Supplier approval and verification program.
(a) Supplier approval and verification program.
   (1) Except as provided in paragraph (a)(6) of this section, the owner, operator, or agent in charge of a receiving facility must establish and implement a supplier approval and verification program for those raw materials and ingredients for which the receiving facility has identified a hazard that is reasonably likely to occur.
   (2) The supplier approval and verification program must provide adequate assurances that the hazards identified as reasonably likely to occur by the receiving facility are significantly minimized or prevented.
   (3) The supplier approval and verification program must include:
      (i) A written list of approved suppliers;
      (ii) For each raw material and ingredient, a written determination of which designated food safety regulation or regulations, if any, the supplier is subject to with respect to the raw material or ingredient. If the owner, operator, or agent in charge of a receiving facility determines that a supplier is not subject to part 110, subpart C because the supplier is a qualified facility, then the owner, operator, or agent in charge of the receiving facility must obtain written assurance that the supplier meets the conditions for exemption as a qualified facility under § 110.2(a) and that FDA has not withdrawn such exemption for the supplier under subpart E of this part; and
      (iii) Verification activities as required by paragraphs (b) and (c) of this section.
   (4) When supplier verification activities are required under paragraph (b) or (c) of this section for more than one type of hazard, the owner, operator, or agent in charge of a receiving facility must conduct the verification activity or activities appropriate for each of those hazards. In some situations, a single verification activity will be appropriate for multiple hazards. In other situations, multiple hazards will require more than one verification activity to provide adequate assurances that each hazard is significantly minimized or prevented.
   (5) For some hazards, in some situations under paragraph (b) or (c) it will be necessary to conduct more than one verification activity and/or to increase the frequency of one or more verification activities to provide adequate assurances that the hazard is significantly minimized or prevented.
(6) The owner, operator, or agent in charge of a receiving facility is not required to establish and implement a supplier approval and verification program for raw materials and ingredients for which the preventive controls at the receiving facility are adequate to significantly minimize or prevent each of the hazards the receiving facility has identified as reasonably likely to occur.

(b) **Supplier verification activities for hazards to be controlled at the supplier's establishment, if the raw material or ingredient is subject to one or more designated food safety regulations.** The owner, operator, or agent in charge of a receiving facility must conduct the following initial and periodic verification activities for hazards to be controlled at the supplier's establishment, if the supplier is subject to one or more designated food safety regulations with regard to the raw material or ingredient:

1. **Initial onsite audit.** The owner, operator, or agent in charge of the receiving facility must conduct or obtain documentation of an onsite audit of the supplier before using the raw material or ingredient from the supplier.

2. **Periodic onsite audits.**
   
   (i) When a hazard that is reasonably likely to occur with a raw material or ingredient is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the owner, operator, or agent in charge of the receiving facility must conduct or obtain documentation of an onsite audit of the supplier at least annually, unless more frequent onsite audits are necessary to adequately verify control of the hazard.
   
   (ii) When a hazard that is reasonably likely to occur with a raw material or ingredient is not one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals, the owner, operator, or agent in charge of the receiving facility must conduct or obtain documentation of an onsite audit of the supplier at least every 2 years, unless more frequent onsite audits are necessary to adequately verify control of the hazard.

(c) **Supplier verification activities for other hazards.** For a hazard that is not subject to paragraph (b) of this section, the owner, operator, or agent in charge of a receiving facility must conduct one or more of the verification activities listed in paragraph (c)(1) through (4) of this section, as appropriate for the hazard, before using the raw material or ingredient and periodically thereafter. Such hazards include hazards to be controlled at the supplier's establishment and the supplier is not subject to one or more designated food safety regulations with respect to the raw material or ingredient. The frequency of verification activities must be based on the risk associated with the hazard.

1. **Periodic onsite audits that the owner, operator, or agent in charge of the receiving facility conducts, or for which the owner, operator, or agent in charge of the receiving facility obtains documentation.**
2. **Periodic or lot-by-lot sampling and testing of the raw material or ingredient from the supplier that the owner, operator, or agent in charge of the receiving facility conducts, or has conducted, for the hazard.**
(3) Periodic review by the owner, operator, or agent in charge of the receiving facility of the supplier’s food safety records (e.g., audits of their supplier for the hazard).

(4) Other appropriate supplier control verification measures based on the risk associated with the hazard.

(d) Records. All supplier verification activities conducted in accordance with this section must be documented in records.

(e) Onsite audit.

(1) An onsite audit must be performed by a qualified individual with the technical expertise obtained by a combination of training and experience appropriate to perform the auditing function; and

(2) If the raw material or ingredient at the supplier is subject to one or more designated food safety regulations, to provide adequate assurance that the hazard is significantly minimized or prevented an onsite audit must consider such regulations and include a review of the supplier’s written plan, if any, including its implementation, for the hazard being audited.

(f) Independence of persons conducting an onsite audit. A person who conducts an onsite audit as set forth in paragraph (b) or (c) of this section must not have a financial interest in the supplier and payment must not be related to the results of the activity. This does not prohibit the owner, operator, or agent in charge of the receiving facility from conducting the audit.

(g) Supplier non-conformance. If the owner, operator, or agent in charge of a receiving facility determines through auditing, verification testing, or otherwise that the supplier is not controlling hazards that the receiving facility has identified as reasonably likely to occur, the receiving facility must take prompt action, which may include discontinuing use of the supplier, to ensure the hazards associated with the raw material or ingredient have been significantly minimized or prevented.

§ 110.175 Records required for subpart C.

(a) The owner, operator, or agent in charge of a facility must establish and maintain the following records:

(1) The written food safety plan, including the written hazard analysis, preventive controls, monitoring procedures, corrective action procedures, verification procedures, recall plan, written list of approved suppliers, and the written determination of which designated food safety regulation or regulations, if any, the supplier is subject to with respect to the raw material or ingredient.

... (5) Records that document the supplier approval and verification program