



FSMA Preventive Controls Preparedness Module and Guidance for BRC-certified Facilities Self-Assessment Tool

BRC GLOBAL STANDARD FOR FOOD SAFETY ISSUE 7

Welcome to the BRC Global Standards Self-Assessment tool

We hope that you will find this useful when preparing your site for an audit against the BRC Global Standard for Food Safety Issue 7 in conjunction with the FSMA Voluntary Module. Please see the BRC GLOBAL STANDARD FOOD SAFETY PREVENTIVE CONTROLS FOR HUMAN FOOD RULE COMPARISON for a detailed description and explanation around the development of FSMA and associated terminology.

How to use the BRC Global Standards Self-Assessment tool?

This tool is designed to help you assess your operation against the requirements of the module and help prepare you for your certification audit in conjunction with the FSMA voluntary module.

The checklist covers each of the requirements of the module and may be used to check your site's compliance with each of these requirements. The checklist also allows you to add comments or identify areas of improvement in the empty boxes provided at the end of each section.

While we hope that this tool is useful in helping you prepare for your audit it should not be considered as evidence of an internal audit and will not be accepted by auditors during an audit.

Training

The FDA Food Safety Modernization Act (FSMA) Final Rules can be a time consuming and confusing task and to help you fully understand the new rules, BRC Global Standards are running a number of courses that covers the Preventive Controls for Human Food Rule and may be useful for the person(s) using the BRC Global Standards Self-Assessment Tool.

For further information on the courses available please visit www.brctrainingacademy.com

Further Information

If you have any further questions about the BRC Global Standards Self-Assessment Tool, the BRC Global Standard for issue 7 or the FSMA voluntary module please do not hesitate to contact the BRC Global Standards team.

Email – enquiries@brcglobalstandards.com

Telephone – 020 7854 8939

**FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL**

Item no.	Regulatory section	Module item	Guidance	Conforms (Y/N)	Comments
1	117.20	Handwashing areas, dressing and locker rooms, and bathrooms must have adequate lighting.	<p>21 CFR § 117.20 requires handwashing areas, dressing and locker rooms, and bathrooms to have adequate lighting. The expectation for adequate lighting in these areas is implied in the BRC Global Standard for Food Safety (referred to from now on as BRC) section 4.8, statement of intent.</p> <p>Adequate lighting is defined as lighting that provides a safe working environment, enables effective cleaning of hands and maintenance of personal hygiene, and facilitates the changing of personal protective clothing.</p>		
2	117.37	The water distribution system must prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage.	<p>21 CFR § 117.37 requires that the water distribution system be protected from backflow and cross-connection from waste water and sewage systems. The expectation for backflow and cross-connection prevention is implied in BRC clause 4.5.2.</p> <p>The water distribution schematic should be reviewed to ensure all points in the system are protected from backflow or cross-connection from waste water and sewage pipework. Where there is a potential for backflow or cross-connection, control must be applied through the application of a backflow prevention device or other mechanism to mitigate the risk.</p>		
3	117.40	All food contact surfaces of plant equipment and utensils used in manufacturing,	21 CFR § 117.40 requires that all food contact surfaces used to manufacture, process, pack, or hold food (including utensils) be corrosion resistant		

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

		<p>processing, packing, or holding food must be corrosion resistant.</p> <p>Seams on food-contact surfaces must be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.</p>	<p>and maintain smooth seams, which are easily cleanable and do not allow organic matter to accumulate, causing unintentional adulteration. The expectation for the use of corrosion resistant materials and sanitary-designed food contact surfaces to prevent cross-contamination is implied in BRC section 4.6, statement of intent.</p> <p>Corrosion is a process which causes metal to deteriorate through oxidation. Undesirable oxides appear on the surface of the metal and can be incorporated into food products as unintentional adulterants. The use of corrosion resistant materials, such as 300-series stainless steel or food grade plastics, is necessary to prevent unintentional adulterants and cross-contamination of food products.</p> <p>The application of smoothly bonded seams is critical to ensuring the effective cleaning and sanitation of food contact surfaces. Microbial harborage sites and the build-up of organic debris, which may contain allergenic proteins or other contaminants, find a natural habitat in porous or nonsmooth seams. The harborage sites or build-up of organic debris can be very difficult to remove once they have become established. They are known reservoirs of pathogenic microorganisms in wet and dry environments and thereby contribute to food product adulteration and outbreaks of foodborne illness.</p> <p>The preventive maintenance program as required by BRC section 4.7 should ensure criteria are established for the use of corrosion-resistant materials and the application of smooth seams on</p>		
--	--	--	--	--	--

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

			food contact surfaces when commissioning new equipment. The program should also include the assessment of in-use equipment against these criteria along with corrective action where corrosion or nonsmooth seams occur.		
4	117.80	Ice used in contact with food must be manufactured in accordance with the good manufacturing practice (GMP) requirements of 21 CFR § 117.	<p>21 CFR § 117.80 requires that ice used in contact with food be made from water that is safe and of adequate sanitary quality. It additionally requires that ice be manufactured in accordance with the GMP defined in 21 CFR § 117. The expectation for the production and use of ice, which poses no risk of contamination to raw materials, ingredients and food products – and is of adequate microbiological and chemical quality – is implied in BRC clause 4.5.1.</p> <p>When microbiological pathogens and chemical contaminants are present in ice they are preserved and have the potential to cross-contaminate food. Potable water sources meeting applicable legislative requirements, which are tested annually as per BRC clause 4.5.1, must be used for the manufacture of ice. Additionally, ice manufacture (whether onsite or from an external supplier) must be performed in compliance with the GMP requirements of 21 CFR § 117.</p>		
5	117.110	<p>Where defect action levels (DALs) are established for a food, quality control operations must reduce defects to the lowest level possible.</p> <p>Defect levels rendering the</p>	DALs are defined in the Defect Levels Handbook for various food commodities regulated by the US Food and Drug Administration (FDA). These levels represent the maximum allowable limit for defects that will be tolerated before the product is considered adulterated and subject to enforcement action under Section 402(a)(3) of the Food, Drug,		

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

		food adulterated may not be reduced by mixing the food with another lot.	and Cosmetic Act. 21 CFR § 117.110 requires the site not only to meet DALs for all applicable commodities but also to implement quality control operations to reduce defects to the lowest level possible. Sites may not mix (dilute) product with defect levels at or exceeding the maximum limit with product containing minimum defects. Blending product exceeding the DAL renders the finished product adulterated regardless of the final defect level.		
6	117.130 (a)	<p>The hazard analysis must additionally identify and evaluate the following known or reasonably foreseeable hazards, which are associated with the food or facility:</p> <ul style="list-style-type: none"> • economic adulterants which affect food safety • environmental pathogens where ready-to-eat (RTE) food is exposed to the environment prior to packaging and the packaged food does not receive a kill step • radiological hazards • unintentional adulterants that affect food safety. 	<p>21 CFR § 117.130 requires a written hazard analysis that identifies and evaluates all known or reasonably foreseeable hazards. The regulation defines 'known or reasonably foreseeable hazards' as a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.</p> <p>21 CFR § 117.130 additionally requires the identification of naturally occurring hazards (e.g., mycotoxins), unintentionally introduced hazards (e.g., allergen cross-contact), and intentionally introduced hazards for economic gain (e.g., economically motivated adulterants) although they will be grouped accordingly as a biological, chemical or physical hazard. Radiological hazards must be identified and evaluated where there is a known prevalence in the raw material or ingredient due to sourcing from a susceptible region or where materials or the food product has the potential to be contaminated (e.g., from water sources in susceptible areas).</p>		

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

			<p>As with Codex Alimentarius HACCP methodology, the hazard evaluation must include an assessment of the severity of illness or injury and likelihood of occurrence if the hazard were to occur in the absence of preventive controls. The evaluation must consider all known or reasonably foreseeable hazards in all materials (or material groups), process steps, the production environment, supply and distribution chain activities, intended and reasonably foreseeable use, and other related elements.</p> <p>Specifically, the hazard analysis must evaluate environmental pathogens where an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a kill step to eliminate or significantly minimize the pathogen. Examples of environmental pathogens include <i>Salmonella</i> spp. (typically found in dry processing environments) and <i>Listeria monocytogenes</i> (common in wet processing environments), although these pathogens are generally ubiquitous in food handling and processing environments.</p> <p>A site's hazard analysis should be reevaluated in consideration of the new regulatory requirements and updated where necessary to achieve compliance. For example, a site may need to consider integrating or cross-referencing the hazard analysis and risk assessments required by the BRC Global Standard for Food Safety (e.g., raw material or allergen cross-contact) to cover the scope of the hazard analysis as required by 21 CFR § 117.130.</p> <p>Subpart F of the regulation allows for the use of</p>		
--	--	--	--	--	--

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

			existing food safety plans and records based on hazard awareness and critical control points (HACCP), which may be supplemented or added to separately to meet requirements of the regulation.		
7	117.130 (b)	All identified, known, or reasonably foreseeable hazards must be evaluated to determine 'hazards that require a preventive control' (i.e., significant hazards).	<p>21 CFR § 117.130(a)(1) requires a hazard analysis to determine 'hazards that require a preventive control' or significant hazards. Hazards requiring a preventive control may be in addition to those for which a critical control point (CCP) has already been applied.</p> <p>According to the FDA, 'hazards that require a preventive control' are those for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would – based on the outcome of a hazard analysis determine that the hazard is likely to cause illness or injury in the absence of preventive controls – establish one or more preventive controls to significantly minimize or prevent the hazard in a food and apply components (e.g., monitoring, corrections or corrective actions, verification, and records) to manage the control(s).</p> <p>A documented decision making process consistent with the expectations of BRC clause 2.8.1 is recommended for determining 'hazards requiring a preventive control'. Justification should be documented on the hazard analysis for qualifying or not qualifying a known or reasonably foreseeable hazard as a hazard requiring a preventive control. For example, <i>Salmonella</i> is a</p>		

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

			known or reasonably foreseeable hazard in raw peanuts. The justification for qualifying <i>Salmonella</i> in the receiving of raw peanuts as a hazard requiring a preventive control lies in the knowledge that raw and processed peanuts have been the source of foodborne illness outbreaks responsible for severe illness and death.		
8	117.135	Establish one or more preventive control(s) for each identified 'hazard that require a preventive control' (i.e., significant hazard) such that the control significantly minimizes or prevents the food manufactured, processed, packed, or held by the facility from being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug and Cosmetic Act.	<p>21 CFR § 117.135 requires the establishment of one or more preventive controls for each identified 'hazard that require a preventive control'. Preventive controls must be risk-based, reasonably appropriate procedures, practices, or processes, that control a specific hazard. The control must be capable of significantly minimizing or preventing the associated hazard. This is consistent with the current scientific understanding of safe food practices. Preventive controls must be written and may include CCPs. A preventive control may also be a procedure, practice, or process at activities or process steps other than at CCPs.</p> <p>For example, where a site handles allergenic (e.g., tree nuts) and nonallergenic materials (e.g., dried fruit) and produces allergen-free products, tree nuts are considered to be a 'hazard that requires a preventive control' because of the potential for allergen cross-contact in nonallergenic products and adulteration/misbranding under FD&C sections 402 and 403. Thus, one or more preventive control(s) must be applied to prevent allergens occurring in nonallergenic food products and ensure accurate labeling (e.g., dedicated lines or utensils, time segregation, allergen cleaning, and label verification). An allergen management</p>		

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

			<p>program as required by BRC section 5.3 should still be applied as a prerequisite program (PRP) to ensure adequate environmental and operational conditions for the overall management of allergens and routes of contamination.</p> <p>Elements of existing PRPs required by the BRC Global Standard for Food Safety (e.g., sanitation, supplier approval and monitoring, and labeling and pack control) may serve as effective preventive controls where an associated significant hazard is identified.</p> <p>Subpart F of the regulation allows for the use of existing HACCP based food safety plans and records, which may be supplemented or added to separately to meet requirements of the regulation.</p>		
9	117.139	<p>Evaluate and update the recall and withdrawal procedure as necessary to ensure it contains procedures and responsibility for the following:</p> <ul style="list-style-type: none"> • notifying consignees of how to return or dispose of recalled product • conducting effectiveness checks to verify recall is carried out • appropriate disposal of recalled product (i.e., destroy, divert, repurpose). 	<p>21 CFR § 117.139 requires a recall plan where the site identifies a hazard requiring a preventive control. The recall plan must include responsibility and steps for notifying consignees about how to return or dispose of product, conducting effectiveness checks and appropriate disposal. The expectation for these activities is implied in BRC clause 3.11.2, which generally requires a plan for recovery or disposal.</p> <p>It is recommended that sites review their recall and withdrawal procedure to ensure it defines responsibility and steps for the specific activities described in the regulation. Template letters for notifying consignees about how to return or dispose of product and conducting effectiveness checks may be drafted in advance and reviewed for effectiveness as a part of the annual mock</p>		

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

			recall. Methods for determining appropriate disposal should be science- and risk-based and determined by an individual(s) with the appropriate knowledge and authority.		
10	117.145	Establish monitoring activities and a written procedure for each preventive control in a manner consistent with the requirements of BRC section 2.10.	<p>21 CFR § 117.145 requires monitoring activities for each applied preventive control. A preventive control is a planned sequence of observations or measurements to assess whether control measures are operating as intended. The monitoring requirements of the regulation are consistent with those defined in BRC section 2.10.</p> <p>Monitoring may not have any critical limits, depending upon the nature of the hazard and preventive control, but it must be performed in a manner and at a frequency that will ensure consistent and effective implementation of the preventive control. A written monitoring procedure must be established and document how to perform the monitoring activity, its frequency, who is responsible, and the recordkeeping requirements. The preventive controls qualified individual (PCQI) is responsible for conducting or overseeing the review of monitoring records within 7 days from the date of creation.</p>		
11	117.150	Establish corrective action procedures when preventive controls are not implemented in a manner consistent with the requirements of BRC sections 2.11 and 3.7.	21 CFR § 117.150 requires corrective action to take place when preventive controls are not implemented. Additionally, the presence of a pathogen or indicator organism following product testing or environmental monitoring as verification activities triggers corrective action. The corrective action requirements of the regulation are consistent with those defined in BRC sections 2.11		

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

		Corrective action procedures must be established and implemented when the presence of a pathogen (or indicator organism) is detected as a part of verification activities (i.e., product testing and/or environmental monitoring).	and 3.7. The immediate correction of a failure to implement preventive controls, followed by a corrective action procedure, is critical to correcting the problem, reestablishing monitoring, evaluating affected product, and determining the root cause of the failure to prevent its recurrence. Corrective action records must be maintained and reviewed by the PCQI (or their authorized designee) within 7 days.		
12	117.160	<p>Validate all established process controls prior to implementation of the food safety plan, upon changes requiring revalidation or within 90 calendar days of the first food production.</p> <p>Validate allergen, sanitation and supply-chain controls as appropriate to the nature of the hazard, control and facility.</p>	<p>21 CFR § 117.160 requires the PCQI to validate the preventive controls. This requirement is fundamentally consistent with BRC clause 2.9.2.</p> <p>21 CFR § 117.160 definitively requires validation for all process controls, which are analogous to critical control points (CCPs), with defined maximum and/or minimum parameters (limits). The regulation does not explicitly require validation of allergen, sanitation, recall plan, and supply-chain controls, although validation is expected where possible (e.g., validation of allergen cleaning practices as required by BRC clause 5.3.8). Other preventive controls as allowed by the regulation do not require validation where the PCQI documents justification that validation is not applicable based on the nature of the hazard, control, and role in the food safety system.</p> <p>Sites should reanalyze all identified preventive controls and consider the need for validation where this is not presently documented.</p>		
13	117.165 (a)	The PCQI (or authorized designee) reviews the	The review of records related to the implementation and management of preventive		

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

		<p>monitoring and corrective action records within 7 days. Where an alternate timeframe exceeding 7 days is used, the PCQI must document justification.</p> <p>The PCQI (or their authorized designee) reviews the verification records for all preventive controls (e.g., calibration records, product testing, supply-chain audits) within a reasonable timeframe after the record has been created.</p>	<p>controls is defined as a core verification activity in the regulation. The PCQI has overall responsibility for it to ensure that any failure in implementing preventive controls is identified within an appropriate timeframe to prevent adulterated product from reaching consumers.</p> <p>21 CFR § 117.165 requires the PCQI to conduct (or oversee) record reviews for monitoring and corrective action records within 7 days and all verification records within a reasonable timeframe. This requirement is consistent with the monitoring expectations for record review, as defined in BRC clause 2.10.2. Consideration should be given to the 7-day timeframe; where a timeline exceeding 7 days is used, the PCQI must document justification.</p> <p>Requirements for the review of corrective action and verification records are implied in BRC clauses 2.12.1 and 3.7.2. The corrective action and verification procedures related to the food safety plan should be evaluated and updated as necessary to ensure there is provision for records to be reviewed by the PCQI or their designee.</p>		
14	117.165 (b)	<p>Where product testing for a pathogen (or indicator organism) or other hazard is used as a verification activity, a scientifically valid and written testing procedure must identify the following:</p> <ul style="list-style-type: none"> • sampling procedure to include method, 	<p>Product testing for a pathogen (or indicator organism) or other hazard is a defined verification activity in 21 CFR § 117.165 of the regulation. Where product testing is used as a verification activity, the site must establish and implement a scientifically valid testing procedure, which defines sampling, frequency, test method, laboratory, and corrective action procedure. Generally, expectations to meet this requirement are defined</p>		

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

		<p>quantity, frequency, and number of samples</p> <ul style="list-style-type: none"> analytical method laboratory conducting an analysis corrective action procedure where a pathogen is detected. 	<p>by BRC clause 5.6.2.3.</p> <p>Where product testing is used as a verification activity to confirm the effective implementation of a preventive control, the site should reanalyze the applicable procedures for analyses that are critical to safety and legality and update them as necessary to ensure that the procedure(s) documents all requirements of the regulation.</p>		
15	117.165 (c)	<p>Where environmental monitoring for a pathogen (or indicator organism) is used as a verification activity, a scientifically valid and written testing procedure must identify the following:</p> <ul style="list-style-type: none"> adequate number and location of sample sites timing and frequency of sampling analytical method laboratory conducting the analysis corrective action procedure where a pathogen is detected. 	<p>Environmental monitoring for a pathogen (or indicator organism) is a required verification activity as defined in 21 CFR § 117.165 of the regulation where RTE product is exposed to the environment before being packaged and the packaged food does not receive a kill step to eliminate or significantly minimize the pathogen. Where environmental monitoring is applied as a verification activity for exposed RTE product, the site must establish and implement a scientifically valid testing procedure, which defines sampling (including location of sites), timing and frequency, test method, laboratory, and the corrective action procedure. Generally, expectations to meet this requirement are defined by BRC clause 5.6.2.3.</p> <p>It is recommended that science-based guidance on the establishment, implementation and maintenance of a pathogen environmental monitoring program be reviewed when determining the test organism, sample locations and number, timing, frequency, and test method. This is because these variables significantly impact the ability of the program to verify the effective implementation of environmental pathogen</p>		

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

			<p>controls.</p> <p>Where environmental monitoring is used as a verification activity to confirm the effective implementation of a preventive control (e.g., sanitation) controlling an environmental pathogen, the site should reanalyze the applicable procedures for analyses that are critical to safety and legality and update them as necessary to ensure that the procedure documents all the requirements of the regulation.</p>		
16	117.165	<p>Devices used to verify preventive controls must be calibrated.</p>	<p>21 CFR § 117.165 requires the calibration of the devices used to verify preventive controls in addition to those used to conduct monitoring. The expectation for the calibration of the devices used to verify preventive controls is implied in BRC section 6.4, statement of intent, which requires calibration of measuring equipment.</p> <p>Where the site establishes verification activities such as product testing, the measuring devices utilized in the analytical method must be calibrated at an appropriate frequency and all calibration activities must be recorded. Calibration records are verification records and thus they are subject to record review by the PCQI (or their designee) within an appropriate timescale from when the record is created.</p> <p>Sites should review their documented list of measuring devices, as required by BRC clause 3.4.1, and this list should be updated as necessary with any additional measuring devices that are specifically used in preventive controls verification</p>		

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

			activities.		
17	117.180	<p>Identify a PCQI responsible for developing the food safety plan, validating preventing controls, review of records, and reanalysis of the plan.</p> <p>Document the PCQI's training or qualifications via job experience.</p>	<p>21 CFR § 117.180 requires that one or more PCQIs (as defined in the regulation) be responsible for developing the food safety plan, validating preventing controls, reviewing the records, and reanalyzing the plan.</p> <p>The PCQI can qualify in one of two ways. The first pathway is to complete training in the FDA recognized preventive controls curriculum, which reviews how to conduct a hazard analysis and develop and apply appropriate risk-based preventive controls consistent with the regulation. The Food Safety Preventive Controls Alliance (FSPCA) training course on preventive controls for human food is the only currently recognized curriculum.</p> <p>The second pathway for qualifying as a PCQI is through job experience of developing and applying a food safety system. Experience of developing and implementing a BRC food safety system may qualify an individual as a PCQI. Whichever pathway qualifies the site's PCQI, their training or experience must be documented.</p> <p>Sites may utilize consultants as PCQIs; however, the responsibilities defined in 21 CFR § 117.180 still apply and the site is responsible for the implementation and management of the preventive controls.</p>		
18	117.305	All records required by 21 CFR § 117 must include:	21 CFR § 117.305 specifically requires site, responsible person and product identification information on all records related to the food safety		

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

		<ul style="list-style-type: none"> the date and time of the activity being documented signature/initials of individual performing the activity or conducting the record review information to identify the facility (e.g., name and location) the identity of the product and lot code where applicable. 	<p>plan. The expectation for recordkeeping identifiers and the signature or initials of the individual responsible for authorized verification is implied in BRC clause 3.3.1.</p> <p>It is recommended that sites review all existing records related to the food safety plan and update the forms as required by the regulation in a manner consistent with the site's document control procedures. New forms must take into account all recordkeeping requirements as described in 21 CFR § 117.305.</p>		
19	117.310	The owner, operator or agent in charge of the facility must sign and date the written food safety plan initially and again upon any changes following reanalysis.	<p>21 CFR § 117.310 requires the owner, operator or agent in charge of the facility to sign and date the written food safety plan, which includes the following: hazard analysis, preventive controls, supply-chain program, recall plan, monitoring procedure(s), corrective action procedure(s), and verification procedure(s) (including validation) where applicable. Additionally, the responsible individual must sign and date it whenever there are changes following reanalysis.</p> <p>This requirement is to ensure the commitment of senior management to responsibility for the food safety plan. This requirement must be met initially and thereafter may be integrated as a component of the senior management review to comply with BRC clause 1.1.3.</p>		
20	117.315	All documents and records relating to the food safety plan (i.e., all records required by 21 CFR § 117) must be	21 CFR § 117.315 requires all documents and records relating to the food safety plan be retained for a period of 2 years regardless of the shelf life of the product. The food safety plan must be retained		

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

		<p>retained at the facility for 2 years after the record is created. Where records are stored offsite, they must be retrievable within 24 hours, with the exception of the food safety plan, which must remain onsite.</p>	<p>onsite; however, documents and records outside the scope of the food safety plan may be retained offsite provided they are retrievable within 24 hours upon verbal or written request by the FDA for official review.</p> <p>Electronic records are subject to all the requirements of this section, but are not subject to the requirements of 21 CFR § 11 unless this is required by other applicable statutory provisions. Electronic records are considered to be 'onsite' where they can be retrieved from an onsite location.</p> <p>Sites should review their document control and recordkeeping procedures to ensure that they comply with the regulation, and they should update their policies regarding record retention and storage as necessary.</p>		
21	117.405	<p>Where a hazard requiring a supply-chain-applied control is identified in the hazard analysis, the receiving facility must establish and implement specific supplier approval and verification activities.</p> <p>Where a hazard requiring a supply-chain-applied control is identified and the control is applied by an entity other than the receiving facility's supplier, the receiving facility is responsible for verifying</p>	<p>The raw material risk assessment as required BRC clause 3.5.1.1 may be utilized for determining materials with hazards requiring a supply-chain-applied control (i.e., the material hazard is controlled before it is received by the receiving facility). Hazards requiring a supply-chain-applied control are subject to verification requirements as defined in 21 CFR § 117.430. Raw material hazards and low-risk materials, which may be adequately controlled by PRPs or other preventive controls at the receiving facility, should be documented on the hazard analysis.</p> <p>In circumstances where the supply-chain-applied control is performed by an entity other than the receiving facility's supplier (e.g., a farm or</p>		

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

		implementation of the control.	processor under different management), the site is responsible for verifying implementation of the supply-chain-applied control. Verification may be completed directly (e.g., second-party onsite audit of the entity) or indirectly through review of supplier-provided verification documentation (e.g., third-party audit report or material test results).		
22	117.420	<p>Supplier approval must be documented before receiving and using raw materials and ingredients.</p> <p>Verification activities must be conducted before receiving and using raw materials and ingredients on a temporary basis from unapproved suppliers.</p>	<p>21 CFR § 117.420 requires documented supplier approval and a written procedure with criteria for receiving and acceptance of materials. Supplier approval must be documented before receiving and using materials. The expectation for supplier approval before use is implied in BRC section 3.5.1, statement of intent. Requirements for a written acceptance procedure are defined in BRC clause 3.5.2.1 and these are consistent with the regulation. Where the receiving facility relies on supplier self-documented methods as a part of its verification activities for acceptance criteria (e.g., a certificate of analysis), the receiving facility is responsible for reviewing the supplier documentation and for documenting completion of the review.</p> <p>Consistent with the requirements of BRC clause 3.5.1.4, 21 CFR § 117.420 allows for the use of unapproved suppliers only on a temporary basis and where adequate verification activities are conducted before receiving and using the materials. Verification activities must be appropriate to the level of risk and consistent with the requirements of 21 CFR § 117.410(b).</p>		
23	117.430	One or more supplier verification activities (as	21 CFR § 117.430 requires verification activities to ensure that supply-chain-applied controls are		

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

		<p>defined in 21 CFR § 117.410(b)) must be conducted for each supplier before using raw materials and ingredients and periodically thereafter at an adequate frequency.</p>	<p>consistently implemented. Verification activities are required only where the site identifies a material hazard requiring a supply-chain-applied control. The term 'verification' in the context of the regulation is analogous to supplier monitoring in the BRC standard. Verification activities must be established and conducted for each supplier of a material with a hazard requiring a supply-chain-applied control before using the material and at an adequate frequency thereafter.</p> <p>21 CFR § 117.430 contains two critical requirements regarding supplier verification activities. The first critical element is § 117.430(a), which requires one or more supplier verification activities as defined in 21 CFR § 117.410(b) for initial approval and periodically thereafter.</p> <p>Verification activities, other than onsite audits, as defined in 21 CFR § 117.410(b) and 21 CFR § 117.410(c) include the following: material sampling and testing, review of the supplier's food safety records, review of the supplier's third-party audit report, and other supplier verification activities as appropriate based on material risk and supplier performance. Determining the appropriate verification activities and frequency is consistent with the requirements of BRC clause 3.5.2.1.</p> <p>The second critical element is 21 CFR § 117.430(b), which requires an initial and annual onsite audit thereafter as the designated verification activity where the supplier controls the hazard. Other verification activities more appropriate to ensure that hazards are effectively controlled by the supplier, or less frequent audits,</p>		
--	--	---	--	--	--

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL

			<p>may be applied where documented justification is provided. Onsite audits must be conducted by a qualified auditor.</p> <p>Sites approving and monitoring medium- to high-risk materials and suppliers through onsite audits as required by BRC clause 3.5.1.2 meet the verification requirements of 21 CFR § 117.430, provided that the onsite audit is conducted initially and annually thereafter, or where documented justification in the risk assessment identifies that less frequent audits are adequate to verify the control of the hazard by the supplier.</p> <p>The regulation defines a qualified auditor as a qualified individual (as defined in 21 CFR § 117) who has technical expertise obtained through education, training, or experience (or a combination thereof) necessary to perform the auditing function as required by 21 CFR § 117.180(c)(2). Qualified auditors may include auditors registered with GFSI-benchmarked schemes, government inspectors or appropriately trained and experienced second-party auditors.</p>		
--	--	--	---	--	--

FSMA PREVENTIVE CONTROLS PREPAREDNESS MODULE AND GUIDANCE FOR BRC-CERTIFIED FACILITIES
SELF-ASSESSMENT TOOL